Bioethical Controversies in Pediatric Cardiology and Cardiac Surgery

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Preface to the First Edition

Bioethical controversies loom large in the field of congenital heart disease, which has emerged as a resource-consuming specialty that has major effects on the lives of patients and their families. While virtually all congenital heart defects can be surgically treated in some manner, the burdens imposed by short- and long-term survival have heightened the relevance and importance of informed consent, shared decision-making, public reporting, and clinical transparency.

The principles that govern ethical behavior in medical practice are beneficence, non-maleficence, justice, and autonomy which are grounded on the ideas that physicians are duty bound to do good, avoid harm, display fairness, and recognize that patients are free to make medical decisions for themselves. Neonates, infants, and children, however, are dependent on their parents to make decisions for them in the child's best interests. To make these issues more problematic, fetal diagnoses of complex heart disease present parents with daunting options that include consideration of women's rights to autonomy and bodily integrity, maternal-fetal conflicts, the potential burdens of long-term care associated with pain and suffering, and the possibility of postnatal comfort care rather than attempts at surgical palliation or cure. These circumstances are considered in the context of enormous advances in congenital heart procedures that, in many cases, are curative and clearly indicated.

The origin of this collection of ideas and inquiries took its roots from the multiple manuscripts that were published by the editors and contributors over a time period that witnessed significant advances in procedural techniques, changes in political social norms, and exposure of the equipoise that surrounds guidelines for parental interactions. Administrative, social, governmental, and media oversight led to increased awareness of clinical outcomes but also brought to the fore unintended consequences that shook the foundation of health care delivery for patients with congenital heart disease. In the near future, changes that might result in a universal one-payer system will challenge and refocus the ethical issues that are discussed herein and will likely signal another edition of this text.

The chapters in this book approach congenital heart disease through the lens of ethical principles. The authors encompass the breadth of contemporary medical experience and thought from surgical residents, young faculty members, philosophy faculty, and widely published, seasoned contributors. Each has an important perspective to consider. The chapters are not arranged by any organizing principle; rather they are discussions of the complex ethical issues that have formed the raison d'etre of this collection.

The reader will find the contents of this book to be interesting, thoughtful, controversial, and poignant. Answers are not provided; rather controversy is highlighted.

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Introduction to Biomedical Ethics

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1 Introduction

In the Classical Age of ancient Greece (fifth century BCE), Hippocrates and his followers established, for the first time in the West, a systematic, observation-based practice that was a recognizable ancestor of what we now call medicine. The *Hippocratic Corpus* is an impressive collection of lectures, case histories, research notes and observations, gathered over the decades and centuries [1].[1] The best-known document of the collection, though, is the Oath—a code of professional conduct that physicians of the Hippocratic tradition were expected to embrace—a revised version of which is still sworn by physicians today [2].

The Hippocratic Oath indicates a recognition that the physician occupies a special position and has special powers—powers that should be exercised responsibly. Because the physician has the power to heal and to harm, it is important that he[2] use that power always and only for healing. Because the physician often has knowledge of personal information about a patient, it is important that he not break confidence. Because the physician has the prestige that accompanies

power and professional status, he should not use that standing for immoral purposes. These are basic common-sense guidelines of ethical behavior, applied to the singular circumstances of the physician who has special power, knowledge, access and prestige.

Modern scientific medicine endows the physician with a kind and degree of power that the ancients could never imagine. Scientific research reveals that the body is more complex (and more interesting) than Hippocratic humoral theory would suggest. Technology allows all manner of strategic interventions, with precise manipulation and control. Specialization, division of labor and institutionalization enhance the efficiency and influence of the profession. In the new world of modern medicine, the physicians' powers are increased, the responsibilities are greater, the cases are more intricate, and the social, legal and institutional context more complex.

Medical professionals today confront specific dilemmas and decisions that no one in human history has ever had to address before. Nowhere is this truer than in pediatric cardiology and pediatric cardiac surgery . Ancient physicians never had to advise a family whose newborn would need repeated open-heart operations and eventually a cardiac transplant in order to enjoy a compromised and shortened life. The ancient Athenians did not struggle to devise an effective and morally sensitive system for collection and allocation of donor organs. Hippocrates never dealt with the risks and problems associated with post-cardiotomy ECMO.[3] The common-sense moral guidelines that underlie the Hippocratic Oath are no less sound today than they were in the ancient world, but they are not enough—they do not provide the kind of guidance that is required in the practice of modern medicine.

Fortunately, especially in the past three centuries, just as our theoretical understanding of biology, anatomy, and physiology has been advancing, so too has our understanding of ethics. And just as we are learning to apply our deeper scientific understanding to the art of healing, we are learning to apply a more developed understanding of ethics to the art of moral decision- making.[4] In this chapter we will try to gain an overview and appreciation of modern bio-medical ethics by tracing these developments in our ethical understanding in three steps. First, we will consider briefly three major ethical theories, with a glance at their historical origins. As part of this discussion we will discuss the

very idea of an "ethical theory " and will consider the significance of reasonable disagreements among the main contenders for the title of "the true theory of ethics." Secondly, we will discuss the rise of specialized fields of "applied ethics "—of which bio-medical ethics is the most prominent. In this context we will consider the effort to condense the insights of ethical theories to concisely stated "principles" which can be used as analytical tools for decision making. We will conclude with some thoughts on the relationship between ethics and religion, and between ethics and the law.

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2 Ethical Theories

2.1 Classical Ethical Theory: Virtue Ethics

Systematic, rational inquiry into what we call "ethics" began with the ancient Greeks in the fifth and fourth centuries BCE. Thinkers in this Classical Age asked, in a number of different contexts, "What differentiates a *good* human being from a *bad* one?" The Greek philosophers answered this central normative question by reference to a person's character . A good person is an individual of good character —possessed of certain excellent traits called "virtues" (Gr. *aretai*), among the most important of which are wisdom, courage, moderation and justice. The focus on these four virtues reflects widely accepted social and moral norms of the day. Socrates , Plato , Aristotle , *et al* sought to understand these virtues—how they relate to one another, how they can be taught and how they are unified in a virtuous person—a person of good character who lives a good life [3]. They focused on the idea of a virtuous *individual*, but there was also discussion of how actions and even institutions could, by extension, come to be called virtuous [4].

Pursuing their inquiries, these thinkers realized that in addition to the qualities that make one a good human being *simpliciter*, there are also more specialized virtues required of a person in a specific social or occupational role. For example, in order to know what qualities, make one a good mother, a good shepherd or a good soldier, one would need to consider the specific functions and responsibilities of each of these roles. This occasionally led to discussion of the characteristics of a good physician, though usually just by way of example [4].

It is interesting (in light of later developments) that the focus was on the person and his/her virtuous or vicious character —not on specific behavior per se. To the extent that a specific action was discussed, it was usually as an expression of or as evidence of a person's character. The focus on the individual's character led to an emphasis on moral training and education—a central topic in ethical theory of the time.

2.2 Consequentialist Theories: Utilitarianism

The virtue-oriented approach to the study of ethics still has its adherents and is still a source of insights today.[5] But the focus of ethical inquiry has changed over the centuries. Simply (too simply) put, current ethical reflection is more likely to concentrate on what makes an action right or wrong than what makes a person good or bad. Talk of virtue and character has largely been displaced by talk of consequences, duties and rights.

Modern ethical theories attempt to articulate what it means to say that an action is moral, and to provide criteria by which we can judge the morality or immorality of a given act. Proponents of such a theory hold that to the extent that an act satisfies the criteria, it can be said to be moral, and the agent can be said to be morally justified in performing the act. How such a theory works can best be illustrated on the basis of an example. We will begin with Utilitarianism, a theory most often associated with the names of its two famous early proponents: Jeremy Bentham (1748–1832) and John Stuart Mill (1806–1873) [5, 6].

Utilitarianism is known as a *consequentialist* theory, for it holds that whether an action is right or wrong depends on the consequences of the action. Specifically, the theory holds that an action (or a practice) is right if and only if, of the options available to the agent at the time, it produces the greatest balance of good consequences for everyone affected by the action. In succinct terms, the theory requires that in order to be moral, we must aim for "the greatest good for the greatest number."

But how are we to understand the "good" that morality requires us to try to maximize? Bentham embraced a hedonistic answer to this question, holding that the good in question is pleasure—the pleasure of

everyone affected by an action. Indeed, Bentham went so far as to propose that we could quantify pleasures (the unit of measurement would be "hedons") and pains (measured in "dolors"), and, subtracting the dolors from the hedons, arrive at a net measure of pleasure for any given act or practice that we might be considering.[6] This net measure of pleasure he dubbed the "utility" of the act or practice—hence the name "utilitarianism." A political radical (for his time), Bentham advocated the use of the utilitarian criterion not only in personal decision-making, but when evaluating public policy initiatives.

J. S. Mill followed Bentham's lead in holding that the morality of an act depends on its consequences for everyone affected. But rather than embracing pleasure as the good to be maximized, he advocated happiness. Mill articulates his "principle of utility" as follows: "Actions are right in proportion as they tend to promote happiness; wrong as they tend to produce the reverse of happiness." Unlike Bentham, Mill did not think that utility could plausibly be quantified in units of happiness. But Mill and Bentham both agreed that the utility principle should be used not only by individuals in their day-to-day moral decision-making, but by legislators and officials in their deliberations about alternative public policy proposals. The principle would dictate that those policies should be adopted whose enactment would maximize utility—for everyone and over the long run. It is important to emphasize that I must take into consideration the effects upon *everyone* affected—not just my family, my friends, my countrymen or members of my generation.[7] This impartiality is part of what makes utilitarianism a *moral* theory and not just a prudential strategy for winning friends or keeping peace in the family.

2.3 Act and Rule Utilitarianism

According to Utilitarianism, if I am trying to decide between two acts—or two courses of action—I should try to estimate which course of action will bring about the greater amount and degree of happiness (utility) for everyone affected by my action. The one that yields the greater utility is the morally right action, and the one that I should perform. I apply the Utilitarian measure directly to the acts that I am considering, and (if I am to act morally) let my decision be governed by the utility estimations. This way of proceeding has come to be called

"act utilitarianism," because the utility test is applied directly to the acts being contemplated.

An immediate practical problem arises, however, when we think about actually putting the utilitarian guideline into effect. In many cases there is no way that I can reliably estimate who might be affected by my action and what effects my actions will (or might) have on those people. And even if it were possible to figure this out, it would take a lot of time —and often, when confronted with a morally weighty decision, we don't have much time for contemplation. In order to address this problem, some have suggested that the utilitarian calculation not be invoked in specific instances requiring a decision. Rather (the suggestion is) we should act in accordance with *rules* that we adopt in advance and resolve to abide by in all cases. But we are to decide which rules to adopt by using the utilitarian calculation. We should adopt those rules which—if everyone abided by them—would maximize utility for everyone in the long run. It might not be easy to ascertain which rules would be the best according to this measure, but we can take the needed time to reflect, discuss and research the question before we find ourselves in a pressing situation in which a decision is needed urgently. This version of the theory has come to be called "rule utilitarianism," for the utility test is not applied to individual acts, but to rules which are then used to decide how to act.[8]

The difference between act- and rule-utilitarianism may seem like something of a technicality, but it turns out to be very important in medical ethics, as we will see when we come to discuss basic principles (below).

2.4 Deontological Theories: Rights and Duties

In modern moral theory the chief alternative to utilitarianism is a conception of ethics based on rights and duties. Such an approach is called a "deontological" theory (after the Greek term for "duty"). Advocates of this conception do not deny the importance of acting in ways that produce good consequences, but they contend that there are limits and constraints on our effort to maximize utility—constraints imposed, for example, by people's rights . We will look first at how rights function, ethically speaking, and then consider how certain rights claims might be justified.

To have a right is to have an entitlement to something. That entitlement imposes obligations on others. For example, if you have a right to life, everyone else has a duty not to take your life—i.e. not to kill you. If you have a right to speak, then all others have an obligation not to prevent you from speaking. And if you have a right to a certain piece of property (say, your home), then all others have a duty not to invade, steal, damage or interfere in your use of that property. Your rights impose duties on all the rest of us—the duty not to prevent you from enjoying and making use of that to which you have a right.

A right is best understood as a kind of ethical trump card , for it often overrides other moral claims. For example, we can imagine a scenario in which a person (Jim) is dying from heart disease, suffers from chronic pain and experiences little joy in life. It might be the case, however, that Jim's kidneys are in great shape, and that there are two potential transplant recipients (currently on dialysis) whose happiness and quality of life would be greatly enhanced if each were to receive one of Jim's kidneys . One might plausibly reason that overall utility would be increased by taking Jim's kidneys , transplanting them into the waiting recipients and letting Jim die. And according to the utilitarian, if utility would thereby be maximized, this would be the right thing to do. But most of us would find that conclusion repugnant, for the kidneys in question are not just an available resource to be distributed in accordance with utility calculations. They are not just kidneys; they are *Jim's* kidneys —parts of his body—and he has a right to decide what happens to them without unwanted interference from others. His right, in this case, overrides the good consequences that motivate the utilitarian.

The fact that rights can override considerations of utility in this way does not mean, however, that such rights are absolute. There are circumstances in which a very important common good can only be achieved by taking someone's property against her will. There are even imaginable (fortunately very uncommon) circumstances in which the catastrophic consequences of not killing someone—of respecting his right to life—are so dire that the violation of his right to life is morally imperative. Most rights theorists would grant that there are such circumstances but would emphasize that they are exceedingly rare.

The aforementioned rights are often referred to as "negative rights " because they entail that others have a duty *not* to interfere. Sometimes, however, it is claimed that we also have "positive rights" which impose upon others the positive duty to provide us with what we need in order to exercise that right. So, your negative right to life entails that I have a duty not to kill you. Your *positive* right to life (if there is such a right) would entail that I (and all others) have a positive duty to provide you with whatever is required to sustain life. This distinction becomes important in the context of health care policy debates. When one hears it said that "health care is a right," the right in question is construed as a positive right —i.e. a right that imposes upon others the positive obligation to provide one with health care.[9]

Traditionally, negative rights have been accorded a higher and more binding status than positive rights. This is reflected, for example, in the UN Universal Declaration of Human Rights [11]. The "right to life, liberty and security of person" (negative right) has pride of place as Article 3 of the Declaration. The "right to a standard of living adequate to the health and well-being of [one]self and of [one's] family, including food , clothing, housing and medical care and necessary social services…" (positive right) does not appear until Article 25. (Interestingly, the right to property appears in Article 17.)

Where do the basic negative rights come from, and what justification is there for recognizing their force? Modern discussions of rights have their origins in the seventeenth and eighteenth centuries—especially in the works of Hobbes [12] and Locke [13]. In the *Second Treatise on Government* (1689) Locke argues that prior to the existence of a state, individuals by nature have rights to "life, liberty and estate." This view is then reflected in the United States of America's *Declaration of Independence* (1776) where Jefferson famously writes that it is self-evidently true that, "…all men are created equal, that they are endowed by their Creator with certain unalienable rights, that among these are life, liberty and the pursuit of happiness."

Rather than deriving rights from divine endowment (as Jefferson does), most modern rights theorists appeal to certain facts and characteristics of human beings that, according to these thinkers, indicate that we should treat them as the bearers of rights. Quinn [16] provides a clear statement of this position:

> A person is constituted by his body and his mind. They are parts or aspects of him. For that very reason, it is fitting that he have primary say over what may be done to them—not because such an arrangement best promotes overall human welfare, but because any arrangement that denied him that say would be a grave indignity. In giving him this authority, morality recognizes his existence as an individual with ends of his own—an independent *being*. Since that is what he is, he deserves this recognition [14].

This passage brings together a number of important points. Quinn denies that the recognition of rights is a means to promote overall human welfare—i.e. he denies that consequential concerns underlie our recognition of rights. He also connects the notion of rights to a person's dignity, arguing that the very fact that we are individual beings with ends (projects and purposes) of our own requires that we be credited with rights.

Quinn's final point draws a connection between his view and that of another important historical thinker of the Enlightenment—Immanuel Kant [15]. Kant argues that since each of us is pursuing his/her own projects and own ends, it is inappropriate (in a sense, self-contradictory) for us to treat another person—who is like ourselves—as if she were a mere means to our own ends . Other people like ourselves (Kant would say "other rational agents") are ends in themselves and hence cannot without self-contradiction be treated as if they were mere tools or instruments for us to manipulate for our own purposes. Rational beings are, in Kant's terminology , autonomous beings entitled to make their own decisions and form their own beliefs —and their autonomy must be respected. Thus Kant, a deontologist like Quinn, points to certain facts about us as human beings (our status as rational agents with ends of our own) and argues that these facts justify the attribution of rights to us.

Before leaving Kant, it should be mentioned that he holds that the admonition to treat others always as ends in themselves—and not merely as means—is one of four different ways of formulating his "Categorical Imperative ."[10] Kant believes that this Categorical Imperative supports not only the basic rights mentioned above, but also

an absolute duty not to lie or deceive others. After all, we lie to others in order to manipulate them for our own purposes, and such manipulation is the very opposite of respect for others' autonomy.

Thus far we have focused upon fundamental rights (to life, liberty and property) and on the duties (of forbearance and non-interference) that one person's rights impose upon all others. But, according to deontological theorists, duties can arise in other ways as well. Most obviously, whenever I freely and voluntarily enter into a contract—formal or informal, explicit or implicit—I impose duties upon myself and (usually) acquire rights that impose duties on the other contracting parties. So, for example , if you and I enter into a contract whereby I agree to provide you with some professional service at an agreed-upon price, I have a duty to provide that service and you have a duty to compensate me for it. Some would say that you acquire a right to my services, and I acquire a right to a certain amount of your money in exchange. Duties and rights can thus be created by agreement between free agents.[11]

In addition to those that arise as a result of contractual agreements , one can acquire duties and rights just by entering into certain natural or socially-defined roles. For example, by having children I take on the duties of parenthood. This might be construed as an implicit agreement, or as a kind of natural obligation, but either way I have duties that I am morally bound to fulfill. Finally—to return at last to our focus—when one assumes the role of physician, nurse, or other health care professional , one takes on certain duties defined by the profession itself and by society's understanding of the profession. When, as a health care professional, one undertakes to care for a patient, one enters into a relationship that is defined, in part, by reciprocal rights and duties. These have sometimes been spelled out explicitly in formal codes of professional conduct and (recently) several "Patients' Bills of Rights."

Before leaving the deontological theory, it should be noted that of course there can be conflicts between the rights of one individual and those of another. Familiar examples abound in contemporary discussions of controversial issues . For example, the abortion debate is sometimes cast as a conflict between the rights of the fetus (a right to life) and the rights of the pregnant woman (the right to control her own

body).[12] Sometimes the debate about single payer health care insurance (financed by increased taxes on the wealthy) is cast as a conflict between a universal right to health care and the property rights of taxpayers. In order to resolve these disputes, one individual's right must be overridden by another's, and for that we need a reliable way of prioritizing rights.

Similarly, an individual can have conflicting duties. Consider a familiar case in the area of end-of-life care : a physician has a duty to relieve suffering, and also a duty not to kill. It may often be the case that the dosage of morphine required to relieve the pain of a terminal patient is likely to induce respiratory arrest. In order to address this sort of difficulty, deontological theorists eschew talk of *absolute* duties and speak instead of *prima facie* duties . A *prima facie* duty to do X obliges me to do X unless the requirements of a more serious duty override that initial (*prima facie*) duty. As in the case of conflicting rights (above), what is needed is a reliable method of weighing and prioritizing duties.[13]

Having examined briefly three ethical theories—one ancient and two modern—the reader might reasonably ask what such theories can contribute to our understanding. What are they purporting to explain? How are they related to each other? Does it make sense to ask which one of them is true?

Each of the two modern theories claims to explain our moral judgments , practices and institutions —based on the account of what makes some acts right and what makes other acts wrong. In addition, the explanation provides a criterion—a decision procedure for judging what acts are right and what are wrong. The Utilitarian says that morality consists in maximizing the good in an impartial way. Actions (and institutions—and people, for that matter) are moral to the extent that they adhere to this "principle of utility ." When faced with the need to make a moral decision, we should weigh the consequences of the various options and go with the one that maximizes positive utility. A deontologist says that morality consists in respecting others' rights and doing one's duty. An action is moral to the extent that it fulfills these requirements. When we have a decision to make, we should ascertain what rights and duties are at stake, and act accordingly.

The two theories offer different accounts of what morality is all about. Is there some way in which they might be reconciled? Over the years, each side has occasionally claimed to be able to explain the appeal of the other theory—and thus subsume the other under its own purview. So, for example, J. S. Mill attempted to explain rights (and their importance) in utilitarian terms. In a sort of rule-utilitarian approach , he argued that adoption by a society of a widely accepted practice of respect for rights would provide for greater utility than a society in which there is not such a practice. And according to Mill, rights are important precisely because (and only because) respect for rights yields good consequences—i.e. greater utility.

From the other direction, deontologists have argued that we have a duty to improve the lot of our fellow human beings. This is sometimes described as an "imperfect duty "—not a duty that we have toward every person at all times (such as the duty not to kill). This is more like a duty to give to charity. We are required to do so, but not to give to everyone all the time. Rather, according to this view, we have discretion in whom we choose to help, and to what extent—but we do have a duty of this sort that we owe to others. The deontologists thus seek to subsume utilitarianism under their theory—as an exaggerated over-emphasis of this one duty, at the cost of more fundamental rights and duties.

The attempts to reconcile the two theories–by declaring one the more fundamental and the other derivative—are ultimately unsuccessful. As noted above, there are cases in which the two theories prescribe different courses of action. In the example of Jim, who is dying of heart disease but has healthy kidneys, the utilitarian might think the best thing to do is to take the miserable man's kidneys and transplant them into the two dialysis patients, greatly enhancing their quality of life and the overall happiness. The deontologist thinks this would be unacceptable, since it violates Jim's right to make decisions about his own body. In such cases it may be impossible to reconcile the perspectives and prescriptions of the two theories. In such cases, the theories cannot provide a decision procedure for the case, for one would first need a procedure for deciding between the two theories!

Each of these theories has proponents who would argue for the priority (or superiority) of one approach over the other.[14] But

ultimately, I think, we have to accept the fact that our ethical norms reflect both perspectives. Both of these approaches have a claim on our moral conscience . We are obliged to consider the consequences of our actions—the way in which our actions will affect others' well-being—when making decisions. And we are obliged to respect others' rights and to fulfill certain special duties that we have as mothers, soldiers, promisers or physicians—rights and duties that may sometimes put constraints on our efforts to enhance the common good. The theories under consideration here remind us that as morally conscientious agents we must consider our actions from both a utilitarian and a deontological perspective. Sometimes seeing the moral dimensions of a problem from both of these perspectives will reveal a dilemma—the two approaches yield different prescriptions about how to proceed.[15]

Though one would seldom hear the terms "consequentialism" or "deontology" in discussions of a case on rounds in the ward, many of the ethical dilemmas that arise in the medical context derive from the fact that our shared moral convictions and sensibilities have a foot in both of these camps. Indeed, many of the chapters of this volume are focused on such dilemmas as they arise in pediatric cardiology and pediatric cardiac surgery. This will be more evident in the discussion of "Principles" (below).

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3 Applied Ethics

The theories discussed above are intended to be comprehensive accounts of normative ethics , applicable in all cases and appropriate to all circumstances. They originated with philosophers and have been elaborated and refined over centuries, in discussions among academics, usually in a university setting or in the pages of scholarly journals. There has been some focus on concrete cases in these discussions, but usually as thought experiments—to illustrate some aspect of the theory or to "test" the theory by applying it to an imagined circumstance to see if its prescription in the case squares with our moral intuitions.

Large-scale historical events and movements are often inspired by ethical considerations, and they involve public argument and discussion of the moral and political principles at stake and their application to the situation at hand. Examples from United States

history would include the revolution, the abolitionist movement, the drive for women's suffrage, the temperance movement, and the civil rights campaign. Closer to home, almost every aspect of our lives has an ethical dimension, and ethical issues can arise anytime and anywhere. We consider our options, think about the values at stake, perhaps discuss the difficulty with a friend, decide what is right, and (sometimes at least) do it.

All of these involve the application of ethical reflection and argumentation to concrete, real-life situations . To that extent, they can be thought of as instances of applied ethics. But in recent decades—since the mid-twentieth century—a more targeted academic subdiscipline has emerged and laid claim to the title "applied ethics" [19]. The specialist in this field analyzes the ethical dimensions of specific real-life circumstances and practices , aiming to resolve tough dilemmas and establish (where possible) guidelines for ethical behavior. The applied ethicist can concentrate on any area of private or public life, but some of the most interesting work has focused on the various professions—medicine, the law, journalism, business, engineering. Given the specialized knowledge required in order to understand and address specific cases in these different professions, the field of applied ethics often involves interdisciplinary training — sometimes with several people from different fields working together.

The bio-medical fields led the way in the advance of applied ethics, and it is worth taking a moment to consider a few factors that might have influenced this development. First, there were specific historical events that triggered a troubled response and a sense of urgency.

The revelation, after the end of World war II, of the atrocities perpetrated by a few physicians in the Nazi eugenic programs and in the concentration camps, was shocking [20]. Very soon after completion of the war crimes trial, the Nuremberg Code of ethics for research on human subjects was formulated (1947)—a seminal document in the modern field of applied bio-medical ethics. Another important factor was the increasing tide of malpractice litigation in US courts since the 1960s [21][16]. Resolution of these cases often hinges on the "standard of care ," and the standard of care often has an ethical dimension that must be articulated and addressed. Finally, and perhaps most important, the rapid advances in medicine and technology in the

mid-twentieth century raised hitherto unimagined ethical issues and set the stage for widespread policy debates. To name just a few of these: organ transplantation (1954), fertility drugs (1967), in vitro fertilization (1978), pre-natal diagnosis via amniocentesis (1965), open heart surgery (1960), vacuum aspiration abortion (1967).[17]

Applied ethicists hope to provide insight that can be helpful to those responsible for devising public policy regarding the various professions. They also hope that their analyses might be concretely useful to practitioners in the field as they confront ethical dilemmas and make tough decisions. For the latter purpose what is needed is a small set of concisely stated principles that can focus the decision-maker's attention on the moral dimensions of the case and guide her reasoning as she weighs the options. Over the years, practical ethicists in the bio-medical field have managed to agree upon a set of principles that condense the insights of the modern ethical theories and provide a convenient tool for analyzing concrete cases. These are four in number: (1) non-maleficence; (2) beneficence; (3) respect for autonomy; (4) justice. We will consider each of these in turn, but first a few thoughts on the relationship between the four principles and the ethical theories discussed above.

Utilitarians and deontologists might not agree on the exact wording of these, nor (importantly) on the order of priority that should be assigned to them, but all four are principles that could be accepted by an adherent of either of the two modern ethical theories. The first two principles are focused on doing good and avoiding harm . As such they are clearly consequentialist and encapsulate the core doctrine of utilitarianism. Still, the Kantian could accept them as expressing our duty not to harm fellow rational agents and our imperfect duty to improve the lot of others (see above). The third principle, by contrast, highlights the deontologist's focus on people's rights and our duty to respect those rights. A utilitarian could accept that a widespread practice of respecting autonomy might, in the long run, tend to maximize the well-being of everyone.[18] The fourth principle—justice—embodies the impartiality that is central to both theories.

Employment of these principles does not guarantee that a solution to a dilemma will be found. There can be ethical issues that arise in the medical context that are not directly addressed by these principles.

More importantly (and more often) two principles might point in conflicting directions with regard to a single case. Principle #1 might counsel withholding the gravity of a patient's condition from him—"for his own good." Principle #3 requires that he be told the unvarnished truth—out of respect for his autonomy. The set of principles does not provide a procedure for adjudicating priority disputes between the principles. Still, a decision maker can be confident that if she has conscientiously considered a given case from the perspective of each of these principles, she is awake to the important ethical dimensions of the problem and is in a position to make a morally sensitive and perceptive judgment.[19]

3.1 Principle #1: Non-maleficence

Often equated with the Latin admonition "Primum non nocere" (First do no harm), the principle of non-maleficence seems at first to be simple and straightforward. It obviously prohibits a person from willfully harming or injuring another "with malice aforethought." But there are other ways in which a person can do someone harm. For example, I can injure another not intentionally but as a result of negligence, carelessness, incompetence or ignorance. In the medical context, where the professional has a clear duty of non-maleficence, causing harm to the patient in any of these ways is a breach of that duty.

Medical professionals are expected to proceed carefully and deliberately, and to provide appropriate treatment and therapy based on reasonably current clinical knowledge and the "state of the art." These performance expectations contribute to the "standard of due care"—a legal term used to designate what a patient can reasonably expect from his/her physician (in a given community, at a given time). If the medical professional acts (or omits to act) in a way that falls below the standard of due care, and if the patient, as a result , suffers harm, the physician is in breach of the principle of non-maleficence. In fact, the physician can be in breach of the principle even if the patient is not harmed—if the patient was subjected to unnecessary risk of harm as a result of treatment (or lack of treatment) that does not meet the standard of due care.

But of course, it is impossible to avoid all harm and all risk of harm when providing medical treatment. Sometimes the treatment itself

requires that the patient be harmed. In order to perform life-saving open heart surgery, the patient's skin must be cut , the sternum divided, and the chest exposed. Taken in themselves these would clearly be injuries to the patient, but since they are necessary conditions for completing a life-saving intervention, they do not count as harms and do not violate the principle of non-maleficence. So, the principle must be read not as prohibiting harm but as prohibiting *unnecessary* harm – harm that is not justified by a greater benefit to the patient.

The standard of due care does not require that the physician be omniscient. Sometimes it is impossible to know all of the consequences of one's well-intended interventions. Unexpected eventualities can occur. The patient may have an unusual reaction to a medication; the minimum dose of morphine sufficient to relieve intense pain may in a given patient cause respiratory arrest; some aspect of the therapeutic regimen may trigger traumatic emotional response. The physician is not required by the principle of non-malevolence to avoid all injurious consequences—only the reasonably foreseeable ones.

Finally, there is not always agreement about what counts as a harm. A terminally ill patient who sees nothing in his future but suffering, expense and a prolonged process of dying may reasonably view the physician's efforts to keep him alive as harmful. For such a patient, death itself is not seen as a harm.[20]

These difficult questions arise in a number of chapters in this volume. Prenatal obstetrics and neonatal intensive care (including cardiology and cardiac surgery) are now capable of keeping alive compromised near-term fetuses and severely disabled newborns that would surely have died in the past. But the quality of life that can be expected in these cases is sometimes so profoundly compromised that it is unclear whether the interventions that kept the patient alive have benefited him or harmed him. Beauchamp and Childress [23] cite several authors who hold that keeping newborns alive in these extreme circumstances is a harm to the patient. "[Some commentators argue] … that aggressive intervention violates the obligation of non-maleficence if any of three conditions is present: (1) inability to survive infancy; (2) inability to live without severe pain; (3) inability to minimally participate in human experience" (p. 173).[21] It should be mentioned here, of course, that the final decision in these matters is not the

physician's alone . On the contrary, the pregnant woman or the parents of the newborn have the decisive voice—though they will of course be heavily influenced by the predictions and counsel offered by the medical professionals.

Beauchamp and Childress conclude that "Managing high-risk pregnancies nonaggressively and allowing seriously disabled newborns to die are, under certain circumstances, morally permissible actions that do not violate obligations of non-maleficence." This conservative conclusion affirms that non-treatment is not a harm but leaves open the question of whether providing aggressive treatment in such cases *would* be a harm (and hence a violation of the duty of non-maleficence). Moreover, the phrase "Managing high-risk pregnancies non-aggressively" carefully skirts the question of the permissibility (or even obligation) of late-term abortion in such cases.

3.2 Principle #2: Beneficence

The second principle, beneficence , tells the physician to do what he can to help and improve the condition of his patients. This makes a somewhat higher demand than the principle of non-maleficence, for improving things requires more than just not making them worse.

There is some question whether we all have a duty of beneficence toward all others as a general matter of morality. Clearly , we are obligated not to hurt others, but do we have a duty to help all others? Utilitarians would certainly say yes, for seeking to maximize the good for everyone concerned is the very principle of utility itself. A deontologist would agree that we have some obligation to be helpful to others but would emphasize that this is an "imperfect" duty. We have to help some people some of the time, but we do not have to help everyone all of the time. We get some choice about whom to help and when to help them.

Fortunately, we do not have to resolve the larger question here, for it is entirely clear and entirely certain that a physician has a duty of beneficence toward his patients. Seeking to help one's patients is definitive of what a physician is. By entering the profession, the physician assumes the obligation to improve the welfare of his patients to the extent that he can. This is true for other medical care professionals as well—nurses, therapists, et al. All have an individual

obligation to promote their patients' welfare. And maybe the profession as a whole has such an obligation toward society as a whole. Medical professionals can improve the well-being of everyone through supporting public clinics, advocating for health and wellness initiatives, and promoting research. All of these are part of the definition of being a medical professional, and the physician shares these obligations.

There are of course limits to the physician's obligation to make sacrifices for his patients' welfare. Servile selfless devotion is not required by the principle of beneficence, but more than members of most other professions the physician is expected to be attuned to patient needs and prepared to put his own immediate interests aside to attend to patients' welfare. Striking this balance can be difficult, and there is no agreed upon "standard of beneficence," on the analogy of the "standard of due care" to provide guidance in hard cases.

As we have seen elsewhere, adherence to this principle can be in tension with other obligations. Sometimes the obligation to help might call for a paternalistic intervention—either directly against the will of the patient or without the patient's knowledge. Such an intervention might involve forcible institutionalization of a suicidal patient or refusing a patient a new and unproven treatment that she expressly requests. To focus on a more modest example, in certain cases the most helpful thing a physician can do might be to prescribe a placebo. Such a prescription might well be beneficial to the patient, but it requires deceiving the patient about the contents of the pill.[22] Coercion, manipulation and deception might sometimes be effective ways of improving a patient's condition, but it would directly conflict with the principle requiring respect for patient autonomy—an important principle to which we now turn.

3.3 Principle #3: Respect for Autonomy

The principle of respect for autonomy is deeply rooted in Western morality and hence, in bio-medical ethics. Jefferson's appeal to our God-given rights to life, liberty and the pursuit of happiness, coupled with Kant's emphasis on rational agency as the hallmark of humanity, have produced a powerful and complex moral norm.

The term "autonomy " comes from the Greek *auto* (self) and *nomos* (law or rule). An autonomous person is one who is self-governing or

self-determining, whose actions are the result of her own decisions and choices. Warren Quinn, quoted above [14], explains that since a person is constituted by his mind and body, "For that very reason, it is fitting that he have primary say over what may be done to them… because any arrangement that denied him that say would be a grave indignity." The principle of respect for autonomy requires that the medical professional give the patient the "primary say over what may be done to [him]." This requires, most obviously, that there be no coercion, force or manipulation used to induce a patient to follow a certain course of treatment or to participate in a clinical study. But independent, uncoerced choice is not enough, for a long tradition in Western philosophy—reaching from Plato to Kant to Habermas—places the locus of human dignity in our ability to reason—in our capacity not just to make choices, but to make *rational* choices. This complicates (and enriches) the moral picture considerably. The emphasis on rational self-determination raises a host of interesting and important issues. We will mention three of these: truth-telling , informed consent and manipulation—and point briefly to some of the complexities involved. Individual articles in this volume will address some of these issues in greater depth, with a direct focus on pediatric cardiology and pediatric cardiac surgery. Footnotes will alert the reader to the chapters that provide a more thorough discussion of a particular question.

Rational decision-making is based on the accurate and complete exchange of information between the physician and her patient. Respect for autonomy requires that the medical professional support the patient's decision-making by providing accurate and (so far as possible) complete information about her condition, about treatment options and about likely results. In short, the physician is called upon to tell the patient the truth so that she can make informed decisions about her health care.

The requirement that the patient be told the truth assumes that there is one agreed-upon truth to be told. But when a team of medical professionals is involved in a difficult case, there may be substantive disagreement about the diagnosis, the prognosis or the likely results of various treatment options. In this context the question is, whose truth should be given to the patient, and who should deliver it?[23] Even in the case of a single caregiver, it may be that she is unsure about important

aspects of the case—so that the truth is that the truth is unknown. In such a case, presumably truth-telling requires that the patient be informed of the high level of uncertainty involved in the information that is being provided. But this can be problematic, for such uncertainty seems unlikely to make the patient's decision-making any easier—or more rational. Moreover, it might have the unfortunate consequence of undermining the patient's confidence in the caregiver's expertise—a significant factor influencing the success of the treatment provided.

The last point serves as a reminder that words have power, and that what the patient is told may affect her state of mind and her state of health. For decades the norm was that patients suffering from terminal illnesses were not informed of the gravity of their condition. The justification most often given was the duty of non-maleficence. To inform a person that she will die soon can sometimes trigger fear, anxiety, depression and hopelessness—and to induce these emotional states in someone, at a time of already heightened vulnerability, is—arguably—to harm her.[24] This norm has of course changed (in the course of the late twentieth century), and except in the most unusual cases, full disclosure is now expected as part of the standard of due care.

It should also be mentioned that there is sometimes a kind of paradox—or at least a tension—in the simultaneous requirement that the physician respect a person's own wishes about what happens to her and also tell her the truth. Sometimes a patient may indicate that she prefers not to hear certain truths and or prefers not to be burdened with the need to participate in difficult decisions. If respect for autonomy requires letting her have the say in what happens to her and requires telling her the truth, what should the ethically conscientious professional do when a patient does not want to hear the truth?

Fortunately, in the cases that are the focus of this volume, these concerns are not usually a problem. In our cases, the patient is often not the decision-maker, so the patient will not be harmed by hearing traumatizing truths nor troubled by the burden of difficult choices. For near-term fetuses, newborns and young children, the responsibility for making decisions shifts to the pregnant woman or the parents. They are acting on behalf of the patient and are assumed (in the absence of evidence to the contrary) to have the best interests of the fetal or

newborn patient at heart. In such cases the medical professional still has the duty to tell the truth—to the parents/decision-makers. This is in part a result of the universal duty we all have to respect others' autonomy (and hence to tell others the truth). The parents are people, too, and deserve not to be lied to or manipulated . But the main reason for the physician's obligation to tell the parents the truth is to ensure that the best interests of the patient are served—to do good and to avoid harm to the patient. Well-informed parents are more likely to make judicious decisions that in fact serve the interests of the patient.

There remains a danger that the parents might be overwhelmed or overburdened by the facts and by the obligation to make decisions at a very high-stress and vulnerable time. The physician or medical team remains obliged to provide the decision-makers with full and accurate information, and to do what can be done to ensure that they understand and are competent to weigh that information.

Conveying factual, useful and (as far as possible) complete information to the parents ensures that when they consent to treatment on behalf of the patient, they are giving *informed* consent. Like the obligation of truth-telling, the duty of securing informed consent is a direct corollary of the principle of respect for autonomy, and it is required by ethics and by the law. Whether the decision is to approve treatment (or refuse it), to allow the patient to participate in a clinical study, or to donate organs, informed consent is the required standard. Since the parents are not medical professionals, it can be difficult to ensure that they understand relevant technical aspects of the situation, but the medical professional is obliged to do his/her best.

The structure of the decision scenario in these cases generates an additional important uncertainty that deserves mention. As noted above, in the case of a sick or disabled newborn or young child, there is a difference between the patient and the persons whose autonomy the physician is obliged to respect by telling the truth and securing informed consent (in most cases, the parents). Ideally, this difference will be unimportant because the parents want what is best for the child and want to avoid harming him/her, as does the physician. The physician bases her judgment of what is best for the patient on the relevant facts and shares those facts with the parents. Since both want the same thing (the patient's well-being) and are both basing their

judgments on the same facts, we might hope that their judgments will coincide. And in most cases, presumably, they do.

But it can happen that the physician has a clear idea of what she thinks would be best for the patient, and the parents don't share that view. Maybe they have a different idea, or maybe they just seem unsure and vacillating. The question arises whether, in such cases, the physician can ethically undertake measures to persuade the parents—measures other than providing facts and rational argumentation. There has been much discussion recently about the use of gently manipulative (not coercive, but not rational) persuasive techniques (called "nudges ") to get a person to do the right thing. The question here is whether a physician may use such gently manipulative non-rational methods without violating her duty to respect the autonomy of those with whom she is dealing.[25]

Finally, there are more extreme cases in which the parents refuse (on religious grounds, for example) to consent to an intervention that the physician thinks is required to prevent permanent harm or death to the patient. In such a case the physician might judge the parents to be irrational—so irrational that they have surrendered their status as autonomous beings and hence forfeited their right to have their autonomy respected. This amounts to a judgment, based on their religious beliefs and religiously based actions, that they are incompetent to make decisions. This sounds like a judgment that many medical professionals would not be comfortable making—given our tradition of respect for religious belief and tolerance of religious diversity. Moreover, if the mother were the patient and she refused life-saving treatment for herself, that refusal would normally be honored. So, it does not appear that such a refusal on religious grounds would by itself indicate that one is incompetent *simpliciter*. Still, the duty to avoid harm to the patient is paramount and requires that the physician intervene. Under current (US) law the physician or hospital can petition to have the state take temporary custody of the child—under the doctrine of *parens patriae*—and order the treatment . This measure does not require that the parents be declared incompetent but is based only on the state's responsibility to care for children's welfare when their parents refuse to do so.

3.4 Principle #4: Justice

The principle of justice is the most complex of the four. It is said to apply to societies, laws, institutions, practices and individuals. There is a separate chapter of this volume (Chap. 18 – "Ethics, Justice, and the Province of American Medicine: A Discussion of the Politicalization of the Duty to Care for Pediatric Heart Transplant Patients who are in the Country Illegally") dedicated solely to the issue of social justice in pediatric cardiac medicine, so the discussion here will focus on conceptions of justice in general . After a brief consideration of justice in the most abstract terms, we will focus on two distinctions: (1) conservative versus ideal justice; (2) procedural versus substantive justice. By exploring these distinctions in brief, we will provide an orientation to the complexities of this principle.[26]

It is easy to formulate the principle of justice in abstract terms, but very difficult to define more concretely. According to Aristotle, the essence of justice is found in the requirement that equals be treated equally, and unequals unequally. Also, from the ancient world comes the idea that justice consists of giving everyone that which he/she is due. These formulations provide an intuitive sense of what justice requires and suggest correctly that justice is about the allocation or distribution of benefits and burdens. But more questions are raised than answered by the vague terms employed. "Equal" in what respects? "Due" on the basis of what obligation?

Maybe, with some creative elaboration, we can derive a rule of non-discrimination from these definitions. After all, the medical services due a person are presumably related to his or her medical condition, and not to his/her race, gender, creed, etc. And presumably the relevant parameters on which equality should be judged, for medical purposes, are medical parameters, not racial or religious characteristics. We saw how both utilitarianism and the deontological view require impartiality, and a rule against discrimination on the basis of irrelevant characteristics embeds that impartiality in the requirements of justice. This is a step in the right direction but does not take us very far. The above-mentioned distinctions will take us further into the complexities.

3.4.1 Conservative Versus Ideal Justice

The Latin root from which our term “justice ” derives (*ius*) means “law,” or “right,” and in the Roman context referred to one’s rights as a citizen of the polity. The term is still most often used with respect to the actual established laws of the state—the “halls of justice,” the “justice system,” the “Department of Justice.” Justice, on this reading, is defined by the law of the state, and what is just is what is in accord with that law. This justice is labeled “conservative” for it preserves the way things are—the norms and practices that define society at a time. From this perspective, the phrase “unjust law” is a contradiction in terms.

But “justice ” can also refer to an idealized conception of how things could be—where benefits and burdens are more equitably or fairly distributed, for example. On this view, actual laws may very well be unjust—think Jim Crow laws or the racial purity laws in Germany in the 1930s. Actual laws can be criticized from the perspective of a “higher” conception of justice based on principles of, say, fairness or equality.

Medical professionals are of course subject to the laws of the actual state in which they practice, and hence have a duty (at least a *prima facie* duty) to obey the laws of that state. But they might find that the laws , as presently in force, produce injustices and tend to conserve a system in which these injustices are perpetuated. In such cases the physician can adopt a higher standard of justice than that defined by the law and try, in his/her practice, to live up to that higher standard. (There will be more to say about ethics and the law in the final section of this chapter).

3.4.2 Procedural Versus Substantive Justice

On some conceptions, the main requirement of justice is to make sure that the rules in accordance with which goods are distributed are fair, non-discriminatory, and impartial. If the procedures are just (on this view), and if everyone acts in accordance with these procedures, then there is nothing more to be said. In a famous thought experiment the Harvard professor Robert Nozick tells the story of Wilt Chamberlain, the legendary basketball star [30]. Wilt Chamberlain enjoys playing basketball, and ten million people are happy to pay a quarter each to watch Wilt play. So, Wilt ends up a millionaire, whereas most of his fellow citizens, by comparison, have much less. Nozick argues that since all the fans willingly gave their quarters, and no one was coerced or

manipulated or deceived, the resulting distribution of money, though quite unequal, is entirely just—because it was arrived at in accordance with just procedures.

Others embrace a more substantive conception of justice, according to which the final distribution of goods can be unjust even if the procedures leading to that distribution were all acceptable in themselves. So, in the case of Wilt Chamberlain, the massive inequality that results from the exchanges is reason enough to declare the system unjust. For the proponent of the substantive conception of justice, the final distribution has to conform to a pattern based on a principle. That principle might be highly egalitarian, or perhaps based on a principle that calls for more resources for those with special needs,[27] or more for those disadvantaged in the past. In order to achieve justice, on this conception, it might well be necessary to redistribute goods in accordance with the justice principle.

In the case of the distribution of medical care in the United States, these two conceptions of justice might point in different directions. For the first conception, if one were to think that the economic system is basically procedurally fair, then the current distribution of health care services—where some can take for granted the very best care in the world while others go bankrupt or do without food in order to pay for medications—will seem just. For the second—substantive—conception, this distribution might seem extremely unjust, depending on one's substantive principle of just distribution.

One might base a substantive conception of justice on the previously mentioned view that everyone possesses a (positive) right to health care. According to this account, not only do others have a duty not to interfere with a person's efforts to acquire health care. On the contrary, on this view others have an obligation to provide a person with whatever is necessary to achieve a reasonable level of health care services. Any distribution of health care resources that leaves some without access would be, on this substantive conception, eo ipso unjust.

Yet this substantive position, too, raises additional issues. If a conception of justice grants a positive right to health care to everyone, one might still debate whether an individual forfeits that right if he engages in risky behaviors known to endanger his health and thus increase the likelihood that he will need to make claim on collective

resources to pay for his more expensive and extensive care. Some would argue that it is unjust to require that others foot the bill for his irresponsibility. Others would respond that even foolish behavior does not entail the forfeiture of one's basic rights.

Justice is a matter of fair distribution of benefits and burdens, of resources and services. The more scarce and costly the resources in question, the tougher the problem of just allocation. In pediatric cardiology and cardiac surgery, the resources can be costly indeed, and are often scarce. Such situations require criteria for allocation—which serve, in effect, as principles of triage. Is "ability to pay" a just criterion for allocation of resources? One might think so if one cares most about procedural justice and if one believes that the economic system that generated the distribution of economic assets was itself procedurally just. In the case of pediatric medicine, though, the patient is not the one who is paying, and it hardly seems just that the parents' inability to pay should cost the newborn patient his life. Should the children of indigent and uninsured parents receive the same extent and quality of care as the children of the wealthy and insured? Many conceptions of justice would answer in the affirmative. But an actual program to make that happen would require a profound change in our present political and economic arrangements. The pediatric cardiologist or cardiac surgeon might, as a citizen, engage politically in support of such a change. As an individual practitioner, though, perhaps the best that she can do is to try to provide equally effective, respectful and professional care for all her patients.

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4 Dealing with Conflicting Obligations

Several times we have seen that two of the basic principles of medical ethics might, in a given case, prescribe contrary courses of action. Respect for autonomy dictates that the patient be told the truth; non-maleficence requires that the patient not be harmed by hearing psychologically devastating news. Beneficence might call for doing all that one can to secure a kidney for a dialysis patient , while respect for autonomy prohibits taking it from a dying patient without his permission. The four principles themselves offer no way of adjudicating the dispute by prioritizing one principle over the other. One might

appeal to the ethical theories of utilitarianism and deontology in hopes of resolving the conflicts, but in these cases the two theories point in different directions, and hence provide no resolution.

Sometimes the conflicts are merely apparent, and more careful consideration of the facts of the case or of the relevant moral principles will yield a solution. But sometimes not. There are, in the end, genuine ethical dilemmas in medicine—cases in which there is no clear "best option," but nonetheless a decision is required. In such cases the ethically conscientious practitioner still has a useful source of moral insight to call to her aid: an ethics consultation. Most hospitals have a formalized advisory process for bringing in experienced professionals (usually medical professionals) trained in clinical ethics to discuss the case. Ethics consultation services are most often called for when there is a disagreement about treatment between physician and family (or between physicians), but they can also be of service to the individual practitioner who is unsure or conflicted about the ethical nuances of a given case.[28]

Early in his *Nichomachean Ethics* [3] Aristotle reminds us that ethics is not an exact science like geometry. There can be ethical principles, but they do not logically entail an answer to every ethical dilemma the way the axioms and definitions of geometry provide a decision procedure for the truth or falsity of every proposed theorem. In Aristotelian terminology, ethics is a *practical* discipline, not a purely theoretical one. As a practical science it deals with human action—always immersed in the social, political, religious and biological complexity—the changing contextual detail—of human life. Learning to act ethically is not just a matter of learning and then applying rules. Rather , there is a kind of skill involved, and developing a skill requires practice and experience. We must acquire, through practice, the skills that enable us to apply our general understanding in ways that are appropriate to each occasion. A person who knows the principles and has acquired, through extensive experience, the skill and the habitual inclination to apply those principles in the right way, possesses what Aristotle calls "practical wisdom " (Greek *phronesis*) [3]. We sometimes say that for such people it is "second nature" to take seriously the ethical dimensions of a case , to discern the nuances that might be morally significant, to really hear what the family is saying, and to

weigh differing perspectives judiciously. When confronting a moral dilemma in the medical context, the judgments of such a practically wise person may be the most reliable source of guidance that can be found. In the best of cases the hospital's ethical consultation team includes one or more such practically wise persons. And of course, the conscientious medical professional might aspire to develop this practical wisdom for him/herself in the course of a career.

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5 Concluding Postscript on Religion and the Law

Attentive readers will have noticed that throughout this long chapter on the subject of ethics there has been almost no mention of religion. This may seem odd, for religion serves as a major source of moral norms for many people, and divine sanction is sometimes taken to be the ultimate foundation of moral authority.

Actually, religion has been very much with us throughout the chapter, even though it has not been mentioned. The ethical theories and principles that have been under discussion are expressions of Western culture, and as such are deeply rooted in its two chief sources —the classical world of Greece and the Judeo-Christian religious tradition. The symbiotic relationship between faith and reason, between Athens and Jerusalem, between committed devotion and Enlightenment criticism—this is the ground from which our shared moral convictions have grown. This dual source of origins helps to explain, too, some of the tensions that we have encountered between competing norms, both of which speak to us with such resonance. So, as we have talked about ethical norms and principles religion has been very much with us, though it has been barely mentioned.

But the important phrase in the last paragraph is "shared moral convictions." We live among many religious communities and denominations which differentiate themselves from one another by different beliefs, rituals and sometimes rules of behavior. Acceptance and even celebration of this diversity is a hallmark of our society. The respect for the faiths of others is itself one of those values hard-won in the confrontation between the deadly religious wars of the Reformation and Enlightenment thinkers' efforts to find a way for people of differing

faiths to live in peace. One of the solutions that emerged from this confrontation was a decision, for purposes of public discourse, to leave aside the doctrinal details of specific faiths and to focus on the foundation of broadly shared moral beliefs.[29]

Ethical theories and applied ethics, as we have discussed them, proceed on the assumption that amongst all the religious diversity there is a shared core of moral beliefs that can serve as the basis for discussion and for establishing broad agreement on guidelines for ethical conduct by professionals. The work of applied ethicists, though fraught with occasional disagreements, is evidence that in fact there is enough shared ethical ground to sustain a productive discussion of how those shared principles are to be applied in specific cases. It is hoped that the chapters of this book, each itself an essay in applied ethics, will be similarly successful.

Some readers may have also found it surprising that there has been very little mention of the law in this chapter. After all—especially in a representative democracy—the civil law can give voice to widely shared moral norms and can provide guidance regarding the kinds of behaviors that are welcome and those that will not be tolerated. The law, with its threat of punishment, encourages good behavior on the part of those whose moral discernment and conscience provide insufficient motivation.

In sum, the law is important and valuable, and (in my view) we all have a very strong *prima facie* obligation to obey the law at all times. Especially in a liberal democracy, in which the citizen has the right to protest and to try to get a law changed, there are relatively few situations in which a citizen would be justified in breaking the law.[30] Fortunately this is not a problem in most cases under discussion here, for the laws and regulations imposed on physicians and other medical professionals are generally intended to protect the patient by ensuring that the standard of due care is maintained—and hence the requirements of the law and the expectations of applied ethics will coincide.

In certain instances, however, the law itself is controversial and the current state of that law is crucial for the practitioner. The most dramatic instance of this sort at the present time relates to abortion—an important issue in the context of prenatal cardiac medicine. The

chapter in this collection dealing with abortion (Chap. 10) thus addresses, in some detail, the changing legal status of pregnancy termination, at various stages and in various jurisdictions. The physician's moral obligation to obey the law is an important factor in judging what is ethically required or ethically permissible.

But that duty—the duty to obey the law—is not the only consideration for the physician, and that is why our lengthy discussion of ethical theories and applied ethics has, on the whole, proceeded without explicit reference to the law. Perhaps in a given case the physician decides, based on the sort of reasoning found in applied ethics, that she is ethically called upon to terminate a pregnancy, though she knows that to do so is illegal under the laws of the state. When she brings in her obligation to obey the law, however, and the likely consequences for her and others if she were to break the law, it may well be that all things considered the right thing for her to do is to obey the law after all—i.e. not terminate the pregnancy. In such a case it is clear that the law is keeping her from doing what would, in the absence of the law, be the right thing to do. This would provide her with some reason to think that perhaps the law should be changed.

In discussing justice, we noted that a distinction can be drawn between conservative justice (defined as obedience to the law of the state) and ideal justice (defined by reference to an independent ethical standard of fairness or equality). It is important, I think, when discussing applied ethics in the bio-medical field, to keep the civil law out of the discussion on the first pass and stay with what we might call "ideal ethics." The law can be (and must be) brought in as well, but that can be at a second stage of deliberation.

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Footnotes

1 It is unclear how much of the Hippocratic Corpus can be attributed directly to Hippocrates himself, and how much of it stems from his later students and followers.

2 A few women physicians are mentioned in the surviving documents from ancient Greece and Rome, but the medical profession at the time was almost entirely a male preserve.

3 These issues are addressed specifically in Chaps. 13, 18 and 8 of this volume – "Informed Consent in Fetal Hypoplastic Left Heart Syndrome," "Between Death and Donation: Ethical Considerations in Pediatric Heart Transplantation,'' and ''Ethical Issues Surrounding the use of Post Cardiotomy ECMO" (respectively).

4 Though some authors draw a distinction between the uses of the terms "ethical" and "moral," there is no agreed-upon way of making this distinction, and the attempt is often more confusing than helpful. The two will be used interchangeably in this chapter.

5 Chapter 2 of this volume – entitled "Autonomy and the Principles of Medical Practice" – makes productive use of the ancient conception of virtue.

6 "Hedon" is derived from the Greek word for pleasure; "dolor" from the Latin term for pain. This quantification procedure, often derided nowadays, is called "Bentham's calculus."

7 Bentham advocated taking into consideration not only all people affected, but also members of other animal species. Since pleasure and pain are the relevant consequences, and since animals are capable of suffering, he reckoned that they should be included in the utility calculus.

8 Mill himself informally hinted at a kind of rule-utilitarian view, though he did not develop it in detail [6]. More thorough and sophisticated versions have been developed and extensively discussed in the twentieth century and more recently. For example, Brandt [7, 8] and Hooker [9, 10].

9 More on this in Chap. 15 of this volume – "Ethics, Justice, and the Province of American Medicine: A Discussion of the Politicalization of the Duty to Care for Pediatric Heart Transplant Patients who are in the Country Illegally." The distinction between negative and positive rights also plays a role in the abortion debate (see Chap. 10 – "Abortion Rights").

10 The first formulation of the Categorical Imperative reads: "Act only according to that maxim whereby you can, at the same time, will that it should become a universal law." The idea is that one should act only in a way that one could will that everyone act in like circumstances. The principle is close to the Golden Rule, but Kant's emphasis is not on whether I would in fact want everyone else to act in this way, but whether it is logically possible for everyone to act in this

way. His best example—if everyone were to lie when it is convenient, no one would believe anyone ever, and lying itself would become impossible. The practice of lying whenever convenient cannot, without self-contradiction, become a universal practice. According to Kant, lying is thus prohibited by the Categorical Imperative, and hence immoral.

11 Deontologists would insist, though, that there are certain contracts which are necessarily null and void and cannot be entered into. For example, one cannot contract to give up permanently one's basic natural rights. So, for example, I may not contract to sell myself into slavery, for in doing so I would permanently destroy my freedom—the very freedom that I am exercising in making such an agreement. Kant would argue that there is a self-contradiction in such an arrangement. For similar reasons, Kant holds that suicide is always a violation of the moral law.

12 See Chap. 10 of this volume – on "Abortion Rights" – for a more detailed discussion of the abortion dilemma and different ways of depicting the conflict.

13 The emphasis upon *prima facie* duties is derived from the work of Ross [16]. Ross denied that we can ever have a clear ranking of duties—from least stringent to most stringent—that would allow us reliably to resolve conflicts between *prima facie* duties.

14 For example, Peter Singer (Princeton) is a well-known proponent of utilitarianism [17], while Robert Nozick (Harvard) defends the primacy of rights and duties [20].

15 Alasdair McIntyre, in a widely discussed book entitled *After Virtue* [18], summed up the way things stand in the following well-known passage: "The most striking feature of contemporary moral utterance is that so much of it is used to express disagreement; and the most striking feature of the debates in which these disagreements are expressed is their interminable character. I do not mean by this just that such debates go on and on and on—although they do —but also that they apparently can find no terminus. There seems to be no way of securing moral agreement in our culture" (p. 6). There are certain issues regarding which MacIntyre's weary description is accurate. But though they are high-profile issues (in great part because of their insolubility), they are not typical.

16 Sonny Bal [21] tell us that, "In the United States, medical malpractice suits first appeared with regularity beginning in the 1800s. However, before the 1960s, legal claims for medical malpractice were rare, and had little impact on the practice of medicine. Since the 1960s the frequency of medical malpractice claims has increased…"

17 Arguments from applied ethicists played an especially important role in the early debates on abortion legalization occurring in the late 1960s and early 1970s. See Chap. 10 of this volume – "Abortion Rights."

18 Mill's *On Liberty* [22] can be interpreted as an extended utility-based argument in favor of respect for individual autonomy.

19 The *locus classicus* for a broad discussion of the principles is Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics* [23]. The work was first published in 1977 and is now in its seventh edition (2009).

20 Currently the standard of due care does not r*equire* a doctor to let a patient die (though in certain circumstances it permits her to do so). Nor (at present) is the doctor required to provide the patient with the means to end his own life. But the latter development is not unimaginable, as a growing number of states have passed laws permitting physician-assisted death/suicide.

21 Beauchamp and Childress, in turn, cite [24] as a source.

22 Actually, this may not be true. Remarkable recent research suggests that in certain cases the placebo effect remains even when the patient is explicitly informed that the pill she is taking is a placebo (and the pill bottle is labeled as such) [25].

23 "Informed Consent in Fetal Hypoplastic Left Heart Syndrome" (Chap. 13 of this volume) provides a nuanced discussion of this difficulty in the context of a diagnosis of hypoplastic left heart syndrome.

24 There is interesting ethnographic data indicating that certain nationalities and certain ethnic sub-groups in the US and Canada are less in favor of a terminally ill competent adult family member's being informed of the diagnosis and asked to participate in the decision-making [26, 27]. The film "The Farewell" (2019) explores this theme beautifully in the context of a Chinese-American family.

25 Recent discussion of this issue was prompted in part by the publication of a book entitled *Nudge*, by Thaler and Sunstein [28]. Two chapters of our volume address related questions––"Informed Consent" (Chap. 3) on a specific case and "Between Death and Donation: Ethical

Considerations in Pediatric Heart Transplantation" (Chap. 18) on the related question of nudging family members to donate the organs of deceased relatives.

26 In structuring the discussion in this way I am following the lead of David Miller in his excellent article in the *Stanford Encyclopedia of Philosophy* [29].

27 For example, Marx's famous principle: "From each according to his ability; to each according to his need" [31].

28 Chapter 14 of this volume ("Role of Ethics Consultation in Pediatric Congenital Heart Disease") provides insightful discussion and case studies of the role and value of the ethics consultation in the context of pediatric cardiac medicine and surgery.

29 The concrete logistics of health care delivery make it inevitable that there will be conflicts that cannot be resolved as easily as this paragraph suggests. For example, many hospitals in the US are owned and supported by churches. The churches in question may impose restrictions on the medical procedures that may be performed – restrictions based on the church's religious tenets and not shared by the wider community. For example, Catholic-affiliated hospitals restrict access to reproductive and end-of-life health services, counseling, and referrals. Cf. *Ethical and Religious Directives for Catholic Healthcare Services, sixth Edition* [32].

30 A possible exception would be the intentional and open breaking of what one perceives to be an unjust law in order to call attention to it—as in the Civil Rights Movement. Martin Luther King, Jr. always explained that although the protesters broke specific unjust laws, they showed their respect for the law by willingly submitting to the legally mandated punishment.

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Autonomy and the Principles of Medical Practice

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1 Introduction

There is virtually universal agreement amongst ethicists and physicians that respect for patient autonomy is an important, even indispensable principle in the ethical practice of medicine [1]. United States law recognizes the centrality of patient autonomy by prohibiting, in ordinary circumstances, the imposition of medical treatment on a mentally healthy adult patient without his or her free and informed

consent [1]. Medical practice is not always straightforward. Conflicts can arise in specific cases, between the physician's obligation to respect patient autonomy and the physician's other ethical obligations—for example, the imperatives: to do no harm; to act in the patient's best interest and to respect justice. In the course of everyday medical practice, challenging cases result in ethical dilemmas owing to the many different and sometimes conflicting responsibilities that physicians have to patients, to society, and to themselves. The field of medical ethics is charged with the study of such conflicts with the promise that better and more just solutions may be achieved by defining the problems and applying the principles that result in successful and morally just patient care: patient autonomy , nonmaleficence , beneficence , and justice . The purpose of this chapter is to examine the medical ethical principle of respect for patient autonomy by exploring the philosophical origins and underscoring the importance of more formalized and structured ethical training in medical practitioner training. Much of this topic has been previously reported by us [2]. The prose of the original article is largely presented herein with minimal redactions.

The two most influential philosophical approaches to ethics (Utilitarian and Deontological theories) agree on the centrality of the principle of respect for patient autonomy. It is interesting to note, however, that they do so for different reasons, which will be examined briefly with the intent to deepen our understanding of the principle and highlight the difficulties that may arise as physicians seek to apply the principle in daily professional practice.

Utilitarian and Deontological approaches will be addressed from their respective theoretical perspectives and contrasted with ethical theories that focus on the virtues and vices that characterize people as good or bad. The latter ethical theories, so called "virtue ethics ", have their origins in the writings of Plato [3, 4] and Aristotle [5], and offer insight both into the debate on patient autonomy and on how ethical thinking can be taught [6]. In the process of this textual interpretation, a theoretical and clinical basis for the importance of patient autonomy as an ethical tenet and for its incorporation into medical practitioner training will be considered.

2 The Centrality of the Principle of Respect for Patient Autonomy

Engaging patients with respect for their autonomy is based on a fundamental acknowledgement of the freedom to hold and to act upon judgments that are grounded in personal values and beliefs. How rationality, freedom, values, and beliefs are interpreted has been the subject of intense and exhaustive philosophical inquiry [7, 8]. Fortunately, the two main sources of contemporary normative ethical theory (Deontological, Utilitarian) do not differ significantly in these areas. They do, however, differ in their reasons for embracing the principle of respect for patient autonomy.

The first of the aforementioned ethical theories stems from the work of Immanuel Kant (1724–1804), who is associated with Deontological (duty-based) ethics [9]. According to Kant, an individual's capacity for reflective judgment and rational choice confers upon the individual the authority and right to determine his or her own moral destiny. Individuals make decisions for themselves, and others have the obligation to respect their judgments and choices. According to Kant, to violate a person's autonomy is to disregard his or her own goals and to treat the individual as a means to someone else's ends, rather than respect the individual as an end in himself or herself. Kant thereby advances a moral imperative of respectful and dignified treatment of persons as ends in themselves [9].

The principle of respect for patient autonomy follows directly likewise from the other main contemporary source of normative ethical theory: Utilitarianism . According to John Stuart Mill (1806–1873; best-known theorist of the Utilitarian school) [10], an action is morally right if it maximizes net utility for all persons affected by the act [11]. In his classic work *On Liberty* [12], Mill argues that people's choices should be respected, and individuals allowed to do whatever they choose to do—so long as their actions do not interfere with others' freedom to do as they choose. Mill opposes paternalism by maintaining that each individual, on balance, is the best judge of what is in his or her best interests. Thus, an individual's judgments of what would maximize his or her utility should be respected. If it is believed that a mature and

mentally healthy individual is choosing something self-destructive , the person can be reasoned with and persuaded to understand the danger, but ultimately the individual should be assumed to be the best judge of his or her own interests, and her choice should be respected.

Because respect for patient autonomy requires that the physician take into consideration the expressed wishes of the patient, this principle conforms to Mill's settled position [10]. Respect for patient autonomy can be seen as a special case of society's larger obligation to maximize utility by allowing people to develop morally in accordance with their own convictions.

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3 From Principles to Virtues

Respect for patient autonomy is, consequently, a principle that both Utilitarians and Deontologists support. Confronted with tough cases (bizarre circumstances that produce strange consequences, or recalcitrant patients), these schools of thought can occasionally diverge in their conclusions. In deriving their initial theoretical commitments neither doctrine considered the complex world of twenty-first century medical decisions. However, to leave behind thousands of years of ethical thinking simply because they do not address specific, medical situations would be to ignore insights that have shaped human thinking to this day. Some practical and psychological difficulties that arise in the application of these theories in a medical setting have been noted in the last four or five decades in other contexts [6, 13–16].

For example, Utilitarianism suggests that moral agency involves or should involve a kind of cost-benefit analysis of the consequences of various alternative actions one is considering. Acting morally involves simply performing that action whose net benefit is greatest. Critics argue that this is an unrealistic account of the way real people make considered decisions in actual circumstances [14]. At the very least, this account distorts conditions by relying on an overly rationalistic and an overly simplified, psychological account of human agency. Critics note that the world is more complicated and the human psyche deeper and richer than this picture suggests [17]. Decision-making is deeply influenced by an individual's emotions, attachments, personal habits, and society's customs and norms. These are not minor psychological

influences that might be eliminated by adopting a more "rational" decision-making procedure. These are fundamental facts about human nature and hence constitutive of us as human beings and (by extension) moral agents. An acceptable and useful ethical theory must take account of these realities and must not substitute a simple, mechanical decision-making procedure for the rich (if sometimes muddled) psychological complexity of real human agency.

Critics of Utilitarianism and Deontology also note that these schools of thought have very little to say about the important issue of a person's moral character [14, 18]. Because these schools focus on the individual act as the locus of moral judgment, the most that can be said is that a person has good character if he or she more often than not performs the right actions. But virtue ethicists hold that moral character is not just a matter of counting favorable and unfavorable outcomes. Character is not primarily a matter of making the right decision in rare, difficult cases. When someone's moral character is examined, the person's long-term and customary way of responding to the ethical aspects of all situations that arise every day in his or her personal and professional life are scrutinized. A person of estimable character is a person who is finely attuned to the moral dimension of his or her interactions with others, intuitively capable of discerning the right thing to do, and naturally inclined to do it. Of course, the hope is that he or she is naturally inclined to do that which moral principles would dictate, but the emphasis here is not on getting the right answer. Rather, the emphasis is on being the kind of person who notices the moral aspect of things, and does what is right because it feels, quite naturally, like the right thing to do. A person's character encompasses his or her perceptual acuity, patterns of attention, capacity for affective resonance with others, moral judgment, and ingrained tendency to do what he or she sees/feels/knows to be the right thing.

One could make the argument that moral character has no direct relevance to the complex world of medical ethics. So long as the correct course of action was followed, and the proper course of consideration and debate adhered to, then the agents pursuing this resolution were correct in their moral thinking. This argument is attractive because it attempts to simplify medical ethics into a prescribed set of principles that, if followed, will yield the right course of thinking/action. It has just

been acknowledged that such principle-based ethical theories will occasionally come into conflict with each other and can be limited by their lack of specific consideration of the complicated world of modern medical ethics, but does this really matter? Can human beings live with the approximations that principle-based ethical doctrines provide for complicated medical ethical problems, or should society instead consider other approaches that may be more difficult to define or teach but that allow for more specific and complicated subject matter by not being bound by simplistic and sometimes anachronistic first principles?

Virtue based ethics, by espousing virtues that pertain more to an individual's habits and relationships with others and with his or her society (i.e., character) can provide such a path to a potentially more relevant ethical discourse in the complicated modern world. As moral character involves cognitive, affective, dispositional and behavioral dimensions, it cannot be summed up in any single principle or dictum. As Aristotle noted, "ethics is not an abstract science and cannot be taught as if it were geometry. On the contrary, moral education is complex, nuanced, and multi-dimensional—a matter of learning principles, yes, but also of developing perceptual acuity, shaping emotional sensibility, and cultivating self-discipline in one's behavior" [19]. If medical ethics is understood in terms of character and if the ultimate objective is to develop an ethically upright physician and healthcare professional, it seems necessary to think more broadly about moral education as part of medical training. In this area, too, insight can be drawn from the ancients and their understanding of character and moral virtue.

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4 Respect for Patient Autonomy as a Medical/Professional Virtue: Classical Understanding of "Virtue" (*Arête*)

The thinker who has made the most significant contributions to society's understanding of moral character is Aristotle (384–322 BCE). According to Aristotle's analysis, character is best understood in terms of certain virtues: a person of excellent character is one who possesses the virtues characteristic of a good person. The Greeks focused on

certain virtues as most important (wisdom, temperance, courage, justice, and piety), but of greater interest is Aristotle's analysis of just what a virtue is, why it is valuable, and how a person can be trained in virtue.

According to the classical concept, a virtue can be thought of as a characteristic of excellence. So, for example, the virtues of a race-horse (i.e., the characteristic excellences of a race-horse) would be those qualities or features that make it a *good* race-horse such as speed, strength, and endurance. Socrates even spoke of the "virtues" of a lowly kitchen knife [4]. In order to be a good kitchen knife, a knife must possess certain qualities that make for excellence such as sharpness, balance, and maneuverability.

Of course, Aristotle was not chiefly interested in race-horses or kitchen knives. These are just examples to help understand the concept of a characteristic excellence (i.e., a virtue). As an ethicist in the classical tradition, Aristotle was interested in what qualities or traits make a person a *good person*. These are the virtues, the characteristic excellences, with which he was concerned. As mentioned above, classical Greek philosophers thought that the list of human virtues include, above all, wisdom, courage, temperance, and justice. Aristotle noted all of these as well, but to understand his view, his analysis of courage is noted as an example.

According to Aristotle, having courage indicates striking the right balance with regard to the emotion of fear. A person who has too much fear or who fears things that are not truly dangerous, is not courageous but cowardly. A person who has no fear, or who fails to fear things that are genuinely threatening, is not courageous but rash and foolhardy. A courageous person has the right amount of fear toward things that are genuinely dangerous.

It should be noted that when possibly dangerous situations are confronted, individuals do not normally make conscious, rule-based decisions about whether to be afraid or not. On the contrary, the tendency to be easily frightened (or not) is more of an abiding disposition or character trait.[1] One's tendency to be more (or less) easily frightened may be partly inborn but Aristotle thought it mostly a result of one's past experiences, training, social customs, and the influential role models that one has encountered along the way. As a

child, the training consists mostly of behavioral conditioning, but as one grows older and confronts more complex and diffuse threats and dangers, one begins to think more reflectively about these matters and perhaps one's fear-response becomes, over time, more informed by a kind of practical wisdom (*phronesis*). If an individual is fortunate, he or she might meet someone more advanced in this kind of practical wisdom (a *phronemos*) and by listening to this person's words, observing his or her emotional responses and watching how and what he or she does, a person can learn what it is like to think and feel and act like a courageous person. Emulating this person's attitudes and actions can refine different habits of feeling and action, and thus an individual can acquire, in a more mature and developed form, the virtue of courage. And in acquiring one of the most important human virtues, we become better human beings.

Everything that has been said about courage can be said of the other moral virtues as well. They involve striking a balance ("finding the golden mean") [5] between two extremes; they involve being attuned to the relevant aspects of a situation, feeling the right emotions in response, and acting with practical wisdom. And as with courage, the other virtues are acquired via experience, practice, reflection, and emulation of a practically wise and virtuous person.

After this extended discussion and focused insight into Aristotle's ethical views, it is possible to explain and defend the contention that respect for patient autonomy should be considered not only as a principle but also as a virtue. It is important that a healthcare professional understand the principle and be able to reflect on why it is important and how it applies to the medical field. But the best healthcare professional would be one who instinctively regards every patient as an individual with beliefs and values that are worthy of respect, one who feels empathic resonance with the patient and is naturally inclined to be attentive to what the patient says and incorporate the patient's perspective into his or her medical decision making . In making treatment decisions the healthcare professional strikes the right balance between strictly clinical considerations and a respect for patient judgment of what is most important. And when it seems to the medical professional that the patient is not grasping the significance or the gravity of the clinical indicators, the physician

engages the patient in conversation, addressing him or her as a person capable of being moved by information and rational persuasion. By doing all of this with the kind of ease that characterizes the graceful athlete or the well-practiced musician, this healthcare professional is worthy of admiration as one who can teach such behaviors effectively.

The analogy to the musician is Aristotle's own; the etymological connection between "virtue " and "virtuoso " is not accidental. A person must learn to be virtuous , Aristotle told us, just as a student learns to play the flute. At first it does not come easy; one has to work at it; one has to practice. At first the finger positions and breath control may seem unnatural and awkward. Indeed, the whole process may be unpleasant in the beginning. But as one learns and practices, the coordination of breath and finger-movement becomes easier, and the skilled motions that seemed so awkward before becoming second nature. Aristotle added that in the process of learning to play well, one is simultaneously learning to enjoy playing while becoming a flautist.

Clearly, to become a virtuoso one also needs a teacher to point out weaknesses in one's technique, to offer constructive criticism, to help one learn what to listen for, to discuss the fine points of theory and practice, and finally to provide a model of excellence in performance. An effective teacher must know music theory, of course. But more importantly, an effective teacher must have a kind of hands-on practical wisdom that he or she also acquired only with a lifetime of practice and dedication to the art. Relating to the everyday practice of medicine, the importance of making rounds with an experienced, virtuous, practically wise professor (*phronemos*) becomes foundational. In order for students to acquire virtue, there is much practice involved that includes but is not limited to instruction in technique, decision-making, and equanimity. The physician's empathy and compassion for his or her patient will resonate rationally and emotionally between them; together they engage in a treatment plan with mutual respect and courage [20].

There will of course be challenges in attaining moral virtue and applying the principle of respect for patient autonomy according to the golden mean in many cases. Problems exist when the physician decides what is best for the patient and the patient disagrees. The virtuous physician will try to persuade the patient using logic and appealing to

rationality. Furthermore, the wise physician will consider the possibility that he or she could be wrong. Part of the virtue of respect for patient autonomy is a measure of epistemological modesty. Aristotle urged us not to expect precision or certainty when dealing with subject matters as imprecise as ethics or the workings of biological systems [21]. Finding the "golden mean" will never be a matter of applying an algorithm or a hierarchical protocol; yet an agent who has achieved moral virtue in this area should be able to resolve the problems that arise in difficult clinical conditions.

Furthermore, the constant evaluation of the "golden mean" allows for reevaluation of experiences and complications that may never have been covered in the extant philosophical or ethical traditions. Such a transition from ethical theory to ethical practice is more easily made through virtue-based ethics rather than through prescribed ethical principles, and, as has been argued, allows for a more effective pedagogical model than merely memorizing principles and conflicts in the history of ethical thought. Daily rounds led by an experienced moral agent (*phronemos*) should not only consider the physiological and clinical status of the patient but also explore the moral issues that are operative or could be operative under these varied circumstances . In this way, ethical reflection and practice become second nature.

The idea that ethics should be taught during residency is not new and has a growing number of proponents. Many authors [22–24] have extolled the benefits of continued ethical education in medicine on every level and on every occasion. The few studies that have been performed on the efficacy of clinically based ethical training during medical school have been resoundingly positive. This should be part of the medical curriculum or at least part of daily practice. Respect for patient autonomy will improve and will help to establish the idea that the principle of respect for patient autonomy will best be served by clinicians who have achieved a measure of virtue in their pursuit of moral excellence.

While we do not claim to have the ideal pedagogical form of medical ethical training , it has been argued that the complicated world of modern medical ethics requires a curriculum that can be easily applicable to complicated problems and that can be taught effectively by those who practice it on a daily basis. Models that are based on

virtues are likely better able to satisfy the needs of the profession. These models are more psychologically realistic and likely to be more effective as a basis for medical ethical training . We look forward to a future of medical ethical debates as the subject becomes less of a compartmentalized specialty and more of a universal aspect of medical training and an everyday concern among healthcare professionals. Such debates will more effectively evaluate and reevaluate the questions of patient autonomy and other cornerstones of medical ethics.

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Footnotes

1 Aristotle's word is "hexis"—sometimes translated as "habit." The important point is that it is not a momentary state, but an enduring disposition to feel and to act in a certain way.

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Informed Consent

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1 Introduction

When one considers the complex aspects of bioethics in the diagnosis and treatment of congenital heart disease , several thoughts summon the practitioner to pause and reflect. "I make bioethical decisions every day in my practice"; "Every decision is different; I try to see the whole picture and make a dutiful decision"; "When several seemingly diverse issues complicate a proposed treatment plan, I sometimes wonder if I am acting in the patient's best interests"; "I perform informed consent in my practice, but am I being comprehensive enough to suit ethical and legal standards"; "When a patient has deteriorated to the point of futility, what is the best course of action when families want to continue care?" [1]. These questions and more seem to surface often in our

practice. Oftentimes, optimal moral and medical resolutions are not always clear.

This chapter deals with the subject of Informed Consent, a process that has not been clearly defined by the medical profession like the more common processes such as: “The time out”, the organized physical examination, and the scripted Brief Op Note, to name only a few. Informed Consent takes place in the setting of transparency, respect for autonomy, ethics of innovation, ethics of fetal interventions, and futility. Many of these topics will be considered individually in this treatise and are based on our own inquiries [1–21]. In most instances, we took the liberty of author ownership and editorial privilege to reproduce the amended prose of the manuscripts.

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2 Informed Consent

Informed consent is a process by which physicians and patients participate in a dialogue to explain and comprehend the nature, risks, benefits, and alternatives, of a procedure or course of therapy. In particular, most families want to understand the disease entity , its natural history, proposed operation or treatment plan, experience of the surgeon, the supportive team structure, reasonable alternatives, and the risks, including complications and mortality. The legal and moral principles hold that the patient is responsible for his/her own autonomy and is free to “make medical decisions that reflect his/her beliefs and healthcare needs” [22]. It is assumed and projected that this dialogue considers cultural diversity , language barriers , psychologic temperaments , socioeconomic conditions , and patient autonomy [23, 24].

The defined process of informed consent was first introduced and established in the case of Salgo v. Leland Stanford Jr. University Board of Trustees [25]. In support of the litigants who claimed that physicians were not adequately performing their duty of responsible and adequate behaviors in their interactions with patients, the court ruled that “a physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment.” Subsequent court rulings have refined and clarified the legal concept of

informed consent by broadening the scope from professional to patient-oriented standards [23] to further emphasize the tenets of autonomy, nonmaleficence, beneficence, and justice.

These legal imperatives notwithstanding, the practice of informed consent is far from standardized [22]. The discussion between patients/parents and physicians largely depends on the informing physician's knowledge of potential complications and interactive skills. These skills have been developed in the course of medical education and instantiated by role models who have taken the time to instill compassion, competence, and duty. In some instances, the informed consent process has been influenced by principles that apply to controlled, randomized, prospective clinical studies that demand certain identifiable consent processes. These are usually documented with comprehensive preprinted forms that have been vetted by Institutional Review Boards [23]. The actual physician-patient interaction has not been emphasized or denotated in a logical standard process thus, allowing the progression to continue under the amorphous scope of "the art of medicine". Several authors [26, 27] have undertaken questionnaire studies that have chronicled physician opinion and offered suggestions, based in part on the occurrence of complications, which may guide the interaction between physician and patient. There remain significant reservations and uncertainties as to what complications should be reviewed in the informed consent process.

To address this equipoise, authors [16] performed an analysis of the Society of Thoracic Surgeons Congenital Heart Surgery Database (STS-CHSDB) [28, 29] to examine occurrence rates of a group of six major complications that are generally but not always specifically discussed with patients and families. How and why physicians choose from the myriad recognized complications in order to properly perform informed consent is unknown. The informed consent process affords an opportunity to establish a personal relationship with the patient and to review the treatment plan, reveal reasonable expectations, instill confidence, project hope, and assure that complications, if they occur, will be treated in a compassionate and expeditious manner [30]. It is the "reasonable expectations " portion of this process that was the focus of the aforementioned inquiry in an effort to provide congenital

heart surgeons with empirically derived data, based on multi-institutional experience to guide discussions of procedural complications during the informed consent process.

The results of the database analysis are paraphrased herein. The 12 index procedures that were reviewed for rates of complications were repair of Atrial Septal Defect (ASD) , Ventricular Septal Defect (VSD) , Atrioventricular Septal Defect (AVSD) , Tetralogy of Fallot (TOF) , Coarctation of the Aorta (CoA) with VSD, Bidirectional Glenn Procedure (BiGlenn), Fontan Procedure, Norwood procedure and Systemic to Pulmonary Artery Shunt (S-P shunt). Arrhythmia was the most frequent complication for VSD (5.8%), TOF (8.9%), and AVSD (14.7%) repairs. There was a high rate of sternum left open (planned, unplanned) for Arterial Switch Operation (ASO) (26%, 7%, respectively), ASO-VSD (29%, 10%, respectively), Truncus Arteriosus repair (41%, 11%, respectively), and Norwood (63%, 7%, respectively). The most frequent complications for other procedures include ASD (unplanned readmission, 1.9%), BiGlenn (chylothorax, 7%), Fontan (pleural effusion, 16%), S-P shunt (reintubation, 10.6%), and coarctation (reintubation, 5.2%).

Being aware and understanding the occurrence and gravity of these complications can help guide the surgeon's interaction with the parents/patients. Some authors [26, 27] have performed survey studies and have concluded that minor complications that occur in over 5% and major complications that occur in over 0.1% of patients, are worthy of discussion. Practical wisdom can guide the surgeon in certain specific conditions. For example, one would discuss the risk of paraplegia when reviewing coarctation repair, but not discuss this complication in the context of most open-heart procedures that do not involve arch reconstruction. The same can be applied when discussing other enduring complications such as heart block, nerve injury, and renal failure. Importantly, this discussion can also explore the concepts of relative risk and long-term outcomes which compares the risks of leaving the disease untreated with the risks of proposed reparative or palliative operation. Such a dialogue can form the rational basis for proceeding with what may be termed a "high risk" operation , when all options are considered. In a broader sense, the idea of learning how to perform informed consent has historical significance and dates back to

antiquity [31]. The essential question has been whether or not moral virtue can be taught. This issue has been assessed by Aristotle who described moral virtue as, “The habit of choosing the golden mean , between extremes, as it pertains to an emotion or an action” [32]. Informed consent therefore condenses into a virtuous way of presenting empirical data to the patient. This tension between scientific evidence and moral authority has been heretofore delegated to the “art of medicine”, a concept grounded in paternalism and practical wisdom. Some authors, based on physician surveys, have suggested certain thresholds to guide the informed consent process. The question arises, is it possible to look at a complication list and categorically state that anything over 5% occurrence rate is worth discussing and anything below is not? Obviously, this is not possible, at least not in the purist rational sense. What is possible is to invoke the “habit of choosing” tenet [32], namely that we acquire a set of principles over a lifetime of study and learning from others who we feel match up with virtuous habits. We physicians then engage our acquired practical wisdom and knowledge of empirical data to do the right thing, namely to engage in a rational, sympathetic, and informative dialogue with our patients and venture to find the right balance of informed consent based on mutual trust, beneficence, and finding the “Golden Mean ”, which may be something today and something else tomorrow based on the circumstances. The common threads are being aware of the empirical data and achieving moral virtue.

The informed consent process for congenital heart surgery may be enhanced by the availability of accurate contemporary data on occurrence of complications associated with a particular procedure. While complication rate thresholds may guide the clinician, rare but important debilitating complications, such as paraplegia after coarctation repair , should also be discussed irrespective of frequency. The authors’ analysis [16] should better inform the process of informed consent by providing the clinician with objective data about complications for each type of procedure.

We should engage in the informed consent process more so for moral reasons based on Aristotelian [32] and Kantian [33] ethical tenets than for legal reasons established by the courts [25]. In a substantial way, being informed of potential complications solidifies the

doctor/patient relationship by open discussion that recognizes the reality of human behavior, error, and disclosure. The process is meant to convey confidence, hope, and acceptance throughout the hospital course and beyond.

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3 Ethical Considerations of Transparency, Informed Consent, and Nudging; Case Presentation and Discussion

There are some particular cases that are excellent examples of numerous ethical principles and deserve our attention. We present this case of a severely symptomatic 9-year old boy with left ventricular endocardial fibroelastosis (LVEFE) . We will encounter considerations of transparency, informed consent, and nudging that are apparent in the planning and execution of the proposed reparative and complex operation [21].

3.1 Case Presentation

A 9-year-old boy was born with bicuspid aortic stenosis , underwent two unsuccessful aortic balloon valvuloplasty interventions, and eventually developed restrictive cardiomyopathy and diastolic dysfunction caused by LVEFE by 2 years of age. The attending cardiologist referred the patient to a high-volume, high-profile congenital heart surgery program 1000 miles away that has accumulated experience with LVEFE resection in a handful of patients with good results. The patient was evaluated there and was thought to be a reasonable candidate for a Ross operation (pulmonary autograft replacement of the aortic root) with concomitant LVEFE resection. Owing to administrative problems with insurance coverage, the parents sought other options for the care of their child. These options included paying out of pocket expenses to have the operation at the high-volume program noted above as well as approaching local programs in their home state for second opinions and eventual therapy.

During this time, the parents interviewed a well-respected congenital heart surgeon for his opinion and operative experience. The surgeon, Dr. George Miller (alias), has considerable experience with the

Ross operation including superior results without mortality and with high freedom from reoperation. He has no experience with LVEFE resection. When specifically asked about this part of the proposed procedure, he described his results with the Ross operation and volunteered that although he had no experience with LVEFE resection, he had considerable experience with right ventricular endocardial fibroelastosis (RVEFE) resection owing to his expertise with arrhythmia surgery for tetralogy of Fallot, which requires RVEFE resection for ventricular tachycardia. In making such a statement, the surgeon is implying that there is little difference between RVEFE and LVEFE resection . The surgeon is aware of the recommendation from the high-profile institution. He offers to perform the operation with low mortality based on his overall experience. He engages in comprehensive informed consent by describing the nature, risks, and alternatives of the operation with special emphasis on the Ross procedure thinking that the difference between RVEFE and LVEFE is slight. He stresses to the family that the local institution could provide an equivalent surgical procedure with comparable outcomes without them having to travel and experience the problems of travel, unfamiliar environment, and high costs. The surgeon then left the decision to the family.

3.2 Introduction

A full discussion of this case and the ethical principles associated therewith is dependent on a proper understanding of the major bioethical principles. These principles include respect for patient autonomy, beneficence, non-maleficence, and justice [22]. Each of these principles can be applied to the present case. The principle of patient autonomy is perhaps the most important, since many of the issues involved with this case are inherent to the process of informed consent. The principles of beneficence and non-maleficence are often conflated. Acting in a patient's best interest and ensuring that no harm is caused are often the same. In this case, the surgeon's selectivity in emphasizing his experience with certain aspects of the case and his ability to offer the same outcomes as the regional center can be assessed in terms of these principles. The principle of justice concerns the equitable distribution of economic, emotional, and societal burdens and benefits.

This principle can be applied to several aspects of this case that are not directly associated with the physician-patient interaction but are nonetheless essential to understand the ethical issues in contention. Such components of this case might include the additional financial and emotional hardship that travelling for care might confer on the family, and how such potential hardships might interact with the additional bioethical principles that are in apposition.

A conscientious professional, Dr. Miller, tries to adhere to the fundamental ethical principles that frame responsible medical practice. Sometimes, however, differing principles can make conflicting demands on the physician, and it is not always clear how these conflicting demands are to be reconciled.

For purposes of analysis and discussion, this case is best understood in terms of tension between the imperatives of beneficence and the obligation to respect the patient's autonomy [17] by acting only with the patient's free and informed consent [20]. The first of these principles tells Dr. Miller that he should act in the best interest of his patient. The second principle tells him that he should provide the patient with as much information and explanation as needed in order to make an informed decision. As is often the case, these two principles are in some tension with each other.

Dr. Miller has a clear conviction about what is in the patient's best interest. He is confident that he can perform the Ross procedure as well as anyone in the country (indeed, better than most), and he believes that his experience with RVEFE resection will provide him the expertise to accomplish LVEFE resection . He acknowledges to himself that performing the resection on the left side is perhaps more complex and more difficult than on the right side but does not think that this will pose a problem. In addition, he considers that the family will be better off staying close to home rather than traveling a thousand miles to the more high-profile institution. The out-of-pocket costs to the young family will be reduced as well. All things considered, Dr. Miller judges that it is in the patient's best interest that he performs the procedure at the local children's hospital.

Because he has a clear concept of what would be best for the patient, he sees it as his obligation to encourage the family to stay locally and allow him to perform the operation. There are presumably

various ways Dr. Miller could influence the parents to agree, but not all of them would respect patient autonomy. The following are a few methods that he *could* use that might well succeed in persuading the parents to agree: he lies, he uses emotional blackmail , dabbles in willful obfuscation, or pressures by fear-mongering. These methods might work, but they would clearly violate Dr. Miller's obligation to respect patient autonomy, as they do not result in a truly informed, rational decision on the patient's part. Rather, these methods result in the patient or parents being manipulated by non-rational, in effect *coercive*, means to secure agreement.

Why are these manipulating and underhanded techniques being mentioned at all? After all, if Dr. Miller is correct, and if he is basing his judgment on rational considerations, the parents do not need to be manipulated into agreeing. They only need to be provided the relevant facts and allowed to draw the right conclusions. If the parents are provided with the same information that persuaded Dr. Miller, and if they are helped to see this information in the same light that he sees it, then the parents will agree. The process therefore will have been an ideal case of informed consent and thus maximal respect for patient autonomy.

Rarely are these ideals actually fulfilled in practice, especially in complicated cases. The parents are informed individuals with internet skills and intellectual curiosity, but short of taking anatomy, embryology, and pathology courses, the nuances of anatomical and functional asymmetry of the two sides of the heart may be lost in translation and explanation. Except for the drawings that Dr. Miller shows the parents, the Ross operation is an abstraction to them, and LVEFE resection does not actually register understanding despite all the metaphors that can be used to explain the operation.

And herein lies the crux of this case. Dr. Miller holds that his obligation to do what is in the best interest of the patient requires that he convince the parents to authorize him to perform the operation. But the facts and evidence that convince him are not really available to the parents nor can he, with the very best of intentions, make these facts available to them. He does not want to be overtly manipulative or disrespectfully paternalistic, but he does want to encourage the parents

to agree with him. How can he convince them to act in the best interests of their son while respecting their autonomy?

3.3 A Digression on Rhetoric, Persuasion, and Psychology

Ancient philosophers have explored dialogue in which rational and non-rational factors can influence a person's health and decisions. Early teachers in classical Athens (often called—non-pejoratively—"Sophists") claimed to be able to teach the art of persuasion, the art of convincing another to agree or to share one's beliefs. Sometimes this art of persuasion relies on strictly rational factors, such as logic and evidence. But non-rational factors can be brought to bear in the effort to persuade as well. In the ancient world, the art of persuasion was sometimes called *rhetoric* , and it was rightly thought to be of great importance in politics, education, commerce, and even family life. In Aristotle's study of the subject, *Rhetoric* [34], he defines it as, "the faculty of observing in any given case the available means of persuasion."

An interesting passage from Plato's *Gorgias* [35] highlights the importance of intense persuasion over informed consent. Gorgias uses his persuasion techniques to help his brother, who is a physician, convince his patient to "lie down and undergo the knife" for therapeutic reasons (*Gorgias*, 456b). Gorgias , when questioned, infers that his technique is applied not necessarily for the good of the patient but for Sophistic principles of persuasion.

Gorgias replies, "Ah, if only you knew all, Socrates , and realized that rhetoric includes practically all other faculties under her control. And I will give you good proof of this. I have often, along with my brother and with other physicians, visited one of their patients who refused to drink his medicine or submit to the surgeon's knife or cautery, and when the doctor was unable to persuade them, I did so, by no other art but rhetoric. And I claim too that, if a rhetorician and a doctor visited any city you like to name, and they had to contend in argument before the Assembly or any other gathering as to which of the two should be chosen as doctor, the doctor would be nowhere, but the man who could speak would be chosen, if he wished" [35].

In the modern world, volition, motivation, and cognition have been studied in great depth in order to ascertain what factors play a role in

influencing decision-making and belief-formation. Psychologists, sometimes in the spirit of pure research and sometimes in the service of high-paying advertisers or politicians, have studied the methods by which people can be persuaded to embrace a certain belief, buy a certain product, or vote for a certain candidate. While this is hardly an exact science, significant progress has been made, and we have now a better understanding than ever before of the ways in which we can influence the beliefs of others and, in turn, how they can influence us.

3.4 Dr. Miller's Responsibility and Psychological Techniques of Persuasion

After Dr. Miller discussed the issues of informed consent, he asked his nurse practitioner to stay with the parents in his absence to answer further questions that the family might have. It was during this time that the nurse practitioner confirmed Dr. Miller's expertise, emphasized his favorable reputation, and allowed the family to ask questions that perhaps they were uncomfortable asking Dr. Miller. She also noted the long distance of 1000 miles to the high-profile institution and how their family support system and geographical familiarity would help their child during the recuperation period. The family confirmed that they liked Dr. Miller and found comfort that a member of the team, namely his nurse practitioner, thought so highly of him. They decided to have the operation at the local institution with Dr. Miller.

Dr. Miller knew that he had the support and loyalty of his nurse practitioner, who has witnessed his excellent results over a 5-year period. He was comfortable leaving his nurse practitioner alone with the family knowing that she would underscore the benefits of staying at the local institution . Of some interest, the nurse practitioner is also financially dependent on the continued clinical volume and well-being of the surgical program. Many provocative ethical questions arise. Was the informed consent comprehensive enough? Was there selective emphasis on the Ross operation over the LVEFE resection? Did Dr. Miller consult the literature to explore the potential differences between LVEFE and RVEFE resection? Does he, in fact, have the expertise to perform this part of the operation? Was there willful or unwilful deception on the part of Dr., Miller or his nurse practitioner? In Dr. Miller's mind, perhaps he determined that too much information

would confuse and scare the parents at a time when he sensed that they wanted confidence. What techniques of persuasion are permissible that do not step over the line into coercion and manipulation?

3.5 Selective Emphasis

During the process of informed consent, Dr. Miller does not give all aspects and every nuance equal weight. Certain conditions or potential complications seem more salient and are emphasized. Others are very rare [16] and are mentioned but not emphasized. There is no intention of concealment per se, but the intent is to give proper weight to the various factors at hand. In this case, Dr. Miller believes that the more difficult part of the procedure is the Ross operation which will, in his mind, make the LVEFE resection easier owing to the increased exposure after native aortic valve resection. He therefore stresses the former over the latter even though he has no experience with LVEFE resection. He truly believes that he is capable of performing this operation and has employed persuasive measures to convince the parents to have the operation at his institution.

3.6 Beneficent Persuasion

Beneficent persuasion permits physicians to employ decision-making psychology to influence patient behavior in a manner that will favor their long-term health [36]. Physicians have a moral duty to enhance and improve patient well-being while respecting patient autonomy. Beneficent persuasion is ethically justified under these circumstances. Swindell and associates [36] note that beneficent persuasion through empathy, respect, and negotiation includes several techniques such as introducing vivid depictions of possible negative outcomes, providing default options to the patient, encouraging patients to think about regret for lost opportunities if medical recommendations are not followed, as well as framing and refocusing. Framing is a technique that can be implemented by noting the benefits of the procedure first, then discussing the risks or side effects, and finally concluding the interaction by once more repeating the benefits. Refocusing reminds patients of past physical and emotional challenges that they have overcome by stressing the end result rather than the temporary effects of pain and suffering during the recuperation period [36].

3.7 Nudging and Informed Consent

As noted, the process of informed consent is grounded on the principle of patient autonomy. Beneficence and non-maleficence often appear to be in tension with respect to patient autonomy when considering the promotion of ethical patient care. Recent reports have highlighted libertarian paternalism as a way of influencing individual decision making that "makes choosers better off while preserving freedom of choice" [37–40] and thereby concurrently merging patient autonomy and medical beneficence. Libertarian paternalism acts as a nudge, helping to "alter people's behavior in a predictable way" and is "paternalistic in that it aims to influence people through means other than rational persuasion to make choices perceived as good for them without threatening their liberty" [37]. Based on a report by Cohen [38], prompting individual decision making or nudging allows the chooser to benefit without affecting his or her free choice. Nudging, if performed correctly and ethically, can bridge the gap between the duty to respect patient autonomy and beneficence. This posture is similar to paternalism and can be appropriate as long as it is ethically legitimate [40]. Nudging, like libertarian paternalism, recruits the use of "choice architects" [37] who construct contexts in which people make decisions by changing the default choice. In the case of Dr. Miller and the family, the default choice is to have the operation; the opt-out choice , which requires some destructive action, is not to have the operation or to have it at another institution. Either choice must be easy and transparent [37]. In reports by Cohen [38] and Thaler and Sunstein [39], nudging must not be used to coerce people into making a specific decision, but rather must adhere to three guiding principles: all nudging must be transparent and never misleading; it must be easy to opt out of the nudge; and nudging must be with the purpose to improve the welfare of those being nudged [40].

3.8 Shared Decision-Making

Decision-making is greatly influenced by an individual's ethos which include: personal sentiments, spirituality, ingrained beliefs, society's tenets, and the law [17]. Whether by life-long learning, societal teaching, or providential influence, humans are capable of discerning moral choices by perceptual acuity, patterns of attention, capacity for

affective resonance with others, and a deep-seated tendency to do what the individual knows to be the right thing to do [17]. Charles et al. [41–43] crafted a context for shared-treatment decision-making with reference to the doctor-patient relationship. This was developed in the context of a "life-threatening disease where several treatment options were available with different possible outcomes" in a specialist oncology practice for early stage breast cancer. The doctor-patient interaction model contained characteristics of paternalism and also left room for the three components of shared-decision making: information exchange, deliberation, and negotiation with treatment plan implementation [41–43].

3.9 Competency, Transparency, and Informed Consent

A fundamental dilemma that often arises in clinical surgical practice concerns the conduct of assessing and performing new procedures, especially in rare cases, in which the collective global experience is limited. General principles dictate that when confronted with such a challenge, practitioners consult the known literature, visit other programs with more experience, and prepare their proposed operation with forethought and comprehensive planning. The looming question in this case remains. Does Dr. Miller have the expertise to perform LVEFE resection based on his stellar experience with RVEFE resection and has he adequately prepared? To make a comparison to another surgical subspecialty, does a board-certified general surgeon who has proven expertise in colon surgery possess the expertise to perform complex pancreas surgery? This is a common dilemma and is attended by surgeon age, clinical experience, and technical expertise. At some point, in order to attain surgical experience, one has to perform independent surgery. Our value system calls for board certification, peer-reviewed hospital privileging, outcomes analysis, and reputation to establish perceived competency. These achievements notwithstanding, the assessment of skill when it comes to rare lesions and previously not performed operations remains problematic.

At first blush the right ventricle is thinner, expected to produce pulmonary pressure (not systemic pressure), and is probably amenable to reparative procedures if the RVEFE resection proves to cause iatrogenic injury to papillary muscles, cords, valve leaflets, and the

ventricular wall. The left ventricle is thicker, expected to support the systemic circulation with higher pressures, and is less amenable to reparative procedures in the event of unwanted iatrogenic injuries that are noted for the RVEFE resection.

As expected, a comprehensive review (PubMed) of the differences between RVEFE and LVEFE resection proved unrewarding. Most literature citations concerning endocardial resection, other than what was published by the high-volume institution [44, 45], were found in relation to ventricular tachycardia/fibrillation treatment in the left ventricle that occasionally required papillary muscle translocation, localized ventriculotomy, and localized cryoablation [46]. The approach to the left ventricle in these patients was transaortic and through the mitral valve. Both exposures are challenging for an extensive endocardial fibroelastosis resection and raise the possibility for unwanted complications. References to RVEFE were mostly confined to postoperative tetralogy of Fallot patients with pulmonary regurgitation, right ventricular dysfunction, and ventricular tachycardia [47]. Recent studies [48] have abandoned RVEFE resection in these patients , preferring instead placement of selected cryoablation lesions between the ventricular septal defect patch and the pulmonary annulus. Some authors [47], however, still perform the RVEFE resection in addition to the cryoablation lesion and under these circumstances it is performed through the existent right ventriculotomy with superior exposure making unwanted surgical mishaps less prevalent than those for the left ventricle. The surgeon therefore is left to review the comparative anatomy of the right and left ventricles, recognize the contrasting exposures, and be prepared to perform the LVEFE resection taking into consideration the team's experience with RVEFE and make necessary adjustments to perform a successful LVEFE resection.

This cursory literature review and the intuitive complexity of the LVEFE resection over the RVEFE resection would leave the surgeon with the idea that the LVEFE resection will be a more difficult operation with the potential for far more serious complications. Dr. Miller does not explain this difference to the family perhaps because he has not considered the possibilities, perhaps because he has not consulted the literature, or perhaps because he truly believes that there is no material difference between the two procedures. Is this hubris or is this

confidence? Should he be more circumspect about the LVEFE resection and offer epistemological modesty; after all, he could be wrong about how easy the procedure in the left ventricle will be. Let us not forget that the Ross procedure in which he has demonstrated expertise is probably the more difficult part of this combined procedure and affords very good exposure for the LVEFE resection . However, unsubstantiated confidence while comforting to the patient and parents may not be appropriate. Overly cautious comments that emphasize all the differences in the procedures may erode patient confidence. And in the end, is Dr. Miller competent enough to perform the operation? The studied answer has to be "yes", but the potential complications were not explained sufficiently as evidenced by absence of a focused literature search and biased informed consent.

3.10 Autonomy and Transparency

Pediatric cardiac surgery clinical outcomes continue to improve [49]. Transparent public reporting of pediatric cardiac surgical results is becoming increasingly common [50–53]. The justification for this transparency is based on the following principles: variation in pediatric cardiac surgical outcomes exist; patients and their families have the right to know the outcomes of the treatments that they will receive [50–53]; and it is our professional responsibility to share this information with them in a format that they can understand [50–53].

Dr. Miller is faced with the unusual challenge of caring for a patient with a rare lesion. This challenge is associated with multiple conundrums, including the moral dilemma of how public reporting can help regarding an operation that is so rare that only a few people in the world have actually performed it. In other words, although public reporting and transparency are virtuous, these qualities are complicated in the setting of a rare diagnoses and avant garde surgery. Adequate data are not available, and an analysis is tentative at best.

Surgeons are confronted with a moral dilemma when asked to transparently share their expected outcomes of a rare operation. The principles of honesty and transparency help solve this dilemma. The logical solution is to share with the parents and family the rare nature of the proposed operation and to then extrapolate the expected outcomes based on the known outcomes of operations of similar

complexity and expected risk. This approach capitalizes on available data and respects the principles of honesty and transparency.

3.11 Clinical Outcome

The patient was taken to the operating room with preoperative and intraoperative assessment that showed aortic stenosis/regurgitation, left ventricular restrictive cardiomyopathy (left ventricular end diastolic pressure 37 torr), and diminished systolic function. The preoperative plan was to perform a Ross operation in conjunction with LVEFE resection. Preparations were made for transaortic and transmitral exposure, retrograde cardioplegia, and moderate systemic hypothermia. After aortic transection, the bicuspid aortic valve showed a well-formed raphe that was supported by a fused commissure and two deep and competent leaflets on either side of the raphe. The fused raphe was incised thereby repairing the aortic stenosis and forming a tri-leaflet aortic valve that appeared to be competent. At this point, it was determined that a Ross operation would not be necessary and that a mild degree of postoperative stenosis and regurgitation would be preferable to a Ross operation. The index operation therefore was changed to LVEFE resection. The LVEFE resection was performed through the aortic valve and the mitral valve orifice after proper exposure was attained through the interatrial groove. The fibrous peel was approached at the apex of the left ventricle and carefully resected by deliberate and precise scissor dissection to delineate the plane between the fibrous peel and the viable myocardium. The resection was accomplished in stages with frequent changes of transaortic and transmitral operative exposure. The papillary muscles were preserved, the integrity of the ventricular wall was maintained , and the chordae were left undisturbed. Nevertheless, the operation proved to be longer, more involved, and more challenging than any RVEFE resection that Dr. Miller performed in the past. Postoperatively, ventricular function and the left ventricular end diastolic pressure improved. The left ventricular end diastolic pressure was measured to be 12 torr and compared favorably with 37 torr as measured preoperatively. Intraoperative transesophageal echocardiography revealed minimal aortic stenosis and insufficiency, excellent relaxation of the left ventricle , and a considerably smaller left atrium. The patient had an uncomplicated

postoperative course with significantly improved symptoms and functional status.

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4 Conclusion

Informed consent in the context of complex congenital heart surgery involving rare lesions is a challenging interchange between patients/parents and the surgeon. Dr. Miller was confronted with moral and scientific choices that were not altogether vetted and considered. It could be construed that Dr. Miller acted in a moral manner without malice and without intent to deceive or coerce. He used selective emphasis, beneficent persuasion, nudging, and shared decision-making techniques to accomplish his goals, namely to convince the parents to allow him to operate on their child. Yet, he may not have achieved what many critiques would have hoped for and expected, namely, comprehensive informed consent. He did not consult the literature on the differences between LVEFE and RVEFE resection; he did not inquire whether the family wanted to return to the high-profile institution and offer to help them; and he underestimated the difficulty and potential complications of LVEFE resection compared with RVEFE resection.

A heightened awareness of comprehensive informed consent in light of review of the available literature and full disclosure should attend all operations. This posture is especially important when considering therapeutic interventions on rare lesions that have not previously been performed by the surgical team and that may require conscientious preparation before operations.

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Conflict of Interest

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1 Introduction

Conflict of interest (COI) is defined by the Institute of Medicine as "circumstances that create a risk that professional judgments or actions regarding a primary interest will unduly be influenced by a secondary interest" [1]. Physicians aim to make clinical decisions in the best interest of their patients, however, many variables can create a COI competing with this goal.

Interactions between the biomedical industry, university researchers, and physicians are common to increase the productivity of both research and industry [2]. Innovation is responsible for advances in the surgical field and have contributed to the continuously decreasing mortality and morbidity associated with an increasingly higher risk surgical population. Minimally invasive surgical techniques such as laparoscopy , thoracoscopy , and endoscopic techniques plus interventional image-guided techniques have revolutionized the field. Likewise, robotic surgery is expanding as indications are derived from risk/benefit assessments. The drive to innovate has resulted in significant improvements in pain management, length of stay, and surgical outcomes; however, direct and indirect COI and how it affects clinical decision-making has been the focus of many ethical discussions.

Practicing physicians play a critical role in creating clinically relevant innovations and policy must support and regulate the physician-industry relationship. The goals of this relationship can be confounded when financial incentives are included. In addition to the COI inherent to industry-surgeon relationships, there is concern regarding industry-supported educational events. Likewise, industry relationships with surgical societies have the potential to cloud clinical judgement. The current lack of consensus on oversight mechanisms for procedural innovation leaves both surgeons and patients vulnerable to significant risks regarding ethical implications. Options for oversight of innovation have been proposed to preserve the delicate ethical balance between innovation and patient safety. Included among many are surgical exceptionalism (the acceptance of the unique priority of our life saving interventions) and departmental, institutional, Institutional Review Board (IRB), regional/national, and societal guidelines.

This chapter reviews the literature on various types of COI facing surgeons. We focus on the COI between surgeon and industry including industry versus physician, educational support, and surgical societies.

We also discuss the COI faced when a surgeon's clinical judgement comes in conflict with the goals of the medical center and the patient's power of attorney. Lastly, we discuss the COI that may arise from clinically practicing physicians publishing in journals.

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2 Industry COI

Cardiac surgery is a relatively young field characterized by new technologies and collaborative relationships, especially cardiology and industry. These multidisciplinary relationships have significantly improved outcomes with expanded indications for both medical and invasive therapeutic approaches. Given the close relationship with industry, the concern for COI is ever present and deserves special attention.

2.1 Industry Vs Physician

Innovation is a critical component of surgery. Practicing physicians are essential for identifying practical needs based on their clinical experience and ability to conduct clinical trials. Subsequently, physicians comprise nearly 20% of patent holders with industry [3]. The financial relationship with industry has also been identified as a focus of motivation, including professional advancement, publications, notoriety , and personal income, yet all are perceived as COI.

In the past, physician's behavior and choices have admittedly been influenced by extravagant gifts and consulting "fees" provided by industry ranging from hundreds to tens of thousands of dollars. Adair et al. revealed that the frequency of visits to a physician by industry representatives directly correlate with escalation in the physician's prescribing the representative's product [4]. Most physicians, however, do not believe the relationship alters their practice and perceive they are consistently making decisions for their patients' best interest [5].

The industry-physician relationship begins early in a physician's career with many young residents receiving "free items" or "SWAG" early in their training. Wazana reported, on average, resident physicians receive six gifts per year ranging from free pens to expensive textbooks [6]. As a physician matures in their career, Blumenthal reports the types of financial incentive evolves and includes grants and

honoraria, including unrestricted educational grants [7]. A cross-sectional study by Chren and Landefeld reveals positive correlations between consulting relationships and utilization of a firm's products [8].

A recent national survey showed that the financial relationship between industry and physician is much greater in certain fields than others. Cardiologists were twice as likely to receive payments for services as compared with family practitioners, and surgeons are 57% less likely to receive payments than family practitioners! Likewise, family practitioners met with industry representatives on average 16 times a month, followed by internists at 10 times a month, followed by surgeons at four times a month. Despite these statistics, the concern for bias fueled by a financial relationship with industry amongst surgeons is still very prevalent [9]. Given their close relationship with industry, orthopedic surgery has generated the most interest. This relationship was a focus of intense scrutiny in a 5-year trial in which individual surgeons were questioned about their relationships with industry, calling into question their ethical choices in patient care [9]. Campbell et al. (2007) reported the manufacturers responsible for 75% of hip and knee replacement hardware paid physician consultants $800 million for 6500 "consulting" agreements [9].

Many organizations and institutions, such as the American Medical Association Council on Ethical and Judicial Affairs, academic medical centers (AMCs) , the Association of American Medical Colleges (AAMC) , and the US Senate Special Committee on Aging, have generated their own policies around the issues of physician-industry relationships to protect their integrity [10–12]. US legislation created the Open Payments website to publicly report financial relationships between physicians and drug or medical device firms [13]. The Department of Veterans Affairs has established a policy for its providers and their business relationships with pharmaceutical industry representation. The directive covers product review, medical education sponsorship, conduct of drug/product studies, and responses to requests for procurement of specific products. Tight regulation on physician-industry relationships limits the interactions with industry creating a "by appointment only" process, thereby attempting to address the previously cited repeated contact concerns [14].

The Office of the Inspector General (OIG) investigates and prosecutes companies and individuals who violate their federal antifraud statutes. Surgeons, as well as organizations, are investigated for device "kick-backs" and excessive "consulting fees" and prosecuted, often having to pay multi-million dollar judgements. In February 2008, the US Senate Special Committee on Aging held a hearing entitled "Surgeons for Sale? Conflicts and Consultant Payments in the Medical Device Industry." The committee found many of the payments inappropriately high or improperly documented [12]. This investigation was one of the hallmark investigations evaluating the relationship between surgeons and industries. It also questioned the integrity of clinical decision making if a financial relationship existed. In 2010, the health system reform legislation created "the Sunshine Act" requiring pharmaceutical and device manufacturers to disclose physician payments, gifts, honoraria, and travel of any amount to ensure transparency between physician and industry [15]. The government is challenged to enforce these laws, while realizing the importance in preserving the doctor-industry relationship for continued progress in pharmacologic and device development.

The relationship between industry and surgeon has become imperative in development and implementation of new technologies such as transcatheter aortic valves (TAVRs) , endoscopic vein harvesting techniques, and various types of valves. A close relationship with industry representatives allows the practicing surgeons an early introduction to these technologies that potentially can reshape our practice as well as provide a role to help guide further development based on clinical need. The restriction and management of clinical trials and close regulation of the distribution of TAVR is a current example of industry working with the FDA to limit access of the technology to only those centers enrolled in the trial. Likewise, this strategy limited the speed with which the technology could be implemented until outcomes data was obtained.

Another example with a managed outcome was the Lung Volume Reduction Surgery (LVRS) trial [16, 17]. The sites were chosen with "equipoise" thus mixing experienced centers with inexperienced. This practice greatly contaminated the outcomes from large volume, experienced centers. Likewise, the sickest patients with the worst

outcomes were published first and the good outcomes group with favorable risk/benefit published later after most had abandoned the technique [16, 18]. Unfortunately, many patients who would benefit are now ignored because of the poor outcomes group's notoriety. Also, with minimally invasive techniques, the risk has dropped markedly since the trial. Some have expressed concern that the trial was designed to save CMS and insurance companies on patient care costs [19].

The development of pediatric surgical devices can be viewed as impractical with limited returns. The complexities of conducting trials on vulnerable neonate, infant, and child populations combined with a small market size disincentivize industry from developing devices indicated for pediatric use [20]. The cost of a clinical trial surges three to five-fold per person when conducted in children as compared to adults [21]. The lack of available drugs and devices indicated for the pediatric population has required widespread "off-label" use of devices and drugs. Off-label use is considered by most as standard practice, but poses risks related to dosing and adverse effects unique to the pediatric population. In these cases, physicians rely on evidence-based practice described in the current medical literature.

The FDA has incentivized development and labeling of pharmaceuticals for children through the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) in 2002 and 2003, respectively [22]. The BPCA grants an additional 6 months of market exclusivity for a drug that has undergone pediatric clinical trials. Likewise, PREA authorizes the FDA to request a pediatric assessment for drugs widely used off-label in pediatrics and requires a pediatric assessment with applications for new drugs expected to be superior to existing pediatric therapy. However, if there is evidence that a new drug is ineffective in children or it is determined that studies are impracticable in subpopulations such as neonates or infants, full or partial waivers can be granted [22]. Between 2007 and 2012, 54 drugs received a 6 month exclusivity extension under the BCPA, 31 of which were efficacious in children [21]. Although the BCPA and PREA have resulted in over 500 labeling changes, less than half of drug products contain pediatric labeling [23].

Unlike pharmaceuticals, development and manufacturing of medical devices for the pediatric population are weakly incentivized. A

retrospective single center study (2005–2008) reported half of pediatric cardiac interventions used adult devices off-label [24]. The passage of the Pediatric Medical Device Safety and Improvement Act (PMDSIA) in 2007 aimed to increase development of pediatric medical devices. In recognition of barriers to pediatric clinical trials, the PMDSIA allowed extrapolation of relevant adult data to pediatric populations when applying for FDA approval. Likewise, the act repealed the restriction on profits from devices developed through the Humanitarian Device Exemption (HDE), a program instituted to approve devices for use in less than 4000 patients annually [20]. Although HDE devices are FDA approved, considerable confusion exists among payors and institutional review boards which falsely consider the devices investigational [20]. Regrettably, the PMSDIA has yielded little increase in pediatric data generation, with only 1 of 22 devices approved for pediatric use studied in any patient younger than 18 [25].

Given the tight regulations, there is increasing concern that many physicians will intentionally avoid industry to prevent any intentional or unintentional bias, or even suspicions of either. The iterative exchange between industry and physician toward new product development is compromised such that future innovation may slow [26].

2.2 Industry Vs Education

Industry has been instrumental in financing educational conferences which are integral in the dissemination of new technologies. The important role of industry to support education is widely accepted and important to preserve. The current focus on continuing medical education is to preserve the high standards of education as well as the integrity of the relationship between industry and education. However, during national meetings and educational events, there is a very real concern that those involved with and sponsored by industry will promote a biased view and fail to disclose the facts of their relationship with the sponsoring organization if unregulated.

In 2003, the AAMC published their evaluation of the impact of industry funding of medical education and real or perceived conflicts of interest between academia and industry [27, 28]. The recommendation was a prohibition of all on- and off-site gifts including meals,

prohibition of samples, barring of travel funds from industry except for legitimate reimbursement for contracted services, barring of unrestricted industry representative access to faculty and trainees, and unrestricted centrally-directed industry funds. The majority of medical societies immediately adopted these recommendations, but societies vary on interpretation of the rules and the resources available to provide oversight.

The Accreditation Council for Continuing Medical Education (ACCME) has set standards for commercial support of continuing medical education (CME) events [29]. The intention of these standards was to decrease the amount of intrinsic bias and potential COI between the sponsoring industry and learner while still creating an environment and opportunity for education. The program and faculty must be designed and determined in advance as independent of the sponsoring organization; commercial support must be independent of sponsor control; commercial promotions must be in appropriate locations and not include educational presentations and materials; the content of the program must be free of commercial bias; and all providers and faculty must fully disclose any COIs prior to beginning educational activity [29].

2.3 Industry Vs Surgical Societies

Many professional medical associations (PMAs) receive funding from industry for education meetings, PMA-endorsed scholarships, and conferences. These meetings are critical for societies to provide continuing medical education to surgeons. The PMA-industry relationship encompasses many facets of education including individual physicians, CME, research, trainee support, hands-on training on new products, and support for the PMA itself. Most societies have guidelines for COI relationship and disclosures; however, these are not uniform or exhaustive. Centers of Medicare and Medicaid Services (CMS) rely on PMAs to create their own policies to regulate the PMA-industry relationship.

The Council of Medical Specialty Society (CMSS) developed guidelines in 2009 recommending many specific ways for the individual PMAs to become more transparent about industry support [30]. They recognize the importance of industry collaboration with PMAs and

proposed policies to avoid COI and preserve relationships with industry. Some propose that industry should be completely removed from PMAs. Rothman et al. proposed guidelines for PMA-industry relationships arguing that industry goals and agendas must be separate from the PMA's goals [31]. He assumes the primary goal of industry is marketing and sales and those of PMAs is education and improving patient care; whereas others , including most in industry, would argue the goals are not discrete. Rothman et al. suggests the PMAs work toward complete freedom from industry support, most notably in funding for research and education [31]. Likewise, PMA leadership should be free of all COIs during their time in office. In stark contrast to Rothman's recommendations, most PMAs are highly dependent on the financial support of industry sponsors to continue scholarship, travel grants, research funding or foundations, and further professional development.

The collaboration between industry and physicians has provided significant education to trainees, CMEs for physicians, funding for PMAs, collaborative research with clinical physicians, and competitive or contractual funding of basic research and technology development. As restrictions on industry funding and relationships continue to increase, there is concern for the overall impact on education, research, and clinical physician participation in industry-sponsored research. The relationship between industry and these entities is delicate and fraught with potential COI. The perfect balance for this relationship has yet to be achieved but may need to be individualized to the physicians, PMA, trainee, or institution to allow the relationships to persist and minimize conflict of interest. The real question is, who is responsible for oversight?

2.4 Surgeon Vs Medical Center Administration

As a surgeon matures their practice, their tool box expands; however, personal experience and expertise often dictates the best tool, such as the choice of a particular cardiac valve or stapler device. Discordance occurs when a surgeon's determination of best choice for a medical application (brand/treatments/procedures) disagrees with a hospital administration's choice as more economically viable. Potentially, this conflict can challenge the ethical values of both the surgeon and

administration, especially because, as Millikan states, “cost…has generally not ranked high on the surgeon’s radar (patient welfare focused) as a discriminator while administration’s goal is typically focused on economic sustainability of the institution within the community served” [32]. The statement “no money; no mission” is frequently heard from administration by the practicing surgeon.

Coupled with the need for sustaining cash flow at the institutional level, there is concern for surgeon-industry COI as the genesis of a surgeon’s technology preferences. Millikan et al. (2018) also identifies the inherent conflict between a surgeon’s valve preferences relative to administration’s demand for standardization to use a different brand. He proposes that contracts with commercial vendors to lower costs may be unethical relative to patient safety. A surgeon’s considerations for valve choice may include: “gradient, durability, ease of implantation, and thrombogenicity” [32], but unknowing bias may exist for a brand perhaps because of established personal relationships with vendors. The conflict between the surgeon’s choice, potentially biased by industry relations, and administrative pressures to cut cost by standardization and contracting, defines the problem.

An individual surgeon’s choice should reflect what they perceive as best for the patient; however a consensus is often difficult to obtain among surgeons, even among partners who are economically co-dependent. Technology preferences are often ergonomically surgeon specific or reflect past experiences or training. The individual’s experience may not be shared by their colleagues, even within their group. The “feel and comfort” of devices are intangible influences that are also surgeon specific. High volume, successful surgeon X may have a different background and experience that disagrees with the preferences of high volume, successful surgeon Y, yet both feel their preferences directly affect patient safety and long-term outcomes. Milliken speculates that a continuum and balance of acceptable and ethical choices for both surgeon and administration can exist. Collaboration, dialogue, and “a health care system that engages us as members of a profession with responsibilities to our patient as healers, but also with responsibilities to society as a whole” [32]. Serving a patient’s best interests must be within the framework of the larger community served. This spirit of compromise may encourage

collegiality, but safety and outcomes focused metrics would support a patient focused priority. Unfortunately, in the push for standardization and contracting, the preferences of the individual surgeons are often compromised or, even worse, ignored. These administrative decisions, however prudent, create an environment of "big brother" controlling practice and the perception of winners and losers among surgeon groups.

In the orthopedic literature, there has been extensive focus on the physician-industry interactions and even proposals for an inducement model to cultivate these relationships. Smieliauskas has evaluated medical productivity in joint replacement surgery. He found that inducements toward productivity resulted in short-term increases with little apparent movement away from established habits or preferences [33]. He also notes a high switching cost to either introduce a single new technology or multiple different technologies used by a single surgical group, as well as an adverse impact of the inducement model on the physician-industry relationship [33]. The physician's own administration may use financial reward to incentivize use of presumably cheaper contracted devices [33]. While inducement limits treatment choices, the argument is to concentrate surgeon experience on a few (or one) devices, forcing surgeons to focus their technological learning curves to ultimately improve outcomes. There is obvious gain both in market share by industry as well as cost-savings from administration to coerce or incentivize surgeons to choose a single technology. Likewise, even the choice itself allows industry to advertise each institutional preference to use peer pressure toward future choices. As can be seen, each interest brings fiscal and market share bias to each aspect of these device choices.

Can we choose a single "best" technology agreed upon by a group of surgeons that is also the best economic choice for the hospital, thereby aiding the financial viability or profit of the facility? Selecting a single technology that can be agreed upon by surgeons and administration within an institution does not erase the inherent COI with industry or industries attempt to use financial inducements; but it does represent a compromise that serves both the institution and the surgeons as buy-in or engagement.

2.5 Surgeon Vs Academic Journal

Surgeons trust research studies published in academic surgical journals to be accurate and honest in order to guide clinical decision making. However, the issue of possible COI first arose in 1980 in the New England Journal of Medicine (NEJM) addressing financial COI between industry and surgical researchers [34]. In 1984, the NEJM established a policy that all contributing authors had to state any and all COIs when publishing [35]. In 1986, the first documented COI was reported, noting direct financial support towards the surgical research by industry [36].

Journals with higher impact factor (IF) have matured to have higher rates of COI reported in comparison to medium or low ranked IF journals ($p < 0.0001$) [37]. Interestingly, Patel et al. reported that robotic surgical studies revealed no statistical significance in the rate of COI published between journals of various IF ($p = 0.46$) [38]. Recently, commercial on-line journals have emerged that actively solicit materials and reviews for on-line publication and then profit from "publication fees" (sometimes exorbitant) they charge the authors. Most of these "journals" ignore COI to aid solicitation.

In 2013, the type of COI shifted from industry sponsored research to consultants (57%) with industry sponsored research comprising 34% of COI [39]. More recently, the Physician Sunshine Act of 2013 in the Affordable Care Act (ACA) required that all industry associated funding (including meals, travel, honoraria, consulting, sponsored research, gifts and more) greater than $100 to be reported [38–40]. Lopez et al. reported the primary source of financial COI by surgeons was industry sponsored research (66%) acting as consultants (21%), and lastly royalties (6%) [39]. This can now be found in a database set up in the OpenSource.gov website [38]. The idea was to increase accountability of the surgeon-scientists as industry payments were now disclosed and available to the public, and the surgeon-scientists would likely be more pressured to report any COIs.

But in 2017, Luce and Jackman reported that the rate of COI in plastic surgery journals has not been increasing over the years despite the strong recommendation in 2007 that COIs be reported [39, 40]. Instead, COIs were either underreported or absent. In contrast, surgeon scientists who were consultants or received royalties from industry were 6.6 and 8.7 times, respectively, more likely to report fiscal

conflicts [41]. Reasons found for the underreporting of COIs include: (1) disclosure of COIs is published with the article and may diminish the impact of the science, (2) COI statements are provided by the authors based on an honor system and are only published when the authors declare a COI, (3) some journals consider COIs as forms for legal purposes and subsequently are not published, and (4) COIs are printed in review series only by some journals [36].

Since physicians place a high degree of trust in the articles published in surgical journals, the editors of journals must ensure accurate scientific information is published along with COIs. Unfortunately, editors have no authority to police these disclosures without a complaint. There is variability among the journals of various IF in even requiring COIs. If a standardized requirement for COI was prevalent and confirmed with the OpenSource database, the issue of lack of reporting COI in surgical journals would decline.

2.6 Surgeon Vs Family Power-of-Attorney

2.6.1 Family Presence During Resuscitation

Family presence during resuscitation is the policy of many hospitals allowing, and sometimes inviting family members to witness cardiopulmonary resuscitation and other life-saving procedures. Although many remain skeptical of this practice, family presence during resuscitation is acceptable and sometimes beneficial to both the families as well as healthcare professionals [42]. Although most of these studies were performed in an emergency department setting, many of the salient points can be transferable to cardiac surgery. Patients who survive CPR are reportedly comforted by their family's presence [43]. Family members present during resuscitation believed that witnessing the procedure eased their grief and aided their dying family member. After implementation of a program to have family presence during resuscitation at University of Michigan, staff noted significantly improved family support without noting any inappropriate family behavior [44]. To date, no litigation has resulted from this program. In fact, every family that was surveyed thought that all appropriate measures had been taken to render care to their family member.

Those against family presence during resuscitation point out that much of the data are from single centers, use only survey data (that can be incomplete and poorly representative), and are underpowered. In one study, only 29% of patients undergoing cardiac operations desired family presence during resuscitation [45]. More so , confidential information that the patient might not want to share could be revealed during cardiopulmonary resuscitation, and at that time informed consent is not possible. Other studies have cited that the majority of healthcare professionals would not want family present during resuscitation if they were the patient [46]. Therefore, prior to adoption of family presence during resuscitation, both positive and negative implications should be considered. Additionally, the local culture of the hospital environment, risk management, and society members must be included in the deliberations.

2.6.2 Conflict Over a Family's Request

Information disclosure is one of the most critical elements of the informed consent process and includes provision of relevant information about the nature of the procedure, benefits and potential harms, and any alternative treatments that might be available, including no treatment. Offering treatment even when the situation is considered to be futile or medically high risk/low yield is common. These situations can give rise to disagreement and conflict even among the health care team. Protocols and management algorithms are important regarding the judgement call of futility. A second colleague can be confirmatory and alleviate guilt regarding a "no treatment" recommendation. One such example in cardiac surgery is that of organ transplantation in patients with Down syndrome . These were rare until the 1995 case of Sandra Jensen, a 34-year-old woman with Down syndrome who was initially denied heart transplantation but received a heart transplant after a successful lawsuit [47]. Recent data has suggested that short- and long-term outcomes are similar or even better for organ transplantation in patients with Down syndrome than those of normal individuals [48]. This holds true for children with Down syndrome and end-stage heart failure who also require transplantation [49]. Mechanical support as a bridge to transplantation in these children is now commonly done and accepted [50]. It is also

generally accepted that the ethical concept of justice requires equal treatment for similarly situated individuals, so children with Down syndrome should not be treated differently from children without Down syndrome. Of course, there are more severe forms of congenital malformation that preclude long-term survival. Also, the issue of organ donation from severely malformed nonviable donors is controversial beyond the scope of this review.

Adherence to the patient's autonomy, or in the case of a juvenile, the medical decision maker's autonomy, can create a significant COI. The Jehovah's Witness faith prohibits accepting blood or blood products, challenging cardiac surgeons to repair congenital heart defects and perform other cardiac operations and interventions without the use of blood products. Most Jehovah's Witness families will allow use of CPB if continuity of blood flow with the body is maintained. Pre-surgical treatment with iron and erythropoietin , intraoperative blood conservation and hemodilution minimization techniques, and use of miniaturized cardiopulmonary bypass circuits can be utilized to increase survival [51]. Some Jehovah's Witness families may accept acellular albumin. Referral centers specializing in treatment of followers of the Jehovah's Witness should be consulted when this COI arises.

2.6.3 Advance Directive Limiting Postoperative Care

When the patient lacks capacity to make decisions, those decisions are generally made for the patient by a surrogate decision-maker who is authorized legally to make decisions on their behalf [52]. Alternatively, these decisions can also be made by a proxy decision-maker, who is a person previously authorized by the patient to make decisions but was not authorized by law [53]. These proxy decision makers may consent or refuse the physician's recommendations. The healthcare professional must make decisions based on substituted judgment, which means that their decision must be based on what the patient would have wanted, not necessarily on what the healthcare agent thinks is best. In the absence of a written document executed by the patient, the decision by the healthcare proxy is final [54]. However, surgeons are not obligated to do anything that will produce more harm than benefit. The risk/benefit ratio along with the healthcare proxy's

decision must be weighed prior to the surgeon proceeding or refusing operative intervention. If the surgeon refuses to do the operation, he also has the option of referring the patient to another surgeon who may offer a differing opinion [53].

3 Conclusion

COI occurs when there is a divergence between an individual's private interests and his or her professional obligations. The dilemma facing surgeons is how to manage and resolve this divergence successfully. Resolution can be successfully achieved by choosing to act in favor of the primary interest, the patient, rather than secondary interests, such as personal gain.

This chapter illustrates that COI can occur in many aspects of practice, education, research, industry relations, funding source, and administrative control. In research, the greatest concern is with conflicts between the primary responsibility of surgeon–investigator toward scientific integrity and the secondary influence from personal interests. In clinical care, the greatest concern is with conflicts between the surgeon's responsibility to the best interests of their patients, their own interests, or those of others. In medical center administration, the dilemma occurs when contractual obligations from the hospital with industry influence or prohibit the preferred tools of a surgeon. Finally, industry is an innovator, educator, partner in science and clinical trials, and a source of funding for multiple aspects of the surgeon's career. The balance between these influences is a challenge that is growing ever more complex.

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Ethics of Surgical Innovation for Congenital Heart Diseases

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Keywords Congenital heart disease – Innovation – Medical ethics – History of cardiac surgery – Evolution of ethics

1 Introduction

Innovation has been on the minds of humans since the discovery of the wheel [1]. It was Plato who famously wrote that, "Necessity is the Mother of Invention' or according to Benjamin Jowett's translation of the Republic [2], "The true creator is necessity who is the mother of our invention". The list for innovation is interminable and forms the basis of exploration, improved living conditions, informatics, data analysis, and sadly, ever growing instruments of war. As concerning the practice of medicine, innovation generally involves the introduction of a new method, idea, treatment, medication, or device to benefit the individual patient. Examples of surgical innovation regarding congenital heart disease are the early attempts by Jatene [3], Yacoub [4], and others to

achieve anatomic rather than physiologic repair of transposition of the great arteries. These innovators were motivated by the belief that their patients would derive a unique benefit from the arterial switch operation because of the theoretical advantages of placing the left ventricle in the systemic circulation. Research, on the other hand, generally involves a hypothesis-driven study, often prospective, aimed at the discovery of new knowledge for mankind, and not necessarily to benefit the individual patient. An example of this strategy would be the conduct of a study in which infants undergo either an anatomic arterial switch operation or a physiologic atrial baffle operation based on random assignment. Analysis of the results would determine the relative merits of each treatment strategy, potentially producing new knowledge, but not necessarily benefitting an individual patient enrolled in the study. Innovation and research, however, are intertwined, and one cannot proceed effectively without the other [5].

The purpose of this chapter is to explore the nature of surgical and medical innovation and consider the ethical principles that guide the moral application of innovation to patient populations. This chapter borrows heavily from our previous report on the subject [6] which recognizes the contributions of fellow co-authors Marshall Jacobs and Jeffrey Jacobs as well as the literature contributions of Marc de Leval and Robert Sade [6].

Innovation in thoracic and cardiovascular surgery has resulted in the development of the heart-lung machine, open heart surgery, the intensive care unit, myocardial protection strategies as well as countless new operations, modified procedures, and new devices. Historical annotations and careful review of these innovations show that most of these advances were not considered casually and were not impromptu ideas applied haphazardly by surgeons who were seeking acclaim, promotion, or monetary gain. For instance, C Walton Lillehei performed dozens if not hundreds of animal studies and carefully considered the accomplishments and advice of many colleagues before embarking on his history-making cross-circulation open-heart procedures [7]. Transplant pioneers Norman Shumway and Richard Lower perfected the technical aspects of cardiac transplantation in the animal laboratory but patiently awaited the validation of antirejection protocols before ever undertaking the procedure in humans [8].

Although Christiaan Barnard, after visiting Shumway, performed the first human orthotopic cardiac transplant using the heart of a brain-dead donor in South Africa [9], Shumway continued to conduct research in his careful, thoughtful, and conscientious manner. A life-long inquiry and multiple contributions attended Shumway's work. These noteworthy contributions, as well as many others, demonstrated the inherent integrity that was deeply ingrained in the training of academic surgeons, even before the advent of institutional review boards, governmental oversight, and international regulation.

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2 Regulation of Surgical Innovations

While the United States Food and Drug Administration has gradually engaged in more monitoring of new drugs and devices, surgical procedures have not been so scrutinized. New procedures, however, have been indirectly regulated by way of hospital accreditation committees, institutional review boards, professional and malpractice standards, ethical standards of beneficence and respect for human dignity, requirements of special skills and above all, the standard for informed consent. This is not to say that operations were never formally monitored. New implantable devices such as prosthetic, bioprosthetic, and homograft valves are monitored by the United States Food and Drug Administration. Likewise, so are pacemakers, defibrillators, and vascular prostheses.

It seems incredible today that some of the first innovations in congenital heart surgery were not monitored by a committee, agency, or administrative body. As noted previously, the first human cross-circulation procedure for open heart surgery was tacitly monitored by the Chairman of the Department of Surgery after a number of animal studies [7]. Institutional review boards have since been established to oversee research involving human subjects by insuring that research is ethical, not unduly harmful, and carried out in the presence of informed consent [10]. The mandate for the creation of these Boards and the processes in which they engage is, in fact, a formal and institutional process that earlier in history was the purview of service chiefs: the respected leaders of the faculty at our nation's leading academic medical centers. Owen Wangensteen, Chairman of the University of

Minnesota Surgery Department, was one of the great surgical educators of the twentieth century [11–14]. It was under his leadership that F. John Lewis, C. Walton Lillehei, Norman Shumway, Richard L Varco, and others contributed to the development of open-heart surgery. In his department, every surgical resident was required to spend time in the surgical physiology laboratory. To the extent possible, ideas for surgical therapeutic innovations were modeled and tested in the animal laboratory, often leading to peer-reviewed publications, before being applied in the clinical realm. In 1940, Wangensteen founded the Surgical Forum of the American College of Surgeons, where young surgeons would present ideas to their peers [11]. The environment was fertile for innovations in surgery, but as important, advances were made in the setting of an established and respected hierarchy of responsibility. Wangensteen ultimately exercised control over the approval and timing of the innovations introduced by members of his department. In a way, his personal code of ethics set the tone and established de facto requirements and criteria for application of innovations that are fundamentally similar, yet less formalized and cumbersome than those utilized by institutional review boards today. The members of today's institutional review boards must of course have enough experience, expertise, and diversity to make an informed decision on whether the research is ethical, informed consent is sufficient, and appropriate safeguards have been put in place. One fundamental difference between the contemporary review process and that in the "Wangensteen era" is the contemporary requirement that institutional review boards include non-scientist members. When asked about the advisability of some form of public oversight during a 1968 US Congressional hearing on the social implications of advances in medicine and biosciences , Wangensteen commented, "If you are thinking of theologians, lawyers, philosophers and others to give some direction....I cannot see how they could help....the fellow who holds the apple can peel it best" [15].

The first iterations of cardiopulmonary bypass machines, prosthetic valves, and the first attempts at repair of tetralogy of Fallot, ventricular septal defect, atrial septal defect, and coarctation of the aorta all took place in the setting of internal departmental oversight as noted. The historical considerations were telling, however. Very few of these

patients would have survived without surgery. Even the slightest chance of success would have been a major step forward. Once cardiopulmonary bypass became standard, there were more innovations resulting in complex operations such as the Mustard, Senning, Rastelli, and Fontan operations. The chance of success, no matter how slim, was welcomed in those early days. These early successes were followed by the arterial switch operation, the Norwood operation, the Ross operation, and the Cox-maze III procedure for atrial fibrillation. One wonders how innovation committees or institutional review board type committees would have impacted these early surgical innovations.

It has been said that nothing is new under the sun. However, it was clear that the introduction of operations such as cardiac transplantation, lung transplantation, the Ross procedure, the Fontan operation, the arterial switch operation, the Norwood operation and the Maze operation were all new. There are other innovations, however, that are not entirely new but are variations on a theme that have been previously explored. For instance, lateral tunnel and extracardiac modifications of the Fontan operation are innovative but not entirely new. The same is true for the double switch operation for congenitally corrected transposition of the great arteries, Maze procedure for patients with congenital heart disease, pulmonary artery banding for left ventricular training, unifocalization and coarctation repair through a median sternotomy using deep hypothermia and circulatory arrest.

Many of these pioneering innovations, by the nature of their importance to humanity and paucity of existing solutions required a rather courageous relationship between the surgeon and the patient [16]. When there is very little knowledge, a significant amount of courage is required for both the surgeon and the patient to persevere. Increased knowledge, however, defines the problem and the solution , which when applied to patient care will require less courage to engage in the treatment plan. G. Wayne Miller, in his book *King of Hearts* [14], expressed the dilemma of the early cardiac surgery experience, “Indeed many doctors dropped out, the human cost was too high, the emotional toll too devastating. But some persevered. Some like C. Walton Lillehei, the father of open-heart surgery, pushed ahead through all the bleeding and the dying until they finally got it right.”

Other innovations had to take an alternative pathway from the original model that was practiced in most surgical laboratories, namely that successful animal models would precede application to the human subject. Francis Fontan had a vision that the right atrium could serve as a pumping chamber in patients with tricuspid atresia. Recently he explained the conundrum he faced four decades ago : “Experimental research on dogs…there were no survivals for more than a few hours (Personal communication, 2008).” This was to prove prophetic. Even today after thousands of successful Fontan operations in humans; there is still no long-term animal model for the Fontan circulation. Clearly, the introduction of Fontan’s concept of managing the single ventricle circulation could not await validation in an animal model. Perhaps an even more delicate balance of therapeutic options became manifest when the arterial switch operation was introduced for the repair of transposition of the great arteries. It was clear that if the arterial switch operation could be performed with low risk, it would likely result in improved long-term results because of left ventricle to aortic continuity. The difficulty was that excellent short-term results were being widely achieved with the atrial baffle operations. The long-term complications of the atrial baffle procedures were for many a secondary consideration, operative survival being the primary measure of success . To their credit, Drs John Kirklin and Eugene Blackstone, in conjunction with the Congenital Heart Surgeons Society undertook a multi-institutional prospective study, which enrolled all patients with transposition of the great arteries and followed their clinical course [17]. In the initial phases of the survey, survival after arterial switch operations in some institutions did not match the excellent results that were being achieved in some high-volume institutions. A candid objective analysis, which included the impact of the institution among potential risk factors, served to emphasize that excellent results could be achieved by committed institutions . This resulted in shared protocols, mutual interinstitutional visits, and ultimately refinements of operative methods. It wasn’t long before the majority of institutions were achieving excellent results for most patients with this rather complex operation. The dilemma of whether to perform the atrial switch operation or the arterial switch operation became moot, with

the demonstration of excellent short- and long-term survival with the arterial switch operation.

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3 Is Innovation a Moral Duty?

It is clear by any mode of philosophical or religious inquiry that innovation is indeed a moral duty . But what moral tenets are we considering? It is no secret to anyone that there are multiple sides to most ethical questions. W. French Anderson, Editor-in-Chief, *Human Gene Therapy ,* said, “We as caring human beings have a moral mandate to cure disease and prevent suffering” [18]. Lord Sainsbury, Great Britain Science Minister, speaking about stem cell research in 2000 noted, “The important benefits, which can come from this research outweigh any other considerations” [19]. Joshua Lederberg, Nobel Laureate in 2003 declared, “The blood of those who will die if biomedical research is not pursed will be upon the hands of those who don’t do it” [19]. These are examples of enthusiastic support of biomedical research, which connote a mentality of careful but deliberate progress towards curing disease as quickly as we can. On the other side of this passionate posture is the cautionary note expressed by Hans Jonas, a noted philosopher, “Let us not forget that progress is an optional goal, not an unconditional commitment….Let us also remember that a slower progress in the conquest of disease would not threaten society….but that society would indeed be threatened by the erosion of those moral values whose loss, possibly caused by too ruthless a pursuit of scientific progress, would make its most dazzling triumphs not worth having” [20]. If one believes that these words are perhaps too cautionary, consider the news-breaking story and dazzling operation that was performed in Loma Linda, California in 1984 when Leonard Bailey and his team performed a baboon to human cardiac xenotransplant in a newborn infant with hypoplastic left heart syndrome [21, 22]. The condition was clear: this child would die without an operation. At that time, the Norwood option was fraught with high mortality and unknown outcomes. So was neonatal cardiac transplantation, to say nothing about xenotransplantation. It was also the time that our society was threatened and challenged by the AIDS virus , which was believed to have had its origins from the primate

population. Did anyone consider the possibility, no matter how remote, that a dangerous and contagious baboon virus could be contracted by the recipient? Was there danger to the planet? How much danger was there for the patient and the family from overzealous animal rights groups? What about the ethical considerations, voiced by many advocacy groups, of using primates as one to one transplant donors? There is no doubt that Dr. Bailey and his group were and are highly motivated, moral, and well-meaning clinicians and scientists. And no doubt, many of these theoretical and possible outcomes were considered. Xenotransplantation [mostly porcine models] as research, was continued for its overall utility, especially in relation to the reality of a limited human donor pool for patients with heart failure. The possibility of porcine retrovirus transmission to humans, however, limited the application to human subjects until the infectious disease problem could be further studied and remedied. At the present time, the National Institutes of Health are not funding xenotransplantation protocols because of this problem. Only recently has this research model become acceptable in light of porcine infectious disease inquiry.

The integrity of the individual as it pertains to the advancement of medical and surgical therapeutics is well established. Jacob J Katz, in *Experimentation with Human Beings* wrote, "When may a society, actively or by acquiescence, expose some of its members to harm in order to seek benefits for them, for other, or for society as a whole?" [23] Clearly, this is a difficult question to answer. However, the Declaration of Helsinki (1964) was written on the premise that, "The interest of science and society should never take precedence over considerations related to the well being of the subject." While this view on human research is generally accepted, some have argued that too enthusiastic an endorsement of these tenets may result in a static state of medical therapeutics. Francis D. Moore, wrote, "By establishing arbitrary ethical standards, one might be surprised to find that while he [the researcher] is protecting the individual patient, he is exposing society to the hazard of a static rather than a dynamic medicine" [24]. The road to ethical behavior was considered by Aristotle. In the Nicomachean Ethics, he defined moral virtue or excellence as "The habit of choosing the golden mean, between extremes as it relates to an action or emotion" [25]. One's reaction to a moral issue is not always

the same. It is based on a lifetime of achieving moral excellence to do what is right in all conditions. Aristotle notes that humans should look into Society and find exemplars of moral excellence and emulate them in their life-long quest of this ideal.

Our institutions have helped us in this quest by establishing guidelines that will allow the participant to understand the basic elements of moral duty and establish a thought process which will guide the researcher, clinician, and human being to act in a moral manner when there are no written rules. To quote Kant on the categorical imperative, "Act only according to that maxim whereby you can at the same time will that it should become a universal law" [26]. In other words, every action can stand on its own as a moral tenet that will be appropriate for that moment and for all time. Now that's something to consider! So, what are some of the guidelines that are in place that govern surgical innovation? Presently, surgical innovation is considered as research when it has to meet a variety of formal regulatory requirements such as Institutional Review Board approval for patients involved in United States Food and Drug Administration-monitored evaluations of devices or drugs. If surgical innovation is considered as the advance in medical practice, it is governed by professional and malpractice standards; surgeons do not have to be reaccredited when they alter practice or when they introduce new procedures.

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4 How Do We Introduce Innovation into Practice?

Clearly, the best way to introduce innovation into clinical practice is by evidence-based decision making. As Douglas Altman states, "Well-designed and properly executed randomized, controlled trials provide the best evidence on the efficacy of health care interventions" [27]. However, randomized controlled trials in surgery are difficult to perform. It is hard to blind the participants of the study as to the therapeutic options. Surgery is confounded by human factors such as skill and learning curves. Rapidly evolving technologies make it difficult to enroll a large number of patients. Human factors such as surgical skill may influence outcomes more than the actual type of procedure.

Randomized controlled trials that do not incorporate blinding are more likely to show advantages of the new intervention over the standard treatment. Moreover, the problem of which surgeons to choose for the trial enters the planning . Questions like, “are all surgeons to be included in the trial or only the better surgeons?” The dilemma of choosing the “better surgeons” is an interesting task, to be sure.

Alternatives to evidence-based medicine can be informative and helpful, especially when a randomized controlled study is not possible. These studies include: nonrandomized contemporaneous controlled studies (observational studies), nonrandomized non-contemporaneous controlled studies (historical controls), anecdotal evidence (single case study such as the first open heart operation, first heart transplant, etc.), and uncontrolled case series, (these are the bedrock of surgical research of the past such as radical mastectomy, tonsillectomy, etc.).

Observational studies can establish associations rather than causation between treatment and outcome. They can be a valuable alternative when ethical considerations, costs, resource, or time prohibit one from designing a randomized controlled trial.

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5 So, What Is the Answer?

Clinical surgery can continue with what is in place now. There has been enormous success with this model. The system allows frequent adjustments and there are less administrative hassles. Sade and associates argue that innovation review committees can be formed within each Institution which would result in formal collegial review, collective opinions before implementation, and follow-up reports [28]. This system puts into formal structure what is now being performed by responsible institutions that require peer review of new operations and careful follow up of complications and outcomes.

The ethics of innovation in surgery have evolved from the actions and tenets of serious and high-minded individuals who have considered their proposed surgical advances in a sea of patient need, limited knowledge, and moral duty. These principles have served our profession and our patients well. Whether more or less oversight is necessary will be determined by the profession as the road to obtaining

"the habit of choosing the golden mean between extremes as it relates to an action or emotion" [25] becomes more manifest.

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Ethical Considerations in Patients with Extracardiac or Genetic Anomalies

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1 Introduction

Patients with congenital heart disease (CHD) often have other comorbidities including extracardiac and genetic anomalies. Epidemiological studies have shown that a genetic or environmental cause can be identified in up to 20–30% of CHD cases [1–7]. The presence of extracardiac or genetic anomalies can negatively impact outcomes in patients with CHD and lead to increased hospital stay, higher in-hospital mortality, unplanned reoperations, and diminished late survival, especially if the extracardiac anomalies are significant or if the heart surgery is complex [4, 8–12]. However, repair or intervention

for CHD patients with extracardiac anomalies does not always pose higher risks [13]. Therefore, recognition and evaluation of anomalies is important to assure proper prognostication, appropriate family counseling, and fully informed consent.

As genetic screening practices evolve and more centers perform broad microarray and whole genome sequencing, genetic anomalies with a known phenotype and those with "unknown significance " will be increasingly reported in patients with CHD [14–16]. Many cases of CHD surgery occur in patients with mild renal or genitourinary anomalies and the analysis of whether to proceed with surgery is not impacted much by these types of extracardiac anomalies. Sometimes the extracardiac or genetic anomaly , however, is substantial enough to cause the timing of CHD surgery to be altered (i.e. delaying full repair of Tetralogy of Fallot in a patient with a large gastroschisis). Other times, conflicts may arise about what is in the best interest of the child, appropriate ethical justifications for not offering surgery, and how to balance justice and societal burdens when the child has significant extracardiac anomalies that may limit his or her lifespan appreciably and/or impact quality of life.

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2 Ethical Issues and Extracardiac Anomalies

Several justifications have been given for withholding surgery for some patients with extracardiac or genetic anomalies including: (1) harm to the infant during and after surgery; (2) quality of life after surgery; (3) lack of data to support that surgery improves the overall prognosis; (4) potential of providing false hope or unrealistic expectations for the family; and (5) concerns about improper allocation of time and resources [17–21].

While these concerns are undoubtedly important, they are points that should be considered for *any* cardiac patient, not just for those patients with extracardiac anomalies. For example, it may be ethical to withhold surgery for a patient with recurrent pulmonary vein stenosis who does not have any extracardiac anomalies for precisely the same reasons listed above. Our profession must be careful to use the justifications listed above fairly and consistently when considering *all* patients, and not just those with extracardiac or genetic anomalies. It is

important to understand the historical perspective and changes in the types of medical care offered to children born with genetic and other anomalies over the past half century to better inform how we make those decisions in the modern era.

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3 Historical Perspectives

Prior to the 1980s, many children born with disabilities were denied lifesaving surgeries and the decisions were largely left to the physician and families of these infants [22, 23]. The social and political landscape, however, changed after an important case in 1982 when a baby boy (Baby Doe) was born in Bloomington, Indiana with trisomy 21 and tracheoesophageal fistula. If not surgically corrected, Baby Doe would die from this anomaly. Baby Doe's mother's obstetrician recommended that the family not pursue surgery, citing a 50% change of survival and poor long-term neurodevelopment. The parents agreed and declined surgical intervention. The pediatrician and family physician opposed this plan as they believed that the family was given flawed statistics about survival and prognosis. These physicians found attorneys and couples who were willing to adopt the child. The local court, however, deferred to the parents' decision and upheld their right to make this decision for their baby. Baby Doe died of dehydration and pneumonia on day of life 6 before the case could be appealed [24].

The Surgeon General at the time, C. Everett Koop, was furious. He had been chief of surgery at Children's Hospital of Philadelphia and had a nearly 100% success rate with repair of tracheoesophageal fistulas. He declared that the family's decision to forego treatment was based purely on the potential for future disability for the child and called it discrimination against children with disabilities [24]. In addition, public outcry about the case was exceptionally loud from pro-life and disability rights groups [25]. In response, the Reagan administration ordered Koop and the head of Department of Health and Human Services to notify healthcare workers that they could lose federal funding if they did not provide treatment to handicapped infants under Section 504 of the Rehabilitation Act of 1973.

In 1983, to help enforce these regulations, the Department of Health and Human Services set up telephone hotlines and required posting of

the “Baby Doe rules ” in all hospital nurseries and required that any person who had knowledge that a handicapped infant was being discriminatorily denied food or customary medical care should immediately contact the Handicapped Infant Hotline. These initial regulations were struck down by the Supreme Court in 1986 because the Reagan administration’s interpretation of Section 504 was declared incorrect [26], but revised Baby Doe rules were passed by congress in 1984 and became part of the amendment to the Child Abuse Prevention and Treatment Act (CAPTA) [27].

The CAPTA amendment Baby Doe rules stated that a physician could not withhold medically indicated treatment for an infant unless: (1) the infant is chronically and irreversibly comatose, (2) treatment would merely prolong dying, not be effective in ameliorating or correcting all of the infant’s life-threatening conditions, or otherwise be futile in terms of survival of the infant, or (3) treatment would be virtually futile in terms of survival of the infant and the treatment itself under such circumstances would be inhumane [27]. Notably, these rules do not allow for the infant’s quality of life to be taken into consideration and they do not mention the “best interest” of the infant.

Around the same time as the Baby Doe rules were promulgated, the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research issued a report that reviewed the standard that should be used when a surrogate makes decisions on behalf of someone who cannot speak for themselves. When there is no history to provide insight as to how that person may have wanted to proceed (as is always the case for infants), the Commission recommended that the best interest standard be used [28]. In the Commission’s report entitled “Deciding to Forego Life-Sustaining Treatment” they specifically stated that “relief of suffering, the preservation or restoration of functioning, and the quality, as well as, the extent of life sustained” could be taken into account when making such decisions [29]. With regard to infants, the report stated that parents “should be surrogates for seriously ill newborns” unless their choice is “clearly against the infant’s best interests.” The report also emphasized that decision-makers should have access to “the most accurate and up-to-date information” when making their decisions [29]. This report emphasizes the ethical principles that are routinely

employed in modern pediatric medicine, including the best interest standard and the importance of informed consent based on accurate information.

The American Academy of Pediatrics (AAP) addressed the conflict between the Baby Doe rules and the reports of the President's Commission by endorsing the best interest standard. The AAP's Infant Bioethics Task Force and Consultants issued the "Guidelines for Infant Bioethics Committees" and recommended that ethics consultation and review be offered when making decisions to forego life-sustaining treatments for infants. The AAP's Committee on Fetus and Newborn issued guidelines on non-initiation or withdrawal of treatment for high-risk newborns in 1995, which were then revised in 2007 [30]. The statement supports foregoing intensive care in cases that were likely fatal or had a high risk for severe morbidity. Importantly, they deferred to parental decision-making with the best interest standard in cases where "the prognosis is uncertain but likely to be very poor and survival may be associated a diminished quality of life for the child."

The AAP Committee's final recommendations included:

1. Decisions about non-initiation or withdrawal of intensive care should be made by the health care team and the parents of a high-risk infant working together. This approach requires honest and open communication. Ongoing evaluation of the condition and prognosis of the high-risk infant is essential, and the physician, as the spokesperson for the health care team, must convey this information accurately and openly to the parents of the infant.
2. Parents should be active participants in the decision-making process concerning the treatment of severely ill infants.
3. Compassionate basic care to ensure comfort must be provided to all infants, including those for whom intensive care is not being provided.
4. The decision to initiate or continue intensive care should be based only on the judgment that the infant will benefit from the intensive care. It is inappropriate for life-prolonging treatment to be continued when the condition is incompatible with life or when the treatment is judged to be harmful, of no benefit, or futile [30]

treatment is judged to be harmful, of no benefit, or futile [30].

The historical context provides a pathway on how to proceed with infants with CHD defects and extracardiac or genetic anomalies. Just as the AAP recommends using the best interest standard for decisions surrounding non-initiation of intensive care or withdrawal of intensive care for *any* medical condition, the cardiologist and cardiac surgeon should use a similar standard when deciding whether to offer cardiac surgery to an infant with significant anomalies that may make surgical outcomes worse or decrease the benefits that the surgical intervention may produce.

The subjective nature of the best interest standard can lead to conflicts among physicians and between parents and phyisicans. The AAP statement on "Guidance on Forgoing Life Sustaining Medical Treatment" states that "when the balance of benefits and burdens to the child shifts, forgoing life-sustaining medical treatment is ethically supportable and advisable" [31]. The AAP also offers guidance when there is disagreement between the care team and the family decision-makers or between family members and suggests that the clinician: (1) Use principles of negotiation and conflict resolution and support from pastoral care providers and consultants in palliative care or ethics; and (2) Allow for reasonable accommodation for the timing of forgoing life-sustaining medical treatment to allow family members to gather but take utmost care to avoid prolonging the patient's suffering [31]. Furthermore, it may be ethically justifiable to forgo life-sustaining medical treatment despite family objections in rare circumstances of extreme burden of treatment with no benefit to the patient beyond postponement of death [31].

Clearly, the way that we treat trisomy 21 has changed considerably over the past 50 years and what is considered "best interest" has evolved with changing societal views and medical outcomes. To discuss every genetic or extracardiac anomaly and combination of CHD is beyond the scope of this chapter, so trisomy 13 and 18 are used here as examples of genetic syndromes where the decision of whether or not to offer cardiac interventions is often debated. Discussion of these syndromes establishes a framework for analysis that can be used for other genetic and extracardiac anomalies.

4 Infants with Trisomy 13 and 18

Trisomy 18 is an autosomal dominant with a prevalence of one in 3000 to one in 8000 live births [32]. Many patients are diagnosed prenatally and do not survive to birth either due to elective termination or in utero demise. Infants with trisomy 18 usually have minor to major birth defects, severe psychomotor and neurocognitive disabilities, and an increased risk of mortality. The majority of CHD in these patients are septal defects and patent ductus arteriosus, although some have more complex heart disease such as hypoplastic left heart syndrome . The major causes of death for these patients are respiratory failure, apnea and heart failure from unrepaired CHD [32].

Historically, trisomy 13 and 18 were considered "incompatible with life" and death frequently occurred within the 1st year of life attributed to causes other than CHD, with 5–10% infants surviving to 1 year of age [33]. More recent data, however, show that with interventions such as congenital heart disease surgery, many infants survive longer. Several studies published in the 1990s and 2000s showed some but still low percentages of patients surviving to 5 years of life and some beyond [32, 33]. In the 2010s, a shift occurred where researchers asked whether children with trisomy 13 and 18 were not surviving because they were not being offered surgery. Several small studies showed survival in children with trisomy 13 and 18 may be longer if they received cardiac interventions [34, 35].

Kosiv et al. used the Pediatric Health Information System (PHIS) database from 2003 to 2015 and identified congenital heart disease in 91% of infants with trisomy 18 and 86% of infants with trisomy 13. These varied across the spectrum of severity. Of this group, only 7% underwent cardiac surgery but those who had surgery had better survival than those who did not [36]. The authors implied that the decision to forego surgery may be based on a mistaken belief that infants with these trisomies die regardless of any intervention [37]. Previously, the lack of data and perceived risk of inevitable death made physicians more likely to withhold surgery for CHD in this population, however these newer studies provide persuasive evidence that CHD surgery should be contemplated in some cases. Certainly, parental informed consent about the infant mortality risk with cardiac surgery

and the expected severe neurocognitive delays with these syndromes still needs to occur [37].

Peterson et al. queried the Pediatric Cardiac Care Consortium (PCCC) database between 1982 and 2008 and found that 29 of 50 patients with trisomy 13 and 69 of 121 patients with trisomy 18 (including mosaics) underwent cardiac surgery. This was one of the largest cohorts of patients with these trisomies undergoing CHD interventions. The in-hospital mortality rates for these patients were 27.76% (trisomy 13) and 13% (trisomy 18), ten times higher than what is "expected" for these types of lesions. Median survival, if they survived to hospital discharge, however, was 14.8 years (trisomy 13) and 16.2 years (trisomy 18) for those patients they were able to track. Patients who were identified as having mosaic or partial forms of trisomy 13 or 18 had approximately 2 years longer median survival than patients who were not reported to be mosaic or partial. Causes of death included cardiac (43.5%), respiratory (26.1%) and pulmonary hypertension (13%). The authors conclude that those patients who were selected for cardiac surgery had longer survival than what was previously reported. They argued that their data could be useful when counseling families and deciding whether to offer cardiac interventions to select patients [38].

As these survival data are emerging, disagreement continues among clinicians about what interventions are appropriate to offer. Kaulfus et al. surveyed 378 clinicians from multiple specialties regarding their attitude towards congenital heart surgery for infants with trisomy 18. Survey respondents included genetic counselors, prenatal physicians, and postnatal physicians. In their study only 48% of respondents agreed that discussing the option of cardiac surgery for these patients was appropriate, however 81% agreed that cardiac surgery may offer the benefit of extending the infant's life. Fifty-one percent thought that CHD surgery could improve the quality of life. Some respondents wrote in the comments section that not having access to a cardiac surgeon who was willing to perform the surgery was a reason why they did not bring surgery up as an option. In summary, they concluded : "Ethical concerns and insufficient outcome data were the most agreed upon reasons for not offering cardiac surgery. Trisomy 18 not being uniformly lethal and expressed parental wishes were the most agreed

upon justifications for offering surgery." All 6 surgeons surveyed, however, reported performing surgery or being willing to perform surgery for these patients for certain heart lesions [17].

Although the examples of trisomy 13 and 18 are used here, there are many other extracardiac or genetic diseases where the decision to depart from the usual course of CHD treatment or repair may arise: extreme prematurity, congenital diaphragmatic hernia, intractable seizure disorders, other genetic anomalies or syndromes with significant neurodevelopmental delays, and syndromes that affect multiple organs systems and potentially require other invasive procedures. Indeed, this is not a comprehensive list but is intended to provide some examples that pediatric cardiologists and cardiac surgeons routinely encounter . All may lead to disagreements about what is in the best interest of the child and who is permitted to ultimately decide upon the course of treatment.

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5 Clinician Perspective

Sometimes pediatric cardiologists and/or cardiac surgeons refuse to offer surgical interventions despite parental requests. In these cases, it is important to understand the reason for placing limitations on parental choice. First, a physician may find that the intervention that is requested will not have the intended outcome or may be technically impossible. For example, a parent may request that a surgeon perform a full repair on an extremely premature infant with Tetralogy of Fallot, pulmonary atresia and multiple aortopulmonary collateral. However, the surgeon may refuse until the infant is larger due to technical reasons or because the surgery is unlikely to be successful based on the infant's weight. Second, a physician may refuse a procedure because he/she does not think the risks are worth the benefits. For example, a surgeon may decline to repair a coarctation of the aorta in an infant who is septic from necrotizing enterocolitis and not expected to live. Another example is a child with trisomy 18 who has hypoplastic left heart syndrome and is not be expected to survive the usual first surgery performed on cardiopulmonary bypass. Here a surgeon may decide to decline to perform the Norwood operation, but may consider a less invasive hybrid procedure (stenting of the patent ductus arteriosus and

pulmonary artery banding) in order to allow the child to leave the hospital and go home with family. This example is in contrast to a child with trisomy 18 and a ventricular septal defect where surgical closure is now increasingly offered. These types of refusals are deemed ethically appropriate because the proposed treatment will either not achieve the intended goal, or the risks are considered to outweigh the potential benefits.

Although many use the word "futile" when deciding not to offer medical or surgical interventions, the use of this word can be problematic "because doing so is disrespectful to patients and families, overly empowers clinicians, and stifles communication" [39, 40]. The American Thoracic Society in its policy statement states: "the term 'potentially inappropriate' should be used, rather than 'futile,' to describe treatments that have at least some chance of accomplishing the effect sought by the patient, but clinicians believe that competing ethical considerations justify not providing them… The term 'futile ' should only be used in the rare circumstance that an intervention simply cannot accomplish the intended physiologic goal. Clinicians should not provide futile interventions and should carefully explain the rationale for the refusal" [41].

In reality, situations with intractable disagreement remain complex when families want continued medical care despite nuanced explanations and discussions as illustrated by multiple ethical analysis and case reports of CHD and associated anomalies [42–44]. Ultimately, as stated by Lantos, "the fundamental question in debates about futility is whether the doctors' way of understanding what is going on is ultimately so obviously and inarguably correct that it should prevail or whether, instead, the alternative understandings of patients and families are also worthy of consideration" [45].

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6 Parental Perspectives

There are few studies that have looked at parental perspectives during real-time decision making about CHD surgery or retrospectively after surgery has occurred. One small survey study of parents whose children had trisomy 18 and had medical or surgical treatment for CHD showed "all respondents agreed that they would choose the same

treatment option again, that their child's quality of life was improved by their choice of care, and that the parental experience was enhanced" [46]. Parental satisfaction with the experience was the same in the intervention and medical management group and did not vary based on whether their child was still alive at the time of the survey. Janvier et al. showed that parents of children living with trisomy 13 and 18 describe their children as happy and enriching to the family [21]. Though these studies are small, they point to the ethical dangers of making assumptions about quality of life on behalf of patients without parental input. In the modern era, there are multiple support groups and internet sites where families share stories of their children with trisomy 13 and 18 and the added value these children bring to their family. Parents post about how their children teach them the meaning of unconditional love. Others describe becoming closer to God through the process of caring for their child [47, 48].

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7 Societal Burdens

Some may argue that offering cardiac surgery to patients with other severe comorbidities is unethical because it is a poor use of societal resources [19]. Furlong-Dillard et al. used the PHIS database between 2004 and 2014 and identified patients who had CHD surgery and a genetic condition. They found that 15% of patients undergoing CHD (14,714 patients) had an associated genetic condition. They stratified based on surgical complexity and grouped genetic conditions and found that all patients with a genetic anomaly had a significantly longer length of hospital stay and higher total cost than the controls except for the trisomy 21 group [49]. The cost is higher for almost all genetic conditions, even the ones with milder cognitive delays such as 22q11 or Turner Syndrome. Realistically, if cost is the argument for limiting interventions, it will be difficult to decide where to draw the line between different genetic anomalies.

Certainly, other countries with national health systems or reduced resources may set limits of care based on established policy on how resources are deployed to deliver healthcare based on the principle of justice . Resources do need to be adequately utilized in order to maximize good. However, in the United States, the health care model

does not currently have broad policy or recommendations on limitations of care. If restrictions on medical or surgical care are going to be made based on expected survival benefit, these decisions need to be made at the governmental policy level. Physicians and clinicians caring for these children should not be rationing or changing care based on their own assessments of the financial burdens and potential quality of life of the child. Limiting care at the bedside based on quality of life or perceived better allocation of resources may also lead to discrimination against certain populations and lead to further disparities in care.

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8 Data Transparency

Over the last decade, there has been a move towards increased transparency and reporting of surgical outcomes in the field of pediatric cardiology and cardiac surgery to improve patient outcomes and health care delivery through knowledge sharing [50]. Lihn et al. in describing their work through the National Pediatric Cardiology Quality Improvement Collaborative, state that "barriers to full transparency persist, including health care organization concerns about potential negative effects of disclosure on reputation and finances, and lack of reliable definitions, data, and reporting standards for fair comparisons of centers" [51]. While we support the move towards increased transparency as part of improving the informed consent process and patient care, how to take into account higher-risk patients becomes imperative. Heart center administrators, pediatric cardiologists, and surgeons who perform CHD surgery may be reluctant to take on patients with multiple co-morbidities including extracardiac or genetic anomalies due to the higher risk profile of these patients and potential inherent increased mortality. This bias may not be overt and occur subconsciously but still results in declining to perform an operation . While pursuing transparency, we must still guard against creating a system where there is inappropriate discrimination against patients with CHD and extracardiac or genetic anomalies.

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9 Importance of Shared Decision-Making

When care is complex and prognostication is difficult, the practice of shared decision-making between parents, patients, and clinicians becomes especially imperative. Providing the most accurate and current data is a first step in this informed consent process. Therefore, further research on the long-term morbidity and mortality of these populations is necessary. The research also needs to evaluate the mosaic or less severe genetic subtypes separately since they have been shown to have a better outcome as well [38].

As more surgeons perform cardiac surgery on patients with extracardiac and genetic anomalies in the future, studies will be needed to better assess factors that may influence the likelihood of increased morbidity so that families can be appropriately counseled. For example, preoperative mechanical ventilation in the trisomy 13 and 18 population was shown to be associated with higher mortality despite congenital heart surgery [52]. Delayed intervention and complete repair instead of palliation may also be better than palliative procedures at prolonging life [38]. Identifying other factors that may predispose to higher morbidity and mortality such as history of previous surgeries, other organ dysfunction and low birth weight are essential to the counseling and shared decision-making that needs to occur on an individualized basis. A comprehensive team-approach should occur with the family to provide balanced and consistent counseling and to avoid potential misunderstanding and mistrust [21].

Finally, data also need to reflect the quality of life of these patients from the parents' perspectives. Relying on physicians' quality of life assessment can be ethically problematic as physicians tend to rate the quality of life for a disabled child lower than their parents rate it [53, 54]. Extreme caution must be taken if the reason to refuse a cardiac intervention is the perception of a poor quality of life of the patient. The conversation with the family instead should be about the risks and benefits of the desired CHD. Is the surgery likely to extend the patient's life in a significant way or is the child so impaired that he/she is likely to have a shortened lifespan regardless of any cardiac intervention?

Sometimes, despite providing as much granular information as possible, parents and physicians might still disagree about whether to pursue cardiac surgery [55, 56]. For diagnoses that are uncertain and complex , the subjective nature of the of the best interest standard can

make decision-making challenging. An ethics consultation may be helpful as well as guidelines such as “Non-initiation or withdrawal of intensive care for high-risk newborns” and “Guidance on Forgoing Life Sustaining Medical Treatment” [29, 30]. While allowing for parental discretion and leeway when complexity is high, all available pediatric ethical principles and guiding frameworks may need to be employed to reach a resolution [57–59].

10 Conclusion

A large number of CHD patients will have genetic or extracardiac anomalies. It is important for cardiologists and cardiac surgeons to treat each case and family as unique. Not all patients with the same diagnosis will necessarily end up with the same treatment (or nontreatment) because parental decision-making is crucial. Just as we allow parents to make decisions for their children without such extracardiac anomalies, we must allow parents to make decisions for their children with these anomalies. Parental authority for decisions should only be limited in the rare case where the parental request is out of line with the standard of care for treatment. Importantly, however, as seen from the historical perspective of trisomy 21, the standard of care shifts with time as new surgical techniques improve outcomes and research changes earlier prognoses about some genetic conditions and anomalies. It is imperative, therefore, that cardiologists and cardiac surgeons stay abreast of the developments for conditions that have previously been considered to have an insurmountable risk of high mortality or morbidity.

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Medical Futility: When Further Therapy Is Hopeless

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1 Introduction

The purpose of this chapter is to consider the important issue of medical futility that has many nuances in the settings of philosophical discourse, spiritual commitment, end of life issues, scientific realities, and societal interpretation. In most instances, we took the liberty of author ownership and editorial privilege to reproduce the amended prose from our chapter in *Pediatric Cardiac Surgery, fifth Edition* [1].

A definition of medical futility has been debated since the early doctrines of medical practice. It was Hippocrates who described the major goals of medical therapy as consisting of cure, relief of suffering, and "refusal to treat those who are overmastered by their diseases" [2]. Plato objected to a cure that results in a life that "isn't worth living". He noted that repeated expenditure of energy that is consistently non-

productive should not be engaged [3]. Schneiderman and associates [4] opined that, “A futile action is one that cannot achieve the goals of the actions, no matter how often repeated. The likelihood of failure may be predictable because it is inherent in the nature of the action proposed and it may become immediately obvious or may become apparent only after many failed attempts.” They offered a considered opinion on futility, “We propose that when physicians conclude (either through personal experience, experiences shared with colleagues, or consideration of reported empiric data) that in the last 100 cases, a medical treatment has been useless, they should regard that treatment as futile [4].”

The ethical dilemma concerning medical futility usually centers around parental insistence to continue therapy when attending physicians, nursing staff, and ethics consultants have determined that the clinical situation is hopeless. To this point, recommendations are usually made for comfort care, which of course is a euphemism for terminal care. Lantos and associated [5] considered a differential diagnosis for medical futility that considers issues that can cause suspicion, confrontation, and disruption of the patient-doctor relationship. Lantos offers five categories that subtends the futility. They are power, trust, money, hope, and integrity.

2 Power

The first category in this debate is power or more precisely, “Who gets to say no”. This question arose in the 1970’s and 1980’s and was mostly centered on the rights of patients to refuse medical treatment. By and large this issue was ethically and legally resolved based primarily on the right to autonomy, recognizing that the individual has the right to his/her own destiny when it comes to accepting or refusing medical therapy. This principle has been generally respected except when it comes to medical decisions on children who are protected by the imposed moral responsibility of the state. For example, the state may choose to opine and dictate care based on blood transfusions, orphaned subjects, and conflict of interest issues. Since this era however, the question of the 1990s, 2000s and to the present day is centered on the rights of patients and their families to demand medical treatment

despite futility issues. This dilemma has been mired in ethical, legal and political controversies as evidenced by the publicized conditions of "persistent vegetative states', severe brain injury, and diseases that have no chance of successful treatment.

And so, one may ask, "Do patients and families have the right to force doctors to squander scarce time and resources on therapies that have no benefit in order to satisfy their potentially irrational wishes?" Conversely, "Do doctors have a right to arbitrarily ignore the values and preferences of patients and families, using only their own value systems to make life and death decisions for others?" Clearly, these debates, stated in confrontational terms for emphasis , require a "Golden Mean" [6] resolution. Kaplan [7] introduced the phrase of "Odds and Ends" to offer a basis in which this debate can be framed. Questions that can be asked about a potential futility crisis are, what chance or probability of success is "worth it", what quality of outcome is "worth it" and as importantly, how do we refrain from pursuing long "odds" to achieve band "ends"? Kaplan further opines, "It is hard to take sides in such a spirited debate. One lesson quickly learned by anyone who engages in conceptual analysis of a bioethical problem is that a concept should not be expected to bear more weight than it can reasonably sustain." Precision vs. ambiguities are inherent in any case the resolution of which may not always be obvious. One reality is secure and unquestionable, "The greater the trust between physician and patient in the United States, the more willing patients will be to refrain from pursing long odds to achieve bad ends" [7].

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3 Trust

The logical continuation of this analysis is the issue of trust. To the extent that patients trust doctors and agree about the values, the "futility debate" disappears [5]. Physicians will tell patients that they believe further treatments to be futile, patients will believe them and together they will decide to forego treatment. The futility debate begins when this process breaks down. At this point, one may ask, "Why would patients want a treatment that is futile?" For one thing, they may not believe that the conditions are futile. There are significant misunderstandings such as clinical endpoints, unclear informed

consent and distrust (patients don't believe their doctors). In addition, there can be a psychological barrier in so far that patients exhibit pure denial.

Distrust is very difficult to resolve in these situations. If patients don't trust doctors to begin with, then doctors' claims to a unilateral right to make decisions to withhold life-sustaining treatment will only exacerbate an already tense and hostile situation. Patients who believe that there is hope , and look to their doctor to affirm that belief, will not only reject a futility assessment but will likely reject the doctor that is making the assessment as well. A retrospective analysis almost always comes to the quality and character of the informed consent process. One might ask, "was the informed consent process conscientious?" Did the doctor and the patient "connect"? Was there a clear outline of potential complications and resolution thereto? If the answers to these questions was a "yes", the chances of rupture of the trust issue is very slight.

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4 Money

What about money ? Does money enter into the futility debate? After all, precious resources may be expended in a futile situation that will influence financial and manpower reserves. Futility debates rarely arise around therapies that are cheap and easy to provide. Arguments about futile therapy take on significance only when millions are at stake . "Given limited resources it is ethically justifiable to limit access to treatments that are expensive and offer minimal benefit" [8]. Doctors will be subjected to financial conflicts of interest between their loyalty to their patients, their loyalty to their organizations, and their social responsibilities. At risk is whether or not our patients will continue to trust us. We are fortunate that futility issues do not occur frequently in our intensive care units [9]. Consequently, when all expenditures are considered for all patient care issues, futility does not play a major role in cost containment. Inherent in this argument is that physicians and patients have time to deliberate and come to rational conclusions about continuing futile care in this setting.

Nevertheless, reimbursement incentives have changed and have become a reality in the present state of coordinated care. Offering futile

treatments, such as cardiac transplantation or other high cost therapeutic interventions lose money for caregivers and institutions. There has been a shifted responsibility to limit excessive treatment given the limited resources that are available. “In such a world, the need to separate our obligations and to be honest with ourselves about which master we are serving, will become more and more important. It will determine whether or not our patients can continue to trust us” [5].

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5 Hope

The concept of hope engenders many ethereal, religious, and spiritual ideas. It is an undeniable principle of medical practice that physicians should never take away hope from their patients; for there is always hope, or is there? David Hume a well-known philosopher/empiricist and acknowledged atheist averred that, “A miracle is a suspension of a law of nature” [10]. His empiricism left no room for divine intervention. Hence, for him, there are no miracles, only nature. On the other hand, Reverend William Sloane Coffin, in his interview on National Public Radio in 1994 noted, “Hope is a state of mind independent of the state of the world. If your heart’s full of hope, you can be persistent when you can’t be optimistic. You can keep the faith, despite the evidence, knowing that only in so doing does the evidence have any chance of changing. So, while I’m not optimistic, I am always very hopeful [11].” Jerome Groopman in his treatise, *The Anatomy of Hope* [12] deliberates the role of optimism and courage in medical therapies and considers how people prevail in the face of severe illness. Viktor Frankl takes us on a stark and poignant voyage through the horrors of a Nazi concentration camp and reflects on what allowed him to prevail. He noted, “To live is to suffer; to survive is to find meaning in the suffering” [13].

There are really no rational conclusions to this debate. The myriad experiences of writers, clergy, and philosophers have their own ideas about hope. Our patients are looking for something that can be possible in a sea of pessimism and in some cases, certain death. Our oath, duty, and empathy require inter-related courage [14] and a supportive posture.

6 Attempts to Define Futility

Virtuous attempts have been made to define futility which can act as guidelines to help clinicians and families make difficult decisions [4, 15]. While these published principles are comprehensive, they do not consider every nuance of care. In general, judgments of futility cannot be made by reference to rules or definitions but must be determined on a case by case basis. To this end, ethics committee consultations , hospital policies , and state law have helped make the painful process of futility and termination of care more tolerable to all concerned. Many hospitals have adopted procedures that require ethics committee consultation, potential patient transfer, support for legal representation, and unilateral decision-making [16].

There are some states, such as Texas [17], that have provided guidelines beyond hospital policy that allow adjudication of futile circumstances. In the event that the clinician has determined that a patient's treatment is futile and is not accepted by the family despite comprehensive consultation, Texas law requires that the physician's refusal to treat be reviewed by a hospital ethics committee. The family must be given 48 hours' notice and be invited to participate in the process. The hospital must make reasonable efforts to transfer the patient's care to others. If no provider can be found in 10 days, treatment may be unilaterally withdrawn. This process has the effect of peer review. Prior to withdrawal of treatment however, the family may request a court-ordered extension , which a judge should grant only if there is a reasonable chance of finding a willing provider. The treatment team is immune from civil or criminal prosecution.

Rarely does this process end in complete rupture in the patient-physician relationship . More often than not, a realization of the situation occurs. Even families who vigorously argue for maintenance of life-sustaining treatments, sometimes seem relieved by the process. Comments like, "If you are asking us to agree with the recommendation to remove life support from our loved one, we cannot. However, we do not wish to fight the recommendation in court and if the law says it is OK to stop life support, then that is what should happen" [18].

Dealing with futility issues is stressful for all. So many times, the events leading to futility occurred from a surgical or medical

complication which engenders regret on the part of the caregivers and resentment on the part of the patient and family. It is of little consequence to recount how the complication occurred, the influence of complexity, or the gravity of the patient's condition. While these issues are important for the learning and review process, the fact remains that the patient is in a futile condition which requires empathy, understanding, and proper conduct by all parties.

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Ethical Issues Surrounding the Use of Post Cardiotomy ECMO

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1 Introduction

The development of the heart-lung bypass machine by Gibbon revolutionized the field of cardiothoracic surgery [1]. By 1972, advances in oxygenator development led to extracorporeal membrane oxygenation (ECMO) technology . Hill and associates successfully applied this technology for an adult with acute respiratory distress syndrome [2]. Soeter and colleagues [3] utilized extracorporeal life support (ECLS) in 1973 after surgical repair of tetralogy of Fallot. This was followed by Bartlett and colleagues who applied ECMO for a neonate with meconium aspiration in 1976 [4]. By the 1980s ECMO support had become an invaluable tool for congenital heart surgery.

In 1989, the Extracorporeal Life Support Organization (ELSO) was established as an international consortium, maintaining a registry of ECMO use in active ELSO centers [5, 6]. In 2009, the registry contained over 40,000 ECMO cases, the majority of which were either neonates or children [5]. Based on 2009 ELSO data, the overall ECMO survival to discharge was 62% when used for cardiac indications. Currently, cardiac indications for ECMO include failure to wean from cardiopulmonary bypass, peri-operative hemodynamic collapse, pulmonary hypertension, post-hypoplastic left heart syndrome (HLHS), or as a bridge to transplantation [7–13]. Since 2000, post-cardiotomy ECMO reports have chronicled accumulating evidence for improved outcomes based on evolving selection criteria [7–13].

We consider the indications and clinical outcomes of post-cardiotomy ECMO over the last decade and explore the ethical dilemmas arising from programmatic, economic, and moral risks that attend its application. Much of this topic has been previously considered and reported by us and co-authors (J. Green, RM Sade, JP Jacobs, and E Kodish) [14]. The prose of the original article was well crafted and is largely presented herein with minimal redactions.

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2 Evolution of Selection Criteria for Post Cardiotomy ECMO

Aharon and associates retrospectively reviewed post-cardiotomy ECMO patients during the years 1997 through 2000 [7]. Fifty pediatric patients between the ages of 1 day and 11 years (median 443 days) required ECMO after repair of congenital heart lesions; two of these children later received a heart transplant. The overall hospital survival was 61% for single ventricle physiology, compared to 43% hospital survival for bi-ventricular physiology. Trends toward increased survival were associated with shorter cross-clamp time (52 vs. 112 min), shorter cardiopulmonary bypass time (116 vs. 146 min), and shorter time of ECMO support (88 vs. 102 h). The only statistically significant predictor of mortality, however, was the presence of renal failure that required hemodialysis during ECMO support.

In 2005, Alsoufi and associates conducted a retrospective review of post-cardiotomy neonates and children between 2001 and 2003 [8].

Thirty-six patients between the ages of 1 day and 8 years received post-cardiotomy extracorporeal life support (ECLS). Specific applications for ECLS utilization were grouped accordingly: ECLS with oxygenator as a univentricular assist device, ECMO for failed hemodynamics, and ECLS for biventricular disease needing only left ventricular support. Separating ECLS or ECMO groups resulted in differences for survival outcomes based on method utilized: ECLS for single ventricle disease (100% survival), ECMO (50% survival), ECLS as ventricular assist device for biventricular disease (100% survival), and ECLS for ventricular assist device (VAD) converted to ECMO (20% survival). By univariate analysis, factors associated with survival included age >10 days and weight >3 kg at the time of surgery, single ventricle disease, <180 h of ECMO, use of ECLS without oxygenator, <2 perioperative complications , and freedom from renal failure, sepsis, pulmonary hemorrhage or insufficiency. However, multivariate analysis revealed no independent factor significantly associated with mortality [8].

Hoskote and associates conducted a retrospective review of infants who had ECLS post repair of single ventricle physiology [9]. Twenty-five patients with a median age of 15 days (range 2–139 days) were grouped for evaluation based on use of an oxygenator. Nineteen infants had ECLS with oxygenator, and six had ECLS as VAD (no oxygenator). Findings from this study reveal an overall survival to discharge rate of 44% and estimated 38% overall survival at 1000 days since ECLS. Survival rate was shown to be higher for elective versus emergent ECLS (55% vs. 36%), for ECLS for VAD alone versus ECLS with oxygenator (60% vs. 40%), and for duration ECLS <120 h versus ECLS >120 h (72% vs. 50%). The period of vulnerability was bimodal: during the first 24–48 h and at 7.5 days post-operatively . Univariate analysis revealed statistically significant risk factors in non-survivors: multi-organ failure, renal failure, sepsis, and presence of arrhythmia prior to ECMO support.

Atik and colleagues described their use of post-cardiotomy ECMO in their 2007 retrospective review of 11 patients from October 2005 through January 2007 [10]. Ten patients had congenital heart disease , nine of whom had surgical repair [10]. The median age of the ten patients was 58.5 days (range 3 days to 8.3 years), and median body

weight was 3.9 kg. ECMO was initiated preoperatively in two patients, although a patient with severe hypoplasia of the ascending aorta did not undergo surgical repair. Eight patients required post-cardiotomy ECMO due to post-cardiotomy low output, failure of cardiac resuscitation, or severe respiratory failure. The mean duration for ECMO support was 58 ± 37 h. Actuarial survival was 40%, 30%, and 20% at 30 days, 3 months , and 24 months, respectively. Three infants survived to hospital discharge, with 2/3 at functional class I. The most frequent complication was coagulopathic bleeding with surgical re-exploration for hemostasis. Five patients were successfully weaned from ECMO and three of these patients were discharged from the hospital. Sepsis, renal failure, or respiratory distress ultimately led to cardiogenic shock, multiple organ dysfunction syndrome, and death for six patients.

In their 2010 study, Kumar and colleagues describe post-cardiotomy ECMO patient outcomes [11]. In their retrospective review of patients from January 2003 through June 2008, 58 patients required post-cardiotomy ECMO. The median age was 12 days and median weight was 3.3 kg. Thirty-one patients had surgical repair for single ventricle physiology, 27 of whom had biventricular repair. The median duration for ECMO support was 6 days (range 3–10 days), although four patients required ECMO support a second time. Seventeen patients (33%) experienced neurological complications, with elevated lactate levels at 24 h identified as the only significant factor associated with neurological complications. Eighteen patients (31%) had renal failure. Findings from this study revealed several major indications for ECMO support which included: cardiac arrest (50%) failure to wean from cardiopulmonary bypass (33%), low cardiac output (14%), and hypoxia (3%). Increased risk of hospital mortality was associated with higher volumes of transfused blood, duration of ECMO support, and sepsis.

Polimenakos and associates retrospectively examined the outcomes of neonates with functional single ventricle who required post-cardiotomy ECMO [12]. Fourteen neonates required post-cardiotomy ECMO (Norwood operation for HLHS in ten patients). Mean age and weight were 7.9 days and 3.4 kg. ECMO was implemented with rapid deployment protocol followed by median ECMO duration of 6 days. Eight patients survived to discharge (57%), seven patients survived

intermediate-term (mean interval 13.2 months), and one required a heart transplant. Although not statistically significant, factors associated with survival include early achievement of negative fluid balance, early evidence of ventricular recovery, and prolonged mechanical ventilation (>15 days). The risk factors for mortality include multiple system organ failure, sepsis or necrotizing enterocolitis, and renal failure. Interestingly, the only statistically significant predictor of mortality was elevated serum peak lactate level (>8.9 mmol/l) within 24 h of ECMO support.

These selected studies discuss short and intermediate-term clinical outcomes with factors for survival and predictors of mortality. Interest in long-term outcomes has increased, yet few studies have explored long-term physical and psychosocial outcomes. Costello and associates explored quality of life of pediatric cardiac patients who required post-cardiotomy ECMO support and compared them to a matched sample from the general U.S. population [13]. Among 397 children requiring ECMO support, in-hospital mortality was 51%, and 6% of survivors died after discharge (8% > 18 years of age and 9% < 5 years of age at the time that the study was conducted). The patient selection criteria for the follow-up study were patients between the 5 and 18 years of age at the time of the study; 94 patients were eligible. The health-related quality of life questionnaire revealed physical capability scores to be significantly lower than those of general population, whereas psychosocial scores were similar to the matched sample. The authors suggest that the similarity of quality of life scores to that of the general population supports the current practice of ECMO.

Another consideration is the cost-efficiency of post-cardiotomy ECMO. The real cost of ECMO has been difficult to assess, because accounting practices vary between institutions. Crow and co-authors describe the importance of cost analyses in the context of life-years gained. When considering costs, they suggest that cost analysis should include expense of inter-facility transport as well as pre- and post-ECMO hospital charges [6]. ECMO service reimbursement is inconsistent among institutions due to payor reimbursement variability, lack of codes for decannulation, and differences in ICU billing practices [6]. No prospective cost-effective analyses for post-cardiotomy ECMO have been conducted. However, retrospective studies

of ECMO utilization in other populations suggest that early use of ECMO may lower utilization of resources and overall hospital costs [15]. Additionally, these studies suggest the cost per life year saved was well within the recommended range of $4500 to $30,000 per life year saved [15]. Prospective studies to evaluate the cost-effectiveness of this technology will yield important information for care-improvement strategies within the limits of economic realities.

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3 Ethical Issues

Moral risks related to post-cardiotomy ECMO may be encountered before, during, and after the open-heart procedure. Encountering moral risks means that each stage of the decision-making process is attended by choices influenced by many factors that may result in decisions that are contrary to the best interests of the patient, parents, or utilization of shared societal resources. These moral risks center around the selection process, informed consent [16, 17], decision making in the operating room, and postoperative maintenance of ECMO [18]. Consideration of such risks is affected by questions of hemodynamic stability, hematologic compromise, neurological status, and family concerns.

Informed consent is a complex process that has no universally accepted standard [16, 17], is highly dependent on each clinician's understanding of the entire process and is generally practiced based on the principles of the "art of medicine" [19]. The process involves conveying information to the patient or the patient's family based on known outcome data, the clinician's experience and personality, and complex language interaction between the patient and the physician [17]. Presently, there are no ECMO-related specific clinical standards to guide clinicians as to how much information should be included in the informed consent process. Some clinicians find the idea of a "laundry list" as too impersonal [19] and likely to interfere with the natural discussion that develops during the encounter. Yet, physicians perform many functions using a predetermined process that ensures comprehensive inquiry and performance , such as the physical examination, methodical inspection of a chest roentgenogram or echocardiogram, and performance of an exploratory laparotomy.

Congenital heart operations are frequent enough that specific guidelines based on large databases [20] could be developed to assist the clinician in the informed consent process. In fact, authors have analyzed the STS Congenital Heart Surgery Database and categorized the incidence of major complications amongst the complexity levels [21]. Attention to the delicate balance between optimism and pessimism [19], accurate transfer of information, and professional demeanor are clearly important in preparing the patient and family for the procedure. Moreover, informed consent is not a single event at a point in time; rather, it is an ongoing process whenever clinical decisions are being made. Post-cardiotomy ECMO need not be discussed in the preoperative consent discussion. Very few surgeons would discuss possible need for ECMO before operation for ASD closure in a 4-year-old child; however, most would discuss this modality for repair of anomalous left main coronary artery from the pulmonary artery with poor ventricular function in a 10-month-old infant.

Few would disagree with the idea that physicians should do the right thing, that is, should act virtuously. While it is beyond the scope of this discussion to offer lengthy discourse on virtue, a well-known viewpoint is that of Aristotle [22], who offered a definition of moral virtue as "the habit of choosing the golden mean, between extremes, as it pertains to an emotion or action." The "habit of choosing " refers to a routine of decision-making developed from a base of knowledge amassed over a lifetime of learning from personal experience, as well as from laws and religious values. This moral self-education creates the basis upon which a reasonable person can make appropriate decisions and perform the right actions. The habit of choosing also contributes to the idea of *conscience* . This term is suffused with moral, religious, and philosophical overtones. Sulmasy offers this definition [23]: "Conscience is defined as having two interrelated parts: (1) a commitment to morality itself; to acting and choosing morally according to the best of one's ability, and (2) the activity of judging that an act one has done, or about which one is deliberating would violate that commitment." "Practical wisdom," *phronesis* to the Greeks, is the virtue of making decisions by applying accumulated knowledge that comes from the habitual practice of basing actions on thoughtful deliberation. In simplified terms, learn what is right; remember what is

right; apply what is right; practice what is right. These tenets should underlie the decision-making process during the entire post-cardiotomy ECMO experience.

Learning what is right involves scientific knowledge as well as moral principles. The more clinicians assimilate reliable data from the published literature, the greater the chance that they will make the most appropriate decision. In the absence of sufficient scientific knowledge or in the presence of unusual circumstances despite sufficient scientific knowledge, courage may be required to make the appropriate clinical and moral choices [24, 25]. In general, there is an inverse relationship between knowledge and courage when it pertains to acting with certainty or uncertainty [24]. Courage may be required in making decisions when only sparse data are available to the physician. These are the times when moral character and informed scientific decisions matter the most. Perhaps the most difficult moral dilemma regarding the initiation of post-cardiotomy ECMO occurs when the surgeon must decide in the operating room because of the acute need for intervention: if the decision is delayed, the patient may die. Courage may be required to make the right choice.

Relative contraindications to post-cardiotomy ECMO are uncontrolled bleeding , severe neurological injury , aortic or neoaortic regurgitation , and prematurity [26]. Despite these established relative contraindications, the emergent need for ECMO in the operating room raises the question of whether it can ever be contraindicated. After all, failure to wean from cardiopulmonary bypass implies that the patient is already on ECLS, so ECMO is merely continuation of current treatment. Moreover, neurological injury cannot be a contraindication because it is impossible to assess during cardiopulmonary bypass. Even if the operative repair were so inadequate that cardiac recovery is highly improbable, there is always the possibility of cardiac transplantation . Such thoughts as these, permit embracing the tacit maxim, “nobody dies in the operating room.”

What are the ramifications of “dying in the operating room” and what are the moral risks? When the patient dies in the operating room, several notable administrative requirements and emotional experiences are triggered. The administrative tasks include reporting the death to the coroner’s office, documenting the failed operation in

the operative report, and completing the death certificate. The emotional experiences involve the dread of informing the hopeful, trusting, and perhaps unprepared parents that their child has died; the ominous reflective process of informing and conferring with the referring physicians and colleagues; and the anticipated critical deliberations of the eventual morbidity and mortality conference.

While many of these duties and emotions would occur whether the child was to die in the operating room or pediatric intensive care unit (PICU) , underlying issues in operating room cases could bias one's judgment when death is virtually inevitable. Transferring a hopeless case to the PICU on ECMO sends the false message that there is still hope and ushers in enormous consumption of resources. In addition, the patient is still alive and transfer to the PICU on ECMO gives the family time to begin the grieving process. Moreover, death in the PICU undercuts attribution of the outcome unequivocally to the surgeon's technique, because extending life with ECMO conveys a sense that the disease process has caused death.

Notwithstanding such rationalizations, using ECMO to permit transfer of a child facing virtually inevitable death to the PICU in order to avoid unfavorable mortality statistics or the emotional burdens of a death in the operating room is unethical and should never be done. Other related principles can also be cited. When the patient does not meet the specified criteria either for starting or for continuing ECMO, "It's his only chance" cannot be justified. The belief that one must attempt to use a technology in every case in which is potentially helpful has been called the technological imperative . The term has different meanings in different disciplines, but generally can be stated in this way: "The doctrine of the technological imperative is that because a particular technology means that we *can* do something (it is technically possible) then this action either *ought* to (as a moral imperative), *must* (as an operational requirement) or inevitably *will* (in time) be taken" [27, 28]. In medicine and medical ethics , it is often used to denote the deeply embedded attitude that patient care demands that we do everything possible for the patient. In other words, if a technology exists that could be helpful for an illness, it must be used, regardless of the context of the illness or the utility of the application. The notion of technological imperative underlying medical decision making over

several decades helped launch and accelerate empowerment of patients in the death with dignity movement [29] and growth of the idea of "shared decision making " [30]. In the case of post-cardiotomy ECMO, some surgeons may feel compelled to use it because it is there, regardless of whether it makes sense in the full context of the situation. This kind of thinking should be assiduously avoided.

The most important consideration is the patient-centered perspective . Do the burdens of ECMO outweigh the benefits? Is the child suffering without associated prospect of improvement? What is the expected quality of life from the perspective of the child, should he or she survive in the long term? Scientific data help to shape medical judgment and a robust informed consent process, but ultimately the best decision making comes from attention to data informed by ethical deliberation, and in this discussion, particularly the special ethical considerations in the care of children [31, 32].

When considering whether to start or to continue ECMO, the projected expenditures of time, effort, and cost should be measured against a preset goal for expected recovery. This goal should be set in advance by the ECMO program and should aim for an expected recovery probability consistent with published norms and collective experience of the patient care team. Several important factors should be considered in continuing ECMO, once begun. Daily hemodynamic, hematological, and neurological evaluations should be performed in the context of the overall goals of treatment. Realistic evidence-based projections for meaningful survival and expected quality of life, as well as the therapies and technologies required to achieve them must be weighed in re-formulating the treatment plan at regular intervals, with the ongoing informed consent of the family. Compassion fatigue [33] within the patient care team imposes constant pressure that require careful attention and resolution. Steady improvement of the patient's condition can be expected in about 50–70% of post-cardiotomy ECMO cases [6]. When positive clinical progress is not made, the health care delivery team, in concert with the family, must make the inevitable decision to withdraw treatment.

The short and mid-term results of post-cardiotomy ECMO are improving. Indications and contraindications are being developed based on overall clinical experience. Ethical concerns, however, must

have a central role in this process, as the preceding discussion indicates. Thorough understanding of the relevant scientific literature, heightened awareness of moral risks, and incorporation of ethical tenets in clinical deliberation will guide the clinician to do the right thing.

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Rare Diagnoses and Allocation of Precious Resources

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1 Introduction

Innovation in medicine has impacted myriad lives and extended the wellbeing and longevity to countless others. It wasn't always this way. In the early twentieth century leading up to the 1950s, life sustaining and expensive technologies such as hemodialysis, organ transplantation, complex open-heart surgery, modern cancer therapy, and specialized antibiotic treatment, among many others, didn't exist. Medicare, Medicaid, and expensive private health insurance programs

were largely unknown and, in fact, unnecessary since most people with these untreatable maladies simply and sadly died without treatment, conferring no further expense to the public and private sector. Significant advances however started to emerge in the mid-twentieth century and continued especially in the field of cardiology and cardiac surgery starting with closed heart operations progressing to open heart surgery, the institution of the intensive care unit , comprehensive diagnostic modalities , cardiac/lung transplantation , ventricular assist devices , interventional therapeutic advances , and pacemaker device improvements . With every innovation came an expensive set of circumstances which included: increased manpower demands, device expenses, hospital charges, physician fees, and administrative costs. These realities have led to efforts to contain costs and in some cases, ration resources.

The purpose of this chapter is to frame the topic of resource allocation in the case of rare and expensive diseases using congenital heart disease as an index example. The argument will be made that the spectrum of diseases within congenital heart disease are each an "orphan disease" by incidence, and this "orphan" distinction will be addressed, specifically in regard to how resources are allocated for treatment. The concept of resource allocation and its resulting ethical dilemmas will be explored further from both philosophical and economic perspectives, using Utilitarian interpretations in the former, and an introduction to the basic tenets of healthcare economics in the latter. Much of this theme has been previously reported by us [1]. The contents of the original article were well crafted and are largely presented herein with a minimum of redactions.

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2 "Orphans" and Rare Diseases

In 2002, the Congress of the United States enacted the Rare Diseases Act, which formally established the definition of a rare disease as a disease that affects fewer than 200,000 Americans [2]. The term "orphan " arose from the conflation with this act and the Orphan Drug Act of 1983, the purpose of which was to facilitate and incentivize drug development for rare diseases [3].Thus the terms "orphan disease" and "rare disease" became interchangeable and share a common legal

definition for the approximately 25 million people in the United States affected by an estimated 6000 rare diseases [4]. The Rare Diseases Act of 2002 established , for the first time, an office with statutory authorization (Office of Rare Diseases of the National Institutes of Health) and a funding strategy for research and treatment of these diseases, and continues to make recommendations for annual funding [2, 4].

There were approximately four million births in the United States in 2014 [5]. The approximately 1% incidence of congenital heart disease means that there were approximately 40,000 new cases of congenital heart disease in 2014, recording it as the most common birth defect [5]. There are numerous types and subtypes of congenital heart disease, which range from relatively common to incredibly rare, but even the more common lesions such as septal defects and tetralogy of Fallot are classified as rare or "orphan" diseases by the National Organization of Rare Disorders owing to their low incidence [6] in the general population. Practitioners and care providers within the fields of pediatric cardiology and congenital heart surgery may not think that the disease processes they treat are "orphans" by any means, especially because of the immense progress that has been made in treatment over the past century, but the relative rarity of these lesions places them in the same category as hundreds of other, more esoteric, congenital diseases.

While seemingly just a matter of semantics, the designation of a disease process as an orphan has important implications for healthcare economics and government funding. Government-level resource allocation represents probably the most basic form of healthcare economics, whose primary concern is how finite resources are allocated for maximum benefit to the population. A more nuanced discussion of the basic principles of healthcare economics follows later.

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3 Basic Government-Level Funding Strategies

In 2014, the United States allocated 2 billion dollars to research in cardiovascular disease and 5.4 billion dollars to research in cancer [7]. Considering that these two disease processes accounted for roughly 600,000 deaths each in 2013, and that each accounted for more deaths

than the next four most common causes of death combined, this prioritization of healthcare resource allocation is unsurprising [8]. By contrast, 3.6 billion dollars were allocated to the category of orphan diseases [7].

Implicit in this government-level resource allocation is recognition and prioritization of the major threats to public health based on disease prevalence. Indeed, a further screening of the National Institutes of Health research resource allocation [8] report yields a correlation between disease prevalence and funding amount for research. Other funding mechanisms do exist on both the micro scale (hospital-wide resource allocation, insurance company reimbursement for disease burden) as well as the macro scale (philanthropic organizations, professional societies, etc.) that supplement government resource allocation.

Acquired cardiovascular disease healthcare costs amounted to approximately $444 billion in 2010 [9], making this disease an example of high incidence and high cost. The significant resource allocation to this disease process is, thus, easy to justify because it is a common disease that kills a large percentage of Americans and represents a significant fraction of healthcare spending. It is difficult to assess healthcare costs of the 30 million Americans affected by disease, because there is considerable variation in healthcare costs. Neonatal surgery for some of the rarer forms of congenital heart disease such as hypoplastic left heart syndrome and transposition of the great arteries carries the most expensive hospitalizations among birth defects [10]. Furthermore, six out of the top ten most expensive birth defect-related hospitalizations are congenital heart defects [11, 12]. Considering resource allocation, congenital heart disease represents a significant problem because of the small population affected and the high cost of disease treatment. The philosophical and economic framework within congenital heart disease follows.

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4 Utility, Economics, and Healthcare Resource Allocation

While the specific issue of government-directed healthcare resource allocation is a relatively recent ethical and public policy problem and

would have been foreign to its initial proponents, the philosophical school of Utilitarianism offers key insights and appears to have had a significant impact on modern healthcare economics [13]. The Utilitarian school of thought was first described by Jeremy Bentham and later John Stuart Mill, and its central thesis is described in Mill's 1863 work "Utilitarianism " as

> actions are right in proportion as they tend to promote happiness, wrong as they tend to produce the reverse of happiness … happiness … is not the agent's own happiness, but that of all concerned. As between his own happiness and that of others, utilitarianism requires him to be as strictly impartial as a disinterested and benevolent spectator [14].

Utilitarianism espouses a kind of detached maximization of utility, or happiness, of the many even if it is at the expense of the few or the individual. The resulting utilitarian ethics become strictly democratic and provide little, if any, consideration of the needs of the minority or of groups who may require more resources to achieve the same level of utility as the majority population. The ethical issues associated with this school of thought have been debated since its initial publication and are beyond the scope of this discussion.

However, while the origins of Utilitarianism and modern healthcare economics are separated by approximately a century, the type of detached maximization of societal benefit that Utilitarianism espouses represents one of the fundamental goals of healthcare economics. The scope of healthcare economics begins with the familiar preface that resources are finite and must be rationed. Three main questions follow: what goods and services shall be produced; how shall they be produced; and who shall receive them? While basic economics might defer to the market to answer these questions, one of the most important problems and the basis of inquiry for both economics and healthcare economics is how to manage so called "market failures ". Having market forces determine healthcare resource allocation has several potential problems stemming from information asymmetry (physicians have greater knowledge than patients): healthcare should be provided based on need and not ability to pay, certain treatments

may not be profitable, and others. These problems form the basis for the myriad economic models that attempt to answer the three main questions while maximizing the wellness of society [15].

The conflicts associated with prioritizing the interests of many over the interests of few while maintaining equitable access to healthcare form the basis of market failures, and the science and practice of healthcare economics involves creating economic models to describe and ultimately address these market failures. Examples of such economic models include cost-benefit analysis, cost-effectiveness analysis, needs assessment, marginal analysis, and quality-adjusted life years. These models are designed to inform policy decisions by quantifying aspects of resource allocation that are often difficult to quantify, such as benefits to society of treating certain diseases, the value of an individual life, the difference in a human life's worth in the case of significant morbidity, the point at which resources should no longer be allocated to a disease process treatment because of futility. These topics may seem more a propos to an ethical discussion and the approach of ethicists and economists may seem completely different at first, but the strongly Utilitarian ethos behind healthcare economics places the resulting economic arguments within an ethical framework. Quantification and evaluation of seemingly ethical variables and problems becomes just another way to inform the fundamental ethical problem of resource allocation. A summary and evaluation of the economic models that inform the healthcare resource allocation debate follow [15].

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5 Healthcare Economics

Because it is easier to quantify treatment costs rather than more abstract concepts such as quality of life, many of the initial and simple healthcare economic models involve an assessment of healthcare costs . In its most basic form, a cost of illness study is simply that, and it is used for this purpose. Treatments can then be assessed based on both the direct costs of treatment as well as any decreased healthcare resource utilization after treatment. While these are among the more straightforward measures of healthcare resource allocation, they inform additional models that balance cost of disease with either

strictly monetary benefit to either individuals or society, as is the case in cost-benefit analysis , or with non-monetary measures of treatment efficacy as is the case in cost-effectiveness analysis. In presenting an objective assessment of the costs associated with a treatment, cost-based analyses can help to supplant sometimes subjective and political decisions with mathematical and economic decisions. Critiques of these models argue that these analyses are rarely thorough and comprehensive, and that, depending on the data they use, have the potential to be just as subjective and political as the decisions they are meant to replace [16].

Rare and expensive disease resource allocation provides a significant challenge to these kinds of analyses, particularly in the case of treatment equipoise and uncertain prognosis. Sample size is paramount to establishing the assumptions and basis for cost necessary for analysis; in the case of complex congenital heart disease, sample size is generally low, and there are often significant discrepancies with healthcare costs, as evidenced by recent analyses on the subject [10]. Postoperative morbidity suffered by patients can also be highly variable in the case of complex congenital heart disease, further confounding analyses of outcomes to provide any prospective, normative guidance regarding preferred or economically beneficial treatment options. Furthermore, the time frame of such an analysis may confound analysis of disease processes that require timely, early and expensive surgical intervention if it does not sufficiently account for the years of hospitalizations and untimely death of a patient who does not undergo corrective surgery.

Because the alternative for critical congenital heart disease is often death, cost-based analyses and healthcare economics in general must at least implicitly place a value on a human life for the purposes of analysis. The most common form of so-called cost-utility analysis is the quality-adjusted life years. The basic premise of this metric is that, if a year of additional life in good health is worth one, then a year of additional life in poor health must be worth less than one [17]. Varying degrees of disability and morbidity are associated with a decimal value (utility value) that corresponds with how studied individuals would rate quality of life associated with a given condition. If degrees of

human suffering carries with it a detrimental cost to quality of life, it is implied that the healthy life also has a value associated with it.

Such implicit valuation of human life becomes problematic when it is made explicit, as is the case in the debate over the value of a single quality-adjusted life year and whether treatments shall be offered or paid for. To be sure, there is a point of healthcare resource spending beyond which no further benefit can be achieved, either because the patient has been cured or because futility of care has been reached. Marginal analysis, the healthcare economic model dedicated to defining such a point, has been very helpful in establishing guidelines and informing medical decision making [15]. The debate over what constitutes an appropriate amount of healthcare resource allocation to an individual in a given year is contentious and the origins of what are generally considered acceptable figures for quality-adjusted life years are somewhat imprecise. A common figure cited is $50,000 as an appropriate amount per year to justify treatment for an individual with a good quality of life [18]. The origin of this figure is said to have arisen from the per annum cost of hemodialysis as it was in the 1970s, but this point is debated and unsettled. The $50,000 per quality-adjusted life year gained widespread acceptance in the early 1990s in the world of healthcare policy, and it has endured as a benchmark figure for healthcare policy decisions [18]. That the $50,000 per quality-adjusted life years has not been formally adjusted for inflation as it remains a benchmark of ethical and economic inquiry is mathematically perplexing, and different organizations have proposed higher quality-adjusted life-year values of $100,000 and even $300,000 [18]. It should be noted that this figure is used primarily as a model.

The favorable economic environment of the United States healthcare system has not forced the issue of using such a value to deny treatments to individual citizens to this point. By contrast, the National Health System in the United Kingdom (UK) routinely applies a cost-effectiveness analysis when approving new drugs or technologies for use. While the National Institute for Health and Clinical Excellence, the governing body in the UK for such decisions, does not publish a strict upper limit of cost per QALY, the threshold above which decisions are subject to a more thorough investigation and possible denial is £20,000 to £30,000, or approximately $24,300–36,450 [19]. The comparison is

worth noting given the economic similarities between the United Kingdom and the United States. As striking are the significant differences between the valuation of a quality-adjusted human life year between the two Western nations—albeit one with universal healthcare and one without.

This explicit valuation of human life , while perhaps ethically troubling, is nonetheless an important aspect of healthcare resource allocation in a society with finite resources. Such valuation is important in evaluating different treatment modalities for common diseases, but its use is much more challenging in the case of rare and expensive medical problems such as critical congenital heart disease. Maximizing quality-adjusted life years places a premium on preserving life years, not necessarily individual lives. Critics of quality-adjusted life years argue that there is a fundamental conflict between a cost-effectiveness approach similar to the maximization of quality-adjusted life years and the "'Rule of Rescue'—people's perceived duty to save endangered life when possible" [20].

Many forms of congenital heart disease treatment are posited within the scope of rescue. Patients can be in extremis and treatment initiation is often time sensitive. Failure to initiate treatment may result in patient death and, thus, deprivation of their life plan and potential. Hyry et al. argue that quality-adjusted life years should not be used in cases where the debate is treatment versus no treatment because of the ethical issues associated with withholding treatment from a certain group for strictly economic reasons [13].

Within the valuation of human life proposed by the limits of quality-adjusted life years and their use in healthcare economic policy are numerous ethical debates beyond the obvious valuation of human life. Depriving a patient of treatment because of cost violates patient autonomy and depriving a healthcare worker the right to initiate treatment to a patient violates the bioethical principle of beneficence. The bioethical principle of justice becomes a matter of debate regarding the proper distribution of healthcare resources: when healthcare dollars or, more practically, resources such as extracorporeal membrane oxygenation (ECMO) circuits or operating room time are allocated to one patient, those same resources are made unavailable for another. And yet, it is difficult to fathom denying expensive treatments

for treatable conditions such as congenital heart disease based solely on economic concerns. Moreover, having limitations on expensive treatment distribution would stifle further development of these treatments that might ultimately lower the cost of treatment. The cost of sequencing the human genome has fallen precipitously owing to technological advances, as have costs for once experimental medications and complicated surgical procedures. Setting cost limits on treatment for otherwise life-threatening conditions not only commits those afflicted to death, but it also prevents research and development of better and perhaps less expensive treatments. Worse still, research into currently expensive technologies and treatments has potential ramifications to benefit more than just those afflicted with the disease by improving medical knowledge and research methods. A society that prioritizes quality-adjusted life years and uses it as a basis for healthcare resource allocation may allow for the current majority to have access to the currently most economic treatment for the currently most prevalent disease processes. However, by limiting resources for research into rare, expensive, or difficult to treat disease processes, such a society has the potential to be ill-prepared to deal with new diseases processes and may ultimately not be able to accommodate the future needs of the many by having ignored the past needs of the few.

Healthcare cost is becoming increasingly important as demand for, and access to, medical care increases both domestically and internationally. The debate on healthcare resource allocation and resulting healthcare economics has its roots in Utilitarianism through their shared telos of prioritizing the utility of the many over the utility of the few. While healthcare economic models can provide a framework by which to make difficult decisions regarding healthcare resource allocation, the treatment of rare and expensive diseases such as congenital heart disease presents a significant challenge to currently used healthcare economic models. The shortcomings of various healthcare economic models to inform the healthcare resource allocation for rare and expensive diseases debate are similar to the shortcomings of their “philosophical parent ” [21] as a basis for a universal ethical system. Putting aside the needs of the few for the needs of the many is a simple idea in concept but becomes significantly more challenging when it is often difficult to assess the quality and

quantity of life gained through the typically urgent surgical interventions necessary to correct critical congenital heart disease in infancy. Further attempts by economists, ethicists and clinicians alike will be needed to best inform the practice of treating rare and expensive disease processes such as congenital heart disease . Such policies might combine the objective quantification of healthcare costs and human morbidity that healthcare economics provides while maintaining the bioethical principles of justice, beneficence, nonmaleficence, and autonomy. Growing populations and increasing access to healthcare resources will continue to push this and other important healthcare resource allocation debates to the fore, and a multidisciplinary approach will be vital to ensure that the needs of the many are satisfied, but not always to the detriment to the needs of the few.

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Abortion Rights

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1 Introduction

Abortions are as old as medicine itself, and it seems that there have always been controversies associated with the practice [1]. The original Hippocratic Oath , for example, explicitly forbids the physician to provide a patient an "abortive pessary" [2]. It is not clear whether this prohibition was mostly based on regard for the fetus or concern about the pregnant woman's health. Or maybe the concern was for the father, whose rights over the child would supersede those of the mother. In any case, this kind of abortion was not a medical service that a good Hippocratic physician would provide.

The prohibition against abortive pessaries has been removed from the version of the Hippocratic Oath often sworn by new physicians in the modern world [3], but (in the United States) the controversy surrounding the practice of abortion has only increased. As this chapter is being written (2019) a fierce Constitutional struggle is brewing as several state legislatures pass increasingly restrictive laws that, if upheld, would limit access to abortion services for millions of women.

Proponents of abortion rights are organizing to resist these moves, and the fight promises to be long and acrimonious.

Both sides of this conflict base their advocacy on what they see as conclusive moral arguments. One side ("pro-life") talks about the fetus's right to life, while the other ("pro-choice") stresses the woman's right to self-determination. The public discussion of the issue tends to be carried out in sound-bites, in rancorous confrontations on cable television and in flame-wars on line. The rhetoric is sometimes quite powerful (and politically effective), but logically speaking the arguments themselves are often question-begging at best (and abusively *ad hominem* at worst). Away from the headlines and political clamor, though, there has been some careful thought and productive analysis in the last 50 years. Applied ethicists on both sides of the issue have clarified the assumptions and principles underlying their own (and their opponents') positions. While there is perhaps no more agreement about conclusions than before, there is greater insight regarding the structure of the respective arguments.

Of course, pediatric cardiac medicine is not about abortion, and the issue only arises in indirect ways. Still, an ethically sensitive and conscientious physician in this field will want to understand the points that divide the two sides, as well as the current state of the law. There are cases, not uncommon, in which severe fetal abnormalities, prenatally diagnosed, portend a truncated life of pain and of marginal quality involving extensive and repeated surgical interventions. Such scenarios raise the question of whether aborting the fetus might be the best course of action for all concerned. In such cases, the perceived morality and legal status of abortion itself might well be a factor in the physician's and (importantly) the family's deliberations. This is especially the case when the diagnosis occurs later in the pregnancy. Additional ethical issues are raised by the fact that certain (especially church-related) hospitals do not allow abortions to be performed in such circumstances. Finally, the profound religious qualms and moral repugnance that some medical professionals feel toward abortion (whether rationally justified or not) can raise thorny issues with important ethical dimensions of their own.

This chapter will begin by surveying the recent discussion of abortion among applied ethicists, highlighting the conceptual inflection

points on which the arguments turn. Secondly, we will survey legal developments in the US from *Roe vs. Wade* (1973) to the present and hazard a hesitant guess about where these developments might lead in the near future. Finally, we will consider several ways in which the complexities of the issue might play a role in the patient's deliberations and the physician's participation in the decision-making.

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2 The Ethics of Abortion: 50 Years of Debate

2.1 The Traditional Argument

In the mid-twentieth century questions were openly raised regarding the prohibition against almost all abortions that was then ubiquitous in the United States. Supporters of the restrictive laws generally responded by defending the prohibition—arguing that abortion is a straightforwardly immoral instance of homicide. The basic lines of the traditional argument can be ordered and summarized as follows:

1. It is always wrong to take the life of an innocent person;
2. The fetus is an innocent person;
3. Abortion takes the life of the fetus;
4. Therefore (from 2 and 3) abortion takes the life of an innocent person;
5. Therefore (from 1 and 4) abortion is always wrong.

This argument is clear and logically tight. If its premises (1, 2 and 3) are true, then they will indeed establish the truth of the conclusion (5). There is no disagreement on premise 3: abortion certainly does take the life of the fetus. So, if the conclusion is to be resisted, one must raise questions about premises 1 and/or 2. The controversies surrounding these two premises in the last half of the twentieth century were lively and productive, and they continue even now. We will begin with the discussion of premise #2.

2.2 The Moral Status of the Fetus

We all agree that certain individuals —your uncle, my sister, our fellow citizens—have rights and dignity, and deserve to be treated with respect. We have moral duties to these individuals that we may not in good conscience ignore. There are other creatures—my cat, for example—which it would no doubt be wrong to torture cruelly, but which do not have the same full complement of rights that we accord to you and me. Finally, there are things—rocks, ice cubes, basketballs—toward which we have no moral obligations at all—of any kind. In the terminology of moral philosophy, the first group is said to have full moral status. The last group has no moral standing at all, and the second group has a kind of partial or attenuated status.

In claiming that the fetus is a person, the proponent of the traditional argument (above) is asserting that the fetus has full moral status —the same moral status as you and I. If this claim can be established, it provides powerful support for the anti-abortion position, for entities with full moral status presumably have rights—including a right to life—that cannot morally be violated. Defenders of the permissibility of abortion thus often dispute the claim that the fetus has full moral status.

This battle over the moral status of the fetus has two fronts—a terminological/rhetorical front and a more substantive front. In the rhetorical contest the two sides are contending for control of the vocabulary in terms of which the public discussion will proceed. The "pro-life" camp refers to the fetus as a "baby" or "unborn baby" or "unborn child" and the woman bearing it as the "mother."[1] Since presumably we all consider babies and children to have full moral status, if we can be terminologically seduced into categorizing the fetus as a baby or a child, we will be well on the way to according it full moral status as well. On the other side, advocates of the pro-choice position prefer the technical (and hence somewhat impersonal) term "fetus" (or "conceptus" or "embryo") and speak of the "pregnant woman" rather than the "mother." There is little mention of abortion at all—rather, the preferred phrase is "termination of pregnancy." These terminological strategies, while not in themselves really arguments at all, nonetheless have persuasive power. When the physician is discussing possible

abortion with the patient or the family, it can be helpful to pay attention to the words that are used.

If challenged on the claim that the fetus is a person, and that it therefore has full moral status, the defender of the traditional argument plausibly responds that the category of "person" is coextensive with the category "living human being." Since the fetus is alive and is a member of the species *homo sapiens sapiens*, it qualifies as a living human being and hence as a person—"with all the rights thereunto appertaining ." It should be remembered, too, historically speaking, that this discussion came hard on the heels of the Civil Rights movement in the US—a time in which it had become all too clear that for centuries African Americans had been denied fundamental rights because of a morally irrelevant feature—race. It was important to emphasize that since black people are human beings, they have full moral status—and that that's all that matters with regard to the possession of rights. How could one deny fundamental rights to a human being?

The critic of the traditional argument, on the other hand, denies that a fetus—especially in the early stages, when it consists of a few dozen or a few thousand cells—has a moral status equal to that of an adult person. It is indeed alive (it's not dead) and is indeed a human being (it's not a tiger or a salamander). But in the view of the critic the fetus's functional underdevelopment and the fact that it is completely dependent upon (and located within) another human being lessens its claim to full moral status.

Because of the initial plausibility and political salience of the position of the defender of the traditional view—the view that a living human being is *eo ipso* a person and thus the bearer of full moral status—the burden of proof falls on the critic of that traditional argument. The 1970s and 1980s saw a series of attempts to pry apart the claim that a fetus is a living human being from the claim that the fetus is the bearer of full moral status [3–5]. The authors in question often note that "living human being" is a biological category, and that whether an individual belongs in *that* category is a straightforward scientific question. Whether an individual is a person and thus the bearer of full moral status is, however, a *moral* question and presumably to be answered not by biology but by ethical/philosophical reflection.

Mary Anne Warren undertakes to answer this question in a widely read and often cited 1973 article entitled "On the Moral and Legal Status of Abortion" [3]. Warren asks, "…how are we to define the moral community, the set of beings with full and equal moral rights, such that we can decide whether a human fetus is a member of this community or not?" She suggests that a fruitful way to think about this question is to imagine a space traveler who lands on a distant planet and encounters creatures unlike any he has ever seen. Rather than ask if they are human beings (which they manifestly are not), Warren thinks that the space traveler should ask if they are people in the moral sense. (Warren uses "people" as the plural of "person"):

> If he wants to be sure of behaving morally toward these beings, he has to somehow decide whether they are people, and hence have full moral rights or whether they are the sort of thing which he need not feel guilty about treating as, for example, a source of food [3].

Warren offers five characteristics that she thinks are central to an individual's being a person—characteristics that the space traveler should look for in the creatures he has newly encountered in order to discern whether they are persons deserving full moral status. The five characteristics are as follows: consciousness; reasoning, self-motivated activity, capacity to communicate, and the presence of self-concept. Granting that it might not be necessary to have all five of these traits, and aware that these traits can be hard to define and hard to discern based strictly on observation of behavior, Warren nonetheless confidently asserts that any creature who has *none* of these capacities could not possibly be considered a person possessed of full moral status.

> I consider this claim to be so obvious that I think anyone who denied it, and claimed that a being who satisfied none of [these characteristics] was a person all the same, would thereby demonstrate that he had no notion at all of what a person is—perhaps because he had confused the concept of a person with that of genetic humanity [3].

Since a fetus is possessed of none of these five characteristics, Warren concludes that a fetus cannot possibly be a person in the full moral sense. And if that is correct, premise 2 of the traditional argument is shown to be false, and the argument fails.

Warren seeks to formulate criteria for personhood that are not just criteria for belonging to the human species. Her criteria lead to the conclusion that the fetus is not a person, and hence vindicate her view that abortion is not always wrong. But it raises problems of its own. Since being a member of the species *homo sapiens sapiens* is neither necessary nor sufficient for being a person, on her view, there may be other humans who are not persons and persons who are not human. She readily grants, for example, that, "A man or woman whose consciousness has been permanently obliterated but who remains alive is a human being which is no longer a person" [3]. It was immediately pointed out to Warren that newborn human beings also fail to satisfy any of her five criteria, and so her argument would seem to justify infanticide. She grants that the newborn is not a person, according to her criteria, and hence that it does not have a right to life that would be violated by killing it. Nonetheless, to avoid the unwanted and uncomfortable conclusion that infanticide is permissible, she argues that infanticide would in most cases be immoral on other grounds.[2]

Opponents of this kind of position often invoke the fetus's *potential* in order to provide grounds for the obligation to respect its life [8]. A fetus does not have consciousness or rationality, but it does have the potential to develop these traits and thus has the potentiality to become a person, and (according to these advocates) should thus be recognized as possessing the right to life. Warren emphatically resists this line of argument [6]. The fact that the fetus has the potential to develop consciousness and rationality means only that it has the potential to become a person and the potential to acquire a right to life. Having the potential to acquire a right, however, does not mean that one has the right, nor that others have a duty to respect the right that one does not yet have.

Warren's conclusions were not widely accepted, but her approach was quite influential and focused attention on the question of what characteristics something must have in order to qualify for full moral status. She is one of several authors who offered criteria that differed

from simply membership in the human species. Baruch Brody, for example, offered "having a functional human brain" as a necessary and sufficient condition for personhood, and reckoned that a fetus would satisfy that condition sometime late in the first trimester of pregnancy [4]. Brody's criterion, like Warren's multi-pronged set of conditions, allows that an entity can gradually acquire, over time, the traits that are characteristic of personhood. Whether one is a member of the human species is presumably an all-or-nothing matter. But perhaps the attainment of full moral status is a developmental process such that one might gradually grow toward full personhood. This idea—of gradually acquired rights and moral status—will be important in the Supreme Court's *Roe v. Wade* decision.

2.3 The Obligation Not to Take Life

The discussions of the moral status of the fetus called into question the second premise of the traditional argument—the claim that the fetus is an innocent person. Simultaneously, critical reflection was brought to bear on the first premise as well—the claim that it is always wrong to take the life of an innocent person. The most important contribution to this discussion came from Judith Jarvis Thomson, whose extremely influential 1971 article entitled "A Defense of Abortion" re-cast the issue in a way that sheds important light on the question [7].

Thomson begins by granting, for purposes of argument, that the fetus is, from conception, a person with full moral status—that is, she grants premise 2 of the traditional argument. Her basic insight is that the prohibition of abortion not only requires that the pregnant woman refrain from killing the fetus but also that she continue, for 9 months, to make her body available to the fetus as a life-support system. These two requirements are quite different, and, in Thomson's view, this difference makes an important moral difference in the abortion debate.

Her argument begins with a fanciful story. Suppose that you were kidnapped during the night by the Society of Music Lovers, were drugged, and then awakened to find yourself hooked up to a famous violinist who was extremely ill and who needed to share your circulation system for 9 months in order to recuperate. The details of the fanciful thought-experiment can be filled out *ad libitum*: Something about your blood type and genetics makes it the case that only your

circulation system will work for him. Importantly, after 9 months he will be recovered, you two can be unhooked and he can return to his busy concert schedule while you go about your life. But if you unhook yourself from him now, he will certainly die.

Thomson asks whether, in the fictional scenario, one is morally required to stay in bed for 9 months in order to provide life support for the violinist. He is certainly a person with full moral status, and he is certainly innocent (he didn't kidnap you or hook you up to himself). And it is clear that if you unhook yourself from him, he will die. Thomson grants that it would be very nice of you to agree to stay and continue to provide life support for the violinist, but it is clear to her that you do not commit wrongful homicide if you unhook yourself and walk away. The violinist has a right to life (as do we all), but he does not have a right to the use of your circulatory system to sustain his life. That circulatory system is, after all, yours, and only you can decide to grant him permission to use it. If you do allow him to continue to use your body as a life-support system, this is a kindness on your part. It is not something he can claim that you have a duty to do based on his right to life.

The kind of argument by analogy that Thomson employs here is widely used in applied ethics. If our moral intuitions are not clear regarding the rightness or wrongness of some act or practice, the author produces a scenario—realistic or far-fetched—in which we have a clearer sense of the morality of the situation, and then maintains that the scenario is analogous in morally relevant respects to the act or practice that we are unsure about. Discussion and criticism then often arise over whether the imagined scenario really is analogous in the important moral respects.

In the case at hand, Thomson is claiming that a pregnant woman is in relevant respects comparable to you, the victim of the Society of Music Lovers. Critics immediately objected that the analogy holds (if at all) only if a woman has become pregnant as a result of rape, since you were forcibly abducted and hooked up to the violinist against your will. In more typical cases a pregnancy results from a sexual act voluntarily undertaken by a woman with knowledge that pregnancy can result. So, the critics say, most cases in which abortion is under consideration are entirely unlike Thomson's fanciful scenario [3].

Thomson replies that there are many other cases in which a woman can be said to have become pregnant "against her will"—most obviously cases of contraceptive failure. A woman makes a good-faith effort to avoid conception, and nonetheless finds herself pregnant. If you knew that the Music Lovers were lurking out there, and you undertook reasonable measures to avoid falling into their hands, they might still manage to get you despite your efforts to avoid capture. And if they did, Thomson thinks you clearly still would not have a duty, derived from the violinist's right to life, to allow your body to be used as life support for him.

One might also criticize the analogy by pointing out that while on rare occasion continuing a pregnancy can require that the woman stay in bed for the duration, most pregnancies are not like that at all. In most cases she can continue to live her active life with only relatively minor inconvenience up until very close to delivery. Thomson agrees that such unproblematic pregnancies make it easier for the woman to continue the pregnancy if she chooses. It would be relatively easy in such a case for her to allow the fetus to continue using her body as a life-support system—i.e. for her to do the nice, generous thing—should she decide to do so. But it remains the case, according to Thomson, that only she can make that decision, and the fetus's putative right to life does not oblige her to do it.

Finally, critics objected to the suggestion that the profound relationship between a mother and her unborn child is in any way analogous to the relationship between a kidnapping victim and a sick stranger [9]. On their view, the suggestion that these are in any way similar is perverse—and this deep *dis*analogy vitiates the entire thought experiment. Thomson would agree that in the ideal case the expectant mother very much wants the child and is motivated by love to do whatever is required to ensure its thriving. But not all pregnancies are of this ideal kind. For various reasons—the circumstances of conception, the woman's family or financial situation, her health, the fetus's expected condition—the ideal relationship might not obtain between expectant mother and developing fetus. Thomson is exploring the moral obligations that are imposed upon the woman by the fact that the fetus is a person with a right to life. Thomson finds

these duties less extensive and less demanding than the traditional argument would have us believe.

Thomson's argument was influential in its day, but it should be noted that it does not, by itself, open the gates to "abortion on demand." It matters, morally, whether reasonable measures were taken to avoid pregnancy. And while Thomson's argument justifies a woman's refusal to let a fetus continue to use her body for life support, it does not give her the right to demand the fetus's death. When the fetus is able to survive on its own (i.e. at viability) the most the woman can ask is that it be removed from her. It could then, presumably, be made available for adoption.

2.4 The Current State of the Debate

The articles and arguments that we have been discussing stem from the early 1970s—nearly 50 years ago. Remarkably little has changed in the state of the discussion since that time. The traditional argument still has many adherents. Often, for a given individual, the premises of the argument are buttressed by religious doctrines, including metaphysical views about ensoulment. But even for the non-religious proponent, the soundness of the traditional argument continues to seem well-nigh self-evident. On the other side, many continue to find the idea that an early stage fetus has the rights—especially the right to life—of a mature adult simply incredible. After all, it has none of the qualities or abilities requisite for participation in the moral community, and hence no plausible claim to full moral status. And finally, there are very many who hold that a woman's rights over her own body clearly encompass the right to decide who may and who may not use that body as a life-support system. It is not, after all, a resource to be deployed at the community's behest for the aid of those in need. It is *her body*.

There is some discussion among these groups, but very little productive dialogue. This helps to explain why, although the Supreme Court issued a ruling in 1973, the legal battle over abortion and reproductive rights has not gone away and is, arguably, more contentious than ever. Though the foregoing arguments may not be concretely applicable to the pediatric cardiac physician, the state of the law—state and federal—will determine the constraints and conditions under which the patient and physician deliberate in tough pre-natal

cases. The legal state of play remains unsettled, but the recent legal-historical background is important for understanding what is happening now and what may happen in the near future.

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3 Abortion and the Law in the United States: Beginning with *Roe*

From the 1880s until the 1960s abortion (except to save the life of the woman) was prohibited by law in every state in the US. The historical conditions that led to this ban are complex—involving the prevalence of midwives, the professionalization of medicine, the influence of the churches, conservative sexual mores and concerns for maternal health. Of course, during these years of prohibition there were tens of thousands of abortions performed annually nonetheless—in sterile operating rooms under the guise of diagnostic or therapeutic dilation and curettage, and on kitchen tables with coat-hangers and knitting needles [10].

In the mid-twentieth century a movement for reform of the abortion laws began—led by doctors and lawyers. In 1959 the American Law Institute proposed a model law that would make abortions legal in cases of rape or incest, fetal abnormality or threat to the health of the mother. From 1967 to 1972 several states passed laws along the lines of this ALI model [11]. Meanwhile, the Supreme Court, in its 1965 decision *Griswold v. Connecticut* , struck down a state law in Connecticut that prohibited married couples from using contraception. The court based its ruling on an implied right to privacy that the justices discerned in the penumbras of the 9th and 14th Amendments [12]. This was important, for Griswold's finding on the right to privacy provided a central precedent for *Roe*.

Early in 1973 the Supreme Court issued its decision in *Roe v. Wade* [13], based on its judgment that the constitutional right to privacy "…is broad enough to encompass a woman's decision whether or not to terminate her pregnancy" (p. 153). Striking down laws in nearly every state, the decision outlined a structure imposing limitations on what states could do to restrict abortion. Adopting a trimester system, the court ruled that a woman's right to choose, in consultation with her physician, to have her pregnancy terminated could not be limited

during the first trimester. In the second trimester reasonable regulation by the states is permissible, but only in the service of women's health. After the fetus attains viability—which the Court reckoned to be about the beginning of the third trimester—the states may regulate to protect the interests of the fetus (which the court usually refers to as "potential life"). Even in the third trimester, however, abortion must be permitted if required for the preservation of the life or the health of the mother (p. 163). The Court also explicitly held that "the unborn" do not qualify as "persons in the whole sense" (p. 162).

It is interesting to note that the Court, in its decision, adopted a kind of compromise position, incorporating elements similar to the arguments of Warren and Thomson as we discussed them above. Denying that the fetus is a "person in the whole sense," the Court nonetheless adopts a kind of gradualist position, arguing that the state's interest in protecting potential life grows in the course of pregnancy until the point of viability. The Court does not explicitly say that at the point of viability the fetus acquires a "right to life," but it does say that the states' interest in protecting its life has become so strong that it may override the concern for the privacy or the liberty of the woman. The states can rule, if they wish, that post-viability abortions are completely prohibited except when necessary to preserve the life or health of the mother. This ruling reflects the idea that the fetus, in the early stages, has no moral status that warrants or calls for state protection at all. But the status of the fetus grows gradually until the point of viability, at which point it "has the capability of meaningful life outside the mother's womb" (p. 163) and warrants serious state protection. Reflecting the common wisdom of 1973, the court held that viability "is usually placed at about 7 months (28 weeks) but may occur earlier, even at 24 weeks" (p. 160).

The governing principle in the whole decision, however, is the paramount importance of the woman's right to privacy and, by extension, self-determination. The state is not justified in interfering with her decision-making in the early stages of pregnancy because there is no competing interest that could outweigh her right to make decisions for herself about what is essentially a private matter. That powerful right is protected by the Constitution. Gradually, though, the fetus grows until it attains viability, at which point it, too, deserves

protection by the state. The last trimester—when the fetus has become viable—is the period during which there is a potential for serious conflict between the woman's privacy and self-determination and the "potential life" of the viable fetus. The Court is pretty clear—after viability the states can override the woman's right to privacy and self-determination in order to protect the fetus's potential life. She cannot simply choose to have an abortion in the last trimester. But even in the third trimester the states cannot prohibit abortions when the life or health of the mother is at stake.

Many of the cases that confront the pediatric cardiac physician late in a pregnancy do not involve a direct threat to the health or life of the mother, but rather serious developmental abnormalities in the fetus. Roe did not directly address such cases, but they have come under scrutiny in court-testing of more recent legislation. We will return to such cases momentarily. First, though, let us look briefly at further developments in case law that have arisen in the years since *Roe*.

Soon after *Roe* was announced a number of states undertook to place restrictions of various kinds on the new right to abortion. Each of these state laws underwent federal review—sometimes at the Supreme Court level—and in the process they clarified the details and contours of the Roe decision. So it was determined that states could not require that abortions be performed in hospitals (*Roe v. Bolton*—1973), could not require that the woman obtain her husband's consent (*Planned Parenthood v. Danforth*—1976), could not require a woman to receive counseling in which she is informed that "the unborn child is a human life from the moment of conception" (*Center of Akron v. Akron Center for Reproductive Health*—1983).

Two important decisions altered the provisions of *Roe* in more substantive ways. In *Webster v. Reproductive Health Services* (1989) the Supreme Court upheld a Missouri law that provided (among other things) that if a physician has reason to believe that a woman has been pregnant for at least 20 weeks, he/she is required to conduct tests to discern whether the fetus is viable. This provision rejected *Roe's* trimester analysis of a pregnancy and thereby suggested a flexibility in its interpretation that opened the door to other attempts by state legislatures to impose restrictions on abortion—restrictions that had, until then, been rejected as unconstitutional [14].

More important still was the decision in *Planned Parenthood v. Casey* (1992) [15]. The United States (Justice Department) sided with the state of Pennsylvania in urging the Supreme Court to use this case as an occasion to overturn *Roe v. Wade* . The Court refused to do so and concluded (much to the disappointment of anti-abortion activists) that "the essential holding of Roe should be reaffirmed" (p. 846). Nonetheless the Court upheld a number of regulations and restrictions on abortions prior to the viability of the fetus—restrictions that would previously have been overturned as inconsistent with *Roe*. For example, the Pennsylvania law required the physician to inform the woman seeking an abortion of the nature of the procedure, the stage of her pregnancy, the risks inherent in both abortion and childbirth, and the alternative of carrying the pregnancy to term. Basing its thinking on the premise that a more informed choice is a more autonomous choice, the Court concluded that a state could also require that she be informed that "…there are philosophical and social arguments of great weight that can be brought to bear in favor of continuing the pregnancy to full term…" (p. 872). The Court also upheld the state's requirement of a 24 hours waiting period after the provision of the aforementioned information, before going ahead with the procedure. All of the foregoing is justified on the basis of the "informed consent " requirement. Most important is the Court's embrace of a new criterion for the acceptability or unacceptability of state regulations and restrictions on early-term abortions. The Court held that states may impose restrictions on pre-viability abortions so long as they do not constitute an "undue burden" on a woman's exercise of her right to have an abortion. This standard has opened to door for a number of subsequent state laws testing the limits of what counts as an "undue burden." The court also further loosened Roe's trimester analysis, uncoupled viability from the 28 week point, and made viability dependent on technology and the varying judgments of state legislatures (p. 881).

Over the decades since *Roe* state legislatures have passed numerous laws designed to rein in abortion rights. Most of these have been rejected as unconstitutional in federal courts, though, as seen in *Webster* and *Casey*, there has been some blurring of the bright lines drawn in the original decision. In addition to the battles in the

legislatures and the courts, there have been endless hard-fought campaigns between "pro-life" and "pro-choice" activists seeking to win over public opinion. Abortion has become a partisan political issue and an important rallying cry for religious conservatives as well as for women's rights groups. In short, almost half a century after the initial decision, *Roe v. Wade*, in a somewhat weakened form, remains the law of the land, and the US remains as divided on the issue of abortion as it has ever been.

As this chapter is written (September 2019) anti-abortion forces, who sense that a new presidential administration and a recently altered Supreme Court balance will be less friendly to abortion rights, are mounting challenges in a number of states across the country. This past spring seven states passed "heartbeat bills " banning abortions after the point at which fetal heartbeat can be detected (6 or 7 weeks into pregnancy)[3] [16]. Defining the fetus as a legal person "for homicide purposes," Alabama went all the way and banned all elective abortions in the state, including cases in which the pregnancy is a result of rape or incest [18]. The only exceptions allowed by the Alabama law are cases in which the fetus suffers a lethal anomaly or in which continuation of the pregnancy would present a "serious health risk " to the woman. (The law makes it clear that mental illness or "emotional condition" are not sufficient grounds unless two doctors certify that these could lead to the death of the woman). If an abortion takes place outside of these very narrow conditions, the physician who performs the procedure is guilty of a felony and can be sentenced to a maximum of 29 years in prison [19].

All of these laws (and many others) are designed to be unconstitutional under *Roe* in order to provoke a challenge in the federal courts which, their proponents hope, will be appealed up to the Supreme Court and will provide the occasion for the Court to overturn *Roe v. Wade* . At this moment, these laws are under review and have not yet taken effect. There is no way to predict the future course of the appellate process, but it is certainly possible that the current Court, with its 5-4 conservative majority, may alter or reverse central provisions of the 47-year-old legal structure based on *Roe*.

4 Late-Term Abortions

Before concluding the survey of abortion and the law, we must consider the special difficulties posed by late-term abortions. As noted above, the trimester structure adopted by the Court in *Roe* gave special attention to the third trimester, during which the fetus was assumed to be viable (or approaching viability). In that period the woman has had time to exercise her right to terminate the pregnancy if she wishes, and the fetus, by virtue of having acquired "the capability of meaningful life outside the mother's womb," has gained a status that the state has a serious interest in protecting.

As time has passed and technology has improved, the point of viability has moved earlier. In 1973 it could be assumed that viability occurred around 26 weeks; now it is closer to 24. But ascertaining whether a given fetus has reached the point of viability is not an exact science, and estimates have to be made on a case-by-case basis. Many states, invoking the viability standard, have passed laws that ban abortions after 22 or even after 20 weeks. These usually include an exception for protecting the life and (in most cases) the health of the mother. A few mention, as another exception, lethal fetal anomaly. Finally, there is a group of twenty states that ban abortion after viability, without specifying a time-frame [19].

Since late-term abortions are more difficult, given the size and developmental stage of the fetus, the actual procedures whereby the abortion is effected have come under scrutiny (and under regulation). Most notorious is the procedure called intact dilation and extraction and known in the popular press and in anti-abortion activist circles as "partial birth abortion." In this procedure the cervix is somewhat dilated, and the fetus extracted in the breach position so that the limbs and trunk emerge first. Then the contents of the cranium are drawn out via cranial incision and suction so that the skull can be more easily collapsed for extraction through the cervical opening. This procedure is sometimes preferable to the alternatives because there is less danger of fragmentation of bones that can injure the cervix [20].

Opponents of this procedure have dubbed it "partial birth abortion" because much of the body of the fetus emerges from the cervix prior to the skull incision which causes death. The description sounds

gruesome and the line between the procedure and infanticide seems negligible to the abortion opponent . Consequently a number of laws were introduced banning the procedure, but each one was struck down by federal courts (including the Supreme Court), most notably by a 5-4 decision in 2000—in part because the plaintiffs argued that the procedure is sometimes safer for the mother, because the laws often did not include an exception for the health of the mother and because the ban replaced the physician's medical judgment regarding what procedure is called for with the medically untutored judgment of state legislators. In 2003 however, the US Congress passed a federal prohibition entitled the "Partial Birth Abortion Ban Act" and in 2007, by a 5-4 vote, the Supreme Court upheld it[4] [20].

Much of the public discussion of abortion in recent years has been focused on late term abortions and especially "partial birth abortions ." It should be noted that the amount of public attention on late abortions is way out of proportion to the percentage of abortions that take place in this time frame. The CDC reports the following numbers from the year 2015:

> The majority of abortions in 2015 took place early in gestation: 91.1% of abortions were performed at ≤13 weeks' gestation; a smaller number of abortions (7.6%) were performed at 14–20 weeks' gestation, and even fewer (1.3%) were performed at ≥21 weeks' gestation [21].

Loosely extrapolating from these numbers, and assuming 23 or 24 weeks as a reasonable estimate for viability, we see that fewer than 1% of abortions take place after viability. With an estimated 862,000 [22] abortions each year, 1% is a significant number—8600 procedures. But it is much smaller than the public discussion would lead one to believe.

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5 Abortion Ethics and Pediatric Cardiac Medicine

The relentless public debate makes it clear that neither religious pronouncements nor applied ethicists' analyses have brought

consensus regarding the moral status of abortion. Moreover, developments in a dozen state legislatures in just the last year suggest that the legal status of abortion is more uncertain in the US than it has been in half a century [17]. This is the fraught environment in which obstetricians and pediatric cardiac specialists sometimes have to inform parents, after prenatal diagnosis, that the developing fetus is afflicted with a serious congenital heart defect. The mother is suddenly confronted with an unexpected and anguished choice. This is the point at which pediatric cardiac medicine and the issue of abortion merge. We will discuss, in a general way, some unusual issues that arise from this convergence.

The mother may decide, under the circumstances, to terminate the pregnancy. Or she may decide to carry it to term and to deal with further decisions as they come. The decision is the mother's to make, based on two strong considerations. First, as discussed above, she has a Constitutional right to privacy which is broad enough to cover her right to make this decision (prior to fetal viability). Secondly, as the parent, she is entrusted with the power to make this decision based on the assumption that she has the fetus's well-being at heart and will act in its best interest. The physician's chief ethical obligation is to provide the woman with complete and accurate information, to the extent that that is possible, and to be supportive of her whatever she should decide to do. But as is often the case, even the first of these—ensuring informed decision-making and informed consent—can be a challenge.

Improvements in echocardiographic technology have enhanced the prenatal detection rate for congenital heart defects (CHD) and critical congenital heart defects (CCHD) . It is usually possible to judge the extent of the malformation, though often with limited precision and confidence [23]. Thus, even though one can reliably predict the kinds of interventions that will be required at (and after) birth and can know the statistically established survival rates for those procedures, it is not possible to predict the outcome in this individual case. In order to make an informed decision regarding the termination of the pregnancy, the mother might want to know (1) what surgical interventions will be required if the child is born at full term; (2) how much pain and suffering is associated with these procedures; (3) what lifelong morbidities will beset the child; (4) how the quality of life will be

impacted; (5) what special care the baby will require, and at what cost; (6) how long his or her life will last. In cases of serious defects, such as hypoplastic left heart syndrome (HLHS) or tricuspid atresia (TA), even with the best of intentions and the best of modern medical science the physician cannot provide answers with great certainty to these questions [23]. There is of course always some uncertainty in medical prognosis, and in cases such as these, that uncertainty is increased. The physician—presumably an obstetrician—must do her best, with the help of colleagues,[5] to convey the relevant facts to the mother—including the fact that there is significant uncertainty regarding these putative facts.

Since the mother's decision may involve abortion, there are additional factors that have to be considered as well—considerations that may complicate the effort to secure informed consent. For example, depending on the stage of the pregnancy there may be an urgency to the decision process. The near-total legal prohibition of post-viability abortion in the US means that if a decision is to be made to terminate the pregnancy, it must happen before the 24th or 22nd (or in some states, the 20th) week. This temporal urgency can present a problem, for studies show that many parents are so emotionally distraught and distracted at first being informed of the diagnosis that they do not hear, process and remember well what they are told. They need time to digest the bad news, to adjust emotionally, to talk with others, to think of and ask questions, to do research, to calm down. Getting questions answered may require multiple meetings with their obstetrician and with cardiac specialists—all of which takes time. And the clock is ticking toward viability.

In addition, if the mother is to be adequately informed of her alternatives, she will have to be informed of what is involved in the abortion procedure should she choose that option. But the same advanced development of the fetus that makes specific diagnoses via echocardiograph possible also makes the abortion process lengthy and more emotionally trying—for many women painful just to hear about, and more wrenching to endure. Abortion after 16 weeks usually involves inducing a miscarriage—expelling the fetus (non-viable at this stage) by normal vaginal delivery in a process that takes hours. If the pregnancy has advanced to 20 weeks it is recommended that the

delivery be preceded by feticide—an injection into the uterus that will stop the heartbeat of the fetus, ensuring that it is dead on arrival. In many hospitals in the US (and as a standard practice in Great Britain's NHS) the lifeless fetus is wrapped in a blanket and the mother is offered the option of holding it after its emergence. She may also be asked to give consent to an autopsy [24].

In a study [26] of couples' retrospective evaluations of the information that they had received after being informed of a positive diagnosis of congenital deformities, most declared themselves satisfied with the level of clarity and detail offered by the specialists in the diagnosed condition. But a number of the respondents who chose to terminate the pregnancy criticized the scarcity of information they had been provided regarding the abortion procedure itself. It is easy to understand why physicians would not want to go into detail regarding the process, for it resembles all too closely the normal process of childbirth and visualizing the scene might intensify feelings of maternal attachment and grief, possibly making the decision more difficult. Still, respect for her autonomy requires that she be informed of the process should she choose that option.

As noted in Chap. 13 of this volume – "Informed Consent in Fetal Hypoplastic Left Heart Syndrome" – in some institutions, for some especially critical defects such as HLHS, there exists the possibility of taking the pregnancy to term, delivering the baby and then choosing "comfort care" (neonatal hospice) instead of active life-saving intervention. If the pregnancy is already beyond the point of viability, and abortion is no longer a legal possibility, the mother should be informed that the comfort care option will be available when the time comes. She might choose it even if the pregnancy is at an earlier stage and termination is still available as an option . She might tell herself that it would provide more time during which the fetus's condition might unexpectedly (perhaps miraculously) improve, or that it might be possible to obtain a more detailed view of the deformity at that time, providing information that would make her decision easier. If these are misinformed and unrealistic hopes on her part, she should be told as much; but they may govern her deliberation, nonetheless. Some patients might find the comfort care option morally preferable for a different reason: abortion involves taking active steps to bring about

the death of the fetus, whereas comfort care can be seen as "letting nature take its course" or "letting the baby die of natural causes." Current law that absolutely prohibits active euthanasia while permitting the withholding of life-saving treatment in extreme cases suggests that the distinction between "killing" and "letting die" is taken very seriously in our law and morality. The pregnant woman in this case may be motivated by a commitment to the moral importance of that distinction. On the other hand, the decision might go the other way —for pre-viability abortion and against comfort care—based on the distinction between a fetus (in the abortion) and a baby (in the comfort care scenario). Despite the best efforts of pro-life activists to elide this distinction by insisting that personhood begins at conception, most Americans continue to recognize an important difference in moral status between a pre-viable fetus and an infant (as does the Supreme Court—as of now) [25].

The mention of pro-life activists reminds us that the controversy over abortion rights is very much alive in the American public square. Advocates on both sides have strong feelings, and the fraught, rhetorically unrestrained and sometimes vicious public discussion of abortion in the US can itself be a factor in a woman's deliberations about what to do when confronted with a prenatal diagnosis of a critical congenital heart defect. Patients hungry for more information, waiting for an appointment with a specialist for more detailed explanation, are likely to turn to the internet. But on topics relating in any way to the subject of abortion, the internet can be a slough of misinformation, gory pictures, political and religious exhortation and *ad hominem* argumentation. If informed decision-making regarding termination of pregnancy is the goal, the internet is as likely to be an obstacle as a resource. The physician can help by providing the patient with a list of sober, accurate websites that will inform rather than frighten or proselytize.

The physician should remember, too, that the decision-maker is part of a social milieu in which it might be much easier to explain and (if need be) defend one decision rather than the other. She might, for example, be concerned about what she will say to those whom she recently happily informed of her expectant status, should she choose to terminate the pregnancy. She may know that abortion is stigmatizing in

her social circle and may feel the need to tell a different story—perhaps a story of spontaneous miscarriage. An interesting article in the *Journal of Obstetric, Gynecological and Neonatal Nursing* (2005) bringing together results from a number of studies of the deliberative processes of expectant women confronting a positive diagnosis of congenital birth defects, reports that women who choose termination tend to dissociate themselves from women who sought abortions for unwanted pregnancies and associate themselves with women who have lost wanted pregnancies through miscarriage [27]. The sensitive physician will listen to the way the mother frames the narrative that she tells herself—the perspective taken, and the vocabulary used. To the extent that she can—constrained by the requirements of basic honesty—the empathic physician will support the decision-maker in her way of conceptualizing her dilemma.

If abortion is legal, it must be presented as an acceptable option. The physician who is providing information and counsel should ideally not seek to sway the patient one way or the other based on the physician's own preferences or moral convictions. The idea is to support the patient's autonomy. But in our world—a world in which people have strong convictions on both sides of the abortion question—it can easily happen that the physician has principled moral objections to all abortions except those performed to save the life of the mother. In light of such objections, she might be unwilling to perform or participate in the abortion procedure should the mother choose that option.[6] In such a case, if that's the mother's decision, the physician is obligated to refer her patient to a colleague who does not have similar scruples. That might address the immediate practical problem, but the issue goes deeper than that. By telling the patient that she will not participate in an abortion procedure, the physician lets her patient know that she sees one of the options offered the patient to be morally unacceptable. One might respond that the physician's belief that abortion (under these circumstances) is morally repugnant is just another piece of information for the patient to consider as part of the complex informed consent process. That is not quite right, though. The relationship of trust between patient and physician gives the latter's words special weight, and her status as a doctor gives her opinions the

appearance of expertise. But on moral questions where there is no consensus, no one is in a position to claim expertise.

To conceal from the mother, during her deliberations, the fact that the physician is unwilling to participate in an abortion is to fail to provide the patient relevant information. After all, who performs the operation might be a significant consideration to the mother. On the other hand, to reveal the fact risks influencing her decision in an inappropriate way. A similar, though less personal issue arises if the institution (for example a Catholic hospital) refuses to allow the procedure to be performed. Practically speaking, the patient can be transferred to another facility, but the knowledge that that such a move is required will be hard to reconcile with the claim that all of the options on offer are acceptable.

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6 Conclusion

Ethically and legally, abortion is a complex and difficult issue. The decision to terminate or to continue a pregnancy after positive diagnosis of a congenital heart defect has all of the usual issues related to abortion, plus more. Such a decision involves: the offspring's suffering and ultimate quality of life; the burdens on the family; a woman's right to make decisions about her body; loss, grief and disappointment. Thinking about the decision may require asking just what the status of this fetal entity is—a living human being, but not a person; soon-to-be-viable, but currently dependent on another for life support; potentially "one of us," but severely compromised in its prospects; capable of acquiring conscious self-awareness, but currently unaware that it exists at all, and hence unaware that it has anything to lose. Confused by the complexities and stirred by religious and near-religious fervor on both sides, our political system has produced a tangle of state laws (some in force and some under challenge), federal legislation and regulation, and court decisions (in force and under appeal). There is reason to fear that that legal thicket is soon to become more tangled still. And finally, the very fact that there is zealous polarization and no consensus gives rise to additional sources of concern for the mother who has decisions to make—concerns about social stigma, about the awful things she reads on the internet, about

the implicit moral condemnation should her hospital or physician be among the many who refuse to participate in abortions.

In this confusing context the conscientious physician should focus on the obligation to respect the autonomy of the patient. The patient, at this pre-viability stage, is the pregnant woman. Her right to privacy and self-determination governs the scenario, and if the interests of the fetus come into consideration, she is (as parent) the decision-maker regarding that fetus's interests. The physician must provide the most complete and accurate information that she can, conveying (where possible) that all legal options are morally and medically acceptable.

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Footnotes

1 The designations "pro-life" and "pro-choice" are of course examples of successful rhetorical strategies.

2 "…infanticide is wrong for reasons analogous to those which make it wrong to wantonly destroy natural resources or great works of art" [3].

3 Some experts dispute that what is detectable at 6 weeks' gestation should be referred to as a "heartbeat." Dr. Ted Anderson, president of The American College of Obstetricians and Gynecologists, says calling the activity a heartbeat is "misleading." "What is interpreted as a heartbeat in these bills is actually electrically-induced flickering of a portion of the fetal tissue that will become the heart as the embryo develops," Anderson said in a statement [17].

4 Between 2000 and 2007 Sandra Day O'Connor retired from the Court and was replaced by Samuel Alito.

5 Chapter 13 of this volume – "Informed Consent in Fetal Hypoplastic Left Heart Syndrome" – provides a thoughtful discussion of the different contributions (and occasional unwitting biases) that the different medical services (pediatric cardiologist, cardiac surgeon, etc.) might bring to the informed consent process.

6 Federal and state laws permit doctors to refuse to perform abortions on grounds of conscientious objection. This right was expanded and strengthened in May, 2019 by a rule issued by HHS according to which clinicians and institutions would not have to provide, participate in, pay for, cover or make referrals for procedures they object to on moral or religious grounds [28].

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Fetal Cardiac Interventions

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1 Fetal Cardiac Intervention

The past several decades have witnessed enormous progress in the surgical management of congenital malformations of the heart. Advances in the techniques of surgery, anesthesia, cardiopulmonary bypass, and postoperative care have combined to improve significantly the outcomes of neonates with complex congenital heart disease [1–4]. Conceptually, the next frontier of interventional surgical and transcatheter approaches is the repair or amelioration of critical features of abnormal cardiac anatomy while the heart is still developing. The possibility of fetal heart surgery has been explored extensively in the laboratory setting that has been successfully applied to the clinical realm. Despite decades of research evaluating the possible application of miniaturized heart-lung bypass circuitry for fetal intervention, the very unique status of the fetal-placental circulation has limited the spectrum of fetal cardiac interventions that can be performed. Among those interventions that have had limited success involve and rely on transabdominal transuterine access under ultrasound guidance. These techniques have been used to establish access to the cardiac chambers to allow catheter-balloon angioplasty to

relieve critical obstruction(s) in the blood flow pathways of the heart [5, 6].

The clinical scenarios that are felt to present the greatest potential benefit from fetal intervention are those where a singular feature of the anatomy causes an obstruction to the normal pattern of blood flow and where that obstruction is believed to be the basis for important secondary features of abnormal cardiac development [7]. One example is the circumstance where critical obstruction at the level of the aortic valve is believed to be associated with progressive maldevelopment of the left ventricular myocardium, leading in some cases to hypoplastic left heart syndrome with critical aortic stenosis (HLHS with CAS). It is postulated that that relief of aortic valve obstruction sufficiently early in fetal development may be followed by birth of an infant with an adequately functioning left ventricle rather than one that is incapable of supporting the systemic circulation due to chronic subendocardial ischemia throughout fetal life [8].

Another example is the very rare circumstance of hypoplastic left heart syndrome with associated intact or severely restrictive atrial septum (HLHS with IAS). The incidence of HLHS is 0.016–0.036% of all live births, and this lesion represents roughly one percent of HLHS cases [9]. These patients tend to do very poorly in the Norwood sequence of reconstructive surgeries, with survival after stage one at a dismal 33% compared with a 70–80% in other etiologies of HLHS [10]. It is thought that these patients do worse than others because the obstruction to left atrial outflow during gestation results in significantly abnormal development of the pulmonary vasculature, which decreases cardiac output in the reconstructed, single ventricle circulation [10, 11]. The rationale for fetal intervention is the postulate that decompression of the left atrium by fetal atrial septal balloon septostomy may allow more normal development of the pulmonary vascular bed [12].

While the prospect of promoting more normal cardiac development by accomplishing a fetal intervention is attractive, it is often difficult to determine with a high degree of confidence which cases are most likely to be associated with unfavorable progression of the cardiac pathology without intervention. Because of progressively higher morbidity and mortality with the aforementioned lesions, prenatal surgical intervention has been attempted. The purpose of such interventions is

to relieve left heart pressure through balloon aortic valvuloplasty in the case of CAS, and through the creation of an atrial septal defect in the case of IAS. Thus far, interventions have not proven to be consistently successful in reducing morbidity and mortality compared with cases with no fetal surgical intervention. Furthermore, many of the cases that are technically successful by relieving left heart pressure and promoting biventricular circulation had circulatory function similar to those cases that had no fetal intervention [2, 13]. Tworetzky and Marshall [8] argue that the cases of fetal intervention that have been reported in the literature to date were performed during the third trimester, which may be too late a stage in gestation to reverse the pathophysiologic progression of the lesions entirely. They go on further to suggest that fetal cardiac interventions, particularly those for CAS, might have better outcomes if they are done between 20 and 26 weeks. There are, however, no data to suggest that an earlier intervention would benefit in cases of IAS [8].

The purpose of this chapter is not to debate the merits of fetal cardiac intervention; the rationale and methodology behind such procedures have been established. The preceding discussion is meant to show that there is a conflict of timing in the diagnosis and treatment of CAS and IAS. On the one hand, it seems logical that earlier fetal intervention could better reverse the pathophysiology, at least in cases of CAS. On the other hand, the earlier the decision is made to intervene, the less confidence a physician has that the defect will ultimately progress to HLHS. Fetal surgery brings with it many potential complications for the fetus, including prenatal death, fetal neurological injury, and preterm delivery [14]. Similarly, the intervention is not without risks to the mother. The severity of potential complications to fetus and mother requires compelling evidence that the lesion will progress to HLHS in order to justify intervention. These issues have been personally considered in a previous article [15], the prose of which has been largely reproduced herein.

Thus, there is a burden of knowledge that accompanies a diagnosis of HLHS with CAS or IAS. The technological advances of ultrasonography and fetal echocardiography have allowed for earlier diagnosis of certain congenital diseases. To be sure, these advances have been beneficial. In the case of HLHS , however, expecting parents

and physicians can be put into a situation where there is a diagnosis without a clear course of action. One is burdened with the knowledge that there is a progressive heart defect without definite knowledge of the defect's natural course and of whether or not it will evolve into a life-threatening condition. The burden is complicated by the hypothesis that earlier intervention would better reverse the defect's pathophysiologic progression because the indications for intervention are very difficult to identify earlier in gestation with the current state of diagnostic equipment and testing.

Because these procedures potentially expose two beings to the risks and benefits of surgical intervention, any proposed intervention needs to have a level of certainty for a positive outcome above that of other medical situations. In this unique medical and surgical situation, there is a burden of knowledge both for physicians and for patients in the interim period between the initial defect diagnosis and the subsequent tests that will indicate or contraindicate surgical intervention. What is worse, our current diagnostic criteria for determining which lesions will progress to HLHS have not been settled. As a result, there is neither a high positive predictive value, nor is there high accuracy in predicting the extent of morbidity and mortality that a fetus may have if the lesion is left without surgical intervention. Thus, both physician and patient have the burden of knowing that there is a progressive problem in utero but that there is no established method to predict the extent of progression. Nor is there a reliable way to reverse it effectively should it progress to a critical stage.

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2 The Problem of Language

The search for a cure for a disease is a burden that drives the majority of medical innovations. In this way, fetal cardiac surgery is no different from any other challenge that modern medicine faces. However, fetal cardiac intervention for HLHS with CAS or IAS raises other issues that are unique. Chief among them is the relationship between mother and fetus and the threat that fetal surgery can pose to both. Besides the obvious ethical issues raised by such a predicament—the details of which are beyond the scope of this discussion—there are even fundamental issues of language raised in cases of fetal surgical

intervention. The notion of a cure in these cases is troublesome, as the disease does not directly affect the patient who consults the physician. A pregnant woman is not ill during pregnancy with an affected fetus, nor can the diseased fetus be considered a disease in itself. Furthermore, because the fetus's viability is questionable during the mean age of diagnosis—around 20–22 weeks—it is difficult to say that the fetus has a disease that warrants intervention. Because of this question of the fetus's viability, it is difficult to say that the fetus assumes any of the risks of the operative procedure, properly speaking. Thus, even though the pregnant patient is not "diseased" and does not stand to gain any direct, physical benefit from the proposed procedure, it is this patient who assumes all the risks associated therewith. Though there have been no reported cases of maternal mortality in fetal cardiac surgery, the general risk of mortality associated with surgical intervention remains, as do more specific morbidities such as pulmonary edema, postoperative bleeding, and premature delivery [16]. Much has been written about the concept of a fetus as a separate patient; not one of these articles takes seriously the notion of putting aside maternal safety in favor of correcting a fetal lesion. Furthermore, because the methods of intervention are still being developed, the burden of knowledge also carries with it the question of whether or not the intervention is worth the risk to both mother and fetus.

The question of sufficiency in language and conventional terms in describing the complexities of fetal surgery has been addressed elsewhere in the literature. The most fundamental issue debated is that of *patienthood* [17]. Chervenak and McCullough argue that it is best to avoid terms like *unborn child*, *mother*, *father*, and *baby* in discussing cases where the viability and thus the dependent moral status of the fetus is uncertain. Instead, they argue that the fetus should be referred to as a patient. Rather than regarding the fetus as a fully separate patient with a separate autonomy and beneficence-based obligation to treat that accompanies such a classification, they argue that decisions of fetal health must be considered along with the autonomy and beneficence-based obligations that a physician has to the pregnant woman. In other words, the fetus is a patient insofar as its patienthood is considered along with its moral status, which is dependent on the pregnant woman until the fetus is fully viable. The authors further

claim that words such as *treatment* and *therapy* should never be used during the informed consent process, as they are insufficient to describe the experimental nature of the interventions [17].

Lyerly and associates [18] challenged the work of Chervenak and McCullough as to whether the term *patient* applies in cases of fetal intervention. They argue that the appeal to the dependent moral status of the fetus is not sufficient to counter the profound connotations that accompany referring to the fetus as a patient. *Patient*, as they argue, is more than a technical term, and any attempt to reduce the scope of such a broad word will foster misunderstandings between physician and patient. The authors fear that misunderstandings might cause pregnant women not to consider, or to consider too lightly, the risks associated with fetal surgery to look after a fetus that, by the connotation of its being a patient, is separate from the pregnant woman. Furthermore, they claim that no word in common usage is sufficient to describe the fetus in this situation and that one risks distortion and misunderstanding by implementing what they refer to as inherited words such as *person*, *patient*, *child*, and others [18].

Another such inherited word not discussed by Lyerly and associates [18] but certainly used throughout literature describing outcomes in fetal cardiac surgery is that of success. The question of what defines a successful outcome is a difficult one in any experimental field, as the procedure in question is a work in progress. The distinction that is made throughout these studies is that of *technical* success rate in fetal surgical interventions, which simply means whether the proposed intervention was able to be performed. This notion of success does not consider the long-term outcome and whether the intervention was justified by the outcome. For example, recent data of balloon valvuloplasty in cases of HLHS with CAS showed a *technical* success rate of 75–80% indicating that the balloon dilatation technique was performed successfully without any major complications in the immediate post-operative period . Of the 75% of cases that were deemed a *technical* success, only 30% had biventricular circulation at birth, which is the desired outcome of the intervention. Another 8% were successfully converted to biventricular circulation after initial univentricular palliation [1], but that still creates a significant discrepancy between what is deemed a technical success and what is

https://t.me/ALGRAWANY

deemed an outcome that successfully achieves the objective for which the intervention was created. Even without delving in too deeply into what level of biventricular circulation determines a long-term, disease-free outcome, one can imagine the difficulties in obtaining informed consent for these operations. Words such as *success*, *patient*, and even *treatment*—fundamental words in describing outcomes—need to be qualified and the full extent of their meaning is often difficult to convey to patients in these situations as a result.

The issues raised by fetal cardiac intervention go beyond the ethical and into the realm of linguistics. The problems presented seem to challenge the foundations of the physician-patient relationship by exposing the inadequacy of language. What constitutes a treatment? Who is a patient? What are the implications of language in ordinary discourse between physician and patient? Can there be effective communication on the subject of fetal cardiac surgery? Has language failed and have definitions become arbitrary in this situation? Must we throw the proverbial baby out with the bathwater and give up attempts to converse about this very delicate issue? Who can help us understand these profound issues?

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3 Aporia and Postmodernism: Philosophical Considerations

The turn toward language to address problems that seem to test the limits of our conventions and definitions is a characteristic theme throughout Postmodern philosophical thought. The twentieth century ushered in profound revolutions in all aspects of life including society, culture , art, and thought. People such as Einstein, Heisenberg, Stravinsky, and Joyce introduced revolutionary concepts in their fields that questioned the very foundation of how humans perceive and understand the world. Such revolutions extended to the realm of philosophy as well; many thinkers started questioning whether the established truths, on which fields such as ethics and metaphysics were based, had any more objective validity than did Newtonian physics or classical rules of artistic expression. Ferdinand de Saussure extended this line of reasoning to the subject of language. He argued that the signifier–or term used to describe something–and the signified–the

thing itself–have no necessary connection in language. Further, he claimed that the definition or meaning of a word can mean nothing outside the realm of language, as it is wholly contingent on the rules established within the system [19]. With this revolutionary line of thinking, Saussure questioned language's ability to represent concepts that defy typical conventions. Because meaning is dependent on differences that are established within the realm of language (subject different from object, man different from woman, alive different from dead), the concepts that exist between these conventions, he argued, cannot accurately be represented in language [19]. The present debate of how to refer to a fetus in cases of fetal surgery provides an analogous example. Because the fetus represents such a gray area between autonomy and dependence, viability and inviability, patient and condition, one can understand how language could fail to capture its meaning because of language's own dependence on conventions and differences.

Saussure's lectures reverberated throughout the philosophical community and helped to shape the burgeoning school of thinkers who would ultimately be referred to as "Postmodern." Jean Francois Lyotard defines the Postmodern era as "incredulity toward metanarratives" [20]. What he means is that Postmodern thinking is a rejection of the notion that meaning is somehow beyond the scope of language and conventions. He, like Saussure, argues that no concept has a meaning outside the system of conventions and opposites in language. Thinkers such as Jacques Derrida and Michel Foucault extended this inquiry and argued that concepts such as *reason*, *morality*, and even the subject, *I*, are nothing but conventional constructions without any external meaning [21]. In questioning the foundations of language and meaning, these thinkers present their readers with a kind of *aporia*, or impasse. This impasse begs the question of how we, as humans, can continue debating philosophical issues in ethics and metaphysics if the language we use is wholly contingent on conventions and cannot express anything authentic. In doing so, they suggest that we recognize the contingency of all systems and that we abandon any hope of creating a kind of objective method of reference even to the simplest of concepts. In the present debate, their thinking would be consistent with the

assertion of Lyerly and associates [18] that no concept in language is sufficient to address the fetus in cases of fetal surgery.

Recognizing the contingency of language and all the resulting ramifications is the primary burden of knowledge in Postmodern thinking. This burden requires its proponents to shatter all notions of objectivity, meaning, and the hopes of ever achieving such concepts in discourse. In many ways , it is against the entire *telos* of western philosophy, which can be characterized by the use of language to prove certain ideas about the natural world or about human interaction. Such a burden is stultifying and is intended to be so insofar as it helps to challenge what we think we know. Fetal cardiac surgery presents us with the same kind of burden of knowledge . When language fails to elucidate such a complex issue as fetal surgery, physicians and patients are faced both with the burden of knowledge that accompanies the diagnosis of HLHS with IAS or CAS and with the more general, Postmodern burden of the inadequacy of language to express certain concepts. The combination of these two burdens leads to an *aporia* and serves as a significant barrier to clear communication between physician and patient at a time when it is most needed.

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4 Postmodernity and Medicine

One could argue that medicine cannot be Postmodern in the way it has just been described. The problems that medical science seeks to solve are not open dialogues but, rather, are often binary variables filled with necessary conventions such as morbidity, mortality, disability, pain, distress, and suffering . These conventions are used in medicine to plot outcomes and are given precise meanings to that end. Such conventions cannot be subject to critical inquiry, as they are based on clinical realities and are vital to providing standards of care, which guide proper patient management. In this way, medicine is very “modern” in that the conventions it uses for its basis are seemingly immutable and immune to critical inquiry. Furthermore, these conventions are rooted in human physiology and pathophysiology and in the limited ways in which physicians can effect changes in these complex systems. Because the domain of medicine lies in clinical reality and the most basic

realities of human science, isn't any inquiry into its methods without a direct consideration of clinical utility simply a wasted effort?

The previous concern rightfully points out that medicine as a whole is incompatible with postmodern thinking because the principles on which it is based need to be accepted in order to make decisions about patient care that are fundamental to the practice of medicine. That having been said, medicine is also a science, and, like all sciences, it must have a method by which it addresses those concerns about which it cannot provide a certain course of action. The scientific method in medicine is the foundation for all such inquiry and is the essence of medical academia. When this method of hypothesis testing fails to elucidate a proper course of action, however, then the "modern" basis of medicine reaches its limit. Fetal cardiac surgery provides such an example of the scientific method failing to elucidate a clear course of action.

Such examples, one could argue, are part of the process of medical science, as these moments spur future studies that are designed to provide a better answer than those presently offered. This cannot be denied , but in the present moment—a moment of flux in both the standard of care for these lesions and in the very meaning of certain words that are used in the discourse between physician and patient in obtaining informed consent—one needs to consider an alternate method of inquiry. Because the Postmodernists have dealt with similar problems, it is justifiable to apply their thoughts to the present debate. What is paradoxical about adopting Postmodern thinking to any medical debate is that, ultimately, the answers derived will feed into medical science, the basis of which is incongruent with the Postmodern insistence on questioning all foundations. This paradox need not preclude adopting parts of Postmodern thinkers' perspectives into such debates because within Postmodern philosophy there exist methods for building new systems of meaning and convention that can be used within other systems of convention such as medicine, as will be discussed below.

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5 The Future of Fetal Cardiac Surgery

How, then, do we proceed in the debate on fetal cardiac intervention? We have reached a point in fetal surgery where we cannot revert back to the comfort and solace of always being able to rely on language to describe adequately the situation at hand, but how can we overcome the angst that accompanies such a lack of certainty? No one has deciphered a way to postulate oneself out of the angst of uncertainty in postmodern thought. For most postmodern thinkers, the constant questioning is more important than ever finding an answer. That having been said, many Postmodern thinkers find comfort in liberating themselves from conventional thinking. The majority of Michel Foucault's later work deals with how to embrace the freedom that comes with recognizing that everything is based on conventions. He argues that removing the certainty of things like language, government, and rationality (which he argues are externally presented) one is free to focus on understanding oneself as being separate from these institutions. Developing oneself is not strictly self-centered, however, as such a process relies on interactions with others and sharing new experiences.

Jürgen Habermas, in a similar line of thought, argues that the way toward fostering understanding and the reestablishment of communication lies in discourse ethics [22]. By "discourse ethics" he does not mean ethics that derives from any ethical discourse; rather, he is referring to ethics being derived from a discourse about the foundations of discourse, itself. Such a discourse is designed to expose the hidden assumptions and biases that tend to confound and complicate traditional ethical theories, and this method is his way of solving the fundamental issue of how traditions, cultures and other biases affect ethical structure and reasoning. He argues that the subject has to create its normalcy out of itself and that only through discourse with others can this occur [22]. By insisting on discourse and development, Habermas is able to rebut claims that Postmodernism provides truth and ethics only to individuals. Thus, the Postmodern, by destroying the truth behind longstanding conventions in language, allows the possibility to establish one's own way of communicating that will be free of the inadequacies and pitfalls of one's inherited language [22]. In discourse with others, these new methods of communication can lead to advances in understanding for all who participate.

In many ways, Habermasian [23] discourse ethics already exists in fetal surgery. At the 1982 inaugural meeting of the International Fetal Medicine and Surgery Society, members put forth a number of guidelines that included a cooperative exchange of information among institutions , a registry of all treated cases, and an establishment of guidelines for the indications of surgical intervention [24]. Further they stated that there should be a multidisciplinary team comprising at least a perinatal obstetrician, ultrasonographer, pediatric surgeon, and neonatologist, all of whom should concur before undertaking fetal intervention [24]. By insisting that many different specialists with different biases and viewpoints engage in discourse about cases, the IFMSS is attempting to control for biases that can confound dialogues when they are not exposed by others, and is committing itself toward the kind of free, open dialogue that characterizes discourse ethics. So, while it may seem strange that some infighting appears in literature about the question of language in fetal surgery, such a debate is indicative of the kind of robust discussion that discourse ethics demands. Rather than being a sign of weakness, these challenging debates should be regarded as invigorating to fetal cardiac surgery professionals because so many gray areas of medicine plague the field.

Because of the burden of knowledge that accompanies the diagnosis of HLHS with CAS or IAS, fetal cardiac surgery discourse ethics should continue to be evaluated. A consensus needs to be formed on what constitutes *success* in fetal cardiac intervention, and this term should account for both technical and functional *success*. After all, it is not enough simply to restore biventricular circulation if the resulting cardiac function is worse than it would be in a corrected univentricular circulation. Because words like *success* and *treatment* are so potentially equivocal in cases of fetal cardiac intervention, it is important to continue evaluating the language used in clinical and in ethical discourse in order to form clear definitions that will help the field make the most educated decisions on the future of the program. Already, these types of evaluations have led to a cessation of performing fetal shunts for hydrocephalus due to its inefficacy [25]. To ameliorate concerns regarding timing and the resulting burden of knowledge in the diagnosis of HLHS with CAS or IAS, researchers should continue to seek out other indicators that will better help physicians decide when it

is appropriate to intervene. The purpose of this discussion is not to argue for or against fetal cardiac surgery but rather to remind us of the mindset necessary to move forward in ascertaining whether the uncertainty of fetal cardiac surgery will be looked upon as a necessary part of revolutionary treatment or if it will remain a sobering reminder of the limits of medicine, of ethical reasoning, or of language itself.

Fetal cardiac intervention, by the many uncertainties it raises, requires both patient and physician to gaze into a kind of abyss. The interventions are experimental, the outcomes are uncertain, and the ethical and medical issues involved are as complex as they are controversial. Further, the language currently in place to describe such interventions is not adequate to foster the best understanding between physician and patient. Looking into an abyss can be a terrifying experience. Nietzsche famously wrote, "if you gaze for long into the abyss, the abyss gazes back into you" [26]. Being at a loss, at an *aporia*, is normal for both physician and patient in cases of fetal cardiac surgery. Nietzsche understood the terror that can accompany being at a loss and staring into the abyss, and in this aphorism, he is telling us not to dwell too much on the nothingness and frustration that the abyss presents. Rather one must, as Postmodern thinkers have done, form a way to live with the knowledge that conventions have no inherent meaning and that language cannot adequately represent reality. Perhaps Jancelewicz and Harrison summed it up best when they wrote that the future motto for fetal surgery should be to "Proceed with Caution … and Enthusiasm" [24]. Whether or not fetal cardiac surgery becomes a preferable option in the near future will depend as much on figuring out ways to confront the issues of communication and language as it will on technical advances. Until there is a clear understanding of concepts such as success, patienthood, and the indications for intervention, there will continue to be a burden of knowledge that will hinder further development in the field. Fetal surgery appears to have adopted discourse ethics as its *modus operandi* to combat the uncertainty that abounds within the field, and this marriage of medicine and post-modernity should be seen as a positive alliance because the methods of Postmodern discourse ethics encourage clear and open dialogue. Clear and open dialogue has always

been essential to medical science's advancement and will continue to benefit this burgeoning field as these very difficult debates continue.

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Ethical Considerations in the Transcatheter Management of Congenital Heart Disease

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1 Introduction

Pediatric clinical cardiac care has experienced significant advances over the last century. It is important to recognize that research regulations in the United States for clinical research are not yet even 40 years old. The Code of Federal Regulations with respect to the Common Rule are currently in evolution even to the present day as the pace of clinical inquiry extends into new areas of investigation. The development of medical technology is a global endeavor, but many countries still do not have formal research regulations. In general, this type of research involves incurring some risk with the possibility of direct benefit to the

patient. A discussion of the ethics of nonbeneficial research in children is beyond the scope of this chapter. The reader is referred to an excellent discussion of this topic in Wendler's treatise on the ethics of pediatric research [1]. Almost without exception research in this realm has been beyond minimal risk but with the prospect of direct benefit.

Treatment of significant congenital heart disease usually involves invasive correction of anatomic variations of cardiac morphology. In the past this has been exclusively the domain of cardiac surgery which evolved at a time when the ethics of innovation were governed predominantly by a sense of duty and professionalism. In the past, the pace of innovation and acceptance into clinical practice occurred at a rate that would be unachievable in the setting of today's regulations. Many surgical advances were intrepid in the setting of high mortality and morbidity. These efforts offered the patient an alternative to sure death. Procedures such as the Blalock-Taussig-Thomas shunt for ductal dependent pulmonary blood flow presented the potential for profound improvement in survival, albeit at considerable risk in that era [2]. The development of cardiopulmonary bypass to facilitate intracardiac surgical procedures was rapid, innovative and risky. Hundreds of thousands of patients have since benefited from the development of this technology. Some of these benefits have been admittedly theoretical. In the modern era perhaps the most striking example of this is the movement away from an atrial switch type of operation such as a Mustard or Senning procedure in favor of the Jatene arterial switch [3]. Even to this day, with rare exception, innovations in cardiac surgery tend to utilize a study design of case reports or small case series retrospectively reported or prospectively gathered. A notable exception to this is the randomization of surgical strategies for pulmonary blood flow in the patient with a single ventricle [4]. Randomized trials such as this are rare resulting in a very real perception that the development of invasive procedures lacks proper oversight of ethics, methodology and review [5].

The introduction of novel medications and devices into practice is regulated by agencies such as the Food and Drug Administration (FDA) in the United States but the agency has no authority to regulate the practice of medicine hence there can be little oversight before a procedure, surgical or transcatheter, receives widespread adaptation

into practice. At the institutional level, Research Ethics Boards (REB) or Institutional Review Boards (IRB) can serve to provide review to ensure protection of research subjects and ethical conduct of research into new procedures. However, many new strategies are undertaken as innovations in clinical care, bypassing the review process [6, 7]. Although not specific to surgery Emmanuel and colleagues have summarized principles of ethical human subjects' clinical research [8]. To be ethical they argue that the research must have the potential to enhance health or knowledge. It must have rigorous scientific methodology. Research subjects should have fair distribution of risks and benefits among groups. The potential benefit outweighs the risk and the risk to participants is minimized. The research is reviewed and approved by an independent body. Privacy is protected. Consent is informed and voluntary.

2 Transcatheter Therapeutic Innovation

The area of transcatheter cardiac therapeutics began in the 1960s with the Rashkind septostomy for patients born with transposition of the great vessels [9]. The ease with which this procedure could be undertaken, and the immediate benefit were such that no clinical trial was required before this was almost immediately accepted by the medical community . In retrospect a recent editorial described the presentation of this technique to the medical community as being met with a combination of "admiration and horror " [10]. This set the stage for the development of further transcatheter therapeutics including valvuloplasty, angioplasty and device implantation. With the advent of transcatheter therapy, decision making in the management of congenital heart disease has evolved to a collaborative approach involving both the interventional cardiologist and the cardiac surgeon. Industry has seen an exponential explosion of the development of implantable devices and tools for use in the catheterization laboratory and in the operating room. In the surgical realm this initially involved designing equipment to facilitate cardiac procedures but evolved into complex technology such as materials for repair, valve implants and adjuncts to cardiac surgery with topical applications of materials to control hemostasis and inflammation. Increasingly these implants and

materials have been subject to formal evaluation and industry regulation.

The transcatheter development of therapeutics for congenital heart disease has largely occurred in the era of regulation. This has necessarily occurred in recognition of the fact that the medical device industry is lucrative, and regulation is required in view of the fiduciary responsibility of industry to its shareholders. In a systematic evaluation of over 1000 studies, Bekelman and colleagues determined that one quarter of investigators had industry affiliations and two thirds of academic institutions had equity in start-up companies [11]. The ownership of intellectual property with respect to the development of devices, whether they be used surgically or in the interventional arena, also carries with it the influence of personal financial gain. These issues represent perceived or very real conflicts of interest [12]. Industry support for physician researchers takes the form of grants, consulting fees or direct financial interest in the form of royalties, stock options, or ownership. Naturally this can interfere with the provision of medical care and must be recognized, even in the setting of a noble profession when one is considering the public trust. Much of surgical advance has been advocated directly for the benefit of the patient with very little personal gain, save for public recognition and professional admiration. In general, there is no intellectual property assigned to innovations in technique.

Most transcatheter techniques have been preceded by an accepted surgical approach to a condition. Often transcatheter therapy is proposed as a less invasive therapeutic option. In this setting a transcatheter or minimally invasive surgical approach for that matter must be evaluated in light of current surgical norms. A less invasive approach to the management of congenital heart disease must consider more than a cosmetic result. Too often the minimally invasive practitioner will cite the absence of a significant scar associated with a surgical approach to be the benefit of pursuing a less invasive procedure. It is a failure of medical and surgical management that focuses on this. While often touted there is very little literature that objectively evaluates the psychological impact of a scar required to save a person's life or improve its quality. More importantly, less invasive strategies should be focused on less morbidity, faster recovery and less

cumulative trauma over a person's lifetime [13]. Comprehensive evaluation for medical and interventional treatment of congenital heart disease is difficult to assess due to the relative infrequency of each condition and anatomic variation in presentation. In essence, no two patient characteristics are exactly the same. This makes assessment of the relative risks and benefits of a particular approach particularly difficult. It is important to recognize that the medical literature is replete with terms that have very different meanings in common usage than they do in the medical literature. The phrase "safe and effective" can mean different things for different individuals. Perhaps the best example of this is the statistical term "significance". To the reviewer or statistician "significance" refers to the probability that a given attribute or finding did not occur by chance. To the layman "significant" can be more aptly described as "important". The medical literature is abundant with examples of findings that are statistically significant but clinically irrelevant. How one describes clinical findings is important. Another term prominent in the medical literature is that of benefit. Benefit can only be assessed by the individual. One must carefully consider whether benefit represents an improvement in life expectancy or quality of life. Much of the literature in interventions and congenital heart disease described the benefit measurable only on clinical testing thus implying an improvement in the patient's well- being. In the symptomatic patient "benefit" can also be the result of will, natural fluctuations of illness and spontaneous improvement; the so-called placebo effect . Benefit is particularly difficult to assess in the pediatric population where an intervention is often undertaken to avoid future problems. An example of this is management of the atrial septal defect where preintervention diagnostics often involves the prediction of the asymptomatic patient developing more morbid problems such as pulmonary hypertension later in life. One must be careful to avoid the technological imperative of simply intervening because the lesion is present. It follows that if the patient has less chance of benefiting from any procedure then the risk associated with the therapeutic intervention should be placed in question. These are often difficult judgments as often the concepts of benefit and harm are compartmentalized in the practice of medicine.

Also problematic are conventions accepted in the management of medical problems. Advances in the ability to diagnose coronary artery pathology in atherosclerotic heart disease and consistently improved outcomes for coronary artery bypass grafting resulted in a debate as to what lesions should be subject to surgical intervention. A trial was proposed which randomized patients to surgical or medical intervention. Many argued that with holding coronary artery bypass grafting in this patient population would be unethical. As a result, Podrid and others undertook a study of patients with coronary artery disease and profound ST segment depression during exercise testing who sought a second opinion and decided to pursue medical management over surgical intervention [14]. The study followed 212 men over the course of 5 years. In the medical management arm 11 died with a mortality of 1.4% and 9 required surgical intervention. These patients faired at least as well as those that pursued surgical intervention. This experience has been repeated in the setting of transcatheter intervention for coronary artery disease where angioplasty and stent implantation are less invasive alternative to open heart surgery. Not surprisingly on the basis of a meta-analysis of well-designed studies no benefit to elective stent implantation was demonstrated over those requiring acute placement for symptomatic disease [15]. In a study of nearly 150,000 patients undergoing non-acute percutaneous coronary interventions only 50.4% were deemed appropriate [16]. In the setting of a disease as prevalent as coronary artery disease this has evolved to the development of specific guidelines with respect to recommended management. Unfortunately, the prevalence of congenital heart disease does not lend itself to such rigorous study. One is forced to practice knowledge-based medicine which includes an assessment of the validity and strength of the literature in the context of experience.

Evaluation of transcatheter interventional strategies in the management of congenital heart disease has been a complex process. As previously discussed, in the United States the FDA regulates labeling of medical devices however it does not regulate the practice of medicine. As a result, many devices are utilized “off label” in children. This is similar to countless drugs used for the management of pediatric patients. Recently a financial incentive to industry was created in the

form of the Best Pharmaceuticals for Children Act and the European Medicines Agency. This encourages a pharmaceutical company to conduct research into the efficacy and safety of a drug in the pediatric population by extending an exclusive patent, often resulting in significant financial gain [17]. It remains to be seen whether this will be a beneficial strategy for the development of the medical management of pediatric disease, however it is a start. The off-label use of medical devices is more pervasive. The development of devices for use in the pediatric population often relies on the need for that device in a larger market. As industry has a fiduciary responsibility to its shareholders decisions to pursue the development of devices for rare conditions is a significant obstacle. A notable example of this is the use of stents to treat vascular conditions in congenital heart disease. Until recently most stents used in the treatment of congenital heart disease were approved only for use in the biliary system and not for use in the vascular system. Very few balloon angioplasty catheters were labeled for use in the pulmonary system where they are most often used in pediatrics and have been so for the last several decades. It is very difficult for regulatory agencies such as the FDA to accept a comparison of a new device such as a balloon angioplasty catheter for use in the setting of pulmonary artery stenosis when there is no labeled existing device. Navigating regulation in the setting of considered conventional management becomes difficult.

Randomized studies comparing a less invasive treatment strategy also are subject to the participant and investigator "knowing" a priori what treatment is best. To be ethical one must offer clinical equipoise in developing a study. In the era of on-line informatics patients may think they are well informed and be reluctant to be randomized. Blinding of subjects and investigators is often not possible and the incentive to receive a less invasive approach often motivates a patient to participate. When this preference is strongly perceived patients may withdraw from a study upon assignment to the more invasive procedure. Furthermore, as illustrated in the investigation of secondary treatment of cryptogenic stroke , the availability of a device to be used "off label" in a procedure may further support this bias and undermine recruitment into clinical trials [18]. Lastly many studies have a "cross-

over" design wherein patients cross from one group to another, underscoring preconceived notions of benefit in the research design.

More recently the fields of congenital heart surgery and pediatric interventional cardiac catheterization have seen the development of registries that are multi-institutional in an effort to develop a cohort for evaluation that provides a meaningful representation of a given condition. In North America perhaps the most noteworthy is the development of the Society of Thoracic Surgeons database which has undertaken a detailed catalog of procedures for congenital heart disease and provides regular analysis of outcomes. The nature of the database is procedural and provides little longitudinal data. The Congenital Heart Surgeons' Society by contrast has accumulated an increasing experience with the long-term outcome of different management strategies for specific congenital heart lesions. Both databases provide important information to the expectation of outcome. More recently interventional cardiac catheterization has also seen similar database development with the advent of the American College of Cardiology/NCDR IMPACT database for cardiac catheterization procedures and the CCISC database for interventions and cardiology and cardiac surgery (albeit more specifically directed towards the impact of therapeutic cardiac catheterization). These databases allow comparison between centers for outcomes of a specific therapeutic strategy and have the capability for providing provider outcome as well. Much of the literature has been devoted to the reporting of risk adjusted outcomes and often report results in terms of observed over expected outcome. These and other catheter-based databases provide a platform for meaningful comparisons between groups and can provide an estimate as to the risk of a given procedure that have implications in quality improvement projects [19–21]. The CCISC database for interventional cardiology is unique in that it has attempted to define the preprocedural risk of a serious adverse event [22–24]. The distinction between risk adjustment and risk assessment is important. The former allows one to adjust outcomes for complexity after they have occurred whereas the latter attempts to assign the possibility of a serious adverse event occurring for given patient having a specific procedure before that procedure is undertaken. It is a common fallacy that the practitioner or program incurs a specific risk

associated with the procedure; rather it is the patient that is impacted most by risk as whether one encounters harm is a binary function.

Evaluating performance of a given program or practitioner is complex and very difficult for the patient to fully understand. It stands to reason that a high-volume program whether be surgical or intervention will have better outcomes [25]. Volume is likely an easily measured surrogate for many processes that may be in place to ensure the best outcome. A low volume program may be able to hide poor outcome within a wide range of unobserved over expected ratio while conversely a high volume program can obscure poor outcomes in a large experience. By convention for example the STS database most reliably reports a 4-year rolling outcome for most procedures as specific procedures are relatively infrequent. In this sense meaningful observed observations to expected comparisons can be made. However, such reporting is not nimble enough to identify acute changes. Rarely, if ever, studied has been an analysis of the effect of resources strained by a high volume of procedures.

The volume argument has been further extended into evaluation of a particular practitioners and maintenance of competence. Cardiac programs are often evaluated on the basis of the number of procedures that they undertake rather than the nature of the procedures themselves. This is particularly profound when one considers the availability of a transcatheter procedure for the treatment of congenital heart disease. The number of surgical procedures and those on cardiopulmonary bypass are important volume metrics for evaluating many cardiac programs. While recommending one treatment strategy over another should not be influenced by volume, a decline in the number of open surgical procedures remains important if one considers volume alone in assessing the quality of a program. As an example, the transcatheter management of atrial septal defects has had an important impact on cardiac surgery. Traditionally these were procedures were considered to be amongst the simplest on cardiopulmonary bypass. As the majority of these procedures have moved to the transcatheter arena the number of procedures left for the operating room continues to diminish. This has an impact both on overall program volume as well as the ability to train surgeons. As the complexity of surgical procedures available to the training position

increases, so has a scrutiny of the outcomes of those procedures. The challenge of training surgeons has been influenced by removal of more routine procedures from the surgical arena as well as the limitation on work hours imposed by residency programs . The experience of a surgeon of today graduating from the program is not the same as a surgeon of a previous era [26].

A very important component to the realm of pediatric interventional cardiology is the inherent influence of industry. Device development is expensive and must rely on industry for support as few institutions can bear the financial burden of regulatory process and oversight. The practicing interventional cardiologist may be motivated to participate in a device trial by the opportunity of providing an alternative strategy that is less invasive to the patient population, thus having the perception of "keeping up" with cutting edge technology. While unavoidable, it is important to recognize that this may represent a significant bias. Even if one has no direct financial conflict of interest one cannot escape the notoriety of being in the position of providing what is considered to be novel and new therapy. This notoriety is particularly important in the academic environment where innovation, publication, and participation in clinical trial is associated with professional advancement in rank within an academic institution and usually associated personal financial gain. Despite professional objections to the contrary, marketing and notoriety can have a considerable impact on advocating one procedure over another. Simply recognizing that one may have a conflict of interest does not substitute for an acknowledgment that such a relationship may have an undue influence on making a recommendation.

Transcatheter treatment of congenital heart disease has seen significant growth since the first valvuloplasty was first reported in 1982 [27]. One of the first surgical procedures undertaken on the cardiovascular system was the ligation of the patent ductus arteriosus [28]. Following Gross' innovation, ligation of the ductus arteriosus became commonplace. The literature is abundant with the controversies associated with ligation of the ductus arteriosus in premature infants. While many studies have argued the relative risk and benefit of closure of the ductus arteriosus whether it be surgically or medically there has been no persuasive evidence as to the true

benefit of closure of the ductus arteriosus in this patient population [29]. Arguably medical therapy carries significant morbidity manifest by renal dysfunction and bleeding. Surgical intervention on the patient with significant chronic lung disease, prematurity and oxygen dependence carries the insult of a thoracotomy. More recently transcatheter occlusion of the ductus arteriosus has become possible as an interventional strategy in the cardiac catheterization laboratory. Early investigation seems to indicate that this can be accomplished effectively and at reasonable risk [30]. Is important to recognize however that it remains to be seen whether this is a strategy that ultimately benefits the patient. Carefully designed randomized studies are necessary in order to be able to evaluate this with any degree of certainty.

So where is the patient to go when considering a therapeutic intervention for congenital heart disease? The management of congenital heart disease is no longer the primary responsibility of the pediatric cardiac surgeon. Pediatric cardiac interventionalist are not classically trained surgeons. Conversely the surgeon is not a trained catheter interventionalist. Modern programs embrace a cooperative atmosphere between the cardiac surgeon and the interventional cardiologist. There is considerable overlap as there are many catheter-assisted surgical procedures and surgically-assisted catheter procedures; more commonly referred to as “hybrid” procedures. This reflects the cooperative nature of pediatric cardiac programs where informed consent remains the anchor of autonomy. Under these circumstances, transparency is important.

In considering intervention whether it be surgical or transcatheter one must truly value the concept of informed consent. This is particularly germane to the interventional cardiologist as the care they provide is often self-referred. The potential benefit must be outlined in detail and be evaluated with consideration to the patient’s exposure to risk. More importantly the patient needs to be informed of the alternatives which may confer a more invasive surgical approach. The patient needs to understand that surgery, especially if established, does not represent a dreaded last resort . The cardiologist must be transparent with respect to any bias that they may be incurred whether that be financial or through notoriety in the field. Certainly, medical

intervention cannot be driven by a technological imperative that dictates we must do something simply because we have the ability to do it. Outcomes need to be evaluated fairly and transparently. Pediatric cardiac care is unique in that for years cardiac surgeons, interventionalists and imaging/diagnostic providers have been encouraged to work in concert to determine the best possible management strategy for their patients. This is often met with considerable controversy and debate. That discussion is healthy and must be undertaken with humility. The program that does not offer this style of management is destined to fail.

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Informed Consent in Fetal Hypoplastic Left Heart Syndrome

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1 Introduction

Informed consent in complex fetal congenital heart disease such as hypoplastic left heart syndrome, sclerotic pulmonary venous stenosis,

common arterial trunk with interrupted aortic arch, severe Ebstein's anomaly, and others involves many concerned individuals who include: the mother, the father, the obstetrician, the pediatric cardiologist, and the pediatric cardiac surgeon, among many other support groups [1]. It is the duty of the physician to administer and perform informed consent under high risk pre- and postnatal circumstances that require high risk surgical options without which the newborn baby would most certainly die [1–3].

To consider each high-risk diagnosis , therapeutic options , and potential complications would require a detailed and exhaustive medical/surgical analysis of each disease entity which is beyond the scope of this analysis. The most prominent diagnosis among those noted is hypoplastic left heart syndrome (HLHS) which is still attended by a persistent high mortality and uncertain long-term future [4–23]. The therapeutic options have evolved to require three open heart operations en route to univentricular anatomy and physiology. Since much diagnostic, therapeutic, and moral attention has been placed on this disease entity and the steps towards eventual palliation [11–21], we center our discussion on the informed consent process as it applies to HLHS as an example for the other high risk diagnoses/operations that are different but share the high risk category that propelled us to this discussion [24–27].

In the not too distant past, physicians presented three options to parents whose child was born with HLHS , namely, Norwood operation, cardiac transplantation, or comfort care (euphemism for humane care not involving interventions aimed at care leading to certain death) [1]. The ethical and scientific debates considered (1) the high risk of the Norwood operation, which requires at least three open heart procedures; (2) the physiologically better option of neonatal cardiac transplantation that has the attendant problems of lifetime immunosuppression, potential for graft failure, and limited donor availability; and (3) the perceived more humane option of comfort care and death that does not cause pain and suffering over a lifetime of hospitalizations, operations , biopsies, chronic medications, limited physical capabilities, and documented behavioral problems.

Improved results with the Norwood operation over time and continued limited donor availability have resulted in near universal

acceptance of the Norwood pathway of three operations [28]. Comfort care has fallen off the decision tree in many institutions owing to improved Norwood outcomes [29]. The introduction of fetal echocardiography has allowed for extensive and comprehensive prenatal diagnoses of all anatomic systems [30]. In particular, physicians performing fetal echocardiography can identify congenital heart lesions with a high degree of accuracy at an early developmental stage [31]. This allows for many management schemes that range from early pregnancy termination to postnatal readiness for prostaglandin therapy, early septostomy, inotropic support, and extracorporeal membrane oxygenation. The informed consent process , therefore, by necessity, has been shifted from the postnatal to the prenatal period which requires a comprehensive understanding of fetal and maternal physiologic interactions, diagnostic methods, surgical options, potential complications, survival statistics, quality of life issues, and ethical considerations [32–34]. Which subspecialty service by virtue of training, clinical practice, and programmatic interest is best equipped to administer informed consent under these circumstances? Is it the Obstetrician, the Pediatric Cardiologist, or the Pediatric Cardiac Surgeon? Is it a combination of all the mentioned clinicians? Recent reports [24–27] have accounted for these dilemmas and have advocated incorporated systems that allow informed consent to be practiced in a timely fashion. The process starts when the fetus has been found to have HLHS which will trigger appropriate counseling and shared decision-making allowing the family to make decisions that are congruent with their family values. An obstetrician or maternal-fetal-medicine (MFM) physician may be the primary point of contact for the family. Similarly, a pediatric cardiologist who specializes in fetal echocardiography plays a critical role in counseling and informed consent when revealing the fetal diagnosis of HLHS . Initial counseling is recommended on the day of diagnosis by the pediatric cardiologist and subsequently by the obstetrician who considers all the maternal health issues in light of the fetal diagnosis of HLHS . Further consultation, in an organized manner, is planned in order for the family to be fully aware of their options and responsibilities. There is support for providing prenatal consultation in an organized multidisciplinary manner. Some institutions offer a comprehensive visit whereby the

family meets the fetal coordinator, cardiothoracic surgeon, neonatologist, geneticist, cardiac intensivist, social worker, fetal nurse practitioner, and sometimes palliative care physicians [26]. In some institutions, parents are provided with a "roadmap" [27] that visually depicts an understanding of the life-long cardiac care, both by physicians and family members, that is required for patients with HLHS who opt for single ventricle palliation (Fig. 1). Once the family has had ample opportunity to process information and ask questions, the team of obstetrician/MFM and pediatric/fetal cardiologist continue to be the primary physicians that assist with decision-making.

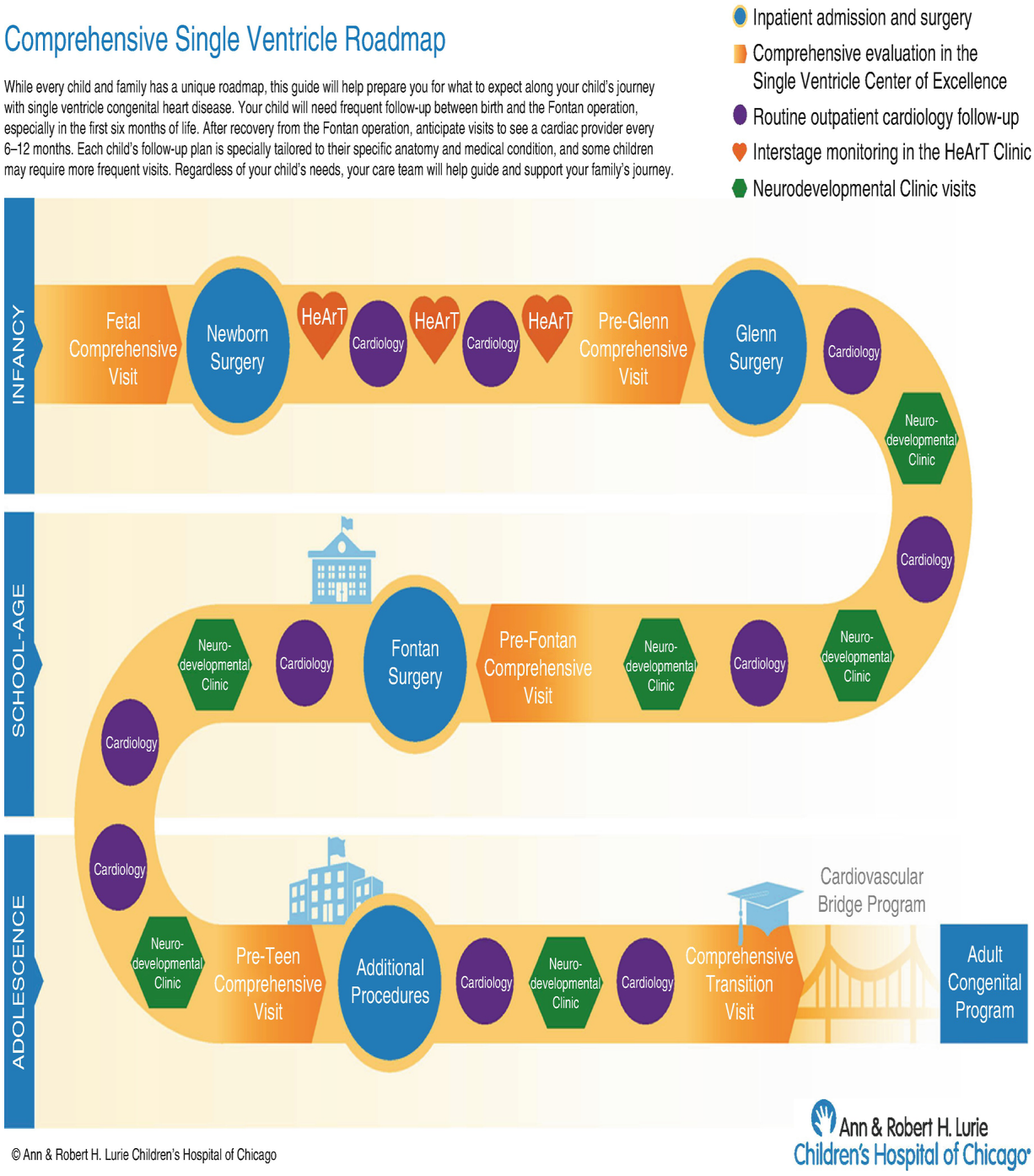

Fig. 1 Comprehensive single ventricle roadmap for patients with HLHS undergoing staged palliation. Reproduced with permission from Lurie Children's Hospital, Chicago, Illinois

This discussion, surrounded by ethical dilemmas, considers the multiple moral tensions regarding maternal-fetal conflict , inherent biases of physicians tilting towards the mother compared to the fetus/neonate and vice versa, and programmatic reputation to the

public. As noted, along the timetable of pregnancy management in the case of fetal cardiac disease are obstetricians, pediatric cardiologists, neonatologists, intensivists, and pediatric cardiac surgeons. In addition, each subspecialist generally works with an advanced nurse practitioner or physician's assistant who necessarily also has opinions about informed consent and how to conduct the process. Each has a part to play in the informed consent process, albeit with different outlooks and perhaps a subliminal sense of who is the primary patient, the fetus or the mother.

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2 The Obstetrician

The first physician who the prospective mother and father encounter is the obstetrician . Initially, she is the mother's advocate to make sure that all the prenatal preparations are made for nutrition, vitamin therapy, and fetal echocardiography. During this time, the obstetrician and the prospective mother form a bond of shared decision making, oftentimes creating an affectionate relationship that is grounded in confidence, empathy, and duty. The treatment plan is created to keep both the mother and fetus healthy for an uncomplicated delivery of a normal neonate. The unexpected revelation that the fetus has HLHS changes the balance of thought and prospective treatment plans that involve "negative autonomy", positive "autonomy", and physician influence [34].

Minkoff, Marshall, and Liaschenko have written a superb ethical analysis of "The fetus, the 'potential child' and the ethical obligations of obstetricians" in which the most basic tenets of maternal-fetal human rights are explored [35]. They write, "The right of pregnant women to refuse obstetric interventions is an established tenet of obstetric ethics, one that has been championed by the American College of Obstetricians and Gynecologists [36]. It comports with the dominant understanding of human rights, which holds that bodily integrity is a foundational right, one that has been written into English law for more than 150 years, and that has been included in the United Nations charter on rights since 1947 [37]. Although occasional legal challenges to women's unfettered right to exercise bodily integrity, i.e., to refuse interventions ("negative" autonomy), persist [38], they have most often been struck

down. In those cases, brought before the courts, they have most frequently found that criminal sanctions lacked legislative foundations [39]. Furthermore, although there are dissenting voices who feel that superseding obligations to a fetus may appropriately attenuate a mother's right to refuse, those voices remain outside the mainstream of ethical thought, at least as it is reflected in the opinions rendered by the American College of Obstetricians and Gynecologists' Committee on Ethics and the British National Institute of Clinical Excellence, which continue to hold that negative autonomy is essentially unassailable [36, 40]. That, however, does not mean that fetal considerations are of no moment. The authors further consider the fetus having a dual essence. They note that the fetus is a mammal that is developing within the uterus and is not viable throughout most of its gestation. However, to its family, the fetus has the status of a "potential child". Little [41] has reasoned that the full moral status of the fetus is something that is anticipatory and something that is achieved. It follows then that this potential child, over time will ultimately attain personhood at delivery. However, in the circumstances of a planned abortion, there are no such considerations.

These aforementioned tenets certainly underscore the woman's right to bodily integrity and the obstetrician's role in affirming these rights. With these principles in mind, the obstetrician in consultation with the mother and father therefore have decisions to make in a timely manner and in a sequence that offers the most informed consent possible for a shared decision-making process [42]. The decisions are (1) to abort the fetus and experience the separation anxiety and personal loss that such a decision comports; (2) carry the fetus to term whereupon the fetus attains personhood; and (3) select a course of action that will lead to the Norwood-Bidirectional Glenn-Fontan pathway or comfort care thus allowing the neonate to die. The obstetrician may feel inexperienced to offer comprehensive informed consent under these circumstances due to many reasons. The field of pediatric cardiology is out of her training expertise, she is an obstetrician and not a pediatric cardiologist. This reality does not allow her the time to monitor and learn the myriad advances that are made in congenital defects in general, let alone the specifics of pediatric cardiology. Nevertheless, she understands the nature of neonatal

surgery; is well aware of the multiple surgical options that are required for HLHS; and is also cognizant that comfort care is a morally acceptable option. In addition, she is explaining these circumstances to her patient, the mother, in a highly charged emotional situation. The general practice is to refer parents to a pediatric cardiologist who will offer more information concerning all choices and engage in the multi-disciplinary informed consent process that is outlined herein.

3 Pediatric Cardiologist

The pediatric cardiologist will establish a warm and trusting relationship with the family. At the outset, she will review the findings of the fetal echocardiogram and reassure the family that the diagnosis is highly likely to be accurate with a high probability of precision. This is an important issue in the event that pregnancy termination or comfort care options are elected. She will also underscore the conclusions of the obstetrician and offer outcomes data concerning the three stages of surgical palliation, long term disabilities, and the possibilities of cardiac transplantation in the future. She may also communicate that neonatal cardiac transplantation is not practiced in the present era owing to donor availability, potential for graft failure, and life-long immunosuppressive medications. Lee and associates [25] have offered a comprehensive outline of discussion points that should be provided to the family regarding their potential child with HLHS (Table 1). These informational points provide a comprehensive roadmap for the informed consent process which outline potential outcomes and parental responsibilities along the surgical and medical pathways leading to univentricular physiology and possible cardiac transplantation. These informational points are best delivered in a multi-disciplinary approach.

Table 1 Elements of prenatal counseling of congenital heart disease (with permission from Lee [25])

• Diagnosis: Provide description of diagnosis and diagram depicting fetal echocardiogram findings compared with normal heart anatomy; discuss the important physiologic alterations from normal
• Diagnostic limitations and uncertainties: may be affected by gestational age, fetal position, maternal habitus

• Known causes or risk factors for CHD: discuss if risk factors are present and provide reassurance to allay any parental guilt that CHD is their fault
• Potential for progression of disease or fetal demise: discuss what may evolve and the anticipated follow-up for remainder of gestation
• Extracardiac anomalies: in collaboration with maternal fetal medicine, it is important to assess for other anomalies and discuss the possible effect on postnatal management and prognosis
• Genetic associations and testing: Discuss possible genetic syndromes associated with the CHD; review prenatal screening results and limitations; discuss consideration of amniocentesis, and if declined, the postnatal genetic testing to be performed
• Increased risks to CHD outcome: may occur with associated prematurity, growth restriction, extracardiac anomalies, heterotaxy syndrome, genetic syndrome
• Pregnancy options: discuss if parents are considering continuation or termination of pregnancy
• Fetal cardiac intervention options: discuss if applicable
• Delivery planning: timing, induction of delivery, site of delivery, site of postnatal cardiac care
• Expected postnatal management: ICU admission, intravenous lines, prostaglandins (PGE1), diagnostic testing (e.g., echocardiogram, angiography, CT, MRI)
• Expected neonatal cardiac surgery or catheterization procedure: nature of procedure(s), survival rates, potential complications
• Expected hospital course and length of stay: mechanical ventilation and vasoactive medication support, sedation, feeding issues (e.g., NPO, need for nasogastric feeding tube, pumping breast milk), medications, therapy involvement (physical, occupational, speech)
• What to expect at hospital discharge: medications, possible need for feeding tube, possible home monitoring of weight and oxygen saturations, home nursing visits, outpatient therapies, cardiology follow-up
• Long-term issues: anticipated or possible surgical or catheterization interventions needed in the future, physical limitations, neurodevelopmental issues, cardiology follow-up into adulthood, possible development of heart failure and need for heart transplant
• Family issues: planning for parental leave from work, housing needs if from out of town, financial considerations and insurance issues, psychological support, sibling support
• Other prenatal consultations: cardiothoracic surgery, neonatology, genetics, palliative care, social work, etc.
• Provide tours of labor & delivery, newborn and/or cardiac intensive care units
• Offer resources for parents: provide written materials on diagnosis and cardiac operations, websites for CHD information, information on support groups; offer to connect parents with other CHD families with a similar diagnosis; provide contact information for fetal nurse coordinator and fetal cardiology physician
• Prior to delivery, parents should identify a primary care pediatrician comfortable following a baby with CHD

The National Pediatric Cardiology Quality Improvement Collaborative (NPC-QIC) is a network of over 50 pediatric cardiology centers whose goal is to improve the outcomes for children with congenital heart disease. Since 2008, the collaborative has focused on HLHS. As part of its initiatives, the Fetal and Perinatal Learning Lab was established to help increase the percentage of infants who receive a prenatal diagnosis to 90% and to improve the percentage of families that receive comprehensive prenatal counseling. They define comprehensive counseling as counseling that "includes a dialog with families regarding the diagnosis, short and long term outcomes, including quality of life, the surgical plan, delivery and pre-operative planning , the interstage (between stage 1 and stage 2 palliation surgery) plan, growth and nutrition during the pre and postoperative stages, the impact on neurodevelopment, family support and resources" (https://npcqic.org/fetal-and-perinatal-learning-lab). The group has established a fetal management plan and check-list that centers can use to provide high-quality, multidisciplinary counseling to the families whose fetus has a diagnosis of HLHS.

At some point in the conversation, pregnancy termination and postnatal comfort care will be broached by the parents or the cardiologist. This will require a sensitive interchange concerning the acceptable moral choices of comfort care, should the family wish to pursue this choice. The family, no doubt, will want to understand that comfort care is an acceptable moral decision and should be made to understand all of the choices. Moreover, the parents must be reassured that neither they nor the baby will be abandoned, and that comfort care will be available for them and the baby as they both experience these emotional and difficult times. If a specialized palliative care team exists at the delivering institution, it can be extremely beneficial to have a consultation performed during the prenatal period so that the family can have detailed questions about comfort care answered such as: What does comfort care look like? Will there be pain and if yes, how is it controlled? How long might my baby live? What if I am scared to have my baby die at home? Will my baby stay in the hospital during this time or is there some place else (i.e. hospice) available? Depending on the institution and state resources the answers to these questions may vary

and the palliative care team will have the most information about how to provide the resources and support that the family will need.

Once the multi-disciplinary informed consent process is completed, the parents then continue to meet with the pediatric cardiologist and obstetrician/MFM throughout the pregnancy for continuation of care.

4 The Obstetrician, Part II

At this point, the parents can elect one of the aforementioned choices; namely pregnancy termination; comfort care after birth; or the Norwood-Bidirectional Glenn-Fontan Pathway .

Pregnancy termination enhances the relationship between obstetrician and mother. The obstetrician now has the responsibility and duty to either perform the termination or refer her patient to another physician to perform the termination in the event that she finds this procedure incompatible with her moral principles or her institution does not provide those services. If termination or comfort care are elected, she is duty bound to see to the well-being of her patient during this grieving process. As of this writing, there are multiple state laws being enacted and being contested in the courts which could change the established tenets of autonomy and a woman's right to bodily integrity [43].

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5 Ethical Dilemma of the Slippery Slope

This grieving process if the mother elects comfort care for the new born baby, is very complicated. The neonate has attained personhood, albeit with significant heart disease. It is not altogether clear whether in today's world or in the near future that such a course of action will be allowed or tolerated by the medical team (neonatologists, cardiologists, intensivists, cardiac surgeons), the ethics committee, or the law. While comfort care has been respected in the recent past, the idea that staged single ventricle palliation can be instituted with perceived improved results could trigger the course of action to stabilize the neonate on prostaglandins, engage the legal process, and offer an adoption process that will formalize the surgical palliation pathway. This course of adoption action might be considered anathema to most individuals and is generally not practiced. However, it is only a matter of time when such courses of action would be entertained. If the parents understand this issue, they could arrange for their child to be born at another sympathetic institution which would avoid this moral tension. If one extends this argument, would the comfort care option be respected for a neonate with tetralogy of Fallot and severe pulmonary stenosis who

could be treated by a systemic to pulmonary artery shunt or complete repair? Perhaps more poignantly, would the same choices, namely surgical palliation or comfort care, be offered to patients with tricuspid atresia (TA)?

This point was recently (2016) debated by Kon, Patel, Leuthnar, and Lantos in their poignant analysis of "Parental Refusal of Surgery in an Infant with Tricuspid Atresia" [44]. The analysis was debated by an intensivist (Alexander Kon, MD), a pediatric cardiologist (Angira Patel, MD), a neonatologist (Steven Leuthnar, MD), and an ethicist (John Lantos, MD), all of whom are well versed in ethical considerations, well published in their respective fields, and thoughtful contributors to these ethical dilemmas.

By and large, these individuals reaffirmed the moral tenet that parents are the best judge of what is best for their children. However, the evaluation of what is in the best interest of a child can be subjective and the authors disagree on this point. The overriding issue in these circumstances is the pain and suffering of multiple operations and a shortened life to which a baby is exposed with single ventricle surgical palliation vs. the goal of preserving life, albeit with the aforementioned concerns notwithstanding. Dr. Kon writes, "When making life-and-death choices for an infant, parents and providers must consider primarily the infant's best interest [45]. However, such decisions are highly value laden. Different parents, and different providers, may judge the same situation very differently. To some, the benefits of prolonging life, even for a short time in the face of significant morbidity, outweigh the burdens of even significant suffering. For others, minimizing suffering is a more important goal than prolonging life. In such case, there is often no single right answer. Furthermore, although the best interests of the infant are central in decision-making, the interests of the parents, siblings, and others may also be considered [46, 47]" He continues, "The American Academy of Pediatrics recognizes that most such decisions fall into a gray area in which several goals of care may be ethically permissible. The academy recommends that providers seek to overrule parents only when parents make decisions that are clearly contrary to the infant's best interests [44, 47]. Merely disagreeing with parents' values and preferences is insufficient. This standard requires that providers intervene only when parents make choices that are

inconsistent with decisions reasonable people would make." The word, "reasonable" is a powerful description of moral tenets that are grounded in philosophy, law, and ethical behavior, all of which date back to Plato [48], Aristotle [49], Kant [50], and Mill [51], to name only a few.

Dr. Kon considers the important issue of electing comfort care for some TA patients who could live longer due to specific anatomical variants than the typical patient with HLHS. He writes, "Because an infant with TA is likely to suffer significantly if surgery is withheld, a decision to forgo life-prolonging interventions cannot be considered consistent with that child's best interest. Although the obstetrician was correct in noting that similar patients should be treated similarly, the difference in the natural course of TA and HLHS leads to different ethically permissible options for affected infants. Therefore, the parents should be educated about the natural course for their son if life-prolonging interventions were not provided, and the providers should explain why they believe that such a decision is not appropriate. If the parents persist in their refusal to give permission for appropriate intervention, the team should seek a court order to authorize medically indicated treatment. In general, when we consider a child's best interests, we tend to focus solely on the potential benefits and burdens of the proposed intervention. This case illustrates the importance of considering not only the potential benefits and burdens of the proposed treatment but also the potential benefits and burdens of the alternatives, including the option to forgo life-prolonging interventions. In some cases, such as this, the alternatives are so clearly contrary to the patient's best interests that a decision to forgo life-prolonging interventions is not ethically supportable."

The debate continues with Dr. Patel's assessment which concentrates on the idea that both TA and HLHS, if palliative surgery be elected, will require multiple operations with all of the complications previously noted in this chapter, not the least of which are a shortened life, decreased functional status, eventual cardiac transplantation which are all associated with pain and suffering . Dr. Patel affirms, "Congenital heart diseases consisting of a functional SV (e.g., HLHS, TA) require staged palliation concluding with a Fontan operation. Over the last 40 years, surgical technique has evolved, and significant strides have

been made to reduce mortality. Historically, HLHS has been technically more challenging with higher mortality than other types of SVs, and end of life (EOL) care has been accepted an ethically permissible option. Contemporary results, especially at high-volume technically excellent centers, show long-term survival for HLHS approaching that of other forms of SV such as TA. Data are difficult to extrapolate because of center-related and era effects, but best estimates range from 80% to 85% for 10-year survival for both HLHS and TA [4, 52, 53]. In actuality, all functional SVs have a similar long-term burden of intensive surgical and medical therapies. The difference in mortality between HLHS and TA is negligible and no longer sufficient to treat the 2 diagnoses as different entities for an ethical analysis. Specifically, life-prolonging treatment involves ≥2 surgeries in the first 3 years of life, cardiac catheterization and interventions, and lifelong need for monitoring and treatment of complications including premature death, ventricular failure, thromboembolic disease, arrhythmia, liver disease, protein-losing enteropathy, and potential need for heart transplantation. These interventions are palliative and not curative. However, the timing of death without intervention for HLHS may be different than for TA; infants with HLHS generally die within 2–4 weeks without intervention, but a small minority of infants with TA (depending on underlying anatomy) can survive longer [53]. Given surgical and medical advances leading to similar survival outcomes for HLHS and TA with the same burden of long-term morbidities, the question now becomes, "Is it ethically permissible to allow a family to forgo life-prolonging interventions for a child with any SV diagnosis? Do we honor the choice of these parents that is probably based on their own family's individual values and preferences? I say yes."

Dr. Leuthner, a neonatologist, emphasizes the importance of a correct diagnosis which, if wrong, can confound prenatal decision-making and lead to inappropriate courses of action. Moreover, he considers the issue that HLHS and TA patients are similar in outcomes. He writes, "If the lesions are equivalent, then the ethical principle of justice, or treating equal patients equally, does come into play. Interestingly, as the survival of infants with HLHS undergoing the staged repair has improved, there continues to be debate about whether parents should still be offered palliative care [19, 20].

Essentially using the justice argument, it is often suggested that with improved HLHS survival and outcomes there are other cardiac cases with worse outcomes, yet palliative care might not be offered in those. When thinking of justice in this way, we should beware of faulty reasoning, because 2 wrongs would not make a decision right. The literature continues to show although the outcomes for HLHS have improved , and there might be a recommended medical plan, they have not yet reached the level for which palliative care is not an acceptable choice that parents should be informed about [21, 54, 55]. In this case, and at this institution, the standard practice is to allow parents of infants with HLHS to choose surgery or EOL care. The neonatologist is correct to suggest that based on justice, because the medical conditions are reasonably equivalent, if it is reasonable to offer EOL care in cases of HLHS, it is reasonable to offer it in cases of TA."

To conclude this interesting analysis, Dr. Lantos, an ethicist, offers his learned opinion based on his experiences and writings. He writes, "Arguments by bioethicists have changed the ways in which we respond to a wide variety of cases. We used to permit parents to refuse life-saving surgery for babies with trisomy 21. We used to refuse to perform life-saving surgery on babies with trisomy 18. The borderline of viability has shifted slowly but steadily and with it the threshold for mandating life-sustaining treatment of premature infants. When disagreements persist, it suggests a lack of consensus in the professional community. In such cases, the proper thing is to defer to parents. Careful consideration of the arguments can help us counsel parents and ensure that their decisions are informed decisions. In that sense, disagreements between bioethicists are no different, and perhaps no more common, than disagreements between cardiologists, policymakers, or other experts. They signal the limits of our collective ability to know what is best and the intensity and integrity of our efforts to keep finding out."

The aforementioned analysis offers a poignant view of the issues of comfort care, palliative surgery, human rights, and the tensions relating thereto that are sure to be further debated in the years ahead. The principles of autonomy, bodily integrity, justice, and human rights will continue to be the foundations of this debate.

6 Pediatric Cardiac Surgeon

The pediatric cardiac surgeon is generally consulted after the family has chosen the palliative surgical pathway or as part of the multidisciplinary counseling to provide the family with more data and specifics about the operations. The purpose of the fetal consult is largely for the surgeon to perform her understanding of informed consent and perhaps to explain more directly the surgical procedures, nuances of postoperative care, and outcomes throughout the multiple operations that is the Norwood-Bidirectional Glenn-Fontan pathway . It is also incumbent on the surgeon to include the 4th operation, which is cardiac transplantation, likely to be required in later life.

Informed consent by the pediatric cardiac surgeon in this setting must be balanced by (1) the reality of multiple operations and the moral duty to convey associated risks of death and complications and (2) the hope of optimism and the surgical team's expertise with the pledge to carry out the operation and treat the complications should they occur. There is still the possibility that the family will opt for comfort care and the decision could very well be determined by the informed consent process that is offered by the pediatric cardiac surgeon. It is likely that the surgical team is biased towards the surgical option. There are many reasons for this posture. First, this is what surgeons do; they operate; they have confidence in their surgical skills , and they are intensely interested in their surgical outcomes which if excellent, will result in more referrals, both with HLHS patients and other types of patients with similar congenital heart defects. This is not to aver that surgeons are mechanical, soulless individuals with only one thing in mind. It is to note that the bias is generally towards staged palliation. The family interaction will be nurtured after birth and during the course of the operations ahead.

7 Pediatric Cardiologist, Part II

Once the decision is made for a term delivery, the pediatric cardiologist has the responsibility to prepare the family for post-natal stabilization with prostaglandin therapy and resuscitation or to arrange comfort care options to affirm the dignity of death through appropriate and sincere efforts to reassure the family as they embark on this very trying and emotional experience.

If palliative care is chosen, the multiple services are engaged and the process towards stabilization and palliative care are enacted.

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8 Summary

So, who is responsible for the informed consent process for HLHS? We have outlined some of the timely issues that confront parents and caregivers which necessarily occur in a sequential manner that involves the obstetrician, the pediatric cardiologist, the pediatric cardiac surgeon, and multiple other concerned services. Critical decisions occur early in pregnancy at a time when the obstetrician is the primary caregiver and ethical agent to help the family with important decisions. While not an expert in congenital heart disease, she is acutely aware of the risks and long-term complications of the palliative pathway for HLHS. And while there are no data or moral tenets to indicate whether she is biased towards the mother or the fetus, her relationship with the mother is manifest and present; she has a relationship with the mother; she has a potential and moral relationship with the fetus. Her referral to the pediatric cardiologist offers a different viewpoint. The pediatric cardiologist establishes a relationship with the parents. However, her primary interests are in the diagnosis and potential treatment plans of the fetus who when is born will attain personhood and will be a candidate for staged surgical palliation. Again, there are no data or moral tenets to indicate whether she is biased towards the mother or the fetus, her relationship, by virtue of time spent with the fetus and time spent determining the complex anatomy, places her attention necessarily on the fetus.

Both clinicians see the parents at the first stages of diagnosis and are in the timely position for the initial stages of informed consent to be

followed by the more comprehensive multi-disciplinary approach which has been emphasized in this chapter. As long as all clinicians and support groups are clinically knowledgeable, then the informed consent process can be grounded in their balanced expertise that will allow parents to make thoughtful and important decisions.

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Role of Ethics Consultation in Pediatric Congenital Heart Disease

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1 Introduction

Ethics consultations and committees were proposed in the 1960s and early 1970s to address ethically controversial clinical situations with new medical technologies , legal precedents , governmental imperitives

, and professional society recommendations [1]. Siegler postulates that the central goal of clinical medical ethics is to "improve the quality of patient care by identifying, analyzing, and contributing to the resolution of ethical problems that arise in the routine practice of clinical medicine" [2]. Ethics consultation services are found in most hospitals today and have become an accepted part of medical care [3, 4]. Over the years, the use of ethics consultation has become widely accepted as a way to help physicians identify, understand, and resolve common ethical issues that occur in patient care situations. These services can be provided by an individual ethics consultant, an ethics consultation team, or an ethics committee [5, 6].

The American Society of Bioethics and Humanities (ASBH) defines healthcare ethics consultation as a set of services provided by an individual or group in response to questions from patients, families, surrogates, healthcare professionals, or other involved parties who seek to resolve uncertainty or conflict regarding value-laden concerns that emerge in health care [7]. In addition to formal ethics consultation, pediatric hospitals have other avenues to address ethical issues as described by Carter, et al. such as: ethics committee meetings , nursing ethics forums , ethics brown bag workshops , PICU ethics rounds , grand rounds , NICU comprehensive care rounds , palliative care team case conferences, and multidisciplinary consults in a fetal health center [4].

2 Role of an Ethics Consultant

The role of an ethics consultant often encompasses tasks beyond performing an ethical analysis of the clinical conflict. As La Puma and Schiedermayer describe, the role on an ethics consultant can also be that of a professional colleague, case manager, patient advocate, negotiator, and educator [8]. In this role, an ethics consultant may have interactions with the primary physicians, subspecialty consultants, and nurses. Importantly, the ethics consultant frequently has extensive involvement with the patient and the patient's family. The skills needed include comprehending specialized medical knowledge, communicating and facilitating between different parties, understanding patient and family perspectives, managing conflict,

clarifying moral positions, exploring multiple options, and helping negotiate an ethically acceptable solution.

An ethics consultant can use different approaches in performing a consultation as described in the ASBH's "*Core Competencies for Healthcare Ethics Consultation*" [7]. An authoritarian approach emphasizes that the consultant acts as the primary moral decision maker who provides necessary guidance . Although this approach may be efficient at providing guidance, it can minimize or exclude the values of key stakeholders and create the impression that the primary decisionmaker's authority is usurped. At the other end of the spectrum, a pure consensus-building approach underscores forging agreement among involved parties. This approach may be adequate, however, only if the agreed-upon resolution falls within ethically justified norms or values; agreement among parties does not necessarily guarantee that the resolution is ethically permissible.

Instead of exclusively relying on the authoritarian or consensus approach, the ASBH proposes that an ethics consultant employ a facilitation approach [7]. The core features of this approach are taken from this reference and shown below:

(1) Identify and analyze the nature of the value of uncertainty

- (a) Clarify the specific ethics question that needs to be addressed
- (b) Gather relevant information (e.g., through discussions with involved parties, examination of medical records and other relevant documents such as codes of ethics, books, or journal articles)
- (c) Clarify relevant concepts (e.g., confidentiality, privacy, decision-making capacity, informed consent, best interest)
- (d) Clarify related normative issues (e.g., the implications of social values, law, ethical standards, and institutional policy)
- (e) Identify the ethics issue being addressed (this is often different from the question initially provided to the consultant)

(f) Help to identify a range of ethically acceptable options within the context and provide an ethically appropriate rationale for each option.

(2) Facilitate the building of principled ethical resolutions.

(a) Ensure that involved parties (e.g., patients, families, surrogates, healthcare professionals) have their voices heard

(b) Assist involved individuals in clarifying their own values

(c) Facilitate understanding of factual information and recognition of shared values

(d) Identify and support the ethically appropriate decision makers(s)

(e) Apply mediation or other conflict resolution techniques, if relevant.

In addition, ASBH argues for the following core ethical responsibilities for individuals performing healthcare ethics consultations:

– Be competent, consistent and professional.
– Preserve integrity.
– Manage conflicts of interest and obligation.
– Respect privacy and maintain confidentiality.
– Contribute and participate in the advancement of the field.
– Communicate responsibly.
– Promote just health care.

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3 Role of Mediation/Conflict Resolution

In contrast to the ASBH recommendation for a facilitation approach to ethics consultations, some have argued that when an ethics

consultation arises due to conflicts between the patient, family, and/or medical team, the role of the bioethics consultant or consult team may be more akin to a mediator rendering an ethical analysis unnecessary. In a traditional ethics consultation, the ethics consultant provides recommendations. In mediation or conflict resolution, the consultant serves as a neutral third-party who helps the parties come to their own resolution [9]. Bioethics mediation has been described as process that is similar to an ethics consultation but where mediators play multiple roles such as: a coach, facilitator, empathizer, information gatherer etc. [10]. The mediator is tasked with maintaining impartiality , identifying areas of conflict, facilitating discussions and optimizing possible resolutions. In mediation, after the mediator has done the fact-finding and met with individual parties, there is usually a meeting of all participants (i.e. "joint session") where the mediator helps the individuals to see each other's views. Then they move into problem-solving and developing options for resolution. If they cannot reach an agreement , the mediator describes how the process will move forward. This may include discussions with hospital administrators, risk management and/or hospital lawyers [10].

Morreim argues that the roles of the mediator and the bioethics consultant not be combined. The mediator should not offer an ethical analysis or sway from impartiality at any point in the process. The fundamental roles of conflict resolution are neutrality, impartiality, confidentiality, and trust. A bioethics consultation service and a conflict resolution/mediation service should be offered separately but in reality, mixing the roles is often hard to avoid [9]. If this is the case, the consultant should be very clear with all parties as to which role he/she is providing. Furthermore, if the bioethics consultant is to be the primary resource for conflict resolution in the hospital, he/she should train in developing and practicing those skills [9].

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4 Process of an Ethics Consult

A clinical ethics consult can be requested when ethical questions arise that impact the decision of how to proceed with a patient's plan of care. A consult can also be requested when conflicts arise between the patient/family and the medical team or when there are conflicts

between different members of the medical team. An ethics consult can be requested by the patient/family or any member of the medical team. In the modern era, clinical ethics consultations are usually an advisory service that hospitals offer to help the medical team members, patients and their families navigate difficult situations by identifying the ethical issues, facilitating discussions, analyzing ethical dilemmas and suggesting the way towards resolution.

There are several different approaches to clinical ethics consultations. The most commonly used frameworks are the ones set forth by the Veterans' Administration and the one by Jonsen, et al. [11, 12].

The Veteran's Administration has a robust ethics consultation service and offers consultation at every VA hospital. They recommend using a standardized CASES approach when encountering an ethics consultation request:

- C—Clarify the Consultation Request
- A—Assemble the Relevant Information
- S—Synthesize the Information
- E—Explain the Synthesis
- S—Support the Consultation Process

Those who developed this approach intended for it to be a systematic framework for analyzing ethical dilemmas and ensuring quality of ethics consultation when the consultant may be pressed for time or have no formal ethics training [12].

Jonsen et all use the "4 box" method to organize and analyze clinical ethical dilemmas [11]. They identify four areas that are intrinsic to every clinical encounter and organize the ethical analysis around these areas. The four areas are: (1) Medical indications: All clinical encounters include a diagnosis, prognosis, treatment options and an assessment of goals of care. (2) Patient Preferences: The patient's preferences and values are considered central in determining the best course of treatment. In pediatrics, it is usually the patient's parent or guardian who gives the preferences, but patient preferences especially as the child approaches their teenage years are given consideration and can on occasion supersede parental preferences. (3) Quality of Life: The objective of all clinical encounters is to improve the quality of life for

the patient. (4) Contextual Features: All clinical encounters occur in a wide social context that goes beyond the physician and patient. In pediatrics, all clinical encounters are seen within the social context of the patient's family or caregivers.

The four areas are present in each case and the clinician is to review these areas in the same order with every case, much like a history and physical examination during a clinical encounter. Once the case has been outlined within these four areas, then the clinician should ask him/herself: What is at issue? Where is the conflict? Is there a prior case similar to this one? How is the present case different from the prior one(s)? This provides a framework to approach a clinical ethical dilemma. However, if after such an analysis, the clinician is still unable to identify and negotiate with the patient/family what the best course of action to take is, a formal ethics consultation may be the next step.

A formal ethics consultation initiates a process where a member who is not part of the ongoing clinical care provides additional expertise and guidance. It is most frequently requested when the medical team and the family disagree about the plan of care. A formal ethics consultation can often involve a multidisciplinary small team who speaks with the various team members, including the patient (when possible) and parents. A nationwide study on ethics consultations showed that this small team model was used by 68% of all ethics consultation services [3]. In many hospitals, the multidisciplinary team usually consists of at least one physician and one non-physician such as a nurse, social-worker, chaplain, child-life specialist or community member. The team usually meets with members of the medical team (either together or individually depending on the situation) and with the patient and parent(s). By meeting with each of these people separately, the ethics team is able to encourage team members to speak openly about their thoughts and state any concerns about issues involved. By meeting with each group separately, the ethics team can serve as a facilitator and a bridge to communication when barriers have been created or trust in one-another destroyed.

In addition, the ethics team has expertise in clinical medical ethics and can offer guidance on what may be an ethically acceptable option(s). Using a methodological system such as the "4 box" or the

CASES approach , the ethics team will create a written ethical analysis that becomes part of the electronic medical record and can be shared with the patient and the family. The ethics consultation opinion usually states a preference for how to proceed in the treatment or care of the patient but is not binding on the physicians and is not a legal opinion.

A similar process is used in Boston Children's Hospital, where a small team of ethics consultants go through the following stages which combines elements of the "4 box" and the CASES approach [13]:

1. Request: Ethics request is made by family, patient or medical team member.
2. Assessment: An ethics team member does an initial intake and decides whether there is a true ethical dilemma where consultation would be helpful. Sometimes the assessment will reveal that the request really is not for an ethics consultation but for clarification of a current policy, or for reassurance that the team is handling the situation properly.
3. Planning: Once the decision is made that an ethics consultation is needed, the small team is assembled. The team reviews the medical records and decides which meetings are needed. They decide whether the ethics team will meet with people individually or in small groups, and/or whether a large group meeting is needed. They may need to meet with each parent separately, or they may decide meeting with them jointly is fine.
4. Meeting(s): The ethics team holds meetings, usually in person, with as many people as needed and learns the different perspectives that the parent(s), patient and medical team members may have.
5. Deliberative: The ethics team deliberates together. During this deliberation it is essential that they identify the ethical questions(s) and provide an opinion. They then provide some options on how the medical care should proceed.
6. Documentation: The entire process is written into a formal ethics consultation note which is placed in the medical record . Copies are also provided to the patient and parent(s). The team offers to

discuss the written opinion with anyone who was involved with the process.

7. Review and evaluation: The ethics team will present the case, process and outcome with the larger ethics committee at subsequent meetings. They will provide updates as the case continues and ask for feedback from the medical team and/or family to see if their input was helpful.

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5 Preventative Ethics Consultations

In many hospitals, ethics walk-rounds where the ethicist speaks with medical staff, nurses and families has been useful to help staff and families discuss ethical issues before they rise to the level of conflict. Another model is to include an ethicist on rounds with the medical team. By teaching ethics in the clinical setting, attendings, residents, medical students, and nurses are exposed regularly to ethics and ideally it become a routine part of their practice to consider ethical issues as part of medical rounds. It may also assist them in articulating the ethical issues that arise and familiarize them with how ethical conflicts may come to acceptable resolutions [14].

Other ethics education within the hospital such as case conferences, ethics grand rounds and ethics resident lectures can also be useful. However, this audience may typically be trainees, who are required to attend, or other medical staff who are a self-selected group already interested in ethics. In contrast, including ethics as part of daily rounds ensures that discussions about ethical issues reach even those who are resistant to having these dialogues. By inserting ethics as an integral part of clinical care, it becomes part of the hospital culture.

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6 Special Consideration in Pediatrics

Pediatric ethics consultation is different than adult ones in many ways. Kon proposes the following differences that must be considered when performing pediatric clinical consultation [15]. There are different

considerations in patients of different ages and developmental stages as to their level of participation in shared decision-making. Those providing clinical ethics consultations for pediatric cases must have expert knowledge in pediatric specific topics, government regulations, statues governing the care of children , seminal cases that affect the care of children, and familiarity with position statements of the American Academy of Pediatrics and other professional organizations. He argues that there are nuances in pediatric ethical analyses including respect for parental autonomy (rather than patient autonomy), differences between informed consent, informed permission and assent, as well as ethical principles that carry significant weight in pediatrics for which there is no adult corollary (i.e. child's right to an open future). Finally, there are meaningful differences when facilitating a family meeting regarding a child patient because "pediatric providers often view themselves as having a significant role in protecting their patient.".

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7 Ethical Conflicts in Pediatric Cardiology and Cardiac Surgery

Presently, the controversial themes that need to be addressed in the field of pediatric cardiology and surgery can be profound and center around the following questions. What to do when the medical team disagrees amongst each other about the medical/surgical options for a baby with CHD [16, 17]? How is the concept of shared decision-making employed when physicians and parents disagree, and when can a family decline cardiac surgery for their child [16, 18]? Are there any extracardiac diseases or syndromes that preclude offering surgical repair of CHD or heart transplant [19–21]? Who should be a candidate for mechanical support and when [18, 22]? Who is a candidate for a fetal cardiac intervention and how should this be determined [23, 24]? How do we ensure high quality care for children with CHD when they transition to adult care [25–27]? How do we promote cardiovascular health and preventive cardiology in children, and what is the responsibility of a pediatric cardiologist in maximizing heart health [28–30]. What is the role of screening with tests such as electrocardiograms for all children or universal genetic testing for all

children with CHD [31–35]? What criteria should be employed in organ allocation for pediatric heart transplantation [19, 36–38]? How can policy impact organizational ethical issues such as transparency, public reporting, and regionalization of care [39, 40].

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8 Case Example 1

Baby Emma is a 2-day old with severe Ebstein anomaly. Her mother was sent for a fetal echocardiogram at 20-weeks' gestation because her level 2 ultrasound detected a possible cardiac anomaly. The first fetal cardiologist she saw made the diagnosis and told her that this type of CHD is so severe (with signs of a circular shunt and poor right ventricular systolic function already) that there was a risk for intrauterine demise. Furthermore, if the fetus made it to delivery, the infant had a very low chance of surviving surgical procedures for a single ventricle palliation. He recommended that she consider terminating the pregnancy, and if not, prepare for likely post-natal palliative care. Emma's mother was heartbroken but also angry at the cardiologist for not giving her any hope that her child may survive. She sought a second opinion from a larger tertiary care center. At this center, the fetal cardiologist agreed with the high-risk nature of the diagnosis but offered some post-natal surgical options . Emma's mother also met with a cardiac surgeon who again presented surgical options but reiterated that they were high risk.

Emma was born at 39 weeks gestational age when her mother went into labor. Shortly after birth she was cyanotic and had poor cardiac output. After a discussion between her mother, cardiologist and cardiac surgeon where all the risks were discussed, Emma proceeded to surgery. She survived surgery and was cared for the in the cardiac intensive care unit (CICU) for several days afterwards where she was her hemodynamics were still tenuous.

On day of life 9, Emma's status worsened and continue to worsen over the course of several hours despite intensive medical management. One of the cardiac surgeons suggested offering another surgical procedure that he thought could potentially be helpful. Another surgeon thought that they should not offer more surgical interventions at this point because he felt sure that the infant would die

while in surgery. The surgeon advocating for surgery planned to discuss the very high risk of mortality with Emma's mother. However, given that her mother had already expressed that she wanted them to "try everything" both surgeons were confident that she would agree to proceed to the operating room if it were offered. An ethics consult was requested at this time by one of the CICU cardiologists who felt that offering the high-risk surgery was unethical given the extremely high likelihood of mortality during the procedure. The conflict was between providers as they disagreed about whether surgery was ethically permissible to offer and therefore, how to counsel Emma's mother with as much transparency and information as possible. The ethics consult team used the Boston Children's Hospital phases :

8.1 Request

The request was made when an attending in the CICU called the hospital ethics committee chair to request a consult.

8.2 Assessment

A brief intake via phone revealed the facts of the case as described above. The person doing the intake agreed that there was an ethical dilemma and that a consultation could be helpful.

8.3 Planning

The ethics consultant decided that the process needed to occur quickly given Emma's declining status. She was able to contact one other member of the ethics team to do the consult with her immediately. The two-member team consisted of one physician and one chaplain. They quickly reviewed Emma's chart and gleaned other pertinent information such as: Emma was her mother's third child. Emma's biological father was not participating in any decision-making and was not a legal guardian. Emma's biological grandmother and aunt had been present at all prenatal meetings and were always at Emma's mother's side. They seemed to provide Emma's mother with emotional support as well help with decision-making.

8.4 Meetings

The ethics team called the CICU and set up individual meetings with the two cardiac surgeons, the CICU attending, and the bedside nurse. These individual meetings occurred over the next 1–2 h. The surgeon who wanted to offer the surgery explained that while he thought it was high-risk, he thought there was some potential benefit. He wanted to offer some chance of survival to Emma and thought that if she could make it through the next procedure, she may have a good chance at long-term recovery. The second surgeon explained that he thought the procedure being offered was "experimental" and that he did not think there was any chance she would survive. He thought he would be causing unnecessary harm and suffering to put Emma through the procedure. The CICU attending and the bedside nurse held similar views as the second surgeon. The CICU attending also expressed that she worried that even if the next procedure went poorly, the surgeon would continue to offer "false hope" to Emma's family and lead them down a pathway where they could not say no to further care.

8.5 Deliberative

The two-member team discussed what they had learned with one another. The mortality risk with the procedure seemed very high, but without the procedure, everyone agreed she would almost certainly die later that night. No one thought she was suffering from any pain currently as she was adequately medicated. In this analysis, the potential benefits of the surgery seemed to outweigh the risks and offering surgery was an ethically acceptable option. Furthermore, if Emma's family wanted to proceed with surgery if presented with the option, doing so would provide respect for Emma's mother's autonomy to make decisions for her child.

The ethics team recommended that the two surgeons and CICU attending speak to Emma's mother and family *together* and explain clearly the risks involved and the poor likelihood of survival. In addition, the ethics team recommended that they share with Emma's mother that given the complexity of this lesion , it is not surprising that the surgeons might have different opinions. The team should involve Emma's mother in shared decision-making while providing guidance and as many known facts as possible. In addition, the ethics team recommended the team clarify with Emma's family what she means by

"try everything" in addition to overall goals of care if additional complications arise. The medical team should plan in advance options that would be offered if complications occurred during the surgery that were life-limiting. They recommended discussing limits of care with Emma's mother in advance the probability of an unsuccessful surgery and when to stop aggressive treatment. Finally, if knowing all the risks, Emma's family decided to proceed with surgery, the ethics consultants thought that this would be an acceptable choice. However, given the high mortality and long-term morbidity for this specific CHD, if Emma's family chose the route of comfort care and no palliative surgery, this would also be an ethically acceptable option. The ethics consultants made these recommendations to the surgeons and CICU physician.

8.6 Documentation

A report that outlined the above was placed in the medical record. Given that the surgery had not yet been offered to Emma's mother for consideration, the ethics consultation was not given to Emma's mother.

8.7 Review and Evaluation

During review of the case several weeks later with the entire ethics committee, some committee members wondered whether the ethics consultant should have also met with Emma's mother to clarify goals. Since the ethics team was asked to address provider conflict, they provided guidance and did not want to undermine the medical team or make the medical/surgery team appear fragmented because they had differing opinions. In addition, the ethics team was able to help with provider-provider conflict and help the physicians navigate the conversation so that Emma's mother had the ability to participate in shared decision-making. Other team members thought that if the ethics team had met with Emma's mother it may have caused her more distress when she was trying to make important decisions for her daughter. Some members of the ethics committee thought that because time was short, not speaking with Emma's family was acceptable. However, if there had been more time, they would certainly recommended meetings with Emma's mother as well to gain a better understanding of the family preferences and goals.

8.8 Case Outcome

The two surgeons and CICU attending spoke to Emma's family together as was recommended. They clarified goals off care with Emma's mother, together conveyed risk and benefits, and emphasized that they would support her in choosing either option of surgery or comfort care. Emma's mother wanted to proceed with surgery and expressed understanding that her daughter may not survive the procedure. The team and Emma's mother decided that if she appeared to be getting worse during surgery, she would be brought back as soon as possible to the CICU so that she could be held by her mother and allowed to die peacefully without additional resuscitation efforts. Emma went to the operating room and her status did decline. The procedure was stopped, and she was brought back to the CICU where she died in her mother's arms. Emma's mother felt thankful to the physicians who had "tried everything" to save her baby and not caused additional suffering when her clinical status declined.

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9 Case Example 2

Jon is a 1-day-old infant with a post-natal diagnosis of D-looped transposition of the great arteries (d-TGA). He was born full term and transferred to the NICU when he was noted to be dusky during this first feeding with his mother. The work-up in the NICU reveals d-TGA and he is promptly started on a prostaglandin infusion. The cardiology fellow explains the diagnosis to Jon's parents at the bedside by drawing pictures and describes the arterial switch operation which is generally performed within the next week. Jon's parents are appropriately shocked and exhausted. The cardiology fellow recommends that they all sit down to talk again the next day, along with the cardiology attending, once Jon's parents have had some time to rest.

The next afternoon, the cardiology attending meets with Jon's parents. When she begins to counsel by drawing the heart as the fellow did overnight, his parents stop her. They ask if they have any other options besides surgery. The attending is confused by their question and asks for clarification. On further inquiry, Jon's parents want to know if they can take him home and choose not to go forward with surgery. The cardiologist explains surgical repair is standard of care for

this lesion in the United States, generally only one surgery is required, and short-term and long-term outcomes are very good. Without surgery, he will die. She states that she will need to call the department of social services if Jon's parents insist that they do not want surgery. Jon's father becomes very angry at the mention of social services and storms out of the room. The cardiologist recommends that they reconvene the next day once Jon's father is willing to return.

Shortly afterwards, the neonatologist hears about the parents' request and calls for an ethics consultation. The ethics intake consultant collects the facts that are presented and agrees to meet with the team and Jon's parents. She does not immediately create a small ethics team for this consultation as she predicts her input may be that of a mediator first.

As an ethics mediator, she first discusses the case with the cardiologist and confirms clinical facts. She understands that the arterial switch operation for d-TGA has a 7-year actuarial survival of 96.3% [41]. Older data shows a 20-year transplant-free survival of ~82% and 97.7% after excluding in-hospital mortality [42]. Very few children need reintervention with reoperation or catheter or intervention [43]. Recent studies show that most children with d-TGA do receive some remedial academic or behavioral services and many also have brain MRI abnormalities but of unknown significance [44]. The mediator learns that within the United States, based on professional consensus, comfort care for this lesion is not generally offered.

The mediator then meets with Jon's parents. They are still angry about their initial meeting with the cardiologist and need to process their anger. They explain that they want what is best for their child and sometimes permitting a child to die is the lesser of two evils. After some gentle prodding, the mediator learns that Jon's father has a niece who was diagnosed with hypoplastic left heart disease who had a stroke after her first surgical procedure (the Norwood operation). She is now 4 years old and has profound neurological delays, has required multiple operations and procedures, and is always in and out of the hospital. The mediator senses that Jon's parents are fearful of a similar outcome for their son. In addition, the mediator learns that Jon's parents have limited resources and no family supports in the area. She wonders if

they may also be worried about the financial implications of surgery and possible long-term expenses.

The mediator sets up a joint session that includes Jon's parents, the cardiology attending and the neonatologist. Sensing that rebuilding trust with this particular cardiologist may be difficult, the mediator also requests that one of the CV surgeons be present to provide surgical data about the arterial switch operation. Finally, she asks that a social worker be available to provide information about what financial supports may be available to Jon's parents. The mediator also offers religious support, but Jon's parents decline.

At the joint session, the mediator introduces herself and explains that her job is to stay impartial. She asks the surgeon to provide information about the arterial switch procedure , including specifics about risks. She asks Jon's parents to share their fears with the group about what could go wrong with the surgery. Jon's parents are reassured and understand that the CHD that Jon has a different risk profile that than of their niece. Through the conversation, it also becomes apparent that Jon's parents think that if something terrible goes wrong with surgery, they will have no choice but to allow the physicians to save their child's life, even if it means he has a grim quality of life. The neonatologist and cardiologist explain that the medical team is always going to work with Jon's parents to help determine what is best for him at every stage of his care. Though unlikely, if he has a terrible complication or significant neurological insult *and* depending on his prognosis and the degree of support he would need, Jon's parents would have decision-making authority to decide what is in the best interest of their child. This may include withdrawing life-sustaining treatment at that time. After everyone was able to give their viewpoints, the mediator asks Jon's parents what they are interested in doing now. They choose surgery.

An important question to address is if Jon's parents had not changed their minds, what would be the obligation of the mediator and the team caring for Jon? In this case, the mediator would have involved a small team of ethicists to conduct an ethical analysis. If they determined that forgoing surgery was not ethically permissible (which would be most likely assessment based on the following: not in the best interest of Jon to decline surgery given the anticipated successful surgical repair, low

mortality, low morbidity, and that the standard of care in the United States is to perform the surgery), the medical team would need to contact the department of social services and potentially hospital administration. Social services would likely take temporary custody and then guardian ad litem would be appointed to make health-care decisions for Jon to consent for surgical correction. The original statement that the cardiologist made in her interaction with Jon's parents about having to call social services was in fact correct, but by using a mediator to clarify goals of care, bridge communication gaps, and educate the family, the team was able to rebuild the relationship with Jon's parents and avoid social services altogether.

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10 Future Directions: Credentialing

The quality of an ethics consultation may vary considerably depending on who is providing the service and how much training or experience they have in ethics. In 2008, the National Working Group for the Clinical Ethics Credentialing Project (CEC Project) was established to address the concern that there is no agreement on the standards for the practice of ethics consultations or qualifications of the consultants, and no reliable measure of the quality and effectiveness of clinical consultations. [34.] This working group developed consensus standards for clinical ethics consultations described below:

- Easy access to CEC for staff, patients and family
- Clear process for information gathering from all stakeholders
- A formal note in the medical record
- A standard format for writing in the chart
- Recognition of clinical ethics consultation as a collaborating service the requires integration and transparency in its functioning
- Institutional and peer oversight
- Ensuring the qualifications and competency of clinical ethics consultants
- Measure for credentialing clinical ethics consultants
- Robust quality improvement process

Almost 10 years after the Working Group published recommendations for promoting high quality ethics consultations, the

ASBH developed a Healthcare Ethic Consultant-Certified (HEC-C) program. This is a certification program to endorse a consultant's knowledge of key ethical concepts. In order to take the exam, the consultant must hold a minimum of a bachelor's degree and have 400 hours of healthcare ethics experience related to specific areas within the past 4 years [45]. The 400 hours may consist of conducting ethics consultations (usually one consult takes many hours), providing ethics teaching sessions, leading staff debriefings of specific cases and reviewing or writing ethics policies. The exam consists of 110 multiple choice questions and a content outline for the exam is available on the ASBH website and the exam was first offered in 2018 when approximately 230 ethics consultants successfully passed and have been certified [45].

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11 Future Directions: Role of National Ethics Database

Given the limited number of formal pediatric ethics consultations that may occur at one specific institution [4] and the even smaller number that may relate to patients with CHD, the need to characterize the types of requested ethics consults is important to understand on a national scale. Multiple registries and national databases exist that quantify mortality and morbidity in patients undergoing surgical repair for congenital heart disease [46, 47]. A similar approach to create a national ethics consultation database is an intriguing proposal.

Various methodologies can be used to characterize ethics consultations. Johnson et al. examined 11 years of pediatric ethics consultations and provided data on the relevant ethical issues encountered at a pediatric academic medical center [48]. They created six broad ethical domains: Level (Quality) of Care, Decision-making, Interpersonal Conflict, Religious/Cultural Issues, Justice, and Professional Responsibility with more specific ethical issues (sub-domains) under each. Antomaria similarly argues for the need to characterize clinical ethics consultations through a robust, generally accepted, typology of ethical issues in order to improve the quality of research on clinical ethics consultation [49]. This may take the form of defining the following: (1) request or demand for, or a refusal of,

treatment, (2) treatment is new or ongoing, (3) type of treatment (e.g., cardiopulmonary resuscitation, mechanical ventilation), (4) reason or justification for the request or refusal (quality of life, likelihood of success, balance of risk and benefit, or religious/ontological), (5) patient's prognosis and/or outcome. Hauschildt, et al. explore the use of an online comment system in ethics consultation and its impact on consensus building and quality assurance. They found that an "online system allows for broad committee participation in consultations and helps improve the quality of clinical ethics consults provided by allowing for substantive discussion and consensus building" and "the use of an online comment system and subsequent records can serve as an educational tool for students, trainees, and ethics committee members" [50].

Any combination of these systems can be applied to ethics consultations for patients with congenital heart disease. Such a database may be important to define the characteristics of ethical conflicts that are occurring such as: (1) what is the specific underlying CHD, (2) who is the conflict between (e.g., parent and providers , between physician, physician and nurse, etc.) (3) what typology was the conflict (e.g., refusal of care, demand for care, emerging technology, etc.), (4) what were the recommendations by the ethics team (e.g., one or multiple options ethically permissible), and (5) what resolution occurred. Such a database can be used for knowledge-sharing, improving patient care and quality, and providing consistency of care across different institutions and regions.

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12 Conclusion

Effective ethics consultation requires a team who are highly skilled and knowledgeable about ethical theory and application of theory to clinical situations. The ethics team needs to have excellent communication and faciliatory skills, and a baseline understanding of medical terms or clinical exposure. Medical and surgery therapies for CHD continue to evolve and will raise ethical questions, many of which are discussed in this chapter. Clinical ethics consultations can be used to support and guide clinicians during this time of rapid advancement in order to serve patients in a thoughtful and deliberate manner.

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Ethics, Justice, and the Province of American Medicine: A Discussion of the Politicalization of the Duty to Care for Pediatric Heart Transplant Patients Who Are in the Country Illegally

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1 Introduction

On Wednesday, September 11th, 2019, Maria Bueso testified before the Oversight and Reform Committee, hoping that Congress would overturn, or, at least, postpone President Trump's decision to terminate the Deferred Medical Action Program which allows her and hundreds of other immigrants to stay in the United States and receive medical treatment that is not available in their home countries. Fifteen years earlier, Maria's family traveled to the United States after she was invited to participate in a medical trial at the University of California-San

Francisco (UCSF) for people with Mucopolysaccharidosis VI (MPS-6) . Fortunately, the UCSF medical trial was successful, and the researchers were able to develop a treatment that helps people with MPS-6 live longer and healthier lives. Maria has been living in the U.S. since arriving here fifteen years ago with her family, and she is receiving treatment for MPS-6 currently. However, after the Trump Administration ended the Deferred Medical Action Program, Maria received a letter from the United States Citizenship and Immigration Service (USCIS) ordering her to leave the country or face deportation. Even worse, hundreds of immigrants are in a similar situation. So, when Maria arrived on Capitol Hill and testified before the United States Congress, she was speaking for them all, at least, symbolically.

Of course, Maria Bueso is not the first immigrant to find herself caught in the cross-section between law and justice. Indeed, in 2003, Jesica Santillan's case was thrust into the center of a national debate about whether or not undocumented immigrants ought to be eligible to receive organ transplants. This controversy began when Jesica was diagnosed with cardiomyopathy and nonreactive pulmonary hypertension, and the medical team at Duke University Medical Center mistakenly transplanted incompatible organs, a heart and lungs, into her body. Not surprisingly, her body rejected the incompatible organs and she was placed on life support. Shortly thereafter, the medical team at Duke UMC located a second set of organs and performed a second transplant in an attempt to save her life. But, unfortunately, the damage had already been done. Jesica succumbed to her illnesses and complications from the initial transplant surgery on February 22nd, 2003.

However, even in death Jesica was in the spotlight. Her case gave rise to criticisms from conservatives who saw her family as free-riders who snuck into the country for the purpose of gaining access to America's organ transplant system . Those who articulated this position argued that Jesica gained access to America's organ network unjustly because she had not contributed to the organ transplant pool [1]. Others argued that, the question of whether or not Jesica is a free-rider is irrelevant, no foreign national ought to have access to organ transplants (or any other scarce medical resource) because they are not citizens of the United States [1]. Still, others took a more practical

approach, arguing that the United States simply does not have the money to pay for transplants for immigrants [2] and that, if we continue to do so, we will become a transplant destination for immigrants who cannot afford to pay for transplants in their home countries. This, they concluded, will bankrupt our medical system [1].

In what follows, I offer ethical analyses of the cases of Maria Bueso and Jesica Santillan (foreign nationals who accessed America's healthcare system) for the purpose of investigating the providence of American medicine and morality in cases where law and justice are in conflict. First, I consider the Trump Administration's decision to terminate the Deferred Medical Action Program . Here, I argue that, while the Administration has the legal authority to terminate the program, the decision to do so runs afoul of the moral standards of both Christian and Enlightenment ethics , and therefore, it is unjust. Secondly, I investigate whether or not there are just reasons for restricting the access of immigrants to organ transplants and other scarce medical resources. Ultimately, I determine that such restrictions are only justified in limited circumstances. More than this, I argue that all people have a human right to life and that U.S. politicians have recognized this in political and legal documents like the *Declaration of Independence*, the *International Covenant on Civil and Political Rights*, and the *Emergency Medical and Treatment Labor Act*. For these reasons, I conclude that, while politicians may pass laws and issue edicts that restrict immigrants' access to healthcare, it is almost always unjust for them to do so.

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2 Seeking Solace

2.1 Law, Justice, and Access to Organ Transplants and Other Scarce Medical Resources

The stereotype of undocumented immigrants crossing the border as "lawless outsiders, using up precious resources intended for Americans," is prevalent in the United States [3], especially in light of the fact that President Donald Trump routinely fans the flames of xenophobia at his political rallies. He has even gone so far as to describe undocumented immigrants as an "infestation" [4]. More importantly, Trump often ends his political speeches with the promise to terminate

the policies that allow immigrants to access medical services in the United States. Unfortunately, however, this time he has kept his promise. On August 29th, 2019, Miriam Jordan and Caitlin Dickerson published an article in the *New York Times* entitled "Sick Migrants Undergoing Lifesaving Care Can Now Be Deported," detailing some of the consequences of the Trump Administration's decision to terminate the Deferred Medical Action Program [5]. In short, the Deferred Medical Action Program allows immigrants to remain in the country illegally while they receive lifesaving medical treatment that is not available in their countries of origin. Shortly after the Administration terminated the program, undocumented immigrants living in the U.S. under the auspicious of the Deferred Medical Action Program begin receiving letters from the U.S. Citizenship and Immigration Services Division of the U.S. Department of Homeland Security informing them that they must leave the country voluntarily or face deportation. The letters read, in part,

> The evidence of record shows that, when you submitted your request, you were present in the United States contrary to law. You are not authorized to remain in the United States. If you fail to depart from the United States within 33 days from the date of this letter, USCIS may issue you a Notice to Appear and commence removal proceedings against you within the immigration court. This may result in your being removed from the United States and found ineligible for a future visa or other immigration benefits. See section 237(a) and 212(a) (9) of the INA [6].

Surprisingly, the Administration's decision came without warning, explanation, or prior notification to the families, doctors, or attorneys of those receiving medical treatment. Of course, the effects of the Administration's decision are that the families have little time to appeal the decision or to make the preparations necessary for moving their sick loved ones to a country that has doctors with the medical expertise to treat them. Nevertheless, as one might have expected, many Americans are outraged by what seems to be wanton cruelty to the most vulnerable members of our society, i.e. the sick. For example,

former Vice President Joe Biden criticized the Administration for "targeting the sick" [7]; U.S. Senator Ed Markey called the Administration's decision "unconscionable" [8]; and more than one hundred members of Congress have denounced the decision as "abandoning the longstanding practice" of allowing sick immigrants to seek "humanitarian relief" in the United States [9].

Nevertheless, on Wednesday, September 11th, 2019, Maria Bueso testified before the Congressional Oversight and Reform Committee on behalf of herself and hundreds of other immigrants who have received similar letters, hoping to convince Congress to stop or, at least, delay the decision from going into effect. So far, Congress has not attempted to stop or delay the decision. Instead, human rights organizations, like the American Civil Liberties Union of Massachusetts and the Irish International Immigrant Center, have launched lawsuits against the Administration, alleging that it "provided no opportunity for notice-and-comment, or any other procedural protection that is required under the Administrative Procedures Act, (APA) ," and that the real reason it terminated the program is its "anti-immigrant agenda that is driven by racial and ethnic animus" [10]. For these reasons, the American Civil Liberties Union of Massachusetts and the Irish International Immigrant Center have accused the Administration of violating the APA and the 14th Amendment to the United States Constitution [10].

However, even if this lawsuit is heard in court, the plaintiffs would have only succeeded in prolonging the inevitable. After all, the Deferred Medical Action Program falls under the purview of the United States Customs and Immigration Services, which, in turn, is a division of the Department of Homeland Security (DHS) . Since the DHS falls under the purview of the Executive Branch of the U.S. government, and since President Trump is the Chief Executive Officer, ultimately, President Trump has the authority to maintain or terminate DHS policies. Consequently, the only way to change this political dynamic is for Congress to pass a bill allowing undocumented immigrants to stay in the country while they are receiving medical treatment. But, of course, this is not likely to happen. After all, Republicans are in the majority in the Senate, and they are unlikely to pass such a bill. Even if they did, President Trump would simply veto it. In turn, Congress would have to

override his veto, which, again, is unlikely. Hence, it seems that President Trump has the legal authority to terminate the Deferred Medical Action Program .

Still, his decision to do so runs afoul of both Christian and Enlightenment ethics , and, for this reason, it is unjust. To be sure, Jesus's *Golden Rule* requires Christians to "Do unto others as you would have them do unto you" [11]. Few, if any, Christians would want to be forced to leave a country in which they or their loved ones are receiving lifesaving medical treatment to go to a country where the medical treatment is not available. Moreover, when Jesus was asked by his disciples, "which is the greatest principle in the law?" he replied: "Thou shalt love the Lord thy God with all thy heart, and with all thy soul, and with all thy mind" [11]. He continued: "And the second principle is like unto the first one, Thou shalt love thy neighbor as thyself" [11]. Surely, few, if any, Christians would want the Administration's decision to apply to them or their loved ones. Hence, by Jesus's *Golden Rule* and second principle, Christians ought not to want the Administration's decision to apply to their neighbors, regardless of their neighbor's residency status. For these reasons, the Administration's decision to end the Deferred Medical Action Program is unjust by Christian ethical standards.

Enlightenment ethics lead us to a similar conclusion. For example, in the *Grounding for the Metaphysics of Morals*, Immanuel Kant tells us that the *Categorical Imperative* requires Deontologists (rational agents who have the capacity of acting according to duties) to "Act only according to that maxim whereby you can at the same time will that it should become a universal law" [12]. Rational agents would not will that the Administration's decision should become a universal law because it would result in hundreds of deaths from manageable diseases, and rational agents would not want to die from manageable diseases. This is evidenced by the facts that humans have established public hospitals, medical schools, and medical facilities like the Center for Disease Control; allow the federal government to allocate billions of tax payer dollars to medical research every year; encourage people to participate in clinical trials; and require all children to be vaccinated before they enter public schools. In short, rational agents engage in these practices precisely because they do not want to die from diseases that are preventable, manageable, or curable. Hence, for these reasons,

the Administration's decision to end the Deferred Medical Action Program is unjust by Kantian ethical standards.

Likewise, utilitarianism leads us to a similar conclusion. For example, in *On Utilitarianism*, John Stuart Mill articulates the *Greatest Happiness Principle*. He tells us that "actions are right in proportion as they tend to promote happiness, wrong as they tend to produce the reverse of happiness" [13]. First, it is important to notice that Mill was not arguing for maximizing pleasure for the majority of people. Certainly not, for such a position is susceptible to the obvious objection that, historically, all kinds of evils against minority groups have been "justified" in the name of maximizing pleasure for those in the majority: slavery, the oppression of women, and so on. Mill, however, was a staunch proponent of liberty and equality for minority groups [14]. In fact, when Mill was a Member of Parliament, he took up the causes of liberty for emancipated African Caribbeans in the West Indies, and suffrage for women [15].

Secondly, in Chap. 5 of *On Utilitarianism*, Mill argues that actions are justified insofar as they accord with social policies, i.e. rules of justice, which maximize the greatest amount of happiness for everyone in the long-term. For example, according to Mill, the rule that "it is unjust to break faith" is a social rule that maximizes happiness for everyone in the long run [13]. In light of this, it is easy to see that the Administration's decision runs afoul of Mill's rule utilitarianism . After all, many undocumented immigrants were promised that they could stay in the U.S. and receive medical treatment that is not available in their countries. Hence, for Mill, given that promise-keeping maximizes happiness for everyone in the long-run and that the Administration's recent decision breaks America's promise, the Administration's decision to end the Deferred Medical Action Program is unjust according to Mill's ethical standards.

2.2 The Province of American Medicine and Morality

Of course, Maria Bueso was not the first immigrant to find herself caught in the cross-section between law and justice. To be sure, at the turn of the new millennium, Magdelena Santillan and her boyfriend, Melecio Huerta, paid a coyote (a colloquialism for a human trafficker who smuggles people between the United States and Mexico) to

smuggle them and Magdelena's three children into the United States from Mexico. As is always the case with a coyote lead, illegal border crossing into the United States, the journey was arduous, particularly for Magdelena's sick child , Yesica Santillan, but Magdelena and Melecio felt that they had no other option because the U.S.'s "immigration laws prevented Jesica from entering the country legally, and from receiving a humanitarian parole," so Magdelena and Melecio decided to take the chance [2]. They managed to elude border patrol agents, and to avoid serious bodily harm and death along the way. They arrived in the United States sometime in the year 2000, and settled in the city of Louisburg, North Carolina. Three years later, Yesica Santillan (who goes by Jesica) was hospitalized at Duke University Medical Center with a restrictive cardiomyopathy and nonreactive pulmonary hypertension . Of course, this is a serious, life-threatening medical condition. To treat it, the doctors at Duke Medical Center recommended that Jesica have a heart and lungs transplant.

The rules of the organization responsible for managing organ transplants in the United States, the United Network of Organ Sharing, does not prevent undocumented immigrants from receiving transplants [2]. More importantly, Jesica's medical team was able to locate a heart and lungs quickly, so she underwent the transplant surgery on February 7th, 2003. Ordinarily, a heart and lungs transplant is followed by a recovery period, prescription medicines, and follow-up visits to the hospital, but, in Jesica's case, a serious medical mistake changed everything. Somehow the medical team failed to notice that Jesica's blood type was O-Positive and the organs they transplanted into her body were type A. The mix-matched blood types triggered an incompatibility response in Jesica's immune system , and her body rejected the organs. As a result, Jesica was again in serious medical jeopardy, and she needed another heart and lungs transplant in order to survive. Remarkably, her medical team managed to locate a second set of organs and Jessica underwent another heart and lungs transplant on February 20th, 2003. Unfortunately, however, Jesica succumbed to her illnesses and complications from the initial transplant surgery two days later. She died on February 22nd, 2003.

However, even in death Jesica was in the spotlight. Her story generated a great deal of controversy in the United States. For example,

in “America’s Angel or Thieving Immigrant?,” Susan Morgan et al explained that “a great deal of animus centered on claims of theft—or (as articulated by one college newspaper) that Jesica came into our country and took organs of not one, but two people, that could have gone to more deserving Americans” [3]. In many ways, the news media helped to create the image of the Santillan family as undocumented free-riders because the coverage portrayed them “as adrift, confused, weak, easily influenced,” and dependent on social services, which, of course, was not the case. Jesica’s medical bills were paid for by private donors [3]. Of course, the free-rider objection is a common criticism of policies that allow undocumented immigrants to access medical services, particularly organ transplants, in the United States. Those who articulate this objection argue that “foreign nationals who receive organ transplants” benefit unjustly from the U.S.’s organ transplant network because they do not contribute to the organ donor pool [1]. They conclude that, since immigrants do not contribute to the organ pool, the principle of fairness requires us to prohibit immigrants from receiving organ transplants in the United States [1].

There are serious problems with the free-rider objection. Firstly, it rests on a claim that is straightforwardly false. After all, some immigrants are “living organ donors ” and others are “deceased organ donors” [1]. In fact, “a review of the data in the US… reveals that 0.3% of all deceased donors were foreign nationals” [1]. Hence, contrary to what those who articulate the free-rider objection would have us believe, some immigrants do, in fact, contribute to the organ donor pool. Secondly, Americans who are not organ donors are nevertheless eligible for organ transplants. After all, being an organ donor is not a pre-requisite for receiving an organ transplant; nor should it be. For, such a policy would allow medical professionals to discriminate against some of their patients based on medically arbitrary criteria, like nationality. Moreover, given the history of discrimination in the U.S. it would be prudent for medical professionals to avoid establishing such a policy. For example,

> From 1945 to 1956, physicians, researchers, and other employees and agents of Johns Hopkins, The Rockefeller Foundation, and Bristol-Myers Squibb designed, developed,

> approved, encouraged, directed, oversaw, and aided and abetted nonconsensual, nontherapeutic, human subject experiments in Guatemala in which mentally ill patients confined to asylums, soldiers, prison inmates, orphans, and school children were intentionally exposed to and infected with syphilis and other diseases [16].

Of course, this case reminds us of the infamous Tuskegee Syphilis Experiment . Like the Tuskegee experiment, the Guatemalan Syphilis Experiment was only terminated when someone discovered what was happening and exposed it in the press [16]. For these reasons, medical professionals in the United States should only use medically relevant criteria, like medical need, organ compatibility, and the efficacy of the procedure, in deciding who should receive organ transplants. Recently, American organ transplant organizations have accepted a similar position. For example, the Organ Procurement and Transplantation Network has a non-discrimination policy which states that "deceased donor organ allocation will not differ on the basis of a candidate's citizenship or residency status" [1].

Those who are sympathetic to the Administration's position might concede that immigrants like Jesica and Maria are not free-riders—because their medical bills were paid for privately—but nevertheless argue that they ought not to have access to organ transplants and other scarce resources because they are not citizens of the United States. Those who articulated this position believe that citizenship confers a special status on people such that, when they become citizens, they gain "the right to vote as well as access to certain collective, scarce resources" that are controlled by the state [1]. They argue that since human organs and many other scarce resources are controlled by the state, "citizenship ought to be a necessary condition for having access to such resources [1]. They conclude that, although Jesica, Maria, and many other immigrants are not free-riders, they ought not to be allowed to have organ transplants or other treatments that require scarce resources because they are not citizens of the United States.

Of course, it is true that citizenship confers certain rights and privileges on Americans. For example, citizens of the United States have the right to vote, the right to run for public office, the privilege of being

appointed to a public office, the privilege of having the immunities associated with holding certain public offices (diplomatic immunity for example), and so on. Notice, however, that the rights and privileges that one gains as a result of being a citizen of the United States relate to the exercise of one's political liberty or the functioning of the democracy. For this reason, citizenship is a legitimate criterion for gaining access to political rights and privileges. By contrast, organ transplantation is a medical treatment. It does not concern the exercise of one's political liberty, or the functioning of the state. For this reason, citizenship is not a legitimate criterion for gaining access to an organ transplant. In fact, the only legitimate criteria for receiving an organ transplant are medical need, organ compatibility, and the efficacy of the procedure. If foreign naturals meet these criteria, then they ought to be eligible to receive organ transplants.

To justify my claim that if immigrants meet the above medical criteria then they ought to be eligible for organ transplants we need to turn to a discussion of natural rights. In the *Second Treatise of Civil Government*, John Locke tells us that all people have a natural right to life [17]. In order to protect this natural right, in the *First Treatise of Government*, Locke argues us that

> God hath not left one man so to the mercy of another that he may starve him if he please; God the Lord and Father of all, has given no one of his children such a property in his peculiar portion of the things of this world, but that he has given his needy brother a right to the surplusage of his goods; so that it cannot justly be denied him, when his pressing wants call for it: and therefore, no man can ever have a just power over the life of another by right of property in land or possessions; since it will always be a sin, in any man of estate, to let his brother parish for want of affording him relief out of his plenty [18].

Of course, here, Locke is referring to food, but his position applies equally to the other necessities of life, like medical care.

More importantly, however, the natural right to life has been articulated in many political documents in the United States. For example, in the *Declaration of Independence* , Thomas Jefferson writes:

"We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty, and the pursuit of Happiness" [19]. Notice that Jefferson is speaking broadly about the rights of all. Also, notice that the rights to which he refers come from a natural source, not the state. Additionally, the *International Covenant on Civil and Political Rights* tell us that "every human being has the inherent right to life" [20]. The U.S. ratified the Convenant on Civil and Political Rights in 1992. More importantly, U.S. politicians provided explicit medical protections for the natural right to life by creating a legal duty for all hospitals to care for every patient who comes into the emergency room. To be sure, in 1986, Congress passed the *Emergency Medical and Treatment Labor Act* which prohibits public and private hospitals from refusing to treat a patient on the bases of his/her ability to pay, residency status, or for any other reason.

Now that hospitals have a fiduciary duty of care some politicians have been attempting to bring hospitals into the fight against illegal immigration. For example, in 2004, Republican Congressmen Dana Rohrabacher introduced a bill which would have required all hospitals to report all undocumented patients to the Immigration and Nationalizations Service for deportation after they received medical treatment [2]. He complained that "we cannot provide medical care for our senior citizens… how is it that we can provide $1 billion dollars to treat illegal immigrants" [2]. Nevertheless, Rohrabacher's bill was defeated by a vote of 331 to 88 [2]. Shortly thereafter, "the Centers for Medicare and Medicaid Services announced that hospitals would not be required to ask patients about their immigration status in order to be eligible for federal funds" [2]. Of course, this is the just position because hospitals are medical treatment centers not policing agencies. Therefore, it is unjust to require them to do the work of policing agencies, especially since Rohrabacher's bill did not give them the personnel, training, or the monetary resources to carry-out policing work. More importantly, however, the creation of the *Emergency Medical and Treatment Labor Act* demonstrates that, like John Locke, Americans believe that hospitals ought to have a fiduciary duty to protect the natural right to life of everyone, regardless of their residency status.

Lastly, in fairness, Rohrabacher's bill was motivated by two worries: that the United States does not have the money to pay for transplants for undocumented immigrants, and that the United States will become a transplant destination for immigrants who cannot afford to pay for transplants in their home countries. First, if it is true that the United States cannot afford to pay for transplants for undocumented immigrants, then, of course, the U.S. cannot be morally blameworthy for refusing to do so. After all, as Immanuel Kant teaches us in *Religion within the Boundaries of Mere Reason*, every moral obligation implies that the moral agent in question can fulfill the obligation. Or, as it is more often put, ought implies can [21]. Hence, if it is not possible for the agent to fulfill his/her duty, then he/she cannot be held responsible for failing to do so. In which case, if the U.S. cannot afford to pay for transplants for undocumented immigrants then it does not act unjust for refusing to do so.

However, given that Congress passed the *Tax Cuts and Jobs Act* recently, from which the "richest 1 percent received 9.3 percent of the total tax cuts, the top 5 percent got 26.5 percent, the top quintile received 52.2 percent" [22], and a 3.3 percent tax cuts went to the bottom quintile [22], it seem disingenuous to argue that the United States does not have the money to cover transplants for undocumented immigrants. In fact, the Joint Committee on Taxation concluded that the tax cuts will add 1.5 trillion dollars to the deficit [23], and the U.S. Treasury Department concluded that the tax cuts will add 2.3 trillion dollars to the deficit [24]. Either way, ending the Trump tax cuts for the rich would provide billions of dollars for medical services, which could include organ transplants for foreign nationals.

Secondly, it seems unlikely that the United States will become a transplantation destination for undocumented immigrants in need of organ transplants. For, the data does not support such a conclusion. For example, a "2005 study found that only 0.9% of patients on the kidney waiting list" were foreign nationals and that only "1.5% of the patients on the liver waiting list were" foreign nationals [1]. Moreover, since the Organ Procurement and Transplantation Network and the United Network for Organ Sharing adopted its nondiscrimination policies , "the data show that less than 1% of new deceased donor waitlist additions and less than 1% of transplantation recipients were non-US

citizen/nonresidents candidates who traveled to the United States for purposes of transplantation" [25].

3 Conclusion

In this article, I have offered philosophical analyses of the cases of Maria Bueso and Jesica Santillan for the purpose of investigating the providence of American medicine and morality in cases where law and justice conflict. First, I have considered the Trump Administration's decision to terminate the Deferred Medical Action Program. I have argued that, while the Administration's decision is legal, it runs afoul of the moral standards of both Christian and Enlightenment ethics, and therefore, it is unjust. Secondly, I have investigated whether or not there are sound reasons for restricting the access of immigrants to organ transplants and scarce medical resources. I have determined that there are not. Lastly, I have argued that all people have a human right to life and that U.S. politicians have recognized this right in important political and legal documents like the *Declaration of Independence*, the *International Covenant on Civil and Political Rights*, and the *Emergency Medical and Treatment Labor Act*. For this reason, I have concluded that, while politicians may pass laws or edicts that restrict immigrants' access to healthcare, it is nevertheless unjust for them to do so.

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The Unintended Consequences of Public Reporting

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1 Background

Centuries ago, doctors treated patients with whatever took their fancy. Therapies like blood-letting, leeches and mercury as well as unnecessary and harmful surgery were inflicted upon patients without a shred of evidence that such medicine did any good. Times have changed, and the last hundred years or so have seen the rise of evidence-based medicine , so that in the current era we would not dream of embarking on a course of treatment unless there was real evidence that such treatment actually works and will benefit the patient. The next step in this evolution was to ask the question: now that we know what the right treatment is, are we delivering it well? The answer to this question came from outcome data. Such data were first used by responsible health care providers to monitor the quality of their service, but the mere presence of the data, together with freedom-of-information legislation and the occasional medical scandal, produced demands that the data be made public. Adult cardiac surgery was a reluctant leader in this field, with the first publication of outcome data

for coronary artery bypass grafting appearing in New York in 1989. In the United Kingdom, a scandal of poor outcomes in Bristol *pediatric* cardiac surger y in the 1990s led, paradoxically, to demands for and, subsequently, the implementation of publishing the outcome data of *adult* cardiac surgery. These are now available to the public on-line, by surgeon and by institution (www.scts.org). Similar initiatives have led to the publication of cardiac surgical outcomes in the United States (https://publicreporting.sts.org), and many other advanced nations are looking to publishing outcomes with varying degrees of success (and even more varying degrees of engagement by the professionals).

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2 Why Publish Outcomes?

On the face of it, this is an easy question to answer. The quality of delivery of medical care is a very important metric. Without it, it is impossible to highlight good practice in order to learn from it or to identify underperformance in order to correct it. Measuring clinical performance should be an integral part of good medical care and this author believes that any practitioner who knows not what his or her practice is achieving and how good (or bad) that achievement actually is in comparison with established benchmarks has no business practising medicine. I also believe, though it is hard to prove, that there is a *Hawthorne Effect* [1] in medical care: the mere measurement of outcomes is very likely to improve results without any further intervention being necessary [2]. We therefore owe it to our patients and to our professional standards to measure what we do, confirm that our results are good enough and act immediately if they are not. The publication of outcomes, however, is another matter.

On a superficial, level, there is everything to be gained by publishing outcomes. Disseminating knowledge about the performance of health care providers has many advantages :

- It helps patient choice and contributes to fully informed consent.
- It acts an encouragement and reward for those who do well and as a spur for those who do not do well to improve their service.
- It provides the ability to compare outcomes between institutions and between individual practitioners, thus opening the possibility of intervention by responsible agencies when outcomes are inadequate.

- By supporting the spirit of transparency, it helps increase patient confidence in medical services.

What is surprising, however, is that the publication of outcomes has produced unexpected negative consequences. These have had an impact on patients and doctors alike and arise out of a number of factors which will be discussed below.

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3 The Imperfection of Reporting

When published outcomes are compared , it is important that like is compared with like. Comparing procedure-related mortality is rarely good enough to establish whether a lower mortality achieved by one provider is actually better than a higher one achieved by another. This is because procedure-related mortality takes no account of the risk profile of the populations studied. In adult cardiac surgery, this problem has been (largely) dealt with by established and validated risk models, such as EuroSCORE [3] and the STS [4, 5] risk models for general cardiac surgery. The models provide a predicted risk-adjusted outcome benchmark against which individual performances can be measured. Even with that, no risk model is perfect and caution should be used when groups of patients with rare or unaccounted-for risk factors are being studied. By and large, however, these risk models apply well in a large datasets of mixed general adult cardiac surgery. In pediatric cardiac surgery, the issue is more problematic. Attempts have been made to risk-stratify pediatric cardiac surgery and there are some models available (RACHS1 [6], the Aristotle complexity score [7], the STS-EACTS Congenital Cardiac Surgery Mortality categories and others), but none have achieved the widespread acceptance of the adult models and all are challenged by the sheer volume and diversity of congenital cardiac conditions. Further difficulties arise when attempting to classify a rare congenital heart problem that may include prominent features of several syndromes which may overlap. Such classification can be sometimes subjective and open to manipulation or gaming. A pediatric cardiac surgeon once cynically defined double outlet right ventricle as a ‘dead Fallot’. These challenges, however, need not be insurmountable and it should be possible, with a determined effort, to reach consensus on a pediatric cardiac surgery risk model that

is easy to use, clinically credible and reasonably accurate for the great majority of procedures.

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4 Gaming by Category Shift

Let us say that you are choosing whether surgeon A or surgeon B will perform your coronary artery bypass graft (CABG) operation and you check their mortality data: surgeon A has a CABG mortality of 1.25%, and surgeon B has a CABG mortality of 2.08%—nearly double that of surgeon A. You would of course choose surgeon A, but you could, in fact, be making a very big mistake, even if both surgeons deal with patients of a similar risk profile. There are a few things about surgeons A and B that do not appear in the figures. Surgeon B is an ordinary person, with a Type B personality. He drives an ageing Saab, is a little obsessive about safety, hates taking risks, and practises medicine on the basis of scientific evidence. Surgeon A, however, has a Type A personality. He drives a Ferrari, cuts corners in the operating theatre as on the road, likes to take risks in his own life and with the lives of his patients, and believes that evidence-based medicine is like painting by numbers—all right for pedestrian artists, but not for him , the self-styled Leonardo da Vinci of the art of surgery. Furthermore, he is getting a little bored with CABG as a blandly predictable, bread-and-butter operation, and wants to explore new ways of treating his patients. So we now have a mental picture of surgeon B as a solid citizen and surgeon A as a cavalier risk-taker. But, I hear you say, despite all that, surgeon A's CABG mortality is definitely lower, and that is surely a good thing. In fact, it is not.

Assume that last year, two lots of 100 identically matched CABG patients were referred for surgery, 100 to each of the two surgeons. This is how the patients are in each of the identical groups:

- All 100 have *triple-vessel coronary-artery* disease and need a triple CABG.
- *Eighty* have good ventricles and are low-risk patients.
- *Sixteen* have a poor left ventricle due to previous myocardial infarction, with a stable fibrotic scar on the heart, and are medium-risk patients.
- *Four* have a poor left ventricle due to previous myocardial infarction and an expanding left ventricular aneurysm. They are high-risk

patients.

Both surgeons do exactly the same for the 80 low-risk patients : a triple CABG. The mortality in this group is expected to be low. Seventy-nine of the 80 patients sail through the operation without a hitch. One unfortunate patient dies as a result of the operation.

Both surgeons do exactly the same for the four truly high-risk patients: a triple CABG and aneurysmectomy. This is a dangerous surgery: one patient out of the four dies as a result, and the other three do well.

In the medium-risk group of 16 patients, surgeon B does a triple CABG, which is all they needed. One dies and 15 survive. Surgeon A, however, gets excited about the scar on the heart. He imagines it to be an aneurysm. He is getting bored with just doing CABG and wants some variety in his professional life. He fancies a challenge and happens to be feeling somewhat overconfident at the time. He decides to cut out the scar, call this additional procedure an aneurysmectomy, and then reshape the heart to make it work better. In this group, surgeon A has three deaths: the one that was expected, plus two more due to the bleeding and arrhythmia problems that arose directly as a result of the unnecessary intervention on an 'aneurysm' that wasn't really there.

Each of the two surgeons has now completed the 100 operations. Surgeon B has three deaths, and surgeon A has five. They submit their results to the auditors, and this is what is published:

Simple Operation (the Benchmark Procedure): CABG on Its Own

- Surgeon B: two deaths out of 96 = 2.08%
- Surgeon A: one death out of 80 = 1.25%

Complex Operation: CABG Plus Aneurysmectomy

- Surgeon B: one death out of 4 = 25%
- Surgeon A: four deaths out of 20 = 20%

In both sets of figures, the surgeon with more deaths has a lower procedural mortality! This is simply the numerical manifestation of classifying the middle risk group (or grey area) as high risk: it improves the results of both the low risk and high risk groups. The above

example shows one rather extreme consequence of 'category shift', and it is a phenomenon that comes into play especially when outcomes are published. I have tried to gauge the prevalence of such behaviour in the United Kingdom by conducting an anonymous online survey of all cardiac surgeons. This was the question I asked my fellow surgeons:

It is possible for a cardiac surgeon to modify the appearance of surgeon-specific outcomes by using 'category shift'. For example, in a CABG, adding a few stitches to the left ventricle and calling the operation CABG + aneurysmectomy, or a couple of stitches to the tricuspid valve to add tricuspid valve repair, or excising a sliver of aorta in an aortic valve replacement (AVR) to call it AVR and aortoplasty, or ascending aortic repair. There are others examples. The net result is that an operation is shifted from a lower risk category to a higher risk category. Have you ever done this?

Their answers are illustrated in Fig. 1.

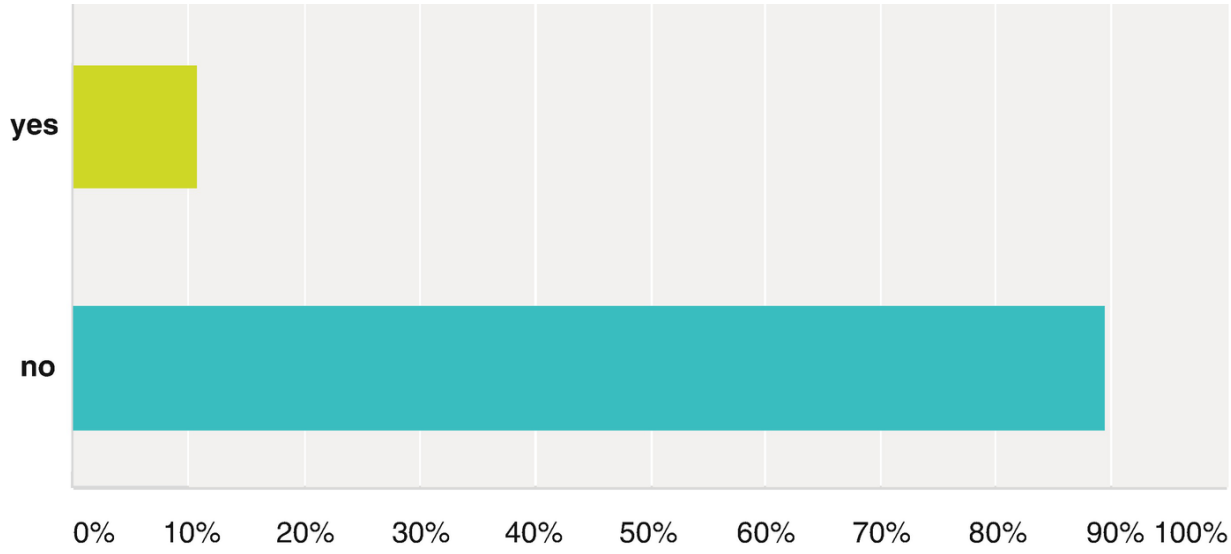

Fig. 1 Surgeons' responses to whether they practise category shift. (First published in Samer Nashef's THE NAKED SURGEON (Scribe, London and Melbourne 2015), reprinted with permission)

The next question was: 'are you aware of other surgeons doing this?' and the responses are in Fig. 2.

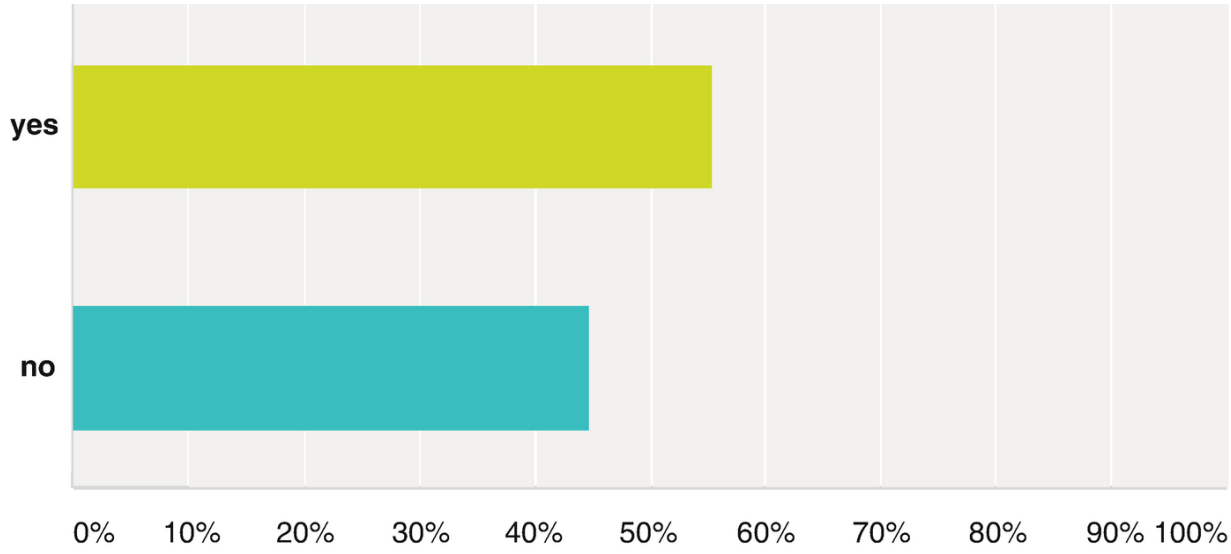

Fig. 2 Surgeons' responses to question about awareness of other surgeons practising category shift. (First published in Samer Nashef's THE NAKED SURGEON (Scribe, London and Melbourne 2015), reprinted with permission)

Of the 115 surgeons who responded, 12 (or just over 10%) admitted to having deliberately practised category shift themselves, and more than half (55%) stated that they were aware of other surgeons doing so. The result of category shift is a combination of damage to patients and unintentional muddying of the waters in the data pool, and the questionnaire findings illustrate that surgeons are aware of this gaming method and that at least some of them will use it to make their figures look better. Publishing outcome figures can only increase such behavior.

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5 Inappropriate Risk Aversion

Patients can be damaged by commission, such as in category shift above, but they can also be damaged by omission, and an even greater risk to the patient arising from the publication of outcomes is when surgeons start to run away from high-risk surgery. High-risk surgery is performed for high-risk conditions, and being denied a high-risk operation because a surgeon is worried about his or her published figures may not be in the interests of the patient. In an effort to determine whether the publication of outcomes has had such an effect

in the United Kingdom, I again surveyed my colleagues, requesting an anonymous reply to a simple question which was the following:

'A high-risk operation may be beneficial to a particular patient. Despite this, a cardiac surgeon may decide not to offer that option to the patient, and recommends continuing medical treatment. This is partly or wholly because of concern about the impact on that surgeon's figures should the patient opt for surgery and then succumb. Have you ever done this?' The responses are in Fig. 3.

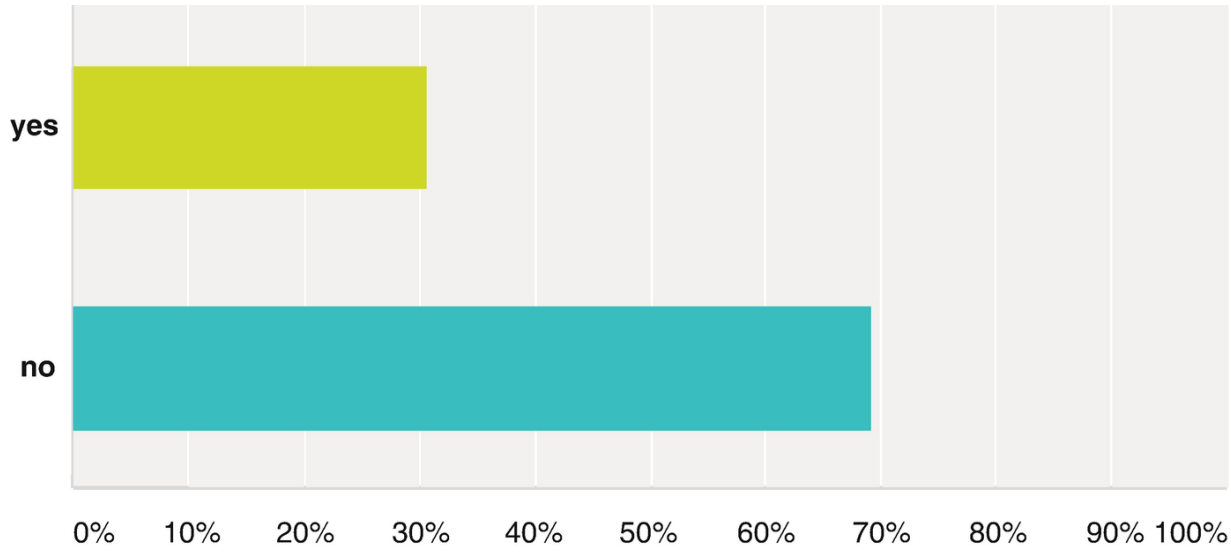

Fig. 3 Surgeons' responses about whether they practise inappropriate risk-averse behavior. (First published in Samer Nashef's THE NAKED SURGEON (Scribe, London and Melbourne 2015), reprinted with permission)

The next question asked: 'are you aware of other surgeons doing this?' and the responses are in Fig. 4.

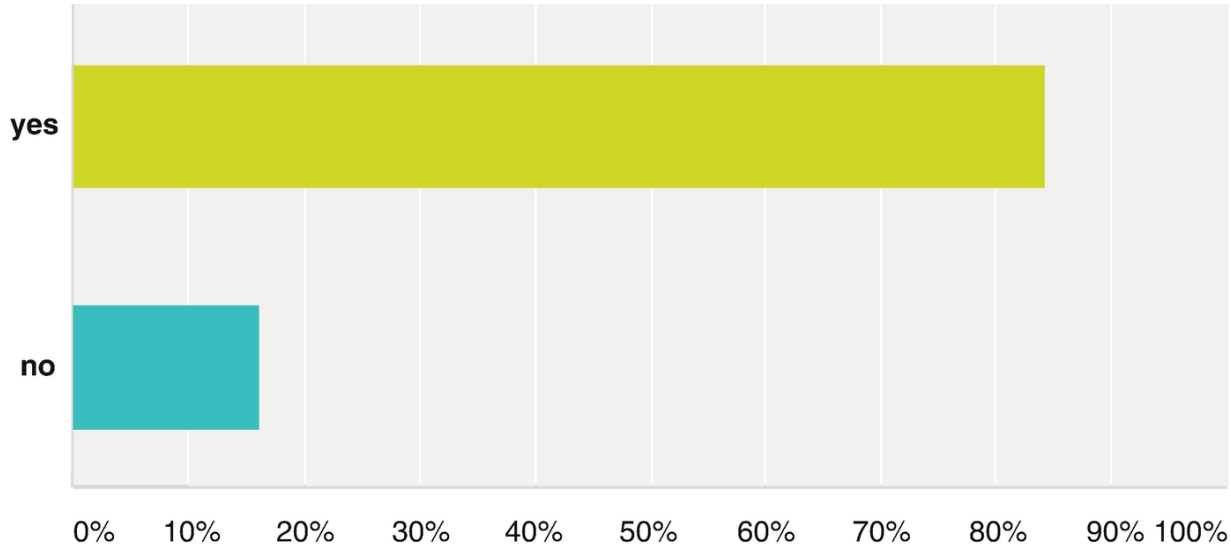

Fig. 4 Surgeons' responses about awareness of other surgeons' inappropriate risk-averse behavior. (First published in Samer Nashef's THE NAKED SURGEON (Scribe, London and Melbourne 2015), reprinted with permission)

This result is alarming: just under a third openly admitted to denying surgery to patients who may benefit because of concern about published figures, and the great majority (84%) reported that they were aware of other surgeons doing the same thing.

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6 The Way Forward

We must continue to refine and improve risk models, as these are the best tools we have for knowing what an outcome should be, so that we know if an observed outcome is good enough. There should be no doubt that the *measurement* of outcomes is essential. It provides a powerful impetus to identify and correct problems and assures patients that the care delivered is continuously monitored and of an acceptable standard. The *publication* of outcomes, however, is a mixed bag. In some ways it contributes towards quality assurance and in others it may damage patients and doctors alike. Having embarked on the path of greater transparency, it is very difficult to see how the profession can now turn away from it: the genie is now out of the bottle and will not go back. It would look highly suspicious if, having already chosen to place our outcomes openly in the public domain, we now decide to shroud

them in secrecy. The natural reaction of the public will be ‘what have they got to hide?’

There are ways in which we can mitigate the adverse consequences of outcome reporting. The first is to reduce as far as possible analyses based on single or ‘index’ procedures: when the entire practice is examined, poor results cannot be hidden away and category shift becomes ineffective. The second to tackle the issue of inappropriate risk aversion by the use of collective responsibility: at Papworth Hospital we now run a ‘Surgical Council’ to assess, make decisions and offer intervention to patients deemed at excessive risk from such intervention. Locally dubbed ‘the Star Chamber’, the Surgical Council examines very high-risk cases, such as those turned down elsewhere and those with a very high EuroSCORE as well as patients who have unusual and particularly challenging conditions and risk factors. The Star Chamber ensures that surgery is offered, where appropriate, to such patients and the entire group of surgeons share the responsibility for the outcome. After many years, the mechanism is now about to be adopted nationally.

Finally, we would all benefit if doctors always behaved to the highest ethical standard. As to how that can be achieved, I have no idea.

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Ethical Considerations in Pediatric Heart Transplantation

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1 Introduction

Pediatric heart transplantation is a widely accepted therapy for children with end-stage heart failure with approximately 600–700

pediatric heart transplants reported annually to the International Society for Heart and Lung Transplantation from 2010 to 2016 [1–3]. Historically, advancements in pediatric heart transplantation have been fraught with ethical questions and controversies that included using non-human donors (xenotransplantation) , anencephalic donors , fetuses as transplant candidates , and whether pediatric heart transplant should even be performed. With the steady improvement in post-transplantation survival (currently 1 year survival for low risk patients surpasses 90%) [3], the discussion has shifted to emerging issues including resource allocation, transplantation of high-risk candidates with associated co-morbidities, informed consent and shared decision-making, the expanding use of ventricular assist devices, and social concerns surrounding patients and their families. As innovation continues and drives the field of pediatric heart failure and transplantation, there is a shift in prognostication, management discussions, and treatment options both before and after heart transplantation. In this chapter we will discuss the historical background and current state of pediatric heart transplantation, explore related ethical themes and controversies, and review published case examples of ethical conflicts and suggested resolution.

2 Historical Perspective and Current State of the Field

Over 50 years ago, Dr. Christiaan Barnard, in South Africa, performed the first heart transplant in an adult patient, which was followed closely by the first pediatric heart transplant performed in New York by Dr. Adrian Kantrowitz just 3 days later on December 6, 1967 [4, 5]. However, the infant died only 5 hours after the procedure [4]. It was not until the 1970s and 1980s that the outcomes of transplantation significantly improved due to progress in rejection surveillance , immunosuppressive management and recognition of opportunistic infections [6]. A review of the earliest cohort of pediatric patients (those who underwent heart transplantation prior to 1982) found that of the 30 children transplanted 22 patients are known to have died with their first heart, and 8 patients received a second heart transplant with a median survival of only 3.5 years [7]. The high mortality rate for these

early patients led to limited enthusiasm for the procedure. Some of the earliest ethical literature questioned whether pediatric transplantation was even an acceptable option given these risks [8].

Specific ethical issues debated in the early stages of pediatric heart transplantation included questions regarding xenotransplantation (cross-species transplantation), the use of anencephalic donors, and listing fetuses as transplant candidates [8–12]. The first case of pediatric heart xenotransplantation was performed in 1984 with the case of "Baby Fae." She was an infant born with congenital heart disease with hypoplastic left heart syndrome (HLHS) and underwent a xenotransplantation at Loma Linda University. She lived for 20 days before succumbing to overwhelming humoral rejection [13]. The case was extensively reported in the media and discussed in the in the medical community and questions emerged regarding ethical issues of informed consent as well as surgical innovation [14–19].

While xenotransplantation has yet to prove to be a viable option, medical and surgical advancements have continued, and ethical questions and controversies have progressed as well. In the current era (2009–2016), the 1 year survival for a pediatric patient undergoing heart transplantation is over 90%, up from approximately 70% in the era from 1982 to 1989 [3]. While the majority of the approximately 700 pediatric heart transplants reported to the ISHLT in 2016 occurred in centers in the United States and Europe, additional centers around the world are performing transplantations [3]. However, with these increasing numbers it is important to acknowledge that pediatric heart transplantation requires a significant amount of resources and availability of ongoing medical care. Currently median costs for the transplant hospitalization alone reported as more than $500,000 per patient, which does not account for a lifetime of further care [20]. With the excellent outcomes there is no longer a question that heart transplantation is a viable option for patients in need. However, many active ethical discussions have emerged in pediatric heart transplantation such as those pertaining to issues of resource allocation, transplantation of high-risk candidates with multiple co-morbidities , multiple re-transplantations , the use of mechanical support with ventricular assist devices (VAD) in the pediatric population, and transplantation in patients who were previously

https://t.me/ALGRAWANY

thought not to be candidates for transplant, such as those with intellectual disability or neurodevelopmental disorders, or patients who are undocumented as well as others [21–30]. Clearly, as the field of pediatric heart failure and transplant continues to grow and evolve, ethical questions and themes will continue to emerge, and it will continue to be important to understand how to apply an ethical framework in order to better face current and future dilemmas.

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3 Recipient Selection and Donor Allocation

One of the more complicated decisions faced by pediatric heart transplant providers is whether or not it is appropriate to list an individual patient for transplantation. A framework for guiding the decision-making process around recipient selection for listing is provided by the Organ Procurement and Transplantation Network (OPTN) ethics committee . They refer to utility, justice, and the respect for autonomy (also stated as “respect for persons”) as the major ethical principles to be balanced in order to achieve an equitable outcome in the allocation of organs for transplantation [31].

3.1 Utility

Utility refers to the concept of maximization of net benefit while taking into account the expected net amount of overall good or benefit compared to harms. When applying the principle of utility to the allocation of organs and selecting a patient as appropriate for listing for heart transplant, the benefit a patient will receive from undergoing a heart transplant should outweigh the risk and harms that come with the procedure. This analysis should be both in the immediate time frame and in the long-term. Beneficial consequences of heart transplantation include saving a life, relieving suffering, removing psychological impairment, and promoting well-being. Possible harmful consequences of transplantation include: death, short term morbidities such as post-operative surgical complications and acute organ dysfunction and/or rejection, long term morbidities such as side effects from medications, potential rejection of the organ, ongoing need for biopsies, and the potential development of coronary disease or post-transplant lymphoproliferative disease (PTLD) [31].

When considering utility in relation to patient selection for heart transplantation, several factors should be considered including: (1) patient survival after transplant; (2) survival of the transplanted heart itself; (3) quality of life of the patient after transplant; (4) availability of alternative treatments; and (5) age of the patient [31]. For example, for a patient with muscular dystrophy with end-stage cardiomyopathy, considerations may include age of patient at time of heart transplantation as this may impact the prognosis of their disease. Depending on the severity of the disease, the patient may also have other serious comorbidities that could affect their survival, regardless of the graft survival. One would want to consider how a heart transplant might improve their quality of life but also, if undergoing a surgical procedure would make their other co-morbidities worse, such as their muscle strength or pulmonary reserve. The principle of utility requires the evaluation of all possible benefits versus possible harms in the decision of whether to list a patient for heart transplant.

Acknowledging that utility informs transplant listing, there is widespread consensus that certain social aspects of utility should not be taken into account. In particular, the social worth or value of individuals should not be considered, including social status or occupation. There is also consensus that it is unacceptable to use variations in transplant outcomes among social groups as a basis for predicting individual outcomes. Even if there is empirical evidence that survival rates of one group exceed those of another, these factors should be excluded from utility models used to justify allocation decisions [31]. An example includes patients with Down syndrome, who had been historically thought not to be candidates for heart surgery itself due to the underlying chromosomal defect [32, 33]. Given the sentiment that an individual's perceived social worth or value should not be taken into account when deciding about transplant selection, patients with chromosomal defects, neurodevelopmental disabilities or autism should not be excluded based on their underlying syndrome *alone* [29, 30, 34–36]. In fact, a recent analysis of the Pediatric Health Information System (PHIS) database, a large administrative and billing database of 43 children's hospitals, found that children who had a chromosomal anomaly and were accepted for heart transplant listing and underwent transplantation had no

increased risk of mortality compared to patients without a chromosomal anomaly [30].

3.2 Justice

Justice is defined as the fair pattern of distribution of benefits and burdens [31]. Examples of justice in the literature include discussions on the merits of repeat transplantation, especially for pediatric patients , while acknowledging the disparity between donor supply and demand [37–40]. Justice is included as a principle when discussing ethics of organ allocation to ensure fair and just access by patients to organ transplantation and an equitable distribution of organs for patients on the waiting list.

In the United States, OPTN operates regional networks which determines waiting lists and placement for all organ transplantations. Allocation schemes consider medical need and benefit by prioritizing the medically sickest patients, even if it is predictable that other patients who are not as sick might have better outcomes. Many other factors are also considered in order to treat potential recipients fairly and allow for opportunity to receive an organ when in need such as (1) medical urgency; (2) likelihood of finding a suitable organ in the future; (3) wait list time; (4) first versus repeat transplants; (5) age; (6) geographical fairness; and (7) multi-visceral transplantation [31].

A case that exemplifies this complicated assessment is that of a 17-year-old highly-sensitized patient with failed Fontan physiology who has been on the transplant waitlist for 5 years. She was originally listed as a heart transplant alone, then heart and liver, and most recently she is being considered for a heart, liver and kidney combined transplant. In the context of justice, is it fair and equitable for one patient to receive 3 organs that could potentially go to 3 other people and save their lives? Or does the need and possible good from saving this one person outweigh that? Given she has been on the waitlist for a long time for a single organ, what is the likelihood to obtain three organs? And, as she has been getting increasingly sicker with worsening organ dysfunction, how does that factor into her potential outcome after transplant? These are complex questions that do not offer a simple solution but must be considered when thinking about justice.

3.3 Respect for Autonomy (Respect for Persons)

Respect for persons is the concept that all people should be treated with respect because they are human beings and inherent in this, is the respect for autonomy [31]. Respect for persons is demonstrated when discussions occur regarding decision-making and quality of life. These discussions with patients and families become particularly important when medical decision-making is complex or concerns end-of-life care [25, 41–43]. Ethical principles can sometimes be in conflict with each other. Depending on the circumstances of the conflict, respect for autonomy may be paramount or be sacrificed for another pertinent ethical principle. For example, the current organ allocation system prioritizes justice over respect for autonomy with regards to selling organs, which is prohibited. The ethical analysis for this is that even if selling an organ is an autonomous decision made by the donor, it creates a market system that increases healthcare disparities among different socioeconomic groups and violates the underlying ethical principle of justice [31].

Factors to consider when applying the principle of respect for persons are: (1) the duty to respect decisions of donors or those who refuse to donate organs; (2) the right to refuse an organ; (3) allocation by directed donation ; and (4) transparency of processes and allocation rules to enable stakeholders to make informed decisions [31]. An example to elucidate the ethical principle of respect for persons is an infant who was being evaluated for heart transplant listing. She has hypoplastic left heart syndrome (HLHS) and RV dependent coronary arteries, which is a high-risk underlying anatomy for surgical palliation. Her parents are Jehovah's Witness and after significant discussion wanted her to be listed for transplant but were concerned about the infant receiving blood products. The team negotiated a way for the infant to receive blood transfusion during her hospitalization and a plan was put into place for the surgical procedure that the parents were comfortable with. However, most infants are listed for transplant as ABO incompatible, which decreases wait time. This practice requires an exchange transfusion at the time of transplant, which the family might find difficult to consent to. Many ethical questions arise from a situation such and include the following: Is it appropriate to discuss the details of an ABO incompatible transplant with these already emotionally

distraught parents at the time of listing, given it is unknown if she will get an incompatible donor? Or does the team list her for an ABO incompatible transplant and discuss the concept with them at the time of donor offer (if necessary)? The team understands that obtaining a donor heart as soon as possible is in the best interest of the child, but also wants to respect the beliefs of the family and be transparent about the donor allocation process.

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4 Recipient, Donor, and the Alternative Recipient

No standard guidelines exist on *how* various transplant programs should apply these ethical principles to decision-making and listing. The OPTN white paper pertaining to the assessment of transplant candidacy states "Transplant centers are encouraged to develop their own guidelines for transplant candidate consideration . Each potential transplant candidate should be examined individually and any and all guidelines should be applied without any type of ethnicity bias" [31]. It is likely that various transplant programs apply these principles very differently [27]. In general, a transplant team has to navigate these ethical questions by attempting to consider the impact of their decisions on three distinct patients: the recipient, the donor and the alternative recipient.

The recipient is the patient directly cared for by the transplant cardiologist and the heart transplant team and is the team's first responsibility. Typically, by the time the patient is referred to the transplant team it is likely there are few alternative medical options. The team takes an active role in generating the individual risk is for that patient not only to survive the procedure itself, but also to have a durable post-transplantation survival and a good quality of life. The calculus of the team is quality and quantity of life without heart transplantation versus the quality and quantity of life with heart transplantation. This necessitates a certain amount of willingness to accept risk by the medical team and family's part. The patient may not do well despite optimal care, but there may be no other "better" alternatives. This risk assessment takes into account multiple factors including the patient's age, medical history, comorbidities, psychosocial

history, and the availability of alternative options that to achieve better quantity and quality of life. To be considered for transplantation, it is often certain that the patient will have a poor quality and poor quantity of life without transplantation. This calculus is not, however, in any way firm. While it is true that certain past medical history (such as renal disease, liver disease, and congenital heart disease) increase the risk of poor outcomes, none of these are in anyway absolute and have to be weighed against other risk factors. While a transplant team may decide that a particular "high risk" patient may have a 50% chance of surviving to a year after transplant, an individual patient has a dichotomous variable as their outcome—they will survive to a year post transplant or they will not . When offered a chance of survival with transplant against an almost certain death without, most families will request transplantation even if the probability of success is extremely low.

The donor is the next patient that the transplant team must consider when deciding if a patient is an appropriate transplant candidate. The organ offered for donation by the donor and the family merits respect for the family's life-saving decision to donate and appreciation of this limited resource. As a community, there is an obligation to assure that these organs are utilized to maximize the good that can be done and to strive that every donated organ goes on to prolong life. Decisions to accept an organ for a recipient without a meaningful probability of increased survival (such as a patient with end-stage incurable cancer who also has cardiac failure from therapy) are therefore inappropriate.

Lastly, any conversation of pediatric transplantation must include the concept of the alternative recipient. While wait list survival has improved over time, there continues to be a meaningful occurrence of patients not surviving long enough to receive a transplantation. Thus, accepting a donor organ for a patient by definition prevents it from being offered to a different patient on the wait list. If an organ is accepted for patient whose probability of survival after transplant is very poor, then potentially both the actual recipient and the theoretic alternative recipient may not survive because of that choice.

Balancing these three patients to assure equitable distribution of organs creates an inherent tension. On one hand the team's first obligation must be to their patient and, of course a family's primary

obligation is to their child. However, a transplant team must consider both the alternative recipient and the donor in their discussions. The transplant team is balancing the ethic of utility when deciding maximum benefit to the patient with the ethic of respect for autonomy/persons (the patient/family desire to undergo transplantation). Complicating this is that at present there is no clear consensus as to what constitutes an appropriate risk that a transplant center should undertake. In a survey, pediatric transplant professionals were asked to provide their beliefs as to what was unacceptable level of survival to warrant listing a patient for transplantation and responses varied very widely [27]. For example, a one-month predicted survival that was adequate to allow proceeding with listing for heart transplantation varied from 50% to 100%. Therefore, at one center a patient who was felt to have only a 50% chance of surviving the acute transplant might be listed for transplantation. That same child would not be listed at the center that felt that risk was too high. Indeed at the center that would require a 100% predicted one-month survival, only low-risk patients would be listed as few centers could guarantee 100% survival from the procedure itself [27]. How to best balance these three patients using the principles of utility, justice, and the respect for persons, so that all patients have the same level of access and all donors have the same probability of their gift helping others, remains unanswered.

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5 Psychosocial Issues in Transplantation

There are no set guidelines or criteria for the psychosocial evaluation of patients undergoing evaluation for transplant. However, there is general consensus that these factors should be evaluated. Transplant centers are encouraged to develop their own guidelines for determining transplant candidacy, though each potential candidate should be considered individually, and all guidelines should be applied consistently and without bias [27]. In the United States, the United Network for Organ Sharing (UNOS) , requires a multidisciplinary approach including a psychosocial evaluation, but the exact components of this is not mandated. Some OPTN guidelines recommend categories that should require psychosocial assessment for

transplant candidacy include organ failure caused by a patient's own behavior due to issues with compliance and adherence [44]. The OPTN Ethics Committee has historically supported the conclusion that past behavior which results in organ failure should not be considered a *sole* basis for excluding transplant candidates. However, transplantation should be considered very cautiously for patients who have demonstrated serious, consistent, and documented non-compliance in their current or previous treatment [44]. Exactly how these evaluations can influence a patient's candidacy for transplantation may vary by center, but at a minimum a thorough psychosocial evaluation should be used as a method of identifying patient and family strengths and risk factors for poor post-transplant outcomes that can be impacted through interventions [45].

In pediatric patients, the ethical issues involved in the psychosocial assessment can be even more nuanced. One commonly debated ethical issue is if a child should be denied transplant due to high-risk findings that are discovered during the psychosocial evaluation. Many pediatric centers are hesitant to do so due to the relative lack of data in the literature to predict post-transplant outcomes [46, 47]. Second, children rely on their families and their environment, and centers are reluctant to deny a child transplantation for factors over which he or she does not have control. Finally, a child's behavior is thought to be dynamic, especially as a child ages, and their current behavior is not thought to be predicative of future behavior [45]. Given the well described adverse outcomes of non-adherence, the presence of psychosocial risk factors must be discussed and mitigated to maximize the likelihood of success after transplant with a limited resource.

One of the important aspects of insuring that a child is able to survive and thrive after heart transplantation is for the family and child to comply with a very complex medical regimen. This involves careful assessment of the family's understanding of the patient's medical needs and their ability to help the pediatric patient adhere to their medical regimen. It is not uncommon during this evaluation process to find the patient with a complicated social situation or with a history of having had difficulty engaging with the medical system. The reasons for this are often multifactorial and complicated and certainly involve societal

factors such as limited education, limited literacy, limited financial resources, housing insecurity, and substance abuse among many others.

While adult patients may be considered ineligible for transplantation due to substance abuse or non-adherence, unique in the pediatric arena is the primary responsibility of the team to the child's best interest. However, defining that best interest is rarely so straightforward. For example, an older teenager whose family may have a long-standing documented history of difficulty keeping medical appointments and getting and giving medications is unlikely to do well with a heart transplantation. Efforts to mediate the family's adherence to medical recommendations and care may or may not be successful, although are clearly to be undertaken. While an alternative exists, i.e. placing the child within a foster system to assure medical care, the impact of removing a child from their family may not necessarily be in the child's best interest. In pediatrics, support is generally given to the family and patient to show adherence in order to maximize medical management so that the child has an opportunity for survival.

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6 Genetic Anomalies and Developmental Delays in Transplantation

Historically, patient with a genetic or syndromic anomaly or developmental disorder were not always offered even general cardiac surgery [32, 33]. While this is no longer the case, it has led more recently to a broader discussion regarding patients with intellectual disability or neurodevelopmental delay undergoing heart transplant [21, 24, 35, 48]. Recent studies have shown no difference in outcomes after pediatric transplant in patients with intellectual disability [22, 29]. Given the growing volume of patients with these conditions, it is important to continue the discussion as it relates to heart transplantation.

The degree to which developmental disabilities play into decisions to offer heart transplantation for pediatric patients is complex. The individual patient's ability to understand what will happen to them varies by age as well as their baseline cognitive abilities. For patients with significant developmental disabilities, it is likely that the family will be the lifelong caregiver for that patient after transplantation and

assessing the family's understanding of this commitment is therefore critical. It can, however, also be very difficult in a developing child to predict their long-term developmental outcomes. For instance, small children on ventricular assist devices may have an elevated risk of stroke but can proceed to recover significant function. Patients with specific genetic syndromes may have highly variable levels of independent adult function. Therefore, prognosticating in a young child is fraught with difficulty, and families should be counselled about that uncertainty. In general, the standard of care in the pediatric heart transplant community has been that developmental disabilities are not in and of themselves absolute contraindications to transplantation. The degree to which these are considered within a comprehensive evaluation also clearly varies and needs further discussion.

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7 Surgical Innovation and Informed Consent

As heart transplantation was developing in the 1980s, debate existed about the ethics of performing heart transplants in children. In particular, questions involved how to obtain informed consent when recommending a procedure that was deemed experimental by some [49]. Some argued that transplantation, especially those in pre-adolescent children, with re-transplant, and in combined organ transplants, should be performed only with protocols in place, approved by the Institutional Review Board, and with family consent for a research procedure, rather than standard medical therapy [49]. The decision to make heart transplant "standard" therapy rather than "experimental" should be based on medical, political, economic and ethical considerations in order to provide the best care for patients and expose them to the least risk [49]. This debate of informed consent was evident in the case of Baby Fae, who underwent a xenotransplantation, and ultimately died . The informed consent process for this procedure was reviewed by the National Institute of Health in 1984. While they found that Loma Linda University and the team who took care of the infant performed an appropriate informed consent that was ethically and culturally sensitive, concerns such as expectations of benefits from the procedure existed [19]. While outcomes for pediatric transplantation have significantly improved, no guarantees exist that

despite optimal care unexpected morbidity and mortality will not occur. As such, majority of clinicians believe that the informed consent process as an integral part of the evaluation for listing for heart transplant allows families decline transplantation once they are fully informed and believe that transplantation is not in their child's best interest.

Sometimes this consent process can feel inadequate or rushed because some patients do present with fulminant heart failure requiring rapid evaluation and intervention. Therefore, a family may consider moving forward with heart transplantation as the only alternative to death for a child and many uncertainties may remain. Several factors should be considered, including: the eventual neurologic outcome of a child who has had a cardiac arrest, the results of genetic testing for etiologies of heart failure that might point to a more-multi-system process, and in the case of an older child, the child's own wishes may remain unknown. In addition, some co-morbidities such as mitochondrial disorders and systemic myopathies may be discovered months or years after transplantation. Providing full and honest informed consent around these issues in the setting of critical illness is intrinsically difficult but should nevertheless be the goal.

Recently, there has been a dramatic increase in the utilization of mechanical circulatory support devices for children, especially those with congenital heart disease. With this, many ethical questions arise around how to best utilize this technology have arisen. Patients with complex single-ventricle CHD appear to fare worse than those with cardiomyopathy [50, 51]. This introduces ethical issues regarding the need for prospective and randomized clinical trials, appropriate oversight of new therapies, equitable access to potentially life-sustaining therapy, and transparency in reporting [52].

One of the most important issues surrounding ventricular assist device (VAD) therapy , or any new device, is evaluating if the device provides clinical benefit. The gold standard for this type of evaluation is a randomized control trial , which exist in the adult populations for different VAD therapies [53–55]. However, this to date has not been feasible in a pediatric population and in those with CHD. In order to undergo a randomized control trial, there must be equipoise, a state of

clinical decision making where there is a significant degree of uncertainty whether the new therapy is better than the old [52].

In the case of VADs in children with CHD, the state of equipoise might never be reached because at the point when the decision to place a support device is needed, it could be seen as potentially withholding a life sustaining therapy. The only FDA approved mechanical support device is the Berlin Heart Excor, which was developed in Germany and by the early 2000s was being used in Europe with good results [56]. It became utilized in the United States in a compassionate use status. At the point when there was consideration for a study trial was being considered to obtain FDA approval, the device was being used too frequently with good results and withholding the device was no longer was deemed ethical. A nonrandomized trial was performed that compared patients with the VAD to a historically matched cohort of patients on ECMO [57]. The trial demonstrated improved outcomes on the Berlin Heart, and the device was approved by the FDA in 2011. While this was a landmark study in pediatric VADs, there are still ethical questions that remain including if the use of historical controls on ECMO was adequate. With new devices on the horizon that would overlap for use with the population being covered by the Berlin Heart, the question of equipoise will continue to be challenging.

In the smallest patients, VAD options remain fraught with complications. Weighing the risk of complications against potential benefit is difficult. In older patients, clinicians are increasingly using adult devices off label with very limited pediatric data to support their use. One example is the durable implantable continuous flow devices that allow for discharge home from the hospital as a bridge to transplantation. In the adult population, for patients who are not thought to be transplant candidates, but still require VAD support for end-stage heart failure, the use of VADs as destination therapy (DT) as emerged [58]. This has become a consideration in pediatrics as well. In one study, pediatric providers who have adopted DT thought of DT as a bridge to decision, rather than a strict destination therapy, as potentially the problems that excluded the patient from transplant could evolve over time [25]. Potential reasons for DT candidacy included patient preference , neuro-muscular diseases, obesity, and some psychosocial considerations, but were not felt to be absolute [25].

The role of these devices in patients with end-stage heart failure and multisystem organ problems that will not allow a long survival is also difficult to assess but is certain to evolve as the devices improve and pediatric data continues to emerge.

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8 Quality of Life and End of Life Care

Heart transplantation can be a difficult process for both families and clinicians, especially since heart transplant is not considered a "curative" intervention, though it does extend life and can improve quality of life . When interviewed about the post-transplant care of children, families described parenting a child with a heart transplant in overall positive terms such as feelings blessed, but they also report being worried and responsible at all times [59]. Families described methods of coping with their stress by focusing on the positive, recognizing the lack of choices, faith, support from others, and balancing [59]. It is not just post-transplant care that can be difficult, but the time waiting for transplantation can be a stressful time for families as well. Families have described this time period as having physical limitations, lethargy, social isolation, discomfort with physical appearance, and academic issues as major themes [60]. Supporting children and their families as they navigate this complex and uncertain journey is warranted, and results invite further research and investigation [60].

While there is little research in end of life care after heart transplantation, there is literature regarding end of life in advanced heart disease. Most children who die in the hospital due to advanced heart failure do so in the intensive care setting after withdrawal from invasive advanced care therapies [61]. Physicians and families appear to have different expectations and perceptions about quality of life and long-term outcomes with regard to end stage cardiac disease. Physicians underestimate how unprepared for end of life families are, and how much parents feel that they receive conflicting information from their child's care team. Parents who were more hopeful for normal life spans and good quality of life for their children at the time of diagnosis, were more likely to report more suffering at the end of their child's life. This demonstrates the importance of communication

between the family and care team regarding a child's diagnosis and expectations for the future [62].

For children with end stage heart disease who are not thought to be transplant candidates, families typically make decisions about end of life care, either to die in the hospital or at home. There has been precedent for discharging patients home with palliative inotropic support to allow patients to pass away at home with their families [63]. Providing palliative support at home can improve quality of life for patients and their families, avoid prolonged hospitalizations, and reduce utilization of resources. It requires collaboration between the inpatient hospital palliative care team, the community hospital providers, and the cardiology teams [63].

Death due to heart failure may also include compassionate deactivation of VADs. With increased demand for donor organs, liberalizing the boundaries of case complexity, and the introduction of DT in children, more children are expected to die while on mechanical support. Compassionate deactivation of VAD support is considered to be both legal and ethical. Deactivation of VADs is not typically considered a form of euthanasia or physician assisted suicide because no new pathology is introduced and the patient dies from the natural progression of the underlying disease [26, 64, 65]. Regardless of whether a patient is actively dying, the principle of autonomy states that a patient should not be obligated to continue a life-sustaining therapy if they understand the risks and considers the burden of the therapy to outweigh those risks.

When transplantation is being considered the majority of pediatric transplant practitioners provide an extensive education around both why it is being recommended but also a thorough discussion of the survival and complications of transplantation. Despite improving outcomes and survival after transplantation, mortality and complications can occur. While the vast majority of patients do choose to proceed, some parents and patients may choose to decline heart transplantation. Moral distress from this is likely to be felt both by the family and the larger medical team. It is imperative to support the family in their choice in that they are prioritizing the perceived best interests of the child.

9 Regulatory Aspects of Organ Donation and Transplantation

A continuing area of discussion within the transplant community surrounds whether only patients who have given explicit prior consent should be considered as willing to be donors. Given the shortage of the donor pool, should patients who have not specifically stated that they are not willing to be donors be considered as potential donors? Currently in most of the United States, positive assent must be given by the adult patient or family before donation is allowed, and by the family for a pediatric patient. In other countries, such as Spain, the assumption is that if a patient does not decline to be a donor then they would be considered as donors. The impact of changing to assumed consent would likely decrease the wait list and improve survival times. However, implementing such a policy for pediatric donors may be more challenging than for adult donors and continues to be an area of discussion.

An additional complicating factor unique to transplant programs relates to the impact of regulatory oversight and accreditation on decision making. For instance, in the United States, transplant centers are evaluated by the United Network for Organ Sharing (UNOS) and the Centers for Medicare and Medicaid Services (CMS) based on their recipient survival outcomes. Programs failing to meet certain outcome measures risk censure and potentially closure of transplant program. While there have been attempts at risk-stratifying outcomes, these are largely felt to be unable to account for the level of complexity variation within the pediatric population, especially for patients with complex congenital heart disease. For example, a “high-risk” patient such as an infant with complex congenital heart disease on a ventilator might be estimated to have a 78% chance of 1 year survival, but a “low-risk” patient such as a teenager with cardiomyopathy on a ventricular assist device as an outpatient might be predicted to have a 92% probability of 1 year survival. Both of these patients are well within the accepted practice of pediatric cardiac transplantation. However, there is a disincentive for a program to proceed with transplantation for the higher risk patient as listing “high-risk” patients on average will lead to

the potential of higher post-transplant morbidity and mortality as compared to just listing “low-risk” patients. Adverse programmatic impacts may influence decision to list. A recent survey of pediatric transplant professionals reports that recent deaths in their transplant program impact their willingness to assume risk around donor acceptance [66].

Exactly how this impacts the patient’s access to transplantation is unclear, but concern remains regarding the application of the justice principle. Some patients could be denied transplantation at a given center with a recent mortality, where they might be offered a transplantation should they have presented elsewhere. There is an inherent ethical tension created by the need for “good outcomes” against what is in the best interest of a particular patient who is “high”, but “reasonable” risk for transplantation. Thoughtful analysis and policy level work is needed to assure that teams are able to meet their ethical responsibilities towards their patient, as well as to the donor and the community.

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10 Case Reports

Descriptions of clinical cases in pediatric heart transplantation where ethical conflicts arise exist in the literature. In this section, we present three recently published cases that highlight ethical conflicts, offer an ethical analysis, and suggest potential solutions.

10.1 When a Child Needs a Transplant But Lacks Familial Support [67]

> AG is a 19-month-old with complex congenital heart disease who is severely symptomatic and who is felt to have a poor probability of long-term survival without a heart transplantation. AG’s father (who is the sole decision maker) is skeptical of traditional medicine but consents to a ventricular assist device with a Berlin heart as a bridge to heart transplantation. Prior to this, the father was asked to demonstrate commitment to transplant success and was provided with enhanced social support. While on Berlin heart, AG is matched to a donor heart, but the father refuses

transplantation. The doctors report the case to child protective services, but they decline to take protective custody. The father subsequently changes his mind and asks that AG be again put on the waiting list for transplantation.

The issues raised by the authors are the following: (1) Should courts order heart transplantation when doctors believe that it is in the child's best interest and parents do not consent?; (2) Once parents refuse a transplant, can they change their minds?; (3) If there are uncertainties regarding whether the child has the social support to make transplantation successful, should the child be relisted? (4) Should a child who is not currently a transplant candidate but who may become one in the future be supported with ventricular assist devices?

The authors have differing opinions on how to handle the conflicts listed above that tackle issues of promoting best interest of the patient, respect for autonomy of parent to make decisions and sometimes change their mind and promoting justice. They conclude, "Competent adults often change their mind about what treatments they want or do not want. They are allowed to do so and do not forfeit their right to life-sustaining treatment because they once said that they did not want it. Parents have the same right. In this case, the problem arises not simply because the dad changed his mind but because of the circumstances. His shifting preferences were coupled with a lack of commitment to the treatment and follow-up that his child needed. Such nonadherence would likely doom a transplant to failure. Because organs are scarce and because many people die waiting for a heart, transplant centers have an obligation to maximize the likelihood of success. As noted, this father has to show that he can be compliant with a complicated medical regimen, and that he is committed to following that regimen, before his child should be eligible for transplant. The decision, then, about whether to continue life-sustaining treatment turns on a probabilistic assessment of the likelihood that the father is truly committed. Given the hope of successful treatment with a heart transplantation, it makes sense to err on the side of generosity and to continue life support, even if that means that the child will be in an ICU for months."

10.2 Genomic Contraindications for Heart Transplant [68]

GP is a 12-year-old boy with Tetralogy of Fallot and pulmonary atresia with multiple aortopulmonary collaterals is admitted with worsening heart failure and is being considered for heart or combined heart and lung transplantation . During extracorporeal membrane oxygenation (ECMO) after a previous heart surgery, the patient experienced a thrombotic event resulting in a left middle cerebral artery stroke, leaving him with right-sided hemiparesis and dysarthria. He has had several venous thromboses, despite normal results on all routine laboratory tests of clotting function. GP also has developmental delay and hypothyroidism. Whole genome sequencing (WGS) is performed both to potentially provide a unifying diagnosis for the cardiac defects, hypothyroidism, and developmental delay, as well as (given the complexity of performing heart transplantation in a child who has had multiple prior cardiac surgeries) to screen for genetic variants that might explain the patient's recurrent thrombotic events. Analysis of WGS confirms that the patient has DiGeorge syndrome (DGS) , a 22q11 deletion, but also reveals that he has a particular variant of 22qDS highly associated with schizophrenia and multiple variants in several other genes associated with schizophrenia. Given the psychosocial challenges associated with management of a transplanted organ in adolescents, the challenges to self-care posed by the patient's already-present developmental delay and stroke, the scarcity of available pediatric donor organs, and with the WGS findings, the heart failure team decides that they will not go forward with listing GP for a transplant. Without the prospect of a future transplant, the team feels the patient would be a poor candidate for a ventricular assist device. The family objects to the team's decision and states that had they known the WGS results could lead to taking away options, they would never have given permission for the test.

Issues raised by the authors in this case include: (1) Should the physicians have a duty to explicitly disclose that findings on WGS may limit a life-saving option?; (2) When and how should WGS be used to make clinical medical decisions given the information is often difficult

to interpret?; (3) Who assesses what is an acceptable quality of life for this child given this known (but not certain) risk of schizophrenia?

The authors agree that the consent process should have included potential impact of WGS on the patient's management and options. The question of to what extent WGS should influence clinical options is more complicated and may be an evolving variable as understanding of findings increases. They also argue that if the current institution is unwilling to list the child for transplantation, the family should be referred to other institutions that might consider transplantation. The authors conclude, "The allocation of scarce resources requires robust theories of justice and political integrity in applying those theories to the real world of individual patients and families who might benefit or be harmed unjustly. Genomics requires humility in the face of highly uncertain and probabilistic findings that we know, given our current state of understanding, can only be tentative and are likely to be inaccurate. The only way to muddle through this domain of uncertainties will be by carefully and humbly presenting and analyzing cases like this one to determine when and whether genomic findings should be part of the equation of organ allocation."

10.3 Should Physicians Offer a Ventricular Assist Device to a Pediatric Oncology Patient with a Poor Prognosis? [69]

> BJ is a 10-year-old girl with refractory leukemia with poor prognosis and chemotherapy-induced heart failure. BJ's family and her oncology team want her "to have every chance" and want her to be considered for a left ventricular assist device (LVAD). The pediatric heart failure team views VAD as clinically inappropriate due to her active oncologic problems.

The issues raised are the following: (1) How can shared decision-making be practiced in the context of new emerging technology (specifically when respect for autonomy and best interest of patient conflict)?; (2) When does the harm of a new technology outweigh the benefit and who ultimately gets to decide?; (3) How are recommendations best communicated to the patient and family?

The authors conclude, "As VAD technology continues to evolve—and as VAD outcomes improve and complications diminish—its use as a

chronic care option or destination therapy might become more commonplace in select pediatric patients. In BJ's case, a poor prognosis and the significant possibility of severe complications given her underlying acute myeloid leukemia should directly inform the physicians' consideration of whether to offer LVAD. If BJ's disease had a higher rate of cure with potential for disease-free status—such that she could be a heart transplant candidate—LVAD implantation as a bridge to transplant candidacy or recovery could be viewed as more compelling. As debate over appropriate uses of VAD technologies continue, thoughtful analysis and conversations are needed among clinicians, families, and patients."

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11 Conclusion

Ethical issues in pediatric heart transplantation cross multiple areas of medical ethics including complexity in shared decision-making, assessment of quality of life, organ allocation in the context of a scarce resource, and use of emerging technology. The fundamental questions remain: (1) who should be listed and obtain a heart transplant, (2) how should this be determined, (3) how do unknown prognosticators such as underlying co-morbidities or genetic abnormalities factor into decision making for listing, and (4) what is the role of emerging technology such as ventricular assist device? Future inquiry will need to focus on these issues to create an equitable and just system that optimizes patient care in the field of pediatric heart transplantation.

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Between Death and Donation: Ethical Considerations in Pediatric Heart Transplantation

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1 Introduction

> If only you knew all, Socrates, and realized that rhetoric includes practically all other faculties under her control. And, I will give you good proof of this. I have often, along with my brother and with other physicians, visited one of their patients who refused to drink his medicine or submit to the surgeon's knife or cautery, and when the doctor was unable to persuade them, I did so, by no other art but rhetoric [1].

Undoubtedly, some medical ethicists will criticize Gorgias because he seems to have violated the autonomy of the patients he persuaded to undergo medical treatment, and because he was not a fiduciary of the patients on whose behalf he claims to have acted. After all, even in the fourth century B.C.E., Hippocrates's rules of medical ethics required

practitioners to do good and to refrain from doing harm to people in their care. Moreover, in light of Gorgias's defense of rhetoric , it is not clear whether or not his actions resulted in good for patients who would have chosen to undergo medical treatment without his counsel, or harm to patients whose autonomy he violated by persuading them to undergo medical treatment against their wills. Of course, the latter was further complicated by the fact that Gorgias was not a fiduciary of the patients he counseled so he was not required to act in their best interest. For example, Gorgias might have been engaged in coercing patients to undergo medical treatment against their wills as a way of testing his rhetorical skills. Either way, there are both medical ethical and legal grounds on which one might criticize Gorgias.

Ethical dilemmas like these arise in the field of pediatric heart transplantation because decisions about whether or not infants will be organ donors are always made by their parents, guardians, or others who are presumed to have the infant's best interest in mind. In such cases, parents, guardians, and others act as fiduciaries of infants because infants cannot make their own decisions about organ donation. Moreover, when a potential organ donor is in the process of dying, or has been declared dead, time becomes a major factor because organs must be removed and transplanted within a window of opportunity. For example, in the case of a pediatric heart transplant, the heart must be transplanted within 6 hours after it has been removed from the infant's body; otherwise it will not be viable.

This short window of opportunity coupled with the problem of organ scarcity has given rise to some *prima facie* ethically questionable practices [2–4]. For example, in "Ethics of Persuasion: Evaluating the Ethical Limits on Attempting to Persuade Families to Donate the Organs of Deceased Family Members," Jennifer Chandler and Vanessa Gruben report that the "Organ Donation Breakthrough Collaborative methodology in the United States encourages a more aggressive pursuit of donation, including reproaching refusing families" [2]. Similarly, in "The Newborn as Organ Donor," Christopher Tomlinson and Jonathan Hellmann cite research which suggests that the "desire for organ procurement has become excessive" [3]. In light of this, in "Organs for Donation: Balancing Conflicting Ethical Obligations," Robert Troug warns that "the pendulum has swung too far in the direction of organ

procurement at the expense of commitments that are fundamental to the patient-physician relationship ” [4]. He concludes that, “if uncorrected, this trend could substantively erode the public’s trust in the transplantation enterprise” [4].

Other important ethical issues arise out of ongoing philosophical debates in the field of pediatric organ transplantation, including whether or not organs that are donated by pediatric patients ought to be reserved for pediatric recipients [5]; whether or not organ scarcity justifies “aggressive” or “excessive” organ procurement practices [2, 3]; and whether or not hospitals should provide follow-up care to parents who have donated an organ of a recently deceased child. Some of these issues arise from the fact that it is not possible for parents to know the wishes of their infant children. This uncertainty is often maximized by the stress of being asked to donate the organ of a dying child shortly after learning of the child’s prognosis [6]. Undoubtedly, the combination of uncertainty and stress makes many parents vulnerable to those who engage in “aggressive” or “excessive” practices in the procurement process [2, 3].

In what follows, I offer philosophical analyses of the problem of organ scarcity and the solutions that have been offered by medical ethicists against the backdrop of a discussion about pediatric heart transplantation. The solution that I find most promising is the practice of “nudging ” as defined by Chandler and Gruben and refined by Constantine D. Mavroudis, Tom Cook, Jeffrey P. Jacobs, and Constantine Mavroudis in “Ethical Considerations of Transparency, Informed Consent, and Nudging in a Patient with Paediatric Aortic Stenosis and Symptomatic Left Ventricular Endocardial Fibroelastosis” [7]. According to Chandler and Gruben, “nudging” is the practice of encouraging families to donate the organs of a recently deceased loved one [2]. Although many scholars argue that “nudging ” can be used to address the problem of organ scarcity ([8]; also see [9]), more needs to be done to protect parents who are thinking about donating an organ of a recently deceased child from agents who engage in “aggressive” or “excessive” organ procurement practices [2, 3].

Towards this end, like Mavroudis et al. [7], I offer refinements to the practice of “nudging ” for the purpose of protecting parents from experiencing psychological harm in the procurement process, and

hospitals from being the subjects of lawsuits. I argue that the Department of Health and Human Services ought to establish uniform policies requiring hospital and organ procurement staff to log all conversations about organ donations; prohibiting the number of times organ procurement staff can solicit donations from parents of a recently deceased child; providing follow-up care to all parents who are asked to donate whether or not they actually do so; and establishing oversight and procedures for reprimanding agents who break the rules. I conclude that adherence to these policies will increase organ donation, remove many of the problems that exist currently in the procurement process, and increase good will among patients, families, hospitals, and organ procurement agencies.

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2 A Separate Organ Market for Pediatric Patients

According to the Organ Procurement and Transplantation Network, as of May 2019, there were 59 infants who were in need of heart transplants but only 37 hearts have been donated by parents of deceased infants [10]. Of course, organ scarcity is not unique to the field of pediatric organ transplantation . To be sure, scarcity is a major problem in the fields of pediatric and adult organ transplantation. For example, as of May 2019, there were 2000 children and 113,000 adults on the national organ transplant waiting list. Moreover, in 2018, there were 36,000 organ transplants performed in the United States [10]. While this set a record for the number of transplants performed in a year in the United States, it was not nearly enough to satisfy the demand for organs. To put it in perspective, if the number of organ transplants that will be performed in 2019 is consistent with the number of organ transplants that were performed in 2018, then, even under record-setting conditions, there will be 77,000 people who will not get the organs they need this year [10]. Even worse, some of those on the organ transplant waiting list will die before compatible organs become available. In 2018, for example, more than 7300 Americans died while waiting for compatible organs [11].

The problem of organ scarcity is equally acute in the field of pediatric heart transplantation because of additional considerations

like size-matching. For example, infants and young children are often too small to receive heart transplants from older children and adults. For this reason, the heart of a pediatric organ donor must be measured to ensure that it is compatible in size with the body of the potential pediatric heart recipient before it can be transplanted; otherwise the organ will not function properly, or it may fail altogether. Of course, blood must be matched for compatibility also. After all, a person with Type A blood cannot receive a transfusion from a person with Type B blood. If this happens , the recipient might suffer an incompatibility response which could be fatal. For similar reasons, tissue must be tested for compatibility. This explains why hospital personnel go through extensive protocols before they perform blood transfusions, and organ transplants.

Notice, however, that there are no compatibility protocols to ensure that organs which are donated by pediatric patients go to pediatric recipients. This might be surprising to some, especially since "a large proportion of pediatric organs… are transplanted into adult recipients " [5] even though "children, especially newborns, have a higher waitlist mortality rate than other patient groups" [3]. In fact, this has led some child advocacy groups to call for organ transplant programs for pediatric patients [5]. However, such a change would mark a major shift in practice because, currently, organs are allocated on the bases of medical criteria like size compatibility and urgency of medical need. Hence, an adult patient who has a more urgent medical need for a particular organ will be higher on the organ transplant waiting list than a pediatric patient who has a less urgent medical need for the organ. In such cases, the adult patient will receive greater priority than the pediatric patient when a compatible organ becomes available, even if the organ was donated by a pediatric patient.

Of course, the problem with reserving organs for one group based on a non-medical criterion like age is that we might find it difficult to refrain from reserving organs for other groups based on other non-medical criteria like economic class, gender, race, religion, or some other phenotypical trait or sociological characteristic . Even worse, phenotypical traits and sociological characteristics like age, economic class, gender, race, religion, and so on, are superfluous for making medical decisions about organ allocation. After all, the religious beliefs

of parents cannot tell us whether or not their child's heart will be compatible in size with the body of a potential organ recipient. Thus, if medical professionals were to make decisions about allocating organs based solely on phenotypical traits or sociological characteristics, then, inevitably, some doctors will unwittingly transplant incompatible organs into the bodies of their patients . Undoubtedly, this would result in harm and thereby violate the Principle of Non-maleficence.

Moreover, given the U.S.'s history of discrimination and medical experimentation on various groups based on gender, mental capacity, race, and sexual orientation it would be imprudent for medical professionals to even include phenotypical traits and sociological characteristics in the decision-making process for allocating organs. For example, in *Bad Blood*, James Jones offers us a detailed account of unethical medical experiments that were performed on African-American males in Tuskegee, Alabama from 1932 until 1972 [12]. The Tuskegee experiments were only stopped because an investigative reporter from the Associated Press, Jean Heller, revealed what was happening in the *Washington Star* on July 25th, 1972 [12]. Not surprisingly, after Heller's article was published there was public outrage and a great deal of distrust of the medical community, particularly among African-Americans.

Even worse, the Tuskegee Syphilis Experiment was not an isolated incident. To be sure, in *Medical Apartheid*, Harriet Washington recounts the details of several other unethical experiments that were performed on African-Americans without their consent [13]. Similarly, in *Medical Bondage*, Deidre Owens explains how unethical gynecological experiments were performed on African-Americans women without their consent [14]. Thus, if doctors were to include phenotypical traits or sociological characteristics in the decision-making process for allocating organs, they would risk undermining the public's trust that medical professionals act in the best interest of all patients. For this reason, I conclude that medical professionals ought not to include phenotypical traits or sociological characteristics in the decision-making process for allocating organs.

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3 An Opt-Out System of Organ Donation

After all, there are other ways to address the problem of organ scarcity. For example, in *Nudge*, Richard Thaler and Cass Sunstein argue that, since many people will act in accordance with whatever the "status quo bias" is, the best way to increase organ donations is to switch the United States to an opt-out system of organ donation [8]. Of course, this would entail placing all Americans on the organ donor registry unless they express a desire to be omitted. Also, this would automatically switch the burden of acting affirmatively from those who wish to donate their organs to those who do not wish to donate their organs. For this reason, some scholars argue that opt-out systems are problematic because they give the state a license to harvest the organs of those who fail to register their desire not to donate [15].

Moreover, for Thaler and Sunstein, opt-out systems are libertarian and paternalistic. In *State, Anarchy, Utopia*, Robert Nozick tells us that libertarians seek to minimize state intervention as a way of maximizing individual freedom [16]. By contrast, in "Paternalism," Gerald Dworkin tells us that paternalists seek to increase state intervention as a way of promoting the interests of individuals [17]. For these reasons, philosophers usually take libertarianism and paternalism to be incompatible, but Thaler and Sunstein believe that they can maintain both positions simultaneously. Indeed, they argue that opt-out systems are libertarian because they preserve individual freedom by allowing people to opt-out if they choose, and paternalistic because they promote the interests of individuals by "nudging" them towards their desired goals [8]. For me, opt-out systems result in "institutional nudging" because the system provides the pressure that induces people to act in a particular way. Later, I will argue for a form of "nudging" that is interpersonal. "Interpersonal nudging" occurs when people provide the encouragement that induces others to act in a particular.

Thaler and Sunstein attempt to justify their position by highlighting survey results illustrating that 97% of those surveyed say that they support organ donation, but only 43% of those surveyed were registered organ donors [8]. They argue that this disparity highlights the fact that the default position in the United States is at odds with the desire of the majority of Americans. That is, the majority of Americans support organ donation but the default position in the U.S. is not to donate. Hence, they conclude that the proper course of action is to

design a system that aligns the default position with the desire of most Americans [8]. For this reason, they support switching the United States to an opt-out system as a way of addressing the problem of organ scarcity.

At first glance, Thaler's and Sunstein's position seems justified, particularly in light of their discussions of the survey results and "status quo bias." However, on closer inspection, I find that Thaler's and Sunstein's arguments do not support their conclusion that the U.S. ought to switch to an opt-out system. After all, their discussions of the survey results and "status quo bias" cannot explain why so many Americans protest against opt-out legislative proposals. For example, Assemblyman Patrick Burke's 2019 legislative proposal to switch the state of New York to an opt-out system of organ donation gave rise to protest [18]. In fact, Assemblyman Burke withdrew his proposal because of the negative backlash it received [18]. This is not surprising because many opt-out legislative proposals attract negative attention . More importantly, most opt-out legislative proposals never make it out of committee. Those that do make it out often fail miserably on the floor in state legislatures. Indeed, opt-out systems of organ donation have been

> considered in the United States before, but never beyond initial considerations. The Ethics Committee of the United Network for Organ Sharing (UNOS) developed a white paper on presumed consent in 1993 and repeated those findings in 2005. It noted there was no clarity whether a large proportion of the population was primed for this type of system . At least three states, Delaware, Colorado, and New York, have considered modifying their laws to presumed consent stances, but these efforts quickly fizzled out [19].

Similarly, opt-out legislative proposals have failed in Pennsylvania in 2016 [20], Texas in 2017 [21], and Connecticut in 2017 [21]. In light of this, it seems clear that, while the majority of Americans support organ donation, they do not support switching to an opt-out system of organ donation.

There is another problem with Thaler's and Sunstein's justification, namely, it fails to account for why some countries with opt-in systems have higher donation rates than others with opt-out systems. For example, the United States has a higher deceased organ donor rate than many countries with opt-out systems, including France, Finland, Italy, and Sweden [22, 23]. This is also true of other countries with opt-in systems. For example, the United Kingdom has a higher deceased organ donor rate than Finland and Sweden [22, 23]. Thaler and Sunstein attempted to explain this contravening evidence by pointing to the fact that the U.S. has a better medical system than many other countries [8]. Notice, however, that this explanation does not work in the cases of the U.S. and U.K., and France, Finland, Italy, and Sweden . After all, they all have similar technologically advanced economies, and therefore, it is likely that they have comparable medical systems. More importantly, if Thaler's and Sunstein's explanation is correct, then they have been arguing for the wrong conclusion. Instead of arguing that the U.S. should switch to an opt-out system, they should be arguing that nations can increase their organ donor rates by improving the quality of their medical systems.

Even worse, it seems that Thaler's and Sunstein's attempt to explain organ donation rates by the quality of a country's medical system also fails. After all, Croatia has a higher deceased organ donor rate than the United States [22, 23]. Moreover, given that the U.S. has a more technologically advanced economy than Croatia it is likely that the U.S has a more technologically advanced medical system than Croatia. This is true of other countries also. For example, Latvia has a higher deceased donor rate than Germany [22, 23]. However, Germany has a more technologically advanced economy than Latvia. In which case, it is like that Germany has a more technologically advanced medical system than Latvia. In light of this, it seems that Thaler's and Sunstein's attempt to account for the contravening evidence also fails. In which case, their conclusion that switching to an opt-out system would increase organ donation rates is not supported by the empirical evidence. For this reason, I concluded that, rather than switching to an opt-out system, we should focus on other ways to increase organ donation rates, like "interpersonal nudging."

Finally, in the *Second Treatise of Civil Government*, John Locke argues us that people have a natural right to property in their bodies [24]. To be more exact, Locke means that autonomous people have the natural right to determine what happens to their bodies. For example, he tells us that each of us "have the freedom to order our actions, and dispose of our possessions and persons as we see fit without asking for permission from anyone," and that the "freedom then of man, and liberty of acting according to his own will is grounded on his having reason" [24]. More importantly, medical institutions in the United States have adopted a similar position because respect for patient autonomy and patient consent are obligatory in the practice of medicine. However, notice that when someone dies, his/her real estate, money, food, and other property go to his/her spouse, children, or next of kin, even in cases where he/she did not leave a will. Thaler and Sunstein recognize this in their discussion of inheritance [8]. Thus, it is perfectly reasonable to demand a justification for why Thaler and Sunstein treat bodily property, i.e. organs, differently from how they treat other kinds of property, i.e. homes. The answer cannot be that a deceased person's heart, lungs, kidneys, and other organs will save lives because a deceased person's real estate, money, and food would save the lives of homeless people if they were given to them upon one's death.

At this point, it seems that Thaler and Sunstein only have three possible ways to respond: first, they might argue that bodily property is fundamentally different from other kinds of property such that it should be turned over to the state upon one's death; secondly, they might argue that all property should be turned over to the state upon one's death; or, thirdly, they might "bite the bullet" and simply accept that their position is inconsistent. The first option does not seem viable because the fundamental difference between bodily property and other kinds of property is material. That is, bodily property is organic while other kinds of property are inorganic. More importantly, however, this fact is irrelevant for determining whether or not property, bodily or otherwise, should be turned over to the state upon one's death. The second option makes Thaler's and Sunstein's position consistent, but it does not seem practicable. After all, very few Americans would accept the conclusion that their property should be turned over to the state

when they die, whether or not there is an opt-out option . In fact, even Thaler and Sunstein didn't draw this conclusion when they discussed inheritance [8]. For this reason, it would be disingenuous to attribute it to them here. This leaves the third option, which is itself a logical reason for rejecting their position. Thus, for the reasons articulated above, I find myself unable to accept Thaler's and Sunstein's conclusion that the U.S. ought to switch to an opt-out system of organ donation.

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4 A Commercial Market for Human Organs

Of course, not all medical ethicists believe that the U.S. ought to switch to an opt-out system of organ donation in order to address the problem of organ scarcity. In fact, in *Organs for Sale by Owner: Human Organs, Transplantation, and the Market*, Mark Cherry argues that the best way to address the problem of organ scarcity is to develop a commercial market for buying and selling human organs [25]. According to Cherry, a commercial organ market can be regulated to ensure the quality of the organs and the physical safety of the buyers and sellers. Moreover, he argues that since people are often motivated by money there will be no shortage of people willing to participate in a commercial organ market, provided, of course, that the financial and other incentives are high enough. He concludes that a commercial market for human organs will greatly reduce or altogether eliminate the large number of people on the organ donation waiting list and thereby save thousands of lives, many of them infants and children.

Even more, in recent years, bioethicists have been more vocal in their advocacy for a commercial organ market. To be sure, Janet Radcliff-Richards, in "The Case for Allowing Kidney Sales" [26]; Benjamin Hippen, in "A Defense of a Regulated Market in Kidneys from Living Donors" [27]; and, L.D. de Castro, in "Commodification and Exploitation: Arguments in Favor of Compensated Organ Donation," [28] have argued for some version of a commercial organ market. In light of this, it seems that we ought to consider the possibility of having a commercial market for organs. After all, there are many ways to design such a market. For example, the seller might be compensated during his/her lifetime for access to his/her organs upon his/her death . Alternatively, the seller's family might be compensated for access to

his/her organs upon his/her death. Or, the exchange of organs and money might take place while the seller is still alive—at least, this is possible when the exchange concerns organs that are not necessary for life.

This position will not seem foreign to many because the U.S. government already allows people to buy and sell their body parts on the commercial market. Currently, people buy and sell human blood, breast-milk, eggs, hair, plasma, sperm, and stem cells on American markets . So, it is perfectly reasonable for Cherry and others to ask: Why not allow people to buy and sell corneas, kidneys, livers, and lungs on American markets also? The answer seems to be that a commercial market for human organs will be coercive to poor Americans. After all, no matter what the incentives are, wealthy Americans are not likely to sell their organs because they have enough money, power, and influence to enjoy all of the advantages of living in high society without undergoing a major surgery to remove a working organ. Similarly, middle-class Americans are not likely to sell their organs because they have access to institutions which allow them to enjoy most of the advantages of living in America without undergoing a major surgery to remove a working organ.

By contrast, the poor have very little money, power, or influence, and, even after accessing social services programs, they are still left at the bottom of American society, often teetering between homelessness, illnesses, and joblessness. As a result, they eke out a meager living in the housing developments of large cities, and the rural communities of dilapidated small towns, hoping for a better life. In which case, the promise of thousands of dollars will be enough to coerce many of them into participating in the commercial organ market. In fact, in the *Concept of Law*, H.L.A. Hart tells us that coercion occurs when one feels psychological pressure to act in a particular way in order to avoid suffering serious harm [29]. Given that the poor teeter constantly between homelessness, joblessness, and illnesses, one can see how they will feel psychological pressure to sell their organs in order to avoid the ills of homelessness and illnesses. More importantly, a commercial organ market will depend on such coercion, especially if it is to solve the problem of organ scarcity; otherwise there will not be enough people participating in it. Hence, given the problem of coercion of the

poor, I find that a commercial market for buying and selling human organs on the U.S. market is unjustified.

Lastly, notice that a commercial market for buying and selling vital organs is much different from the aforementioned market for buying and selling blood, breast-milk, eggs, hair, plasma, sperm , and stem cells. After all, the current market does not depend on coercing the poor. In fact, the majority of people who participate in the current market are middle-class. For example, for-profit egg donation agencies often advertise in the newspapers of elite colleges like U.C.L.A [30]. Moreover, the median household income of a student at U.C.L.A. is $104,000 per year [31]. Hence, by default, middle-class women are much more likely to be egg donors than poor women. For profit sperm and hair agencies have similar recruiting practices. Either way, most of the body parts that are sold on the current market are replenished by the body naturally, and therefore, the seller's capacity to function is not reduced. For these reasons, I find that it is morally permissible to allow people to sell non-vital human body parts like blood, breast-milk, eggs, hair, plasma, etc., on the U.S. market.

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5 "Interpersonal Nudging" as the Solution to the Problem of Organ Scarcity

A better alternative is to engage in "interpersonal nudging " within an opt-in system. This approach would allow us to increase the supply of organs and avoid the problems I've highlighted with Thaler's and Sunstein's opt-out proposal. According to Chandler and Gruben, "nudging" is the act of "using persuasive techniques to encourage families to consent to donate the organs of a deceased love one" [2]. For me, the "nudging" in question is interpersonal if the encouragement that induces a person to act comes from another person. More importantly , however, those engaged in "interpersonal nudging" must be careful to avoid engaging in behaviors that would undermine the public's trust or violate patient autonomy. For, Chandler's and Gruben's phrase "using persuasive techniques to encourage families to consent to donate" might be interpreted to include a broad range of behaviors [2–4].

To be sure, Chandler and Gruben tell us that some organ procurement agents engage in aggressive persuasive techniques like "reproaching refusing families" or "evoking feelings of guilt" to influence parents to donate [2]. This is confirmed by a "critical care physician in Chicago" who told a reporter for the *Washington Post* that "he has seen these guys come in and almost browbeat families into submission to get them to donate organs" [4]. Similarly, an intensive care nurse at a hospital in Madison, Wisconsin reported that "the people I work with sometimes feel they are too pushy" [32]. Michael Grodin reported having the impression that they are "like vultures, flying around the hospitals hovering over beds waiting for them to die so they can grab the organs" [32]. David Crippen warns that "the demand for organs is very intense, and the organ-procurement organizations have become much more aggressive about supplying it" [32]. Like Robert Troug, he concludes that, if we are not careful, "some of the changes in the logistics of organ procurement could compromise public trust" [32]. I would add that procurement agents who "reproach," "guilt," "pressure," "browbeat," or "push" parents into donating the organs of their recently deceased child violate patient autonomy, and therefore, act unethically.

It's worth noting that not all procurement agents act in these ways. Probably, only a small minority of agents do so. Nevertheless, I can understand how some might feel encouraged to engage in such behaviors , given the fact that some organ procurement agencies

> are evaluated based on their conversion rates (percentage of potential donors who become actual donors), they are paid on the bases of the number of donors they secure, and their employees are presumably hired, fired, and promoted on the basis of how well they promote these goals [33].

After all, as Michael A. DeVita, reminds us: "If you promote organ donation too much, people lose sight that it's a dying patient there" [32]. Consequently, in light of the evidence above, I believe that it is imperative for the Department of Health and Human Services to establish clear standards for governing the behavior of hospital staff and private agents involved in the organ procurement process.

Mavroudis and associates move us in the direction of this goal in "Ethical considerations of transparency, informed consent, and nudging in a patient with paediatric aortic stenosis and symptomatic left ventricular endocardial fibroelastosis" [7].

According to Mavroudis and associates, there are four persuasive techniques that allow agents to engage in the practice of "nudging" without violating the autonomy of the parents: *selective emphasis*, *beneficent persuasion*, *nudging and informed consent*, and *shared decision-making* [7]. *Selective emphasis* allows a doctor to offer explanations to parents that are proportional to the different levels of risks involved in a procedure. For example, a doctor might emphasize the importance of the salient features involved in identifying a compatible organ donor for a potential pediatric heart transplant recipient while de-emphasizing a rare negative outcome that might occur. Of course, the point of selective emphasis is not deception or concealment, but rather, "to give proper weight to the various factors at hand" [7].

Beneficent persuasion allows a doctor to use empathy, respect, and negotiation to improve the long-term health of his/her patients. For example, a doctor might use beneficent persuasion to encourage parents to think about the opportunities their child might lose if they fail to consent to a much-needed heart transplant [7]. Of course, the doctor is not attempting to guilt the parents into consenting to the procedure, but rather, he/she is simply directing them to think about the long-term effects that their decision will have on the health of their child. More importantly, *nudging and informed consent* allows a doctor to "bridge the gap between his/her duty to respect patient autonomy and beneficence" [7]. In other words, a doctor might engage in "interpersonal nudging" as a way of inducing parents to do what they already know is in the best interest of their child, and are leaning towards doing anyway. Mavroudis and associates explain that "nudging" must be "transparent and never misleading, easy to opt-out of, and done with the purpose of improving the welfare" of the child [7]. Lastly, *shared decision-making* allows the parents and the doctor to weigh different treatment options for the child. They achieve this when there are shared information exchanges, deliberation, and negotiations between the doctor and the parents.

The techniques Mavroudis and associates offer are important standards for guiding the behavior of medical professionals when they are engaged in advising parents about various treatment options for their child. Moreover, the techniques of beneficent persuasion, interpersonal nudging, and informed consent can be used to increase organ donations without violating the autonomy of the parents to choose. However, when the conversation turns to organ donation, additional standards are needed to protect parents from experiencing psychological harm in the organ procurement process, and hospitals from being the subject of lawsuits. After all, some parents have reported experiencing trauma as a result of having to deal with aggressive organ procurement agents while their child was dying in a hospital. Moreover, some parents have launched successful lawsuits on the grounds of emotional harm [34].

More importantly, however, to prevent other families from experiencing emotional or psychological harm, the Department of Health and Human Services ought to establish uniform policies requiring hospital and organ procurement staff to log all conversations about organ donations. Every log entry should include the time and date of the request to donate, the names and titles of the hospital and organ procurement staff who were engaged in the conversation, and the conditions under which the conversations took place. In this way, it will be easy to keep track of the conversations about donating and identify how often the parents were approached. In addition, parents should be given a sufficient amount of time and space to make a decision and to report back to the hospital. Of course, the amount of time needed will vary, but this can be negotiated at the time when the conversation about donating occurs. If the parents decide not to donate, the hospital staff and organ procurement agent should be required to accept their decision without attempting to persuade them to do otherwise.

Even more, the Department of Health and Human Services should require hospitals to provide follow-up care to all parents who are asked to donate the organs of their recently deceased child, whether or not they actually donate any organs. The purpose of this is to give the parents an opportunity to share their thoughts about the organ procurement process . This also gives the hospital staff an opportunity

to make changes to the process if any are needed, and it allows the hospital staff to do due diligence by offering follow-up care to parents. Finally, there must be oversight to ensure that the policies are followed and that organ procurement agents who violate the policies are reprimanded. These changes coupled with those offered by Mavroudis et al are justified because they protect the autonomy of parents insofar as they afford them time and space to make an autonomous decision, give them the possibility of opting out, and offer them follow-up care. Additionally, they allow medical staff to do due diligence by giving them guidelines for engaging in "interpersonal nudging" without violating the autonomy of patients while providing follow-up care to those who might need it.

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6 Conclusion

In this chapter, I have offered philosophical analyses of the problem of organ scarcity and the solutions that have been offered by medical ethicists against the backdrop of a discussion of heart transplants in pediatric patients. I have argued that "interpersonal nudging" in an opt-in system, as opposed to "institutional nudging," offers us the best potential for addressing the problem of organ scarcity while avoiding the ethical problems associated with other solutions. While I have agreed with Chandler's and Gruben's definition of nudging, and the standards for engaging in justified nudging offered by Mavroudis and associates, I have argued that more needs to be done to protect parents who are thinking about donating an organ of a recently deceased child from aggressive organ procurement agents and hospitals from lawsuits. Towards this end, I have argued that the Department of Health and Human Services ought to establish uniform policies requiring hospitals and organ procurement staff to log all conversations about organ donations; limit the number of times staff can ask parents to donate; provide follow-up care for all parents who are asked to donate whether or not they do so; establish oversight, and reprimand agents who violate the policies repeatedly. I have concluded that adherence to these policies will increase organ donation, remove problems with over-zealous organ procurement agents, and increase good will among all concerned.

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Active and Passive Euthanasia in the Context of Severe Congenital Heart Disease

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1 Introduction

Euthanasia is commonly associated with the popular term "mercy killing ," but its etymology (from the Greek *eu-* [good] and *thanatos* [death]) suggests a wider range of circumstances, broadly classified as active and passive euthanasia. Active euthanasia, or mercy killing , describes the act of causing death for beneficent reasons by an active intervention, such as injecting a solution of potassium chloride to stop cardiac muscle contractions or a massive overdose of morphine to cause euphoria, narcosis, and respiratory arrest. Passive euthanasia

describes an act of omission, such as withholding or withdrawing life supporting therapies.

The commonly held view in the bioethics literature is that withholding and withdrawing life support are morally identical, although there is some debate about their equivalence [1]. Certainly, to health care professionals who either withhold endotracheal ventilation or withdraw it after it has begun, the two decisions produce very different emotional reactions—the active intervention of pulling the plug of a ventilator feels like killing, while passively withholding such technologies seems more like "letting die " and feels less uncomfortable.

For many decades the law has viewed withdrawing life support as letting die rather than killing, thus allowing physicians to remove life support from hopelessly ill patients without fear of prosecution for manslaughter or murder [2]. A small but growing group of bioethicists argue that withdrawing life support is actually an act of killing, but agree with the law treating this helpful and morally praiseworthy act as a form of passive euthanasia [3]. They label this approach as a useful "legal fiction ," similar to the fiction of "legal blindness " of persons who are not truly blind, but whose vision is no better 20/200—legal blindness qualifies them for social services for the blind.

Assisted suicide could also be considered a variety of euthanasia. In this case, the good death is brought about by the person themself, with the arms-length help of a second person. The laws of nine states and the District of Columbia in this country allow assisted suicide when the assist is provided by a physician under certain limited circumstances (physician-assisted death, or PAD) [4]. The same is true in seven countries in Europe and the Americas [5].

Voluntary active euthanasia —active intervention to cause death at the request of a patient—is not legal in any US state, but it is legal in Belgium, Colombia, Luxembourg, and the Netherlands (and perhaps in Canada where its status is unclear) [5]. Because of the recent expansion of the number of states that have legalized PAD (six of the ten jurisdictions passed their PAD laws since 2015), it seems plausible that active euthanasia will be approved in one or more of the US states in the foreseeable future.

A subcategory of active euthanasia is non-voluntary active euthanasia , which refers to euthanasia of an individual who cannot participate in the decision, such as unconscious or demented patients and small children. Some laws that permit voluntary active euthanasia also permit the non-voluntary variety. Only one country permits euthanasia of children: the Netherlands, under the Groningen Protocol, which we will discuss shortly.

When a newborn child or infant is diagnosed with complex cardiac anatomy that is likely to result in a short and uncomfortable life, physicians and parents are often faced with a daunting dilemma . Should they embark on multiple palliative operations or should they withhold life-sustaining treatment and choose palliative care? This decision is often complicated by its impact on the well-being of parents, siblings, families, and health professionals. Although not currently a possibility in this country, there may be a third option—non-voluntary active euthanasia, which will prevent prolonged suffering after the decision is made not to embark on a surgical course. We present such a case that will focus the main discussion of this chapter.

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2 The Case of the Ill-Fated Newborn

A full-term newborn infant was noted to turn blue while feeding a few hours after birth. Evaluation by a pediatric cardiologist revealed hypoplastic left heart syndrome (HLHS) with aortic and mitral atresia, ascending aortic diameter < 1 mm, and markedly hypoplastic left ventricle. The patient was also noted to have a single kidney and microcephaly. The cardiologist meets with the parents, explains the diagnosis, and outlines three alternative courses: surgical treatment, comfort care with feeding, and euthanasia.

Surgical treatment will require at least three risky heart operations before five years of age. If all the operations are successful, the child might survive to his teenage years, most likely with a poor quality of life, but may not survive to adulthood. The severity of his malformations places him in a higher risk category than the typical HLHS patient.

With *feeding and comfort care only*, the baby would be expected to become progressively disabled and distressed, and would most likely

die in a few weeks or months, up to a year.

Euthanasia at this point would prevent future suffering. It is an option only if the jurisdiction in which the hospital is located has a policy allowing physician-assisted death under these circumstances.

The parents consider this information and discuss it with other family members, close friends, and their spiritual advisor before making their decision. At the cardiologist's next visit, they tell him that if they had known about this problem, they would have terminated the pregnancy, because they do not wish their child to have a poor quality of life. Because they did not know the problem before birth, they believe euthanasia is the most humane of the three available options, as it will avoid the suffering associated with a slow death. Should the physician help them in this way? (Adapted from Sade, 2015) [6].

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3 The Option of Palliative Care

To address the parents' request we must first assess whether offering palliative care is still an option. Many advances in the care of children with HLHS have occurred since the introduction of the Norwood operation over 30 years ago [7, 8]. They include incremental improvements in perioperative care , surgical techniques, management of cardiopulmonary bypass in newborn infants, and implementation of inter-stage home monitoring programs [9]. As a result of this trend about 70% of children born with HLHS may live long enough to reach adulthood [10].

Surgical intervention can therefore be offered to children with syndromes that would have precluded them from consideration in an earlier era [11]. In the United States, advances in the care of children with HLHS have moved many physicians away from recommending pregnancy termination when HLHS is diagnosed by ultrasound, more so than in other western countries; in fact, some physicians advocate for a paradigm shift towards surgical interventions [12, 13]. Yet patients with HLHS are still at risk of multiple morbidities and mortality at each of the serial stages [14, 15]. The 5 year transplant-free survival is only around 60–64% [16, 17].

Patients with factors associated with higher than usual risk fare worse than average. High-risk factors include severe hypoplasia of the

ascending aorta, restrictive atrial septal defect, low birthweight, earlier gestational age , poor ventricular function, and tricuspid regurgitation. Associated congenital anomalies, such as are seen in the present case, are strongly associated with poor outcomes [18, 19]. For some families, the cumulative mortality and morbidity risk justifies choosing a palliative care option, which, in our view, should still be discussed with every family [20, 21].

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4 The Groningen Protocol

Outcomes of the treatment of HLHS are still far from ideal, in terms of mortality, morbidity, and quality of life, so when the diagnosis is made prenatally, many families choose to terminate the pregnancy at that time. Some families, such as the one in our introductory vignette, did not have a prenatal diagnosis, but if they had, would have chosen to terminate the pregnancy. Discovering the diagnosis immediately after birth, should they be able to choose to facilitate ending the life of their newborn child? In the Netherlands this has been allowed and the Groningen Protocol (the Protocol) was developed to address this particular scenario [22]. The protocol requires all of the following: [1] "The diagnosis and prognosis must be certain" [2], "Hopeless and unbearable suffering must be present" [3], "The diagnosis, prognosis, and unbearable suffering must be confirmed by at least one independent doctor" [4], "Both parents must give informed consent," and [5] "The procedure must be performed in accordance with the accepted medical standard." In 2005 the Dutch Association of Pediatrics approved and adopted the Protocol [23, 24].

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5 The Debate About the Protocol

5.1 Autonomy and Health Maximization

Supporters of the Protocol emphasize the ethical principle of respect for autonomy and the utilitarian notion of health maximization [25]. By ensuring that both parents provide informed consent, the protocol recognizes the parent's right to act on behalf of their newborn and the necessity to have their undivided agreement on decisions made for their child. Parents would have the opportunity to weigh their child's

continued suffering while in the process of dying slowly, against euthanasia that would provide compassionate relief from suffering in the face of ineluctable death [26]. At the same time the protocol also reduces overall resource utilization and costs by causing an early death, thus favoring "the utilitarian idea of seeking the greatest good for the greatest number—that is, resources should be used to maximize the health of all rather than that of an individual" [27].

5.2 Nonmaleficence

The Protocol's opponents argue that an ethical consideration of at least equal or perhaps greater weight than respect for autonomy is non-maleficence, the do-no-harm principle, and actively causing death is contrary to this principle [25]. "Hopeless and unbearable suffering" is indeed eradicated, according to one observer , but the protocol will eliminate the suffering "by eliminating the sufferer" [28], which is morally unacceptable [23, 29]. Instead of accelerating an approaching death, we should focus on helping with the dying process [30]. In the last couple of decades the growth of hospice care and of palliative care services both within and outside of health care facilities exemplify the kind of caring support on which we should be focusing for those close to death. In the case of a child whose end is near, supportive medical care can completely relieve the patient's suffering, if not that of the parents and family. Our first concern, on this view, should be to do what is best for the child, and the discomfort of the parents and other family members should be of only secondary importance.

Proponents of the Groningen Protocol take a different view of nonmaleficence : bringing on death earlier is perfectly consistent with that ethical principle. When comparing euthanasia with treatment of terrible diseases, such as the severe HLHS in our vignette, they ask whether it is more harmful to intentionally end life or to allow the suffering associated with series palliative surgical interventions. The concern here is "postoperative pain, possible prolonged mechanical ventilation, central access, and possible end organ damage with no potential for the long-term benefit of a productive life" [27, 31]. Is it more harmful for parents to participate in a decision to end life early or for them to live through their child's inevitable suffering both from multiple surgeries and from disabilities and frailty associated with their

underlying diagnosis? Comparing euthanasia with the option of comfort care, which does not include surgical interventions, the suffering of patients and also of parents, siblings, and extended family may be unnecessarily prolonged. If inevitable death cannot be avoided, there is no advantage to extending it. One observer has argued for allowing euthanasia in certain circumstances, stating, “Once we have concluded that death is what is in the best interest of the infant, it is unreasonable not to bring about this death as painlessly and as much controlled in terms of timing by the parents as is feasible” [32].

5.3 A Slippery Slope

Making another point, opponents of the Protocol wonder whether, if a political jurisdiction, such as the Netherlands, opts to allow euthanasia, its scope could be effectively limited. The second criterion for euthanasia permissibility under the Protocol, “Hopeless and unbearable suffering must be present ,” can be interpreted in many different ways. What about children with severe neurological compromise or missing limbs? They certainly are suffering. Will permissiveness toward actively causing death lead to elimination of the handicapped? [32].

The actual data strongly dispute this argument. In the Netherlands, the legitimacy of euthanasia has not led to widespread implementation. Between 1995 and 2005 the lives of only four children were ended through facilitated death, and between 2005 and 2010 there were none [32, 33]. The opponents’ slippery slope argument is a consequentialist logical fallacy. The success of such arguments depends on providing a warrant, that is, demonstrating a known process that leads to the preferred conclusion, in this case, elimination of the handicapped. The evidence here, however, points to the opposite conclusion: there appears to be no slippery slope associated with the Groningen Protocol.

5.4 Impeding the Science and Art of Medicine

Some have argued that electing an earlier death through euthanasia might adversely impact the development of the science and art of medicine [34]. For example, children with Down syndrome were at one time believed to be at high risk of cardiac surgical intervention, which far exceeded potential benefits, such as meaningful quality of life;

surgery was therefore avoided for many [35]. As attitudes toward cognitively handicapped children changed, however, surgery was offered more often, and today children with Down syndrome fare better than their unaffected peers after biventricular repair [36]. Had the pediatric cardiology and cardiac surgery community chosen comfort care (or euthanasia if it were permissible) for these children, the current success could not have occurred [34].

Supporters of the Protocol might propose that this argument is an example of the continuity fallacy—it assumes that all or most previous decisions denied surgery to Down syndrome children, and that all or most decisions about euthanasia for children with severe forms of congenital heart disease would favor immediate death. Yet neither of these assumptions is valid, because the acceptability of active or passive euthanasia for such children will vary from place to place and from time to time, over wide ranges. The progress of the art and science of medicine will not be slowed by a single policy, such as the Groningen Protocol.

5.5 Culture and Religion

For some, the decision to end life is governed by faith and belief systems. Those who believe that life is sacred from the time of conception or that the "human person is not the owner of his life but the steward" [37] will find that euthanasia is not an option [32, 38]. Many world religions, texts, and communities strictly prohibit the killing of an innocent human being even if done for compassionate reasons. Furthermore, many families from countries with underdeveloped health care systems where the only option would be non-surgical palliative care migrate to countries with advanced health care systems, such as the Netherlands. These families are now geographically separated from their extended family support systems and may also be confused when presented with the surgical palliative care and euthanasia options. Parental informed consent is a critical component of the Protocol if the principles of medical ethics are to be fulfilled [25]. A family's lack of familiarity with the proffered options and inability to consult with their families and elders when it comes to end-of-life discussions may be a considerable obstacle for their consideration of euthanasia [39].

6 Conclusion

As we conclude this chapter, we should remember that whenever a child dies, whether after cardiac surgery, comfort care, or euthanasia, parents and families need support [40]. End-of-life decisions are extremely difficult and stressful. Support from other family members, religious advisors, and social institutions is needed [41]. The euthanasia option is not for all families nor would many physicians, including the authors of this essay, participate [42]. While this chapter has discussed euthanasia for pediatric patients with complex medical problems, a larger point concerns adult patients. In 2016 only 57% of US physicians felt that PAD should be made available to adult patients [43]. In 2012 55% of US adults favored permitting PAD for adults with fewer than 6 months to live [44]. These statistics indicate that 43% of physicians and 45% of the US population do not support PAD for adults. Active euthanasia of adults is illegal everywhere in this country. Euthanasia of children who may not be terminally ill and who cannot make any decision for themselves lies far beyond the case of terminally ill adults making this decision for themselves. Instituting a policy like the Groningen Protocol in any state in this country is far from the mainstream of public opinion and would likely subject physicians and institutions to harsh public criticism. The relatively rapid recent expansion of the number of states legalizing PAD makes the possibility of future legalization of voluntary active euthanasia plausible, but we hope it will not happen on our watch.

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Ethical and Legal Controversies Concerning Consolidation of Congenital Heart Programs in the United States of America

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1 Introduction

Variation in outcomes across congenital heart surgery programs is concerning to surgeons, hospitals, administrators, pediatric networks, state health systems, third party payers, and ethicists [1]. Media attention in the United States and Europe has resulted in closure and re-structuring of congenital heart programs accused of paternalistic patient management and lack of transparency regarding outcomes and complications [2, 3]. Previous attempts to consolidate pediatric congenital heart surgery programs have been contentious with unclear benefit. Hospital administrators and leading congenital heart surgeons

have vigorously debated how to best optimize patient outcomes with the unavoidable constraints of patient access and hospital capacity. Several lower volume congenital heart programs achieve excellent clinical outcomes comparable to or exceeding higher volume programs [4, 5]. Regionalization of care is a proposed solution to improve outcomes in patients undergoing congenital heart surgery on a national scale. Several large databases allow modeling of different consolidation approaches to achieve regionalization [6]. The glaring ethical considerations , however, must be carefully considered in all regionalization schemes.

Regionalization may have the unintended consequence of limiting access to care. Likewise, decreasing the number of centers may limit innovation within congenital heart surgery; historically the genesis of modern-day heart surgery. In addition, congenital heart programs generate revenue that may help support underfunded programs in children's hospitals. Finally, regionalization threatens a hospital's community obligation or right to treat underserved populations. This chapter will address the available data and the ethical issues involved regarding national recommendations towards congenital heart programs.

2 The International Perspective

In the early 1990s, clinical staff of the Bristol Royal Infirmary, a prestigious hospital within the National Health Service (NHS) in England, raised concerns about the above average mortality rate seen within the pediatric cardiac surgery program. In 1995, the death of an 18-month old boy during an arterial switch operation sparked a media firestorm and two inquiries into Bristol's congenital heart surgery program . The first inquiry, conducted in 1998 by the General Medical Council, concluded that two cardiac surgeons and the chief hospital executive were guilty of professional misconduct [7]. Later that same year, the Secretary of State for Health launched a full public inquiry. The inquiry (1998–2001), which later became known as the Kennedy report, identified 30–35 deaths above expected mortality occurred in children under 1-year of age undergoing heart surgery in Bristol between 1991 and 1995. The report contained nearly 200

recommendations, including a standard that congenital heart programs meet a minimum annual case volume in order to perform pediatric cardiac surgery [8].

In 2003, the European Association of Cardio-Thoracic Surgery (EACTS) Congenital Heart Disease Committee issued an expert opinion on the structure of congenital heart surgery programs in Europe. The committee concluded that a congenital heart program should be staffed by at least 2 surgeons, each of whom perform 125 surgeries per year, totaling a minimum of 250 annual cases. Population data analysis showed a center must serve approximately four to six million people to achieve the recommended case volume (with no case leakage or overlapping catchment areas among institutions). The committee reasoned that it is "usually recognized that a surgeon needs to perform a minimum of three surgical procedures per week (a bare minimum)." Assuming three surgeries per week for 42 weeks per year, a surgeon was predicted to perform 126 operations annually [9]. The EACTS minimum volume recommendation prompted the NHS to consolidate congenital cardiac services in England and Wales. The NHS consultation was one of the largest in the organization's history and produced the 2011 Safe and Sustainable report. The report proposed that the existing 11 programs consolidate into 7 higher volume centers each staffed by 4 pediatric cardiac surgeons "so that round the clock [skilled] cover [could] be provided." The report further stipulated these centers should perform 500 pediatric procedures/year and each surgeon should be required to perform 125 procedures/year "to maintain their skills" [10]. At the time the report was issued, the population of the United Kingdom was 63 million and the number of pediatric heart surgeries was approximately 3600/year. The report reasoned 7 centers performing 500 operations each would theoretically support this volume and improve outcomes.

The Safe and Sustainable initiative assessed outcomes data to choose which centers would survive and which centers would close. According to the Central Cardiac Audit Database project, the existing 11 centers performing pediatric cardiac surgery had survival outcomes at or above predicted levels with survival rates ranging between 96.8 and 99% [11]. Facing the threat of elimination and armed with outcome data and local support, programs mounted legal challenges, prompting

the first lawsuit between NHS organizations. The first legal challenge was brought by the Royal Brompton Hospital (London) . The court ruling came down in favor of consolidation citing the Safe and Sustainable consultation as fair and lawful. Shortly thereafter, the Joint Committee on Primary Care Trusts (JCPCT) , the NHS decision-making body, announced the finalized decision to close four programs including the Royal Brompton Hospital (London), Leeds General Infirmary (Leeds), East Midlands Congenital Heart Centre (Leicester), and John Radcliffe Hospital (Oxford) . The decision was met with significant local backlash. The chair of Leeds Teaching Hospitals NHS Trust spoke out against the decision stating, “We are surprised that the clear wishes of >600,000 people from this region appear to have been disregarded. On geography and population density alone, the case for Leeds remains as strong as ever” [12]. Leeds is one of the largest urban areas in England and was performing an average of 300 pediatric heart surgery cases per year at the time the JCPCT ordered closure [11]. For perspective, in the United Sates in 2017, only 22 out of 82 centers performed more than 300 pediatric heart surgery cases per year [5].

A grass-roots campaign to save the Leeds pediatric cardiac surgery program again lead to court-hearings, but with a different outcome [13]. The judge suspended the JCPCT’s decision thereby effectively halting the Safe and Sustainable initiative. The judge’s decision was based on the opinion of the Independent Reconfiguration Panel, an advisory group that makes recommendations on contested changes to healthcare services, which stated the decision to close pediatric heart surgery programs was based on “flawed analysis of incomplete proposals and their health impact.” Despite the ruling the NHS medical director suspended pediatric cardiac surgery in Leeds based on mortality rates above the national average. Then, the mortality data were revealed to be flawed and the program resumed operation.

NHS England took over decision-making for the suspended Safe and Sustainable initiative and in 2015 issued “Congenital Heart Disease Standards & Specifications” [14]. The standards set by the Safe and Sustainability initiative were criticized for including subjective outcome metrics. Therefore, NHS England recommended consolidation, based purely on volume standards. They set minimum volume standards to include 3 surgeons (4 surgeons within 5 years of implementation) each

performing 125 cases per year. Considering 3 surgeons performing 125 cases each, a minimum total of 375 cases was required per center (only 3 met these criteria). For perspective, in the United States in 2017, only 9 out of 82 centers performed at least 375 cases per year [5]. At the time of the British report, the most up-to-date data showed only 3 programs out of 11 met the 375-case minimum. Ultimately, only three programs were recommended for shutdown [14–16]. The renowned cardiothoracic surgeon Sir Magdi Yacoub famously called the decision to close the Royal Brompton center a disaster stating, "You shouldn't kill a centre of excellence just for planning reasons" [17]. The decision to close these pediatric cardiac surgery programs was reversed in late 2017, but the Manchester center eventually closed due to the inability to hire and retain staff [18]. Ironically, following over a decade of recommendations and debate, 10 of the original 11 centers are still active in 2019.

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3 The Ethical Perspective

Is closing a center with excellent outcomes, as attempted in the United Kingdom, ethical? Proponents on both sides of the argument claim to seek clinical excellence. Supporters of consolidation argue that the best outcomes are achieved at high volume centers. Opponents point to outstanding clinical outcomes achieved at lower volumes and the arbitrary nature of proposed volume minimums. Data comparing outcomes before and after consolidation capture the complexity of the problem.

In the 1990s, Sweden undertook an effort to consolidate pediatric heart surgery from multiple programs. The National Board of Health investigated outcomes of all four centers from 1988–1991 and proposed centralizing care to the two centers with the best 30-day mortality outcomes: Göteborg and Lund. The proposal was disputed because no significant difference in mortality was found when the data was adjusted for case mix. After a more detailed analysis, the center with the highest mortality closed. By 1993 most cases were referred to Göteborg and Lund with a small number of less complex cases performed in a third center. The overall mortality rate for pediatric open-heart surgery fell from 9.5% in 1988–1991 to 1.9% in 1995–1997

(n = 2808, p < 0.001) with significant decreases in mortality for the most complex operations (Grade II: 11 vs 0.3%, p < 0.001; Grade III:17.9 vs 4.4%). Mortality decreased for closed procedures (2.7 vs 2.0%) and Grade I open procedures (2.0 vs 0%) but significance values were not provided. The significant decrease in overall mortality is compelling and is often cited when making the case for consolidation. Outcomes in Sweden were also likely improved by the formation of surgical teams devoted to pediatric cardiac surgery allowed by centralization. The data falls short of illustrating the degree of this contribution compared to the changing landscape of the field overall. Likewise, the development of new surgical techniques, most notably the treatment of hypoplastic left heart syndrome with Norwood surgery (used in the later period) and advances in catheter-based interventions, overlapped with the time period [19].

Extrapolating the events in Sweden to the United States is challenging. Comparing the country of Sweden to the single state of Texas provides context. Sweden is about half the size (173,626 versus 268,596 square miles) and 1/3 the population (10 million versus 29 million) of Texas [19, 20]. The total volume of operations performed in the Swedish study is still fewer than the single largest pediatric congenital heart surgery program in Texas today (620 Göteborg and Lund versus 676 Houston, Texas) [5].

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4 Volume Analysis

In the United States, congenital heart surgery outcomes are analyzed and published by the Society of Thoracic Surgeons (STS) congenital heart surgery database , a voluntary registry capturing over 90% of pediatric and congenital cardiac surgery programs. The STS database publicly reports 4-year averages of overall operative mortality and risk stratified operative mortality. Based on the overall risk-adjusted observed/expected (O/E) operative morality ratio each program is assigned an overall rating of 1, 2, or 3 stars. One star represents higher than expected operative mortality, two stars represent expected mortality, and three stars represent lower than expected mortality [21].

An understanding of how the risk estimates are derived is required before comparing program outcomes. Initial STS database risk

estimates were based on the Aristotle Basic Complexity Levels and the Risk Adjustment for Congenital Heart Surgery-1 Categories. In 2010, the Society of Thoracic Surgeons-European Association for Cardio-Thoracic Surgery Congenital Heart Surgery mortality risk (STAT mortality risk) tool was implemented. STAT mortality risk ranks procedures into five categories of increasing risk according to the estimated in-hospital mortality. STAT 1 represents the lowest risk procedures and STAT 5 represents the highest risk procedures. The STAT mortality score is derived from the combined data of the STS and European Association for Cardiothoracic Surgery (EACTS) allowing for empirically driven risk estimates [22].

An analysis of the STS database, conducted before implementation of STAT mortality risk categories, evaluated the relationship between mortality (adjusted for individual patient risk) and case volume. The database review capturing 30,000 operations performed by 48 programs (2002–2006) produced a volume-mortality curve that showed an inverse relationship until an inflection point at approximately 200–300 cases/year after which case volume did not appear to affect outcomes (Fig. 1). The largest volume programs (350+ cases/year) had similar mortality to medium volume programs (150–249 and 250–349 cases/year) and significantly lower mortality than the smallest volume programs (<150 cases/year, $p = 0.0005$) [4]. The largest volume programs had lower adjusted mortality for more complex procedures than small programs (OR, 2.41; $p < 0.0001$). All volume groups performed similarly for low complexity cases. Detailed analysis concluded that the best outcomes occur at an inflection point that shifts between 200 and 400 annual cases depending on multiple other variables [4].

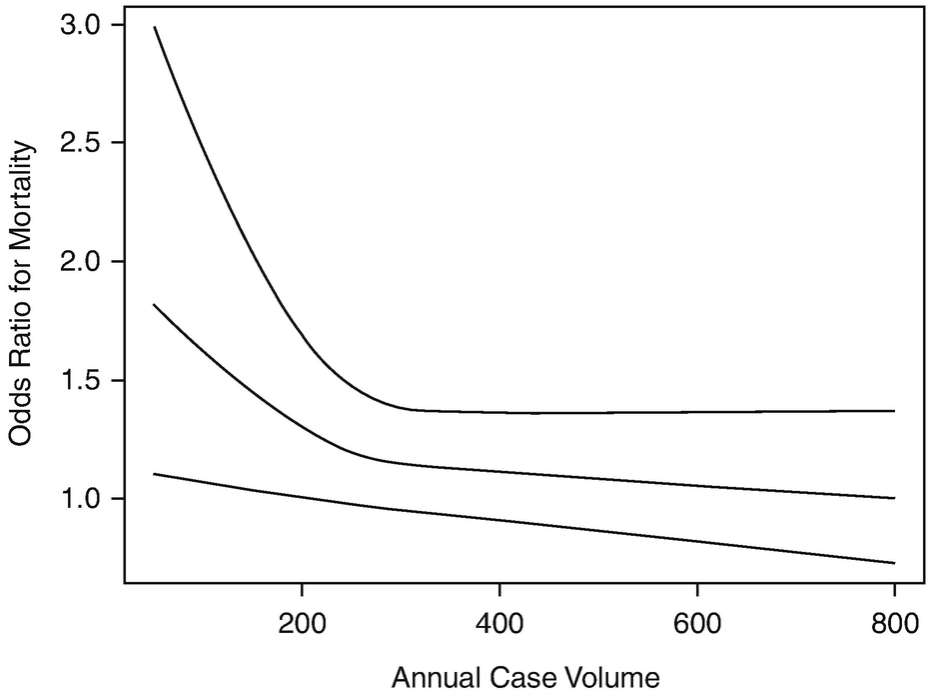

Fig. 1 Risk-adjusted mortality versus annual case volume . A volume of 800 annual cases was chosen as an arbitrary reference value representing an odds ratio of 1.0. From Welke et al., *The complex relationship between pediatric cardiac surgical case volumes and mortality rates in a national clinical database* J Thorac Cardiovasc Surg 137(5):1133–40

The most recent STS data (2014–2017) shows 3-star centers (lower than expected mortality, $n = 12$) had a median annual volume of 290 cases, while 1 star centers (higher than expected mortality, $n = 9$) had a median annual volume of 122 cases. Of the 12 centers with a 3-star rating, 7 had less than 300 annual cases and three had less than 200 annual cases, but all had above 100 annual cases. This data is consistent with the inflection point described by Welke et al. between 200 and 300 annual cases (Fig. 1). Likewise, case-adjusted mortality was 5.4% for programs averaging 100 annual cases (well below the inflection point) compared to 1.7% for centers with an average of 300 annual cases ($p < 0.01$).

The effect of implementing a program of regionalization based on volume requires first establishing the current hospital distribution and travel patterns. Then a model closing sequential hospitals with the hypothesis that higher volume leads to decreased mortality must be developed. Welke and colleagues have recently published these models [6, 23].

In the first analysis, state inpatient databases from 39 states were used to identify 153 hospitals performing 19,064 congenital heart operations. One-quarter of patients already travel greater than 100 miles (median 38.5 miles), with most traveling to the highest volume quartile centers [23]. The second analysis was a model that simulated progressive closure of hospitals beginning with the lowest hospital volume. Patients were sequentially moved to the next closest hospital and mortality rates were serially addressed. When regionalization progressed to a point where all remaining hospitals performed more than 310 operations, 37 (out of 153) hospitals remained with 17.4% potential lives saved. These predicted lives saved were calculated based on the improved outcomes assumed by the modeled higher volumes . Note that only 12 programs (out of the 153) actually performed 310 cases/year, so the additional 25 programs were created by theoretically transferring patients. Patient travel distance increased by a mean of 31.6 miles [6]. Of the 116 programs "closed", state boundaries, cities, reimbursement arrangements, medical schools, nursing schools, other allied health programs, financial impact, facilities, or ethics were not considered. Similar limitations applied to the 37 remaining centers who may not be able to accommodate or afford the proposed influx of transfers.

In California, a theoretical analysis regarding consolidation of pediatric congenital heart surgery programs proposed a potential decrease in mortality from 5.34 to 4.08% if all cases were referred from low (less than 70 cases per year) and medium (70–170 cases per year) to high volume hospitals (170+ operations per year). Authors conclude, "regionalization of pediatric cardiac surgery in California had no apparent effect on reducing surgical mortality until more than one-third of current hospitals (those with a case volume of less than 70 per year) were 'closed'." Any significant improvement in mortality would have required closure of 9 of the 20 congenital heart surgery programs included in the analysis. The study used administrative discharge data from California hospitals performing 10 or more pediatric cardiac surgeries from 1995–1997 [24]. Applying the study methodology to the current landscape would close 4 of 8 California programs. Interestingly, all of the active centers in California have the same 2-star rating [5].

The assumption that the high-volume centers could accommodate the volume influx from consolidation has not been tested or addressed. Table 1 shows the volume of patients who would be displaced at progressive volume cutoffs that may be imposed as a percentage of "unserved patients". Data included in the table were obtained directly from the STS congenital heart surgery website (https://publicreporting.sts.org/chsd) in July 2019 and does not capture centers that do not participate in public reporting [5]. The STS database reported cumulative data over a 4-year period reflecting operations from January 2014–December 2017. Volume data was divided by 4 to approximate annual volume. If we impose a minimum volume of 200+ cases per year, 37 of 82 centers (45%) would remain open, displacing (un-serving) 28% of the patient population. Likewise, if we impose a minimum volume of 300+ cases per year, only 22 of the 82 centers (27%) would remain open, displacing (un-serving) 48% of the patient population. Most likely, patients would be redistributed to create more high-volume centers than simply the original group as performed by Welke et al. and Change et al. [6, 24]. Regardless of the schema for reassignment, closing these smaller centers would displace over 1/4–1/2 of the patient population. Closing centers using minimum volume cutoffs as a criterion to improve quality offers no guarantee that larger centers would have adequate operating room space, ICU beds, or staff to accept the displaced volume. Likewise, the influx of volume to create or add to higher volume centers does not guarantee maintenance or improvement of quality. This brief volume-based analysis also does not account for geography, regional distribution, state borders, third party payors , political influence, physician or patient preference or the ability of centers near volume cutoffs to accept more patients, thus meeting the volume minimum.

Table 1 Volume of congenital heart surgery programs in the USA participating in the Society of Thoracic Surgery's public reporting database

Case volume (# of centers)	Annual cases	Cases unserved	% Unserved
All publicly reporting USA centers (82)	18,902	0	0
500+ (6)	4142	14,760	78
400+ (8)	5040	14,272	76
350+ (14)	7224	11,678	62

Case volume (# of centers)	Annual cases	Cases unserved	% Unserved
300+ (22)	9807	9094.75	48
250+ (30)	12,054	6848.00	36
200+ (37)	13,644	5257.75	28

Cases unserved represents the annual number of cases performed at centers of lower volume

A recent review (2018) of the European Congenital Heart Surgeon's Association (ECHA) database (which is mostly comprised of European data but also contains some data from other continents) analyzed the volume-mortality ratio in neonatal congenital heart surgery. The study included more than 27,000 neonatal congenital heart surgery cases performed in 90 centers across 35 countries outside the US. The data showed increased volume was associated with decreased mortality until a threshold of 60 neonatal operations per center per year , after which volume increase did not significantly affect mortality [25]. The recommendation of 60 neonatal cases/year is consistent with the reported (and discussed earlier) inflection points of 200–300 and up to 500 cases/year considering that that usually 20–30% of cases at large programs are neonates (200 total cases = 40–60 neonatal cases, 300 total cases = 60–90 neonates) [4, 9, 10].

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5 Approaches to Consolidation in the USA

Consolidation of congenital cardiac programs can be based on (1) policy (as in the United Kingdom or Switzerland), (2) population, or (3) geography. A population-based model would distribute higher volume centers in densely populated areas across the country. This model forces lower population areas to send patients to another region for treatment. This is problematic in the USA where public and private health plans cover a network of providers, usually restricted to a single state. Patients also can choose their site of healthcare, if they can afford their choice. Despite referral and network restrictions, some hospital networks have modeled successful regionalization of healthcare services in the USA. Northeastern Ohio established a collaborative "regional trauma network" with multiple hospital systems including a

single level 1 trauma center, four level 2 trauma centers, and seven non-trauma center hospitals. All centers use the same triage protocol and all transfers are sent to the level 1 trauma center. Analysis of the State of Ohio's Trauma Registry maintained by the Ohio Department of Public Safety found a reduction in hospital mortality from 5.3% before regionalization (2006–2009) to 4.3% after regionalization (2010–2012, $p < 0.001$) despite an increase in patient age ($n = 121,448$, $p < 0.001$). Moreover, the regional trauma network was the only Ohio region to demonstrate a significant reduction in mortality. During the study period two level 2 trauma centers closed, independent of any decision by the regional network [26]. Coincidentally, systems improvements and medical advances during the 6 year period, may have influenced these outcomes.

Congenital cardiac surgery is commonly regionalized as a hub-and-spoke network within a state. Smaller area hospitals (spokes) refer patients to larger centers that provide specialized care (hubs). A retrospective study of a regionalized congenital heart disease network in the state of New York compared outcomes of neonates who required transfer for heart surgery to those born in the surgical hospital. Transferred patients travelled a median distance of 91 miles and had similar 30-day survival to those born in the surgical hospital (transfer 90% versus birth 89%, $p = 0.7$) [27].

Another approach is consolidation of independent programs into a multi-site/one program consortium. This approach was developed by the partnership of University of Kentucky program with Cincinnati Children's hospital . This public-private partnership gives patients in the University of Kentucky network direct access to the Cincinnati Children's program as well as shared protocols, personnel, and governance. Both entire surgical teams train in Cincinnati to a single shared protocol while Kentucky surgeons split their time between the two locations with 75% of the time in Kentucky (smaller volume) and 25% in Cincinnati (larger volume). STAT 5 (highest risk) procedures are performed in the larger Cincinnati location.

The multi-site one-program congenital heart model avoids reducing the number of residents, when programs collaborate. Cardiothoracic surgery residency programs are limited to 1–3 residents per year and eliminating training programs at a time when the field needs

cardiothoracic surgeons is counterproductive . The Kentucky-Cincinnati partnership allowed both sites to continue educating residents in separate residencies. The collegiality, shared experiences, educational opportunities (especially residencies) and outcomes with this arrangement have been outstanding over the last 2 years. The cost and time commitment has been significant for both programs, so we await a cost/benefit analysis.

General surgery programs previously adopted a similar approach to deliver care to patients in rural areas "where small operating rooms are recognized as extensions of core referral hospital programs" [28]. The joint position paper on rural surgery and operative delivery eloquently stated when "low volumes are used as a convenient, but inappropriate, alternative to outcome measures… many rural surgical services and programs will be forced to close, not because they do not provide quality care, but because they do not perform as many procedures as their urban counterparts." It is easy to replace "rural surgical services" and "urban counterparts" with "congenital cardiac surgical services" and "higher volume counterparts."

6 Conclusion

The core principles of respect for person, beneficence, and justice must be reviewed relative to this discussion. All volume-based criteria assume better outcomes with higher volume, which we have clearly shown to be oversimplified. Physician choice, cost, travel, and family preferences must be considered in a consolidation plan. For beneficence, community and family needs become paramount. Finally, for justice, fairness and distribution of resources could be argued to best stay loco-regional, as in the case of Leeds hospital. Pitfalls regarding state boundaries, reimbursement arrangements, medical education requirements, have yet to be fully realized and may prove to be major ethical challenges.

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