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## Chapter

# 1

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# NUCLEAR ENERGY

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The energy released by the change in the nucleus of atom is known as nuclear energy. The changes in the nucleus of atom is normally caused by either nuclear fusion or nuclear fission. The technology that manipulates such changes in nucleus (nuclear reaction) of some specific elements and transform into energy is known as nuclear technology. The energy released through the nuclear reaction is very high. For example, the fission of 1 kg of uranium-235 releases about 18.5 million kilowatt-hours heat. Nuclear reactions naturally occur in chain reactions and hence keep releasing energy in continuity. In 1942, the Italian physicist Enrico Fermi first successfully produced the nuclear chain reaction.

## Nuclear Power Policy of India

- ❑ In the beginning of the Eighth Plan, it was aimed to produce 10,000 MW of power by 2000, to increase the nuclear power share in total power production. In order to achieve the above objective, the Central Government established Nuclear Power Corporation to coordinate various nuclear power organisations in 1989.
- ❑ But, it was unlikely to achieve this objective, particularly after the disintegration of USSR, and then the target was reduced to 9000 MW. However, still it was not possible in the near future. Indian scientists have planned to achieve the above target in future through the development of **three generations of nuclear reactors**:
- ❑ **First Generation Nuclear Reactors:** These are the pressurized Heavy Water reactors (PHWR) with the capacity of 235 MWe each and use natural uranium as fuel. Plutonium is the by-product.
- ❑ **Second Generation Nuclear Reactors:** These are planned to be the fast breeder reactors with the capacity of 500 MWe each, and use Plutonium, a by-product of the first generation reactors, as the fuel.
- ❑ **Third Generation Nuclear Reactors:** These are also planned to be the fast breeder reactors (FBR). This generation reactors will use fuel derived from second generation reactors and convert more Thorium into Uranium-233. So, the plan is to use vast Thorium deposits found in India.
- ❑ India has established first generation nuclear reactors at Tarapur, Kalpakkam, Narora and Rawatbhata. Other two reactors of this grade are located at Kakrapar (Gujarat) and Kaiga (Karnataka). The first generation reactors have reached commercial stage. The generation of power from nuclear energy began in India in 1969 with the commissioning of first atomic power station at Tarapore (TAPS).

- The second generation reactor has commenced with the successful operation of the **Fast Breeder Test Reactor (FBTR)** named KAMINI (Kalpakkam Mini Reactor) in 1985 at the Indira Gandhi Centre for Atomic Research (IGCAR) at Kalpakkam in Tamil Nadu.
- The Kalpakkam reactor is the **world's first fast-breeder reactor**. The reactor has successfully used the mixed uranium - plutonium carbide fuel, hitherto untried elsewhere. Progress has also been made in the third generation reactor with the successful development of a U-233 based fuel. Work has commenced on the design of an Advanced Heavy Water Reactor which will make the use of thorium in power generation.

### □ Pros of Nuclear Energy

- **Low Pollution:** Nuclear power also has a lot fewer greenhouse emissions. It has been determined that the number of greenhouse gases has decreased by almost half because of the prevalence in the utilization of nuclear power. Nuclear energy has the least effect on nature since it doesn't discharge any gasses like methane and carbon dioxide, which are the primary "greenhouse gasses."
- **Low Operating Costs:** Nuclear power produces very inexpensive electricity. The cost of the uranium, which is utilized as a fuel in this process, is low. Also, even though the expense of setting up nuclear power plants is moderately high, the expense of running them is quite low. The normal life of a nuclear reactor is anywhere from 40-60 years, depending on how often it is used and how it is being used.
- **Reliability:** It is estimated that with the current rate of consumption of uranium, we have enough uranium for another 70-80 years. A nuclear power plant when in the mode of producing energy can run uninterrupted for even a year. As solar and wind energy are dependent upon weather conditions, the nuclear power plant has no such constraints and can run without disruption in any climatic condition.
- **More Proficient than Fossil Fuels:** The other primary point of interest in utilizing nuclear energy is that it is more compelling and more proficient than other energy sources. A number of nuclear energy innovations have made it a much more feasible choice than others. They have high energy density as compared to fossil fuels. The amount of fuel required by the nuclear power plant is comparatively less than what is required by other power plants as the energy released by nuclear fission is approximately ten million times greater than the amount of energy released by fossil fuel atom.

### □ Cons of Nuclear Energy

- **Environmental Impact:** One of the biggest issues is the environmental impact in relation to uranium. The process of mining and refining uranium hasn't been a clean process. Actually transporting nuclear fuel to and from plants represents a pollution hazard. Also, once the fuel is used, you can't simply take it to the landfill – it's radioactive and dangerous.
- **Radioactive Waste Disposal:** A nuclear power plant creates 20 metric tons of nuclear fuel per year, and with that comes a lot of nuclear waste. Considering each nuclear plant on Earth, that number comes to approximately 2,000 metric tons a year. The greater part of this waste transmits radiation and high temperature, implying that it will inevitably consume any compartment that holds it. It can also cause damage to living things in and around the plants.
- **Nuclear Accidents:** The radioactive waste produced can pose serious health effects on the lives of people as well as the environment. The Chernobyl accident that occurred on 26 April 1986 at the Chernobyl Nuclear Power Plant in Ukraine was the worst nuclear accident in history. Its harmful effects on humans and ecology can still be seen today.

- **High Cost:** At present, the nuclear business let waste cool for a considerable length of time before blending it with glass and putting away it in enormous cooled, solid structures. This waste must be kept up, observed and watched to keep the materials from falling into the wrong hands and causing problems.
- **Uranium is Finite:** Just like other sources of fuel, uranium is also finite and exists in a few of the countries. It is pretty expensive to mine, refine and transport uranium. It produces a considerable amount of waste during all these activities and can result in environmental contamination and serious health effects, if not handled properly.
- **Target for Militants:** Nuclear energy has immense power. Today, nuclear energy is used to make weapons. If these weapons go into the wrong hands, that could be the end of this world. Nuclear power plants are a prime target for terrorist activities. Little lax in security can be brutal for humankind.
- **Renewable:** Nuclear energy is not a renewable resource. Uranium, the nuclear fuel that is used to produce nuclear energy is limited and cannot be produced again and again on demand. On the other hand, by using breeder and fusion reactors, we can produce other fissionable elements. One such element is called plutonium that is produced by the by-products of chain-reaction. Also, if we know how to control the atomic fusion, the same reactions that fuel the sun, we can have almost unlimited energy.

## The Three-Stage Indian Nuclear Power Programme

The importance of nuclear energy, as a sustainable energy resource for our country, was recognised at the very inception of our atomic energy programme more than four decades ago. A three-stage nuclear power programme, based on a closed nuclear fuel cycle, was then chalked out.

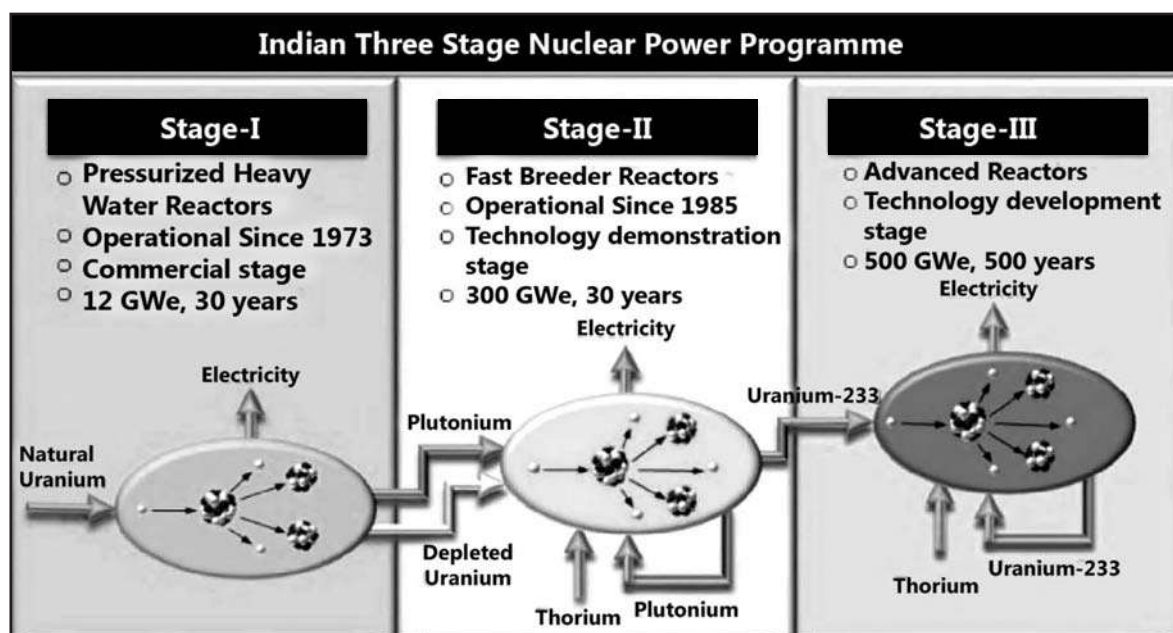
### The three stages are:

- ❑ Natural uranium fuelled Pressurised Heavy Water Reactors (PHWRs)
- ❑ Fast Breeder Reactors (FBRs) utilising plutonium based fuel
- ❑ Advanced nuclear power systems for utilisation of thorium

### Development status of the three stages in India

- ❑ **First Stage:** For carrying out an efficient production of plutonium, the fissile material needed to fuel further growth in nuclear power capacity, a natural uranium fuelled heavy water moderated reactor is the best option. Thus we started the indigenous development of nuclear power plants based on uranium cycle in PHWRs, in the First Stage.
- ❑ At present we have twelve such reactors under operation, four are under construction, and several others have been planned. We have become self-sufficient in all aspects of the PHWR technology. The capacity factors of our operating PHWRs have been close to eighty percent during recent years, an excellent performance even with respect to international standards.
- ❑ **Second Stage:** As a part of the Second Stage, we started the FBR programme with the Fast Breeder Test Reactor (FBTR), at IGCAR, Kalpakkam. This reactor, operating with indigenously developed mixed (U+Pu) carbide fuel, has already yielded a large volume of operating experience and a better understanding of the technologies involved. This has enabled us to design 500 MWe (prototype) FBR that will utilise plutonium and the depleted uranium from our PHWRs.

- Third Stage:** Technologies pertaining to utilisation of thorium have been under development, mainly at BARC, right since the inception of our nuclear power programme. The main products included in this road map, in different time frames, are the following:



- Stage 1:** Advanced Heavy Water Reactor (AHWR).
- Stage 2:** High temperature reactor based power packs.
- Stage 3:** Accelerator driven fertile converters.
- Stage 4:** Accelerator driven system with a fast reactor sub-critical core together with a mainly thorium fuelled thermal core somewhat similar to that present in AHWR.

## Non-energy Applications of Nuclear Energy

- Applications of Radio-isotopes:** When a combination of neutrons and protons, which does not already exist in nature, is produced artificially, the atom will be unstable and is called a radioactive isotope or radioisotope. There are also a number of unstable natural isotopes arising from the decay of primordial uranium and thorium. Overall around 1800 radioisotopes have been so far found. About 200 of these are used on a regular basis, and most-are produced artificially.
- Radioisotopes have useful properties: radioactive emissions are easily detected and can be tracked until they disappear leaving no trace. Alpha, beta and gamma radiation, like X-rays, can penetrate seemingly solid objects, but are gradually absorbed by them. The extent of penetration depends upon several factors including the energy of the radiation, the mass of the particle and the density of the solid. These properties lead to many applications for radioisotopes in the scientific, medical, forensic and industrial fields.
- Naturally Occurring Radioisotopes and Their Applications**
  - Chlorine-36:** Used to measure sources of chloride and the age of water (up to 2 million years)
  - Carbon-14:** Used to measure the age of fossils (up to 50,000 years)
  - Tritium (H-3):** Used to measure 'young' groundwater (up to 30 years)

- **Lead-210:** Used to date layers of sand and soil up to 80 years
- **Artificially Produced Radioisotopes and their Applications**
  - **Americium-241:** Used in backscatter gauges, smoke detectors, fill height detectors and in measuring ash content of coal.
  - **Caesium-137:** Used for radiotracer technique for identification of sources of soil erosion and deposition, in density and fill height level switches.
  - **Cobalt-60:** Used for gamma sterilization, industrial radiography, density and fill height switches.
  - **Gold-198 and Technetium-99:** Used to study sewage and liquid waste movements, as well as tracing factory waste causing ocean pollution, and to trace sand movement in river beds and ocean floors.
  - **Strontium-90, Krypton-85, Thallium-204:** Used for industrial gauging.
  - **Zinc-65 and Manganese-54:** Used to predict the behavior of heavy metal components in effluents from mining waste water.
  - **Iridium-192, Gold-198 and Chromium-57:** Used to label sand to study coastal erosion.
  - **Ytterbium-169, Iridium-192 and Selenium-75:** Used in gamma radiography and non-destructive testing.
  - **Tritiated Water:** Used as a tracer to study sewage and liquid wastes.
- **Industrial Applications:** Modern industry uses radioisotopes in a variety of ways to improve productivity and, in some cases, to gain information that cannot be obtained in any other way. The continuous analysis and rapid response of nuclear techniques, many involving, radioisotopes, mean that reliable flow and analytic data can be constantly available. This results in reduced costs with increased product quality.

Sealed radioactive sources are used in industrial radiography, gauging applications and mineral analysis. Many process industries utilise fixed gauges to monitor and control the flow of materials in pipes, distillation columns, etc., usually with gamma rays. **This process is used in common industrial applications such as:**

- **The automobile industry**—to test steel quality in the manufacture of cars and to obtain the proper thickness of tin and aluminum.
  - **The aircraft industry**—to check for flaws in jet engines
  - **Construction**—to gauge the density of road surfaces and sub-surfaces
  - **Pipeline companies**—to test the strength of welds
  - **Oil, gas, and mining, companies**—to map the contours of test wells and mine bores, and
  - **Cable manufacturers**—to check ski lift cables for cracks.
- Short-lived radioactive material is used in flow tracing and mixing measurements. Gamma sterilisation is used for medical supplies, some bulk commodities and, increasingly, for food preservation.
- **Gamma Sterilisation:**
    - Gamma irradiation is widely used for sterilizing medical products, for other products such as wool, and for food. Cobalt-60 is the main isotope used, since it is an energetic gamma emitter. It is produced in nuclear reactors, sometimes as a by-product of power generation.
    - Large-scale irradiation facilities for gamma sterilization are used for disposable medical supplies such as syringes, gloves, clothing and instruments, many of which would be damaged by heat sterilization. Such facilities also process bulk products such as raw wool, archival documents and even wood, to kill parasites.

- Smaller gamma irradiators are used for treating blood for transfusions and for other medical applications.
  - It is also used for food preservation. When food is irradiated it passes through a chamber where it is exposed to ionizing energy. This penetrates the food and destroys harmful organisms without cooking or otherwise altering its physical or chemical properties. For this reason, irradiation is currently the best available technology suitable for treating raw and partially raw food. It leaves no residue, does not change the taste, colour, or smell of the food, nor does it make food radioactive.
- **Food irradiation:**
- greatly reduces or eliminates the number of disease causing bacteria and other harmful organisms;
  - helps to keep meat, poultry and seafood fresh; also helps to maintain certain food and vegetable for longer periods and reduce food spoilage;
  - can replace potentially harmful chemical fumigants when used to eliminate insects from dried grain, legumes, spices, dried fruit etc.; and
  - has the potential to be used for meeting quarantine requirements for international trade in fresh fruits and vegetables.
- **Nuclear Medicine:** Nuclear medicine is defined as the branch of medicine that uses radioactive isotopes, nuclear radiation, electromagnetic variations of the components of the atomic nucleus and related biophysical techniques for the prevention, diagnosis, therapy and medical research. Clinical applications of radiopharmaceuticals cover virtually all medical specialties. **Its scope includes the following:**
- **Prevention:** In this regard, the nuclear medicine applies the knowledge and skills that are proper hygiene, prophylactic and preventive medicine and radiation protection.
  - **Research:** Nuclear medicine is developed in basic and applied research using radioactive isotopes and related biophysical techniques.
  - **Diagnosis:** mainly includes the realization of functional, morphological, and analytical tests based on biochemical, physiological and pathophysiological principles, aimed at achieving a better knowledge and understanding of the structure and function of the human body in health or disease.
  - **Therapeutics:** In addition to the important impact of diagnostic techniques of nuclear medicine for the treatment and management of patients, this specialty includes in its scope, some specific therapeutic indications made by the administration of radiopharmaceuticals to patients (therapy metabolic, endolymphatic, intracavitary, etc.). It also includes the treatment and prevention of biological effects from exposure to ionizing radiation, especially when exposure is due to external radiation or radioactive substances caused by pollution unsealed.
- **Agriculture:** Nuclear techniques are used in farming and agricultural communities to combat disease and provide other benefits. **The benefits are:**
- **Combating pests and diseases:** the sterile insect technique involves mass producing insect pests and sterilizing them with gamma radiation emitted by radioisotopes; when the males are released in the target region and mate with wild females of the pest population, they create no offspring. Gradually, the population is reduced.
  - **Increase crop production:** exposing plants to small doses of radiation helps change the genetic make-up of plants and lead to improved varieties.
  - **Protecting land and resources:** isotopes measure soil, water and nutrient storage, soil erosion, and fertilizer and pesticide waste; they enable farmers to keep closer track of their operations and use vital resources more sparingly and effectively.
  - **Ensuring food safety:** irradiation is used in food to kill bacteria such as E.coli.

- **Increasing livestock production:** scientists use isotopes to study hormones and learn more about reproduction cycles, which helps in areas such as the timing of artificial-insemination programmes.
- **Mining and minerals**
  - Radioactive sources are used widely in the mining industry. For example, radioactive sources are used in non-destructive testing of pipeline blockages and welds; in measuring the density of material being drilled through; in testing the dynamic characteristics of blast furnaces, in the measurement of combustible volatile matter in coal, and for on-stream analysis of a wide range of minerals and fuels.
  - Mining companies use radionuclides to locate and quantify mineral deposits, to map geological contours using test wells and mine bores, and to determine the presence of hydrocarbons.
  - In milling and flotation operations, instruments using radioactive sources are widespread. These devices have the advantage of providing reliable non-contact measurement. Examples include the measurement of density and moisture in ore or slurries (important for process control and achieving final concentrate target moisture content). Other examples include measurement of levels in process tanks, slurry density and flows in piping, and levels in ore crushing chutes to detect blockages.
  - Various sources are used in such devices, for example americium-241 and caesium-137. Density measurement is based on the absorption of gamma radiation as it passes through process material. Absorption is proportional to changes in material density, and as the measuring path is held constant, this indicates density.

## Impact of Radiation

- There are many forms of radiation. Whether natural or man-made, radiation can be both harmful and beneficial to the environment. The sun, for example can have positive and negative effects on plant and animal life. At low levels, radiation can be beneficial to the environment. On the other hand ionized radiation such as x-rays, gamma rays, alpha and beta particles can be particularly harmful in excessive amounts.
- **Plant Growth:** Natural radiation is often beneficial to plant growth. It is necessary for many plants to receive some form of non-ionizing radiation. Radiation that produces light in order for photosynthesis to occur is a positive effect that radiation has on plant life. However, according to the Environmental Literacy Council, ionized radiation that occurs from nuclear material may result in weakening of seeds and frequent mutations. For instance, a nuclear plant, called Chernobyl in Russia leaked in 1986 that caused excessive amounts of radiation pollution in that region. A huge cloud of radiation was formed which resulted in a massive amount of destroyed plant life; particularly pine trees in that area. High doses of radiation can be devastating to the environment.
- **Animal and Humans:** The effect of radiation in the environment can be dangerous and fatal to humans and animals. The damage it causes depends on the level of radiation and the resiliency of the organism. Radiation causes molecules to lose electrons thus destroying it. Killing certain enzymes in the body can simply make you sick. However, once radiation damages DNA the body may not be able to repair itself. This can increase the chances of both animals and humans developing cancer. According to the US Department of Energy, after two nuclear explosions in Hiroshima and Nagasaki, survivors experience higher cases of cancer and child deformities. The nuclear explosions are examples of high levels of radiation. However, low doses of radiation can kill germs and decrease the number of food poisoning cases.

- ❑ **Marine Life:** The effects that radiation has on marine life can be dangerous. High levels of UV or ultraviolet radiation can cause a reduction in reproduction capabilities. It can also disrupt the timing that plants flower, which can result in changes in pollination patterns. According to NASA, it can also reduce the amount of food and oxygen that plankton produces. Plankton can respond to excessive amount of **UV-B or Ultraviolet-B light** by sinking deeper into the water. This decreases the amount of visible light required for photosynthesis, which reduces growth and reproduction. An increased amount of UV-B can also increase the amount of ozone produced at the lower atmosphere. While some plants can use this extra layer as a protective shield, other plants are highly sensitive to photochemical smog.

## Issue of Radioactive Waste

- ❑ Radioactive wastes are generated during various operations of the nuclear fuel cycle. Mining, nuclear power generation, and various processes in industry, defense, medicine and scientific research produce byproducts that include radioactive wastes.
- ❑ Radioactive waste can be in gas, liquid or solid form, and its level of radioactivity can vary. The waste can remain radioactive for a few hours or several months or even hundreds of thousands of years. Depending on the level and nature of radioactivity, radioactive wastes can be classified as exempt waste, Low & Intermediate level waste and High Level Waste
- ❑ **Low and Intermediate level (LIL): Liquid wastes** have generally high volumes and low levels of radioactivity. They are further classified as short lived and long lived wastes.
- ❑ Low level nuclear waste usually includes material used to handle the highly radioactive parts of nuclear reactors (i.e. cooling water pipes and radiation suits) and waste from medical procedures involving radioactive treatments or x-rays.
- ❑ **Solid waste:** Significant quantum of solid LIL wastes of diverse nature gets generated in different nuclear installations. **They are essentially of two types:**
  - ⦿ Primary wastes- comprising of radioactively contaminated equipment (metallic hardware) spent radiation sources etc.
  - ⦿ Secondary wastes- resulting from different operational activities, protective rubber and plastic wears, cellulosic and fibrous material, organic ion exchange resins filter cartridges and others.
    - **Gaseous waste:** The air in the working area and the environment is free from radioactive contamination. The off gas ventilation system in nuclear power plants play an important role in ensuring clean air.
    - **High Level Waste:** High level radioactive liquid waste (HLW) containing most (~99%) of the radioactivity in the entire fuel cycle is produced during reprocessing of spent fuel. Issue of the long lived radioactive waste has been the focal point of debate for the success of nuclear power. Planning for management of HL waste thus takes into account the need for their effective isolation from the biosphere and their continuous surveillance for extended periods of time spanning several generations. To meet this objective in the long term, waste isolation systems comprising multiple barriers are employed so as to prevent the movement of radionuclides back to the human environment.
- ❑ **Management of radiation wastes**
  - ⦿ In consideration to the primary objective of protecting human health, environment and future generations, the overall philosophy for safe management of radioactive wastes in India, is based on the concept of

- ▶ **Delay and Delay**
- ▶ **Dilute and Disperse**
- ▶ **Concentrate and Contain.**
- Effective management involves segregation, characterization, handling, treatment, conditioning and monitoring prior to final disposal.
- **Proper disposal** is essential to ensure protection of the health and safety of the public and quality of the environment including air, soil, and water supplies.
- Radiological hazards associated with short lived wastes <30 years half-life get significantly reduced over a few hundred years by radioactive decay. The high level wastes contain large concentration of both short and long lived radionuclides, warranting high degree of isolation from the biosphere and usually calls for final disposal into geological formation (repository)
- A key idea was that long-term disposal would be best carried out by identifying suitable sites at which the waste could be buried, a process called deep geological disposal
- **Low level waste** is comparatively easy to dispose of. The level of radioactivity and the half-life of the radioactive isotopes in low level waste are relatively small. Storing the waste for a period of 10 to 50 years will allow most of the radioactive isotopes in low level waste to decay, at which point the waste can be disposed of as **normal refuse**.
- In **Solid waste** substantial amount of LIL wastes of diverse nature, gets generated in different nuclear installations. Treatment and conditioning of solid wastes are practiced, to reduce the waste volume in ways, compatible to minimizing the mobility of the contained radioactive materials. A wide range of treatment and conditioning processes are available today with mature industrial operations involving several interrelated steps and diverse technologies. **A brief summary of the various radioactive waste management practices followed in India has been presented below:**

#### □ **Management of High-level radioactive wastes**

- This concerns management and disposal of highly radioactive materials created during production of nuclear power. High level radioactive waste is generally material from the core of the nuclear reactor or nuclear weapon. The waste includes uranium, plutonium, and other highly radioactive elements made during fission. Most of the radioactive isotopes in high level waste emit large amounts of radiation and have extremely long half-lives (some longer than 100,000 years) creating long time periods before the waste will settle to safe levels of radioactivity. **The management of high level waste in the Indian context encompasses the following three stages:**
  - ▶ **Immobilization** of high level liquid waste into **vitrified borosilicate glasses**.
  - ▶ **Engineered interim storage** of vitrified waste for passive cooling and surveillance over a period of time qualifying it for ultimate disposal.
  - ▶ **Ultimate storage** disposal of vitrified waste a **deep geological depository**.
- The basic requirement for geological formation to be suitable for the location of the radioactive waste disposal facility is **remoteness from environment, absence of circulating ground water** and ability **to contain radionuclides** for geologically long periods of time.

#### □ **Initiatives in India**

- At present, the nuclear waste produced by power plants are stored in underground facilities.
- The areas, where the disposal structures are located, are kept under constant surveillance with the help of bore-wells laid out in a planned manner. The underground soil and water samples from these bore wells are routinely monitored and to confirm effective confinement of radioactivity present in the disposed waste.”

- Much of the 'waste' produced by current plants is intended to be mixed with Thorium after 30-40 years to be used as fuel.
- India is one of the few countries to have mastered the technology of vitrification. Over the years BARC has developed the technology for vitrification of HLW. India has a unique distinction of having operating vitrification plant at Tarapur and Trombay. In our existing plant at Trombay vitrification process is essentially batch operation consisting of heating and fusing of pre-concentrated waste and glass forming additives and is carried out in melters based on induction heating.
- Radioactive waste disposal practices have changed substantially over the last twenty years. Evolving environmental protection considerations have provided the impetus to improve disposal technologies, and, in some cases, clean up facilities that are no longer in use. Designs for new disposal facilities and disposal methods must meet environmental protection and pollution prevention standards that are stricter than were foreseen at the beginning of the atomic age.
- Disposal of radioactive waste is a complex issue, not only because of the nature of the waste, but also because of the stringent regulatory structure for dealing with radioactive waste. India has achieved self-reliance in the management of all type of radioactive waste. Decades of safe and successful operation of our waste management facility stand testimony to international standards. An ongoing effort to upgrade technology to minimize radioactive discharge is also on.

## Safety Standards in Nuclear Power Plants

- The performance of Indian nuclear power reactors in respect of safety has been excellent, with about 340 reactor years of safe, reliable and accident-free operation. The releases of radioactivity to the environment have been a small fraction of the limits prescribed by the Atomic Energy Regulatory Board (AERB). The yearly radiation dose around the Indian NPPs, measured over the last many years, is an insignificantly small fraction of natural radiation dose and the stipulated regulatory limits.
- At all nuclear power stations, state of the art safety measures are provided based on principles of redundancy (more numbers than required) and diversity (operating on different principles). These include fail safe shutdown system to safely shutdown the reactor, combination of active and passive (systems working on natural phenomena and not needing motive power or operator action) cooling systems to remove the heat from the core at all times and a robust containment to prevent release of radioactivity in all situations. In addition, all nuclear power plants are designed to withstand extreme natural events like earthquake, flooding, tsunami etc.
- A multi-tier safety mechanism comprising of safety review committees within Nuclear Power Corporation of India Limited (NPCIL) and safety review committees in the regulatory authority (Atomic Energy Regulatory Board- AERB) is in place to monitor the safety of nuclear power plants. In addition, a framework of periodic safety reviews, audits and inspection is in place.
- Nuclear power stations in coastal areas are designed taking into account the technical parameters related to earthquake, tsunami, storm surges, floods etc. at each site. Appropriate bunds are provided at Tarapur, Kalpakkam and Kudankulam sites for shore protection.
- The shore protection measures are designed and constructed to withstand the possible impact of natural events. Surveillance of these protection measures is carried out periodically. Post Fukushima, the safety review of all nuclear power plants was conducted by task forces of NPCIL and the expert committee of AERB. These safety reviews have found that Indian nuclear power plants are safe and have margins and features in design to withstand extreme events like earthquakes and tsunamis.

### ❑ CAG Report related to Safety of Nuclear plants

- ◉ Comptroller and Auditor General (CAG) has pointed out some issues, **which needs serious consideration**:
  - ▶ **Legal status of AERB**: The sole regulatory agency AERB, still acts as an arm of government, without much authority to frame and revise rules related to nuclear safety.
  - ▶ **Inadequate emergency preparedness**: Most of the power plant lack state of art technology & protocols to deal with emergency situations.
  - ▶ **Location & site clearance**: Persistent land acquisition and environmental clearance issues and lack of proper planning of the nuclear unit may impair the ability to respond to exigencies. E.g. approach road to Tarapur atomic power station is highly congested.
  - ▶ **Other issues** like uncertainty over compensation clause in nuclear liability act, has raised great concern given the poor record of India to give compensation to affected in case of industrial disasters (eg. Bhopal gas tragedy).

### ❑ What can be done?

- ◉ CAG highlighted the urgency to bolster AERB's regulatory capacity by giving it a statutory backing and making it complete independent to frame and implement safety rules.
- ◉ Incorporate state of art safety infrastructure in power plants under construction.
- ◉ No compromise is selecting the most geologically stable location and other safety requirement
- ◉ Minimizing human handling of process in power plants and replacing them with smart robots & UAV.
- ◉ Promoting power plants to reuse nuclear waste to minimize waste generation.
- ◉ Greater awareness building among local community & district administration. About the risks, benefits and safety infrastructure at place.

## Insider Threats and Nuclear Security during a Pandemic

- ❑ International Atomic Energy Agency (IAEA) held discussions over the impact of the pandemic on nuclear plant operations, safety, and security during operations under COVID-19 circumstances, radiation protection, and emergency preparedness.
- ❑ Insider threats could possibly worsen during extremely stressful conditions like the ongoing pandemic.

### What are insider threats?

- ❑ Employees of nuclear installations and power plants, as well as security personnel posted at such sites, depending on the level of access, have a fair understanding of the functioning of nuclear facilities, their security systems, and their established security protocols, as well as any loopholes and security vulnerabilities that may exist.
- ❑ These employees are authorized to go through the multiple layers of security systems in place increases the vulnerabilities.

- ❑ Because insiders are known and trusted colleagues, it is almost impossible for others within a facility to spot any odd or suspicious behavior.
- ❑ Institutional security culture-related practices need to be strengthened to ensure early reporting of potential dangers from insiders.
- ❑ Almost all the recent incidents of nuclear thefts or losses of Highly Enriched Uranium (HEU) and Plutonium (Pu) have occurred with the help of an employee, or even worse, the crime has itself been committed by an employee.
- ❑ This highlights the vulnerabilities and the salience of this growing threat.

## Methods to curb insider threats

- ❑ One of the most effective means in checking insider threats has been by executing extensive background checks on possible employees before they are employed.
- ❑ These checks are repeated on a periodic basis or when an employee is being transferred to a more secure installation or is given a higher security project.
- ❑ But these are not foolproof measures and they provide no guarantees against security breaches.
- ❑ A more comprehensive and thorough approach – these could include ways to address a disgruntled employee’s problems, undertake better inventory management, and more stringent material accounting processes – is required.
- ❑ The IAEA has been proactive in this regard, and launched a COVID-19 Operational Experience Network, a pilot peer-to-peer network aimed as a “repository for planned or implemented response actions” during the pandemic.

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## Chapter

# 2

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# BIOTECHNOLOGY

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Biotechnology is defined as the industrial application of living organisms and their biological processes such as biochemistry, microbiology, and genetic engineering, in order to make best use of the microorganisms for the benefit of mankind.

## Different types of Biotechnology

- ❑ **Green biotechnology:** Green biotechnology is defined as the application of biological techniques to plants with the aim of improving the nutritional quality, quantity and production economics. It is done by implanting foreign genes to plant species that is economically important. **This contains three main areas:** plant tissue culture; plant genetic engineering and plant molecular marker assisted breeding.
- ❑ **Red biotechnology:** Red biotechnology is concerned with the discovery and development of innovative drugs and treatments. A key prerequisite was an increasing understanding of how proteins function, their roles in communication between and within cells, and the diseases caused when these proteins malfunction. **This includes:** Gene Therapy, Stem Cells, Genetic Testing, etc.
- ❑ **White biotechnology:** This field of biotechnology is connected with industry. White biotech uses moulds, yeasts, bacteria and enzymes to produce goods and services or parts of products. It offers a wide range of bio-products like detergents, vitamins, antibiotics etc. Most of the white biotech processes results in the saving of water, energy, chemicals and in the reduction of waste compared to traditional methods.
- ❑ **Blue biotechnology:** Blue biotechnology is concerned with the application of molecular biological methods to marine and freshwater organisms. It involves the use of these organisms, and their derivatives, for multiple purposes, the most remarkable are the identification process and development of new active ingredients from marine origin.
- ❑ **Yellow biotechnology:** Yellow biotechnology refers to biotechnology with insects -- analogous to the green (plants) and red (animals) biotechnology. Active ingredients or genes in insects are characterized and used for research or application in agriculture and medicine.

## Biotechnology and Medicine

- Biotechnology techniques are used in medicine for diagnosis and treating different diseases. It gives opportunities for the people to protect themselves from dangerous diseases.
- The field of Biotechnology, genetic engineering has introduced techniques like gene therapy, recombinant DNA technology and polymerase chain reaction which use genes and DNA molecules to diagnose diseases and insert new and healthy genes in the body which replace the damaged cells.
- **There are some applications of biotechnology which are playing their part in the field of medicine and giving good results:**
  - **Biopharmaceuticals:** The drugs are being developed with the use of microorganisms without using any synthetic materials and chemicals. Large molecules of proteins are usually the source of biopharmaceutical drugs. They when targeted in the body attack the hidden mechanisms of the diseases and destroy them without any side effect(s). Now scientists are trying to develop such biopharmaceutical drugs which can be treated against the diseases like hepatitis, cancer and heart diseases.
  - **Gene therapy:** It is used in delicacy and diagnoses of diseases like cancer and Parkinson's. The apparatus of this technique is that the fit genes are under attack in the body which either obliterate the injured cells or replace them. In some cases, the fit genes make corrections in the genetic information and that is how the genes start performance in the favor of the body.
  - **Pharmaco-genomics:** Pharmaco-genomics is an additional genetically modified method which is used to learn the genetic information of a personality. It analyzes the body's reply to sure drugs. It is the mixture of pharmaceuticals and genomics. The aspiration of this field is to expand such drugs which are inserted in the person according to the genetic information there in the individual.
  - **Genetic Testing:** It is a technique of heredity is used to conclude the genetic diseases in parents, sex and carrier screening. The technique of genetic testing is to use DNA probes which have the sequence alike to the mutated sequences. This technique is also used to recognize the criminals and to test the parenthood of the child.
- **Benefits of Red Biotechnology**
  - Biotechnology offers immense opportunities for improving quality and quantity of life. Diseases impact the life of individuals and impede national development. Many families fall into the vicious circle of poverty because of health problems.
  - Many medicines, such as vaccines for treating malaria and cholera, can be delivered to patients in the form of new antigens synthesized within common fruits and vegetables bred by modern biotechnology. These foods will reduce the rates of illness, death and associated expenditure by individuals and governments in many countries.
  - Various types of hereditary disabilities and mitochondrial DNA related diseases like Parkinson disease can be solved by using red biotechnology. This will not only improve the quality of life but also help in removing the associated tensions in the family.
  - New advances in the field will provide entrepreneurial and employment possibilities and will help in reaping digital dividend.
  - Many of the healthcare and medicinal products can be derived from plants using biotechnology. This combined with green biotechnology can help in revolutionizing agriculture.
- **Challenges in the field of Red biotechnology**
  - Though red biotechnology offers various new opportunities and can open new frontiers in the field it faces certain challenges:

- ▶ The states capacity to **regulate the red biotechnology field is limited** especially in case of developing countries. It raises the issues regarding intellectual property, pricing etc. How to ensure a balance between all will be seen. Laws, rules & regulations and institutional structures are absent in countries like India.
- ▶ The **field has not been duly recognized in India** and allocations for the sector are minimal. The availability of resources (financial, human resource etc.) for countries like India is a challenge.
- ▶ The result of gene transplantation and organ transplantation needs to be verified for whole life. In many cases the genetically corrected liver cells were recognized as foreign and rejected by the healthy immune system in the patients (as happened in treatment of Hemophilia case).
- ▶ Ethical issues regarding cloning, surrogacy (wherein India became a destination for fertility tourism) needs to be settled. Otherwise these things will result into exploitation of the poor and the commoditization of body parts.
- ▶ Privacy issues will crop up with increasing use of biotechnology. As medical practitioners become well versed in using gene therapy or genetic engineering, they will have access to personal information which if revealed will lead to violation of privacy of the patients.
- ▶ It will be possible to know the future health problems an individual is going to encounter, but this will also create ethical issue like whether that information should be revealed or not because it may have negative impact on employment, insurance and in other areas.
- ▶ **Equitable access:** The cost issues of these technologies are going to create a divide among the citizens. A situation may be created wherein certain people are dying because of hunger or TB or dengue and at the same time some persons are getting the facility of gene therapy at very high costs.
- ▶ **Bioprospecting and bio-piracy:** as the field grows there will emerge issues regarding bio-piracy. How countries tackle these issues will determine the future of the technologies.
- ▶ **Biological terrorism or war:** Rogue nations or individuals can use the advancements in biotechnology for the purpose of terrorism; various viruses can be used to infect individuals or populations etc. How to control the possibility of such events remains a challenge.
- Red biotechnology as a field offers great opportunities for individuals, societies and countries to get rid of various diseases and health problems which have prevented them from making the lives of individuals dignified and worth. There is a need to establish cooperation among all the countries and stakeholders to ensure equitable benefits arising from these, so that the humanity as a whole benefits from this.

## Biotechnology and Plant

- Green biotechnology is defined as the application of biological techniques to plants with the aim of improving the nutritional quality, quantity and production economics. It is done by implanting foreign genes to plant species that is economically important. **This contains three main areas:** plant tissue culture; plant genetic engineering and plant molecular marker assisted breeding.
- **Benefits of genetic engineering:**
  - Biotechnology has helped to increase crop productivity by introducing such qualities as disease resistance and increased drought tolerance to the crops.
  - Farmers use crop-protection technologies because they provide cost-effective solutions to pest problems which, if left uncontrolled, would severely lower yields.

- Biotechnology has allowed new options for improving the nutritional value, flavor, and texture of foods.
- Biotechnology can result in improved keeping properties to make transport of fresh produce easier, giving consumers access to nutritionally valuable whole foods and preventing decay, damage, and loss of nutrients.
- Due to reduced use of pesticide, less pesticide residues is present on foods thus minimize farm worker exposure to hazardous products?

### □ Initiatives for Social development

- **Ginger Cultivation:** A project on livelihood promotion of tribal communities in Kandhamal District, Orissa by using biotechnology.
- **Black Pepper:** Scientific organic cultivation of pepper through efficient use of bio-control agents and bio-pesticides was propagated among the Tribal and Rural farmers of Idukki District, Kerala.
- **A project on promoting the use of invasive species,** as an important bio-resource, to enhance livelihood of forest dwelling tribal communities was implemented by Atree Foundation, Bangalore.
- **Women farmers** were trained in hybrid maize seed production covering parental line sowing methods, crossing, harvesting F1 seeds, processing and marketing.

### □ Issues Related to GM Food

- **What are Genetically Modified food?**
  - ▶ A genetically modified organism (**GMO**) is an organism in which one or more genes (called transgenes) have been introduced into its genetic material from another organism using recombinant DNA technology.
  - ▶ Foods produced from or using GM organisms are often referred to as GM foods.
- **Arguments for GM Crops**

The arguments that have been put forward for the use of GMOs in agriculture include:

- ▶ **Potential benefits for agricultural productivity:**
  - ♦ **Better resistance to stress:** If crops can be made more resistant to pest outbreaks and severe weather (such as frost, extreme heat or drought), then it would reduce the danger of crop failure.
  - ♦ **More nutritious staple foods:** By inserting genes into crops such as rice and wheat, we can increase their nutritious value which can solve the problem of malnutrition.
  - ♦ **More productive farm animals:** by inserting Genes into cattle we can, for example, raise their milk yield.
  - ♦ **Longer shelf lives:** The genetic modification of fruits and vegetables can make them less likely to spoil in storage or on the way to market. This could expand trade opportunities as well as reduce massive wastage incurred in transport and supply.
  - ♦ **More food from less land:** Improved productivity from GMOs might mean that farmers in the next century won't have to bring so much marginal land into cultivation.
- ▶ **Potential benefits for the environment:**
  - ♦ **GMOs might reduce the environmental impact of food production and industrial processes:** Genetically engineered resistance to pests and diseases could greatly reduce the use of pesticides and insecticides needed for crop protection. This could not only reduce environmental impact - they could also improve the health of farm and industrial workers.

- ♦ **Rehabilitation of damaged or less-fertile land:** Large areas of cropland in the developing world have become saline by unsustainable irrigation practices. Genetic modification could produce salt-tolerant varieties.
- ♦ **Bioremediation:** Rehabilitation of damaged land may also become possible through organisms bred to restore nutrients and soil structure.
- ♦ **Biofuels:** Plant material fuel, or biomass, has enormous energy potential. For example, the waste from sugar cane or sorghum can provide energy, especially in rural areas. It may be possible to breed plants specifically for this purpose.
- ▶ **Potential benefits for human health**
  - ♦ **Pharming (Vaccines and Medicines):** Plants are being engineered to produce vaccines, proteins and other pharmaceutical products not only for humans but also for farm animals. This process is called “Pharming”.
  - ♦ **Hunger:** According to data from the World Food Programme, around 795 million people do not have enough food to live a healthy life. So many people are still suffering from starvation and malnutrition. And this can become even worse as the populations continue to grow, conflicts devastate regions and the effects of global warming take effect.
- ◉ **Arguments against GM crops**

The main arguments that have been put forward against the use of GMOs in agriculture include:

  - ▶ **Potential negative effects on the environment:**
    - ♦ **Genes can end up in unexpected places:**
      - ◉ Through “gene escape” they can pass on to other members of the same species and perhaps other species.
    - ♦ **Genes can mutate with harmful effect:**
      - ◉ Artificial insertion of genes could destabilize an organism by encouraging mutations.
    - ♦ **Interaction with wild and native populations:**
      - ◉ GMOs could compete or breed with wild species.
      - ◉ GM crops could pose a threat to crop biodiversity, especially if grown in areas that are centres of origin of that crop.
      - ◉ In addition, GM crops could compete with and substitute traditional farmers’ varieties and wild relatives that have been bred, or evolved, to cope with local stresses. If genetically modified crop varieties substitute them, they could be lost.
    - ♦ **Impact on birds, insects and soil biota:**
      - ◉ Potential risks to non-target species, such as birds, pollinators and micro-organisms, is another important issue.
      - ◉ Besides, it is feared that widespread use of GM crops could lead to the development of resistance in insect populations exposed to the GM crops.
  - ▶ **Potential negative effects on human health:**
    - ♦ **Allergenicity (Transfer of allergenic genes):** These could be accidentally transferred to other species, causing dangerous reactions in people with allergies.
    - ♦ **Outcrossing:** The migration of genes from GM plants into conventional crops or related species in the wild (referred to as “outcrossing”), as well as the mixing of crops derived from conventional seeds with GM crops, may have an indirect effect on food safety and food security. Cases have been reported where GM crops approved for animal feed or industrial use were detected at low levels in the products intended for human consumption.

- ♦ Studies in the U.S. have shown a strong correlation between growth of GM crops, and diseases such as acute kidney injury, diabetes, autism, Alzheimer's and cancers in the past 20 years in the U.S.
- **Potential socio-economic effects:**
  - ♦ **Loss of farmers' access to plant material:**
    - Biotechnology research is carried out predominantly by the private sector and there are concerns about market dominance in the agricultural sector by a few powerful companies.
    - This could have a negative impact on small-scale farmers all over the world.
    - Farmers fear that they might even have to pay for crop varieties bred from genetic material that originally came from their own fields when they buy seeds from "**companies holding patents**" on specific genetic modification "events".
  - ♦ **Intellectual property rights could slow research:** The proprietary nature of biotechnology products and processes may prevent their access for public-sector research.

## Biotechnology and Animal Husbandry

- ❑ Animal biotechnology is the use of science and engineering to modify living organisms. The goal is to make products, to improve animals and to develop microorganisms for specific agricultural uses. E.g.
- ❑ Creating transgenic animals (animals with one or more genes introduced by human intervention),
- ❑ Using gene knock out technology to make animals with a specific inactivated gene and producing nearly identical animals by cloning.

### ❑ Different examples are:

- **Transgenic Animals:** A transgenic animal is one whose genome has been altered by the transfer of a gene or genes from another species or breed.
- **Benefits:**
  - Used in the laboratory as models in biomedical research.
  - Transgenic farm animals are also being explored as a means to produce large quantities of complex human proteins for the treatment of human disease.
  - A cheaper option would be to develop a means to produce recombinant proteins in the milk, blood or eggs of transgenic animals.
- **Cloning**
  - Scientists use reproductive cloning techniques to produce multiple copies of mammals that are nearly identical copies of other animals, including transgenic animals, genetically superior animals and animals that produce high quantities of milk or have some other desirable trait. To date, cattle, sheep, pigs, goats, horses, mules, cats, rats and mice have been cloned, beginning with the first cloned animal, a sheep named Dolly, in 1996.
- **Artificial Insemination**
  - A project on dissemination and use of biotechnology tools in livestock for sustainability development for the families in desert areas of Rajasthan was implemented by BAIF Research Foundation, Pune.
- **Concerns:**
  - Potential health effects to humans from food products created by transgenic or cloned animals.

- ▶ The potential effects on the environment due to alteration of the ecologic balance regarding feed sources and predators.
- ▶ The introduction of transgenic animals that alter the health of existing animal populations and the disruption of reproduction patterns and their success.
- ▶ Animal biotechnology is unnatural. Its processes, they say, go against nature and, in some cases, cross natural species boundaries.
- ▶ Animal welfare: For example, calves and lambs produced through in vitro fertilization or cloning tend to have higher birth weights and longer gestation periods, which leads to difficult births that often require cesarean sections.
- ▶ Religious issues: These technologies are considered blasphemous. In effect, God has created a perfect, natural order, they say, and it is sinful to try to improve that order by manipulating the basic ingredient of all life.

#### ❑ What can be done?

- Before animal biotechnology will be used widely by animal agriculture production systems, additional research will be needed to determine if the benefits of animal biotechnology outweigh these potential risks.
- Labeling: Whether products generated from genetically engineered animals should be labeled.

### Benefits of Animal Biotechnology

- ❑ Increased growth rates, enhanced lean muscle mass, enhanced resistance to disease or improved use of dietary phosphorous to lessen the environmental impacts of animal manure.
- ❑ Transgenic poultry, swine, goats and cattle that generate large quantities of human proteins in eggs, milk, blood or urine also have been produced.
- ❑ Use of animal organs in humans.
- ❑ Hormone injected into dairy cows, increasing their milk production by 10 to 15 per cent.
- ❑ The advantages of biotechnology can be optimized only when the farmers, the end-users of agricultural biotechnology, are able to make informed decisions. As scientific community stands divided on the benefits and issues related to use of Biotechnology in Agriculture, Applications must be limited to nonfood areas only. Meanwhile a strong regulatory mechanism and safety assessment system be put in place to address the concerns of all stakeholders.

## Biotechnology & Industry

White biotechnology, also known industrial biotechnology, refers to the use of living cells and/or their enzymes to create industrial products that are more easily degradable, require less energy, create less waste during production and sometimes perform better than products created using traditional chemical processes. It uses scientific techniques and technologies to improve both the efficiency and environmental footprint of modern industrial production.

### Microorganism's as a basis for white biotechnology

- ❑ Since the 80s and 90s, the demand for a sustainable economy has placed existing natural resources ever more in the social spotlight. As a result, both politics and business have come to the realization

that safeguarding the natural resources for future generations with current industrial processes is not possible in the long term. Above all, the finite nature of fossil fuels has contributed to a rethinking, and has pushed forward the search for alternatives.

## Significance and Impact on society

- ❑ Recent scientific advances in the fields of genomics, molecular genetics, metabolic engineering and catalysis, coupled with advances in enzyme and fermentation technology as well as external factors such as soaring energy prices, renewed environmental concerns and energy security fears, have combined to make white biotechnology more important than ever.
- ❑ White biotechnology is already part of our daily life - vitamins and medicines as well as enzymes in washing powders are only a few of the many examples.
- ❑ Biocatalysts in detergents allow the washing to be completed at a lower temperature. And in the textile industry, biotechnologists have developed enzyme-based procedures to help give jeans the popular stonewashed look. This was previously achieved in a laborious process using pumice stone.
- ❑ Also well-established are food additives such as citric acid, and drugs such as antibiotics, which are produced using genetically modified microorganisms. These can now be counted among the most economically important products in industrial biotechnology. Thus white biotechnology is reducing the cost of production & enabling the availability of products to lower strata of society.
- ❑ After getting to know about the basic applications, now we are analyzing the impact of white biotechnology on different areas.
- ❑ Currently Food & beverage sector is the most prominent when it comes to application of white biotechnology. For example, microbes (yeast) or enzymes are used to produce beer and wine as well as dairy goods such as cheese. However, biotechnology is being increasingly applied to improve manufacturing processes and to solve environmental problems.

## Applications of Biotechnology

### ❑ Chemical Production:

- Chemical industry includes its excessive reliance on non-renewable energy and resources; environmentally damaging production processes that can be unsafe and produce toxic products and waste; products that are not readily recyclable and degradable after their useful life; and excessive regional concentration of production so that social benefits of production are less widely available. Advances in genetic engineering and other biotechnologies have greatly expanded the application potential of biotechnology.
- **Two major areas of biotechnology** that are driving transformation of the conventional chemical industry are bio-catalysis and metabolic engineering. Genetic engineering and molecular biology techniques have been used to obtain many modified enzymes with enhanced properties compared to their natural counterparts. Metabolic engineering, or molecular level manipulation of metabolic pathways in whole or part, is providing microorganisms and transgenic crops and animals with new and enhanced capabilities for producing chemicals.
- A future bioethanol based chemical industry, for example, will rely on **biotechnology in all of the following ways**: (1) generation of high yield transgenic corn varieties having starch that is readily accessible for enzymatic hydrolysis to glucose; (2) production of engineered enzymes for greatly improved bioconversion of starch to sugars; (3) genetically enhanced ethanol tolerant microorganisms that can rapidly ferment sugars to ethanol; (4) ability to recover ethanol using high-efficiency low-expense bioprocessing.

- **Metabolite production:** Microorganisms produce a number of metabolites during their growth using cheap substrates such as Acetone-butanol, Alcohol, Antibiotics, Enzymes, Organic acids Vitamins.

## Biotechnology and Environment

- The application of Biotechnology to solve the environmental problems is called Environmental Biotechnology.
- According to the International Society for Environmental Biotechnology - the environmental Biotechnology is defined as an environment that helps to develop, efficiently use and regulate the biological systems and prevent the environment from pollution or from contamination of land, air and water have work efficiently to sustain an environmental friendly Society.
- In other words, it can be defined as the optimal use of the natural resources through the plants, animals, bacteria, fungi and algae in order to produce the energy that comes from the resources which are natural such as sunlight, wind, air, waves (renewal able energy), food and nutrients.
- The optimal use of the these natural resources can be done by re-cycling and utilizing the waste from these resources and find unique ways of creating processes to utilize the waste and where the waste of each process created becomes the feedstock for another process.

### Applications and benefits of environmental biotechnology

#### □ **Bioenergy:**

- The collective purport of Biogas, biomass, fuels, and hydrogen are called the Bioenergy. The use of this application of Environment Biotechnology is in the industrial, domestic and space sectors. One of the pioneer examples of green energy are the wastes collected from the organic and biomass wastes; these wastes help use to over the pollution issues caused in the environment. The Biomass energy supply has become a prominent importance in every country.

#### □ **Bioremediation:**

- Various products (chemicals) generated by the modern technologies are posing a great threat to the natural breakdown processes and the natural mechanisms of maintaining ecological balance. Many of these pollutants are complex in nature, and are hence difficult to break down. Such pollutants are accumulating in the natural environment to an alarming rate.
- The application of biotechnology has helped in the environmental management of such hazardous contaminants by bioremediation. This process is also referred to as bio-restoration or bio-treatment. Bioremediation involves the use of naturally existing microorganisms to speed up the breaking down of biological substances and degradation of various materials.

#### □ **Biosensors:**

- Biosensors are biophysical devices that can detect and measure the quantities of specific substances in a variety of environments. Biosensors include enzymes, antibodies and even microorganisms, and these can be used for clinical, immunological, genetic and other research purposes.
- The biosensor probes are used to detect and monitor pollutants in the environment. These biosensors are non-destructive in nature, and can utilise whole cells or specific molecules like enzymes as biomimetic for detection. Their other advantages include rapid analysis, specificity and accurate reproducibility.

- Biosensors can be created by linking one gene to another. For instance, mercury resistance gene (**mer**) or toluene degradation (**tol**) gene can be linked to the genes coding for proteins showing bioluminescence within a living bacterial cell.

#### □ **Biodegradation of Xenobiotic Compounds:**

- Xenobiotics are man-made compounds of recent origin. These include dyestuffs, solvents, nitrotoluenes, benzopyrene, polystyrene, explosive oils, pesticides and surfactants. As these are unnatural substances, the microbes present in the environment do not have a specific mechanism for their degradation.
- Hence, they tend to persist in the ecosystem for many years. The degradation of xenobiotic compounds depends upon the stability, size and volatility of the molecule, and the environment in which the molecule exists (like pH, susceptibility to light, weathering etc). Biotechnological tools can be used to understand their molecular properties, and help design suitable mechanisms to attack these compounds.

#### □ **Oil Eating Bugs:**

- Accidental oil spills pose a great threat to ocean environments. Such spills have a direct impact on marine organisms. To counter this problem, scientists have now developed living organisms to clean up the oil spills. The most common oil-eating microorganisms are bacteria and fungi.
- Dr. Anand Chakrabarty, a leading US-based scientist of Indian origin, has successfully created bacterial forms which can degrade oil into individual hydrocarbons. These bacteria include *Pseudomonas aureginos*, where a gene for oil degradation has been introduced into the *Pseudomonas*.
- *Penicillium* species has also been found to possess oil degrading features, but its effect needs much more time than the genetically engineered bacterium. Many other microorganisms like the *Alcanivorax* bacteria are also capable of degrading petroleum products.

#### □ **Bio-mining:**

- Among the oldest industries in the world, mining is the source of alarming levels of environmental pollution. Modern biotechnology is now being used to improve the environment surrounding mining areas through various microorganisms. For instance, a bacterium *Thiobacillus ferrooxidans* has been used to back out copper from mine tailings. This has also helped in improving recovery.
- This bacterium is naturally present in certain sulphur-containing materials, and can be used to oxidise inorganic compounds like copper sulfide minerals. This process releases acid and oxidising solutions of ferric ions that can wash out metals from the crude ore. These bacteria chew up the ore and release copper that can subsequently be collected. Such methods of bio-processing account for almost a quarter of the total copper production world-over. Bio-processing is also used to extract metals like gold from very low-grade sulfidic gold ores.

#### □ **Pollution Control:**

- With the help of modern biotechnology, naturally occurring biocatalysts can be used to detoxify harmful chemicals being released into the environment. Such biocatalysts have helped get rid of carcinogenic compounds like methylene chloride from industrial wastes. These special bacteria are exposed to the waste in a bioreactor, wherein the bacteria consume the noxious chemical and convert it to water, carbon dioxide and salts, thus completely destroying the chemical compound.

#### □ **Weed Control:**

- New herbicides have been developed, which will be selective to the target and harmless for the non-target organisms. Genetically engineered herbicide resistant plants have also been developed

in a number of crops, which would help in the use of environment friendly herbicides. Genetically engineered insect resistant plants have also been successfully developed in certain crop species, thus suggesting the restricted use of pesticides in future.

□ **Pest Control and Bio-pesticide:**

- Bacterial pesticides are now being synthesised by transferring bacterial gene (*Bacillus thuringiensis*) Bt into plants. This gene encodes a protein, which when ingested by feeding insects, results in the solubilisation of the insect's digestive tract (mid gut) and releases protoxins. This leads to disturbances in the equilibrium and ultimately kills the insect.

□ **Viral Pesticides:**

- Viral pesticides are environmentally safe and carry lower risk of toxicity. These pesticides can also be used against the pest strains, which have otherwise become resistant to chemical pesticides. A number of entomopathogenic viruses (virus infecting insects) have been used as safe and effective pesticides. These viruses kill specific pest species and have no adverse effects on useful insect pollinators, insect yielding useful products, parasites or predators. They are safe even in long scale spray operations.

□ **Bio-fertilisers:**

- These have also been used to reduce the cost of fertiliser applications and to reduce the environmental hazards caused by chemical fertilisers. Recently marine plants (seaweeds) have been used as bio fertilisers. They have proved to be very encouraging and thus reducing the burden of using chemical fertilizers.

□ **Biomarker:**

- This type of Application of environmental Biotechnology gives response to a chemical that helps to measure the level of damage caused or the exposure of the toxic or the pollution effect caused. In other word, Biomarker can also be called as the Biological markers the major use of this applications helps to relate the connection between the oils and its sources.

**Examples of usage of biotechnology in the removal of Oil and Grease deposits**

- The oil spills from oil tankers on land surface as well as in seas and oceans are a major environmental hazard. This not only kills the aquatic flora and fauna by destroying the habitat but also creates health problems for the local inhabitants. Traditionally chemical dispersants are being used as remediation efforts. However these chemical dispersants are also toxic in nature and they persist in the environment for a long time. The present techniques of washing the oil off the gravel and cleaning the area of oil spills, is very expensive and time consuming.
- In order to overcome some of these problems, the oleophilic fertilizers are being developed which allow rapid growth and multiplication of microbes which further leads to the increase in the biodegradation process for removal of oil.
- In recent years, using genetic engineering, oil utilizing microorganisms have been produced which can grow rapidly on oil. The genetically engineered microbes for cleaning oil spills are mixed with straw. At the site of oil spill, the straw mixed with microbes are scattered over the oil spilled area. The straw soaks the oily water and the microbes break the oil into non-toxic and non-polluting materials thereby cleaning up the site.

- Some of the oil utilizing microbes can also produce surface active compounds that can emulsify oil in water and thereby removing the oil. A strain of *Pseudomonas aeruginosa* produces a glycolipid emulsifier that reduces the surface tension of oil-water interface which helps in the removal of oil from water. This microbial emulsifier is nontoxic and biodegradable and has shown promising results in the laboratory experiments. Some of the microorganisms which are capable of degrading petroleum include pseudomonads, various corynebacteria, mycobacteria and some yeasts.
- The two methods for bioremediation of oil spills are: a) using a consortium of bacteria, and b) using genetically engineered bacteria/microbial strains. (discussed under the topic of bioremediation) Both bacterial and fungal cultures from the petroleum sludge have been isolated. The fungal culture could degrade 0.4% sludge in 3 weeks. Degradation of petroleum sludge occurred within two weeks when the bacterial culture (*Bacillus Circulans*) was used. A significant degradation of petroleum sludge was observed in 10 days when the fungus *B. Circulans* and a prepared surfactant were exogenously added to petroleum sludge.

◦ **Benefits of environmental biotechnology**

- The major benefits of environmental biotechnology are it to keep our environment safe and clean for the use of the future generations. It helps the organisms and the engineers to find useful ways of getting adapted to the changes in the environment and keep the environment clean and green. The benefit of environmental biotechnology helps us to avoid the use of hazardous pollutants and wastes that affect the natural resources and the environment.
- The environmental biotechnology has a role to play in the removal of the pollutants. Biosensors are biophysical devices which can detect the presence of specific substances e.g. sugars, proteins, hormones, pollutants and a variety of toxins in the environment. They are also capable of measuring the quantities of these specific substances in the environment.
- The biological material in use (e.g. an enzyme) is immobilized by conventional methods like physical or membrane entrapment, non-covalent or covalent binding. A contact is made between the immobilized biological material and the transducer. The analyte binds to the biological material to form a bound analyte which in turn produces the electronic response that can be measured. Sometimes the analyte is converted to a product which could be associated with the release of heat, gas (oxygen), electrons or hydrogen ions. The transducer then converts the product linked changes into electrical signals which can be amplified and measured.
- The uses and methods of environmental biotechnology applications have many diverse implications and benefits. Biotechnology is constantly being used to help adapt organisms and engineer useful ways to help clean up the environment and keep it green for the future generations. As well as eliminating the use of pollutants and wastes that affect our environment, there is a need to be able to promote and sustain the development of our society with the lowest possible impact on the environment.
- Similarly biotechnology can be used in the conservation of biodiversity.
- The extinction of wild species due to the destruction of habitats and ecosystems has raised serious concerns about the biodiversity in general. Biodiversity provides genes from wild species for biotechnology exercises and experiments hence biotechnology and biodiversity are interrelated. Besides taking steps to minimize and regulate the factors responsible for causing loss of biodiversity, efforts are on to develop the techniques of conservation of biodiversity. One of the methods involves the establishment of “gene banks” leading to “in situ conservation and ex situ conservation. The in situ conservation involves the conservation of plants and animals in their natural habitat and ecosystems. The ex situ conservation includes conservation of species

away from their habitats. The ex situ conservation uses sample populations and establishes the “gene banks” which includes resource centers, zoos, botanical gardens, national parks, culture collection centers etc.

- ▶ Biotechnology offers special methods to conserve both animal and plant genetic resources especially in the conservation of endangered plant species. The tissue culture method is being used to multiply an endangered plant species. The method of embryo transfer and artificial insemination is used for the multiplication of endangered animal species.
- ▶ New breakthroughs in methods of biotechnology applications including genomics, proteomics, bioinformatics, sequencing and imaging are all producing vast amounts of information.
- ▶ Both changes to the functional and metagenomic approaches are adding to our understanding and knowledge about the importance of having different pathways and types of networks to use in particular environments.
- ▶ This may help in bringing applications of biotechnology at the ground level so that inclusive growth may be achieved.

## 1,000 Genomes Project

### □ Introduction:

- Launched in January 2008 with the goal of developing a comprehensive resource of human genetic variation across worldwide populations.
- It was an international research effort to establish by far the most detailed catalogue of human genetic variation.

## Scientists planned to sequence the genomes of Biotechnology Projects

- ❑ at least one thousand anonymous participants from a number of different ethnic groups.
- ❑ It was the first project to sequence the genomes of a large number of people, to provide a comprehensive resource on human genetic variation.
- ❑ This resource will aid about understanding of the role of genetic variation in human history, evolution and disease
  - **There are two kinds of genetic variants related to disease.**
    - ▶ Rare genetic variants that have a severe effect predominantly on simple traits (e.g. Cystic fibrosis, Huntington disease).
    - ▶ More common, genetic variants have a mild effect and are thought to be implicated in complex traits (e.g. Cognition, Diabetes, and Heart Disease).
      - ◆ Between these two types of genetic variants lies a significant gap of knowledge, which the 1000 Genomes Project is designed to address.
      - ◆ Data from the 1000 Genomes Project was quickly made available to the worldwide scientific community through freely accessible public databases.

## International HapMap Project

### □ Introduction:

- The International HapMap Project was an organization that aimed to develop a haplotype map (HapMap) of the human genome.
- HapMap is used to find genetic variants affecting health, disease and responses to drugs and environmental factors.
- The information produced by the project is made freely available for research.
- The International HapMap Project is collaboration among researchers at academic centers, non-profit biomedical research groups and private companies in Canada, China, Japan, Nigeria, the United Kingdom, and the United States.
- It officially started with a meeting on October 27 to 29, 2002.

### □ Objective:

- To determine the common patterns of DNA sequence variation in the human genome and to make this information freely available in the public domain.
- The HapMap will allow the discovery of sequence variants that affect common disease, will facilitate development of diagnostic tools, and will enhance our ability to choose targets for therapeutic intervention.

### □ Details:

- The DNA sequence of any two people is 99.5 percent identical. The variations, however, may greatly affect an individual's disease risk.
- Sites in the DNA sequence where individuals differ at a single DNA base are called single nucleotide polymorphisms (SNPs). Sets of nearby SNPs on the same chromosome are inherited in blocks. This pattern of SNPs on a block is a haplotype.
- Blocks may contain a large number of SNPs, but a few SNPs are enough to uniquely identify the haplotypes in a block. The HapMap is a map of these haplotype blocks and the specific SNPs that identify the haplotypes are called tag SNPs.
- The HapMap is valuable by reducing the number of SNPs required to examine the entire genome for association with a phenotype from the 10 million SNPs that exist to roughly 500,000 tag SNPs.
- This makes genome scan approaches to finding regions with genes that affect diseases much more efficient and comprehensive, since effort is not wasted typing more SNPs than necessary and all regions of the genome can be included.

### □ Uses:

- Use in studying genetic associations with disease.
- A powerful resource for studying the genetic factors contributing to variation in response to environmental factors, in susceptibility to infection, and in the effectiveness of and adverse responses to drugs and vaccines.
- Using just the tag SNPs, researchers are able to find chromosome regions that have different haplotype distributions in the two groups of people, those with a disease or response and those without.

- Each region is then studied in more detail to discover which variants in which genes in the region contribute to the disease or response, leading to more effective interventions.
- This also allows the development of tests to predict which drugs or vaccines would be most effective in individuals with particular genotypes for genes affecting drug metabolism.

## Human Genome Project

### □ Introduction:

- The “genome” of any given individual is unique; mapping the “human genome” involved sequencing a small number of individuals and then assembling these together to get a complete sequence for each chromosome. The finished human genome is thus a mosaic, not representing any one individual.
- The Human Genome Project (HGP) was an international scientific research project.
- Funding came from the US government through the National Institutes of Health (NIH) as well as numerous other groups from around the world.
- It remains the world’s largest collaborative biological project.

### □ Goal:

- Determining the sequence of nucleotide base pairs that make up human DNA, and of identifying and mapping all of the genes of the human genome from both a physical and a functional standpoint.

## Applications:

- From the start, the Human Genome Project supported an Ethical, Legal and Social Implications research program to address the many complex issues that might arise from this science.
- It can help us understand diseases including: genotyping of specific viruses to direct appropriate treatment.
- Identification of mutations linked to different forms of cancer.
- The design of medication and more accurate prediction of their effects.
- Advancement in forensic applied sciences.
- Biofuels and other energy applications.
- Agriculture, animal husbandry, bioprocessing; risk assessment; bioarcheology, anthropology and evolution.
- Commercial development of genomics research related to DNA based products, a multibillion-dollar industry.
  - ▶ As a result of the Human Genome Project, today’s researchers can find a gene suspected of causing an inherited disease in a matter of days, rather than the years it took before the genome sequence was in hand.

### □ Techniques include:

- DNA Sequencing.
- The Employment of Restriction Fragment-Length Polymorphisms (RFLP).
- Yeast Artificial Chromosomes (YAC).

- ▶ Bacterial Artificial Chromosomes (BAC).
- ▶ The Polymerase Chain Reaction (PCR).
- ▶ Electrophoresis.

## Frozen Ark Project

### □ Introduction:

- A British-led project called “Frozen Ark” is preserving the DNA of endangered species before they disappear.
- It is a charitable frozen zoo project created jointly by the Zoological Society of London, the Natural History Museum and University of Nottingham.
- The project aims to preserve the DNA and living cells of endangered species to retain the genetic knowledge for the future.
- The Frozen Ark collects and stores samples taken from animals in zoos and those threatened with extinction in the wild, with the expectation that, someday, cloning technologies will have matured sufficiently to resurrect extinct species.
- The Frozen Ark was a finalist for the Saatchi & Saatchi Award for World Changing Ideas in 2006.

### □ Mission:

- To collect, preserve and store tissue, gametes, viable cells and DNA from endangered animals for use both in conservation programmes and to enable society to benefit itself and all life on earth. The project focuses on the thousands of animals that are threatened with extinction.

### □ Plan:

- To support the establishment of genome resource banks of endangered animals in many countries, to establish a database listing where genetic materials are stored worldwide and identifying which species are most in need of sampling.

### □ What happens with the material collected by The Frozen Ark Project?

- Much of The Frozen Ark sample collection of frozen material is being preserved in -80oC freezers.
- Cultured mammalian cells, tissue and gametes are being prepared and stored in liquid nitrogen.
- Other preservation methods for the long term are ultra-low freezing in pure ethanol, as dried samples on Whatman paper and as freeze dried samples. These methods are useful for countries having unreliable supplies of electricity.
- The DNA contained in cells and tissues is very stable when it is stored at a cold enough temperature. DNA can be copied quickly and easily, extracted from just a few cells and amplified millions of times in just a few hours.

## Decoding the Wheat Genome

### □ Introduction:

- The **International Wheat Genome Sequencing Consortium (IWGSC)** is a non-profit organisation established in 2005 by a group of wheat growers, plant scientists and breeders from 55 countries.

- The IWGSC to which India is a partner published the international journal Science a draft sequence of the bread wheat genome.
- The goal of the IWGSC is to make a high quality genome sequence of bread wheat publicly available, in order to lay a foundation for basic research that will enable breeders to develop improved varieties.
- India has contributed in developing the draft sequence of the bread wheat genome.
- Wheat has largest content of DNA among all the food crops.
- Decoding genome sequence of wheat can help in developing climate smart wheat.
- Largest genome to be sequenced to-date - raising the prospects of bigger and faster disease-resistant crops to meet the looming global food shortage.
- The plant is among the world's most important crops and the researchers say the information could help farmers create disease-resistant strains of the global food staple.

#### □ **Advantages:**

- A complete and accurate description of the wheat genome will allow for the quick identification of critical genes that code for everything from drought resistance to stress resistance.
- Breeders can make sure these genes are in their breeding populations and this will help them improve their productivity.
- It will help in identifying genetic characteristics which can boost crop productivity and allow farming in difficult environments.
- This genomics resource has made thousands of markers available to wheat researchers which will facilitate mapping and cloning of genes of agronomic importance in much lesser time and cheaper cost than was available earlier.
- Decoding wheat genome will facilitate our understanding of gene function which will enable develop new genetic gains of wheat. Taking forward with molecular breeding and genetic engineering we would be able to develop climate smart wheat (drought/terminal heat tolerance) with higher yield.

#### □ **Genetically Modified Mosquito**

- A genetically modified insect is an insect that has been genetically modified for various reasons such as agricultural production, oil production and pest control.
- Scientists have moved on from using bed nets and insecticides to kill malaria-spreading mosquitoes, to genetically modify the mosquitoes by inserting a gene that leads to the production of male offsprings.
- Since only females carry the malaria-causing microorganism, the spread of the disease is controlled in the short-term while eventually the whole population gets wiped out.
- Scientists injected a gene from a slime mould into the mosquito which attached itself to the X chromosome during sperm-making process effectively masking the sperms leading to production of male offsprings.
- **Methods:**
  - ▶ The British company Oxitec use a technique called Release of Insects with Dominant Lethality (RIDL), that can produce fertile male adults that induce a high mortality of the descendants. The adults generated with this technique and released in the environment are not sterile but their descendants have a survival rate of 0% . This lethality can be switched off by introducing the antibiotic, tetracycline, into their diet.

- **Concerns**

- ▶ There are concerns about using tetracycline on a routine basis for controlling the expression of lethal genes. There are plausible routes for resistance genes to develop in the bacteria within the guts of GM-insects fed on tetracycline and from there, to circulate widely in the environment.

- ◻ **Designer babies' or Three parents babies**

- A number of children each year are born with faults in their mitochondrial DNA which can cause diseases. Due to it the parts of the body that need most energy are worst affected: the brain, muscles, heart and liver. Faulty mitochondria have also been linked to more common medical problems, including Parkinson's, deafness, failing eyesight, epilepsy and diabetes. Thus, three-parent babies' mechanism has been evolved to decrease the number of children born with diseases.
- Three-parent babies are human offspring with three genetic parents. The procedure replaces a small amount of faulty DNA in a mother's egg with healthy DNA from a second woman, so that the baby would inherit genes from two mothers and one father. The procedure is intended to prevent mitochondrial diseases including diabetes mellitus and deafness and some heart and liver conditions.
- The mitochondrial replacement technique has, unsurprisingly, raised objections and ethical considerations. **These are as follows:**
  - ▶ It raises concerns of bioethics because it creates genetic links between the offspring and three parents, as the child's DNA consists of the genetic material of three people.
  - ▶ The method used for this purpose constitutes inheritable germ-line genetic modification. This means that it is not just the offspring's DNA that is modified, but also the DNA of the generations to follow.
  - ▶ Mitochondrial transfer passes on genetic changes from one generation to another. That raises ethical concerns because any unexpected problems caused by the procedure could affect people who are not yet born, and so cannot give their consent to have the treatment. Mitochondria are not completely understood, and the DNA they hold might affect people's traits in unknown ways. For that reason, some scientists believe mitochondria should be better understood before the procedures are legalized.
  - ▶ The Catholic Church opposes one form of mitochondrial transfer, called pronuclear transfer, because a fertilized egg from the mother is destroyed in the process. Catholic ethicists have also complained that mitochondrial transfer introduces a "rupture" between mother and father and "dilutes parenthood".
  - ▶ Implications for identity are another ethical concern that has psychological and emotional impacts on a child's life regarding of a person's sense of identity. It debates whether the genetic make-up of children born as a result of mitochondrial replacement affect their emotional well-being when they are aware that they are different from other healthy children conceived from two parents.
- **Pros of Designer babies**
  - ▶ Reduces risk of genetic diseases.
  - ▶ Reduces risk of inherited medical conditions.
  - ▶ Better chance the child will succeed in life.
  - ▶ Better understanding of genetics.
  - ▶ Increased life span.
  - ▶ It can give, the child genes that the parents do not carry.
  - ▶ Prevent next generation of family from getting characteristics/diseases.

● **National Guidelines for Gene Therapy Product Development and Clinical Trials 2019**

- ▶ The Indian Council of Medical Research (ICMR) along with the Department of Biotechnology (DBT) released the National Guidelines for Gene Therapy Product Development and Clinical Trials 2019 to cater to the requirements for gene therapy trials.
- ▶ Gene therapy refers to the process of introduction, removal or change in content of an individual's genetic material with the goal of treating the disease and a possibility of achieving long term cure.
- ▶ These guidelines are not meant to be construed to replace or overrule other regulatory requirements.
- ▶ These guidelines serve to clearly outline the ethical and scientific requirements for gene therapy trials keeping in mind patient safety and efficacy. These guidelines will be periodically updated on the basis of scientific development in the field.
- ▶ The US FDA and EU guidelines were referred to while drafting the guidelines. The guidelines which were framed keeping in mind the existing rules and regulations provides a broad framework on ethical, scientific and regulatory requirements of gene therapy products (GTPs).
- ▶ Gene Therapy Advisory and Evaluation Committee (GTAEC) has also been constituted and notified by Department of Health Research (DHR) under Union health ministry as an independent body of experts representing diverse areas of biomedical research, concerned government agencies and other stakeholders.
- ▶ Amongst other functions this committee shall provide a hand holding for the investigators/industry and also give pre-IND consultations.
- ▶ Gene therapy encompasses all such processes wherein a nucleotide sequence (DNA or RNA) with or without its regulatory elements required for correction of a deleterious or defective genotype or phenotype is being introduced. It also encompass such a process for improving the therapeutic efficacy of other gene therapy products.
- ▶ A gene therapy product (GTP) is thus defined as any entity which includes a nucleic acid component being delivered by various means for therapeutic benefit. The first successful gene therapy clinical trial was conducted in 1989 at the NIH Clinical Center, for severe combined immunodeficiency.
- ▶ Recent advances in innovative technologies have ushered a new era of cell and biological therapeutics. Amongst these, gene therapy is emerging as the potential treatment option for genetic disorders particularly for monogenic and rare diseases, as well as some of the multi-factorial diseases such as cancer.
- ▶ For some of these conditions, therapeutic strategies are yet to be established, but the genetic basis of the disease is understood, making gene therapy a modality of choice for clinical management.
- ▶ This is because these conditions result from gene defects or mutations and the reconstitution of a normal copy of the gene has the potential to mitigate the clinical phenotype. Furthermore, development of suitable vector systems, better clinical trial designs and monitoring, have made gene therapy a reality in the current scenario.
- ▶ Globally, very few gene therapy products have been approved. The scientists and industry involved in the field seek advice and directions regarding regulatory requirements for pre-clinical studies and clinical translation.
- ▶ Taking cognisance of this gap, ICMR proactively initiated the process of drafting the national guidelines for gene therapy product development and clinical trials in consultation with the experts in the field and government agencies including DBT and Central Drugs Standard Control Organisation (CDSCO).

- ▶ As per the New Drugs and Clinical trial Rules (2019), the GTPs falls under 'new drug' and shall always be deemed to be 'new drug'. Thus, as per these rules 'academic trials' are not applicable to clinical trials using GTPs.

## Issue of Bio-Piracy

Recently the Commerce Secretary highlighted the issue of bio-piracy and stated that to check bio-piracy and exploitation of traditional knowledge holders in developing countries by big global companies there is an urgent need for an effective international legal regime.

### □ What is bio-piracy?

- Bio-piracy is a situation where indigenous knowledge of nature, originating with indigenous people, is used by others for profit, without permission from and with little or no compensation or recognition to the indigenous people themselves
- Developed countries are exploiting developing countries genetic resources and indigenous communities traditional knowledge in the name of patents on the inventions derived from those genetic resources. This leads to bio piracy.
- Bio-piracy operates through unfair application of patents to genetic resources and traditional knowledge. Biopiracy is the theft or usurpation of genetic materials especially plants and other biological materials by the patent process example: use of indigenous knowledge of medicinal plants for patenting by medical companies without recognizing the fact that the knowledge is not new, or invented by the patentee, And thereby the piracy deprives the indigenous community to the rights to commercial exploitation of the technology that they themselves had developed.

### □ Why legal regime needed?

- The asymmetry between the benefits earned by companies that commercially exploit products derived from traditional knowledge and the lack of benefits for traditional knowledge holder together with misappropriation of traditional knowledge under patents and other IPRs lead to loss of knowledge and profits.
- However, national laws alone can never address fully the issues of misappropriation of existing knowledge in foreign patent offices and therefore an international regime in order to address issues related to bio-piracy.

### □ Example:

- Basmati patent- Rice Tec (US Co.) obtained a patent (US 5663484 ) on a type of rice produced by crossing a strain of Indian basmati rice with an American variety; The patent claimed rights in respect of basmati-like rice grown anywhere in the Western Hemisphere. It also claimed future rights on any new varieties produced by crossing the new variety with existing Asian varieties.
- The farmers argued that an American rice producer should not be allowed to use the name 'basmati'. Basmati rice is a valuable export crop earning India approximately US\$800 million a year.
- As a result of a worldwide citizen campaign against RiceTec Basmati patents, USPTO struck down large sections of the Basmati patent.
- Attempts to patent medicinal properties of neem, turmeric and ashvagandha in Europe and the US have also been done. These are examples of the adverse effects that a patent monopoly over traditional knowledge can have on indigenous communities that hold such knowledge.

Bio-prospecting is the process of discovery and commercialization of new products based on biological resources.

Bio-prospecting may involve bio-piracy, the exploitative appropriation of indigenous forms of knowledge by commercial actors, and also includes the search for previously unknown compounds in organisms that have never been used in traditional medicine before.

## Bioinformatics

- Bioinformatics is the collection, organization and analysis of large number of biological data using networks of computers and databases. It refers to the convergence of IT and biotechnology.
- The term bioinformatics first came into use in the 1990s and was originally synonymous with the management and analysis of DNA, RNA and protein sequence data. India was one of the first countries in the world to initiate a Bioinformatics Programme during 1987-88.
- India has evolved a National Bioinformatics Network for sustainable utilization of biological data available through online and offline methods. The network is made up of distributed information sub-centres in specialized areas of Biotechnology.
- Application of bioinformatics
  - Bioinformatics have a comprehensive application of mathematics (e.g., probability and statistics), science (e.g., biochemistry), and a core set of problem-solving methods (e.g., computer algorithms) to the understanding of living systems.
- It is used in the following fields:

|                               |                                             |
|-------------------------------|---------------------------------------------|
| Molecular medicine            | Antibiotic resistance                       |
| Personalized medicine         | Forensic analysis of microbes               |
| Preventative medicine         | Bio-weapon creation                         |
| Gene therapy                  | Evolutionary studies                        |
| Drug development              | Crop improvement                            |
| Microbial genome applications | Insect resistance                           |
| Waste cleanup                 | Improve nutritional quality                 |
| Climate change Studies        | Development of Drought resistance varieties |
| Alternative energy sources    | Vetinary Science etc.                       |
| Biotechnology                 |                                             |

- Advantages of bioinformatics:
  - Allows visualization of molecular genetics
  - Helps store massive quantities of repetitive and non-repetitive information
  - Rapidly advancing technology
  - Algorithmic data mining

- Pattern recognition
- ❑ Disadvantages of bioinformatics:
  - Expensive to run
  - Expensive to buy
  - Not for personalized use
  - Complicated topic
  - Broad subject
- ❑ The future of bioinformatics is integration. For example, integration of a wide variety of data sources such as clinical and genomic data will allow us to use disease symptoms to predict genetic mutations and vice versa. The integration of GIS data, such as maps, weather systems, with crop health and genotype data, will allow us to predict successful outcomes of agriculture experiments.
- ❑ Finally, a key research question for the future of bioinformatics will be how to computationally compare complex biological observations, such as gene expression patterns and protein networks. Bioinformatics is about converting biological observations to a model that a computer will understand. This is a very challenging task since biology can be very complex. This problem of how to digitize phenotypic data such as behavior, electrocardiograms, and crop health into a computer readable form offers exciting challenges for future bioinformaticians.

## Manav

- ❑ A new **human atlas** initiative known as **Manav** has been launched by the **Department of Biotechnology and Persistent Systems, a biotechnology company** to create a unified database of molecular network of all the tissues in the human body and to derive a holistic picture of working of the human body.
- ❑ **About**
  - This mega project will collate and integrate **molecular information** on human tissues and organs that currently lie hidden in research articles in an unstructured and disorganised form.
  - It would utilise large biological community, both students and scientists, for extracting and adding the information from scientific literature at the level of cells and organs.
  - The undergraduates and postgraduates from the various distinct fields of biology such as zoology, biotechnology, botany, biochemistry, pharmacology and medical sciences can register and contribute to this project
- ❑ **Background**
  - The idea emerged from the success of **Smart India hackathon**, a nationwide contest in which large number of engineering students are being encouraged to find solutions to pressing problems.
  - In the same way, Manav will engage biology students to build their skills in reading scientific literature and deepen their understanding of biological system.
- ❑ **Aims of Manav**
  - To orient students involved in biological courses towards an aim that will train them to read scientific literature, analyse it and also the knowledge on how to design experiments.
  - This initiative will not only seal the gaps in knowledge on human body but will also create a trained population of biologists.

- The project aims to create a unified database, which would eventually help researchers in identifying gaps in current knowledge and help in future projects in diagnostics and disease biology.

#### □ Features of Manav

- In this public-private venture, Department of Bio-Technology (DBT) and Persistent Systems will invest Rs 13 crore and Rs 7 crore respectively.
- The project will be executed by **Indian Institute of Science Education and Research (IISER)** and **National Center for Cell Sciences (NCCS)** based in Pune.
- While the institutes will train students, the technology platform and data management will be provided by the private partner.
- Students and faculty from DBT Star colleges and Biotechnology Information network system (BTIS) network will also be involved.

## Biotechnology & IPR Issue

The WIPO is one of the specialized agencies of the United Nations and has provided guidelines for the intellectual property and intellectual property rights especially for the following:

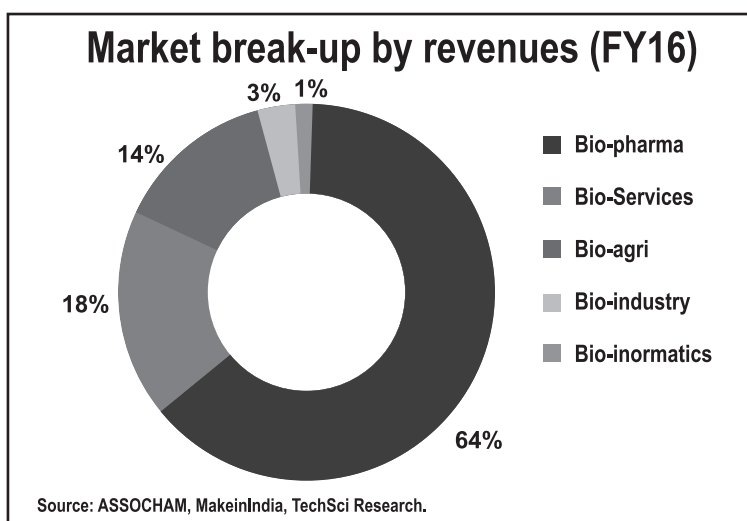
- Scientific works, artistic and literary works, innovation in all fields of human endeavor, scientific discoveries, trademarks, industrial design, protection against unfair competition, and all other rights resulting from intellectual activity in the area of industrial, scientific, literary or artistic fields.
- The intellectual property is protected by and governed by appropriate national legislation. The national legislation specifically describes the inventions which are the subject matter of protection and those which are excluded from a protection, e.g. methods of treatment of humans or therapy and invention whose use would be contrary to law or invention which are injurious to public health are excluded from patentability.
- These efforts at International level will ensure that the ethical issues related to application of biotechnology in agriculture and health care are addressed properly at different forums. A combined International approach will help us to assess the risk of using and releasing genetically engineered plants and animals in the environment, the use of recombinant microorganisms in commercial ventures and the use of transgenic species etc.
- Patents
  - A patent gives its owner a monopoly right to make and sell or use the patented product or process of an invention for a limited period of time. **A Patentable matter should meet certain criteria such as**
    - ▶ Utility,
    - ▶ Novelty, and
    - ▶ Statutory subject matter.
  - The laws pertaining to patency may vary from country to country. A patented pharmaceutical product in USA, has to undergo a regulatory purview by Food and Drug Administration (FDA) before its clinical use is allowed. According to the U.S. Federal Insecticide, Fungicide, and Rodenticide Act, before the release of genetically engineered microbial pesticides, it is customary to obtain a permit from the Environmental Protection Agency (EPA). The Indian Patents Act of 1970 allows “process patents but no “product patents” for foods, chemicals, drugs and pharmaceuticals. Patents are granted or complaints of infringement of these patents decided by courts in accordance with the patent law of the concerned country.

- **A patent consists of three parts:**
  - ▶ **The Grant:** The grant is filled at the patent office which is not published. It is the actual signed document which is the agreement that grants patent rights to the inventor.
  - ▶ **Specifications:** The specifications part is narrative and describes the subject matter and explains about the process of invention. It is published as a single document which is made public at a minimum charge from the patent office.
  - ▶ **The claim:** The claim section specifically defines the scope of the invention to be protected by the patent to which the others may not practice.
- According to the International conventions, **one cannot patent certain things such as a)** the use of drugs, antibiotics or vaccines for any form of diagnosis, prevention or cure of diseases; **b)** artificial insemination, and **c)** in vitro fertilization and embryo transfer.
- **The advantages of patents and other forms of IPR are:**
  - ▶ These practices help in encouraging and safeguarding intellectual and artistic creations.
  - ▶ They help to disseminate new ideas and technologies quickly and widely.
  - ▶ They promote investment.
  - ▶ They help the inventor to provide the fruits and benefits of his creation and invention to the public.
  - ▶ They provide increased opportunities for the distribution of the above effects across countries in a manner proportionate to national levels of economic and industrial development (OECD, Paris, 1989)
- The introduction of the concept of “patenting” to biotechnology has added a financial angle to the area of research. In the past, research used to be mostly for academic interest and worthwhile scientific contributions. The main support and funding used to be provided by the government/universities/institutes. With the financial support of the private companies, the scenario has changed considerably. When the companies finance any project, they do expect some returns for their investment which adds the concept of financial gains also besides the academic recognition for the researcher. The consequences are, that some people carry out research in secrecy and opt for patenting of their discoveries rather than publishing.
- **Intellectual Property Issue**
  - With the fast pace development in the field of biotechnology, the issues related to legal characterization and the treatment of trade related biotechnological processes and products are of immense importance. These are popularly known as Intellectual Property. Intellectual Property includes Patents, trade secrets, copyrights, and trademarks. Intellectual Property Rights (IPR) is a collective term applied to a number of different types of legal rights granted by each country.
  - The right to protect this property prohibits others from making, copying, using or selling the proprietary subject matter.
  - In biotechnology, the intellectual property covers the **processes and products** which result from the development of genetic engineering techniques through the use of restriction enzymes to create recombinant DNA.
  - Another example of intellectual property is the development of crop varieties which are protected through **“plant breeder’s rights or PBRs**. The PBRs ensures that the plant breeder who developed a particular variety gets the exclusive rights for marketing the variety.
  - Agriculture for the first time was included in the trade related intellectual property rights (**TRIPS**) and TRIPS is a major concern for developing countries. **The following two major steps were taken in consideration of PBRs:**

- ▶ The Food and Agriculture Organisation (FAO) has an International treaty on plant genetic resources for food and agriculture. This treaty consists of a particular class which refers to operation of farmer's rights.
- ▶ The 'Plant Varietal Protection and Farmer's Rights Act 2001' agrees for the right of farmers, breeders, and researchers. The protection is provided by making compulsory licensing of rights, and inhibiting the import of plant varieties consisting of 'genetic use of restriction technology' (GURT) e.g. terminator technology of Monsanto.
- **Following conditions should be fulfilled to grant protection to the new varieties:**
  - ▶ The new variety must always be new i.e. it should not have ever been exploited commercially.
  - ▶ It should be biologically distinct and possess different characters.
  - ▶ The new variety of the plant must have uniform characters.
  - ▶ The distinguishing character of new variety must be stable for generations.
  - ▶ The new variety should have taxonomic validity i.e. systematic position, generic and species names etc.
- Recently Utility patents for both plant and animal genetic materials, have been allowed in some countries. This forbids the use of patented material for further breeding. The farmers are allowed to use and save the seeds for cultivation only after paying a fee to the patent holder.
- Some concerns have been voiced regarding the implications of IPR on the genetic diversity and the conservation of genetic resources. IPRs will directly or indirectly affect the food security and distribution around the globe, biological diversity and ecological balance, employment avenues in the poor and developing countries, and the use of new and effective agricultural practices.

## Ethical Dimension in Biotechnology

- The biotechnology sector of India is highly innovative and is on a strong growth trajectory. The sector, with its immense growth potential, will continue to play a significant role as an innovative manufacturing hub. The sector is one of the most significant sectors in enhancing India's global profile as well as contributing to the growth of the economy.
- India is among the top 12 biotech destinations in the world and ranks third in the Asia-Pacific region. India has the second-highest number of US Food and Drug Administration (USFDA)-approved plants, after the USA and is the largest producer of recombinant Hepatitis B vaccine. Out of the top 10 biotech companies in India (by revenue), seven have expertise in bio-pharmaceuticals and three specialize in agri-biotech.
- India has no dearth of talent in biotechnology, as a number of institutions, both government and autonomous, provide the necessary opportunities for the students seeking to obtain a degree in this



sector. The Government of India has provided adequate scope to this sector by providing facilities for Research and Development (R&D) in the field of biotechnology.

### □ Ethical Dimensions in Biotechnology

- Biotech healthcare is going through the challenge of defining its ethical boundaries. Research, costs, and privacy issues spawn concerns that third-party payers, employers, providers, and policy makers will face for years to come.
- In an age when medical technology improves with increasing rapidity, the availability of new treatments increases almost as quickly. However, with advances, come dilemmas - scientific, financial, and especially moral; these issues are likely to multiply as groups with vastly different viewpoints and resources battle over the direction of health policy in India.
- In the 21st century, Biotechnology Healthcare has identified five topics that dominate ethical discussions of biotech medicine. **These issues will continue to generate controversy in the foreseeable future:**
  - ▶ **Protecting Human Subjects in Clinical Trials:** This issue has generated considerable debate since 1999 on the issues of disclosure of crucial information on consent documents, criteria for accepting volunteers, and enrolling volunteers who were ineligible for the clinical trials. It is critical to ensure that research is conducted responsibly throughout the entire study cycle, from the way participants are selected to the way data are entered, analyzed, and reported. Attention to each aspect of research conduct is necessary to the success of the scientific enterprise and to the protection of study participants and others from unnecessary harm. The issue, of course, is complicated, because patients - especially suffering patients - are willing to try something new, even when physicians acknowledge that a complete side-effect profile isn't known.
  - ▶ **Affordability:** The rising cost of healthcare - and the cost of medications in particular - is a debatable issue. Affordability is an issue because when we say we want the best treatment, it's an ethical dilemma as at what point will people say 'Enough is enough?'. What happens when some patients can't afford the out-of-pocket share of a given treatment? What if an insurer declines to add a biologic to its formulary because of its acquisition cost? What happens when a patient on an expensive chronic therapy maxes out his lifetime insurance benefit? Such instances may not be the norm, but their possibility disturbs some experts who see a pivotal clash between patients and profits
  - ▶ **Privacy:** Protecting patient privacy is a growing concern; it's a boon that technology is making it possible to decode the human genome. But as scientists become adept at deciphering a person's genetic composition, it is increasingly likely that compromising information about a person's future health is going to become available. This creates enormous problems. For instance, it may become possible to know that a 5-year-old is going to develop serious heart disease later in life, but does a prospective employer have the right to know this piece of information. Also, how will this knowledge affect the individual's ability to obtain a job, insurance? Should such information be available to insurers and others is matter of concern.
  - ▶ **Stem Cell Research** - Whether privately or publicly funded, researchers should be mindful of the ethical issues that may be raised when research involves embryos, fetal tissue, cloning, or other controversial questions. Nevertheless, medical research often requires a balancing of perceived risks against potential benefits. The tremendous potential of stem cell research for the treatment of diseases means that the balance of benefits and risks is now clearly in favor of going forward with the research, even if it involves ethically sensitive areas. Stem cell research promises great good and is a worthy scientific priority as long as we pursue it ethically. Obtaining stem cells from

people without seriously harming people in the process can be ethical. However, obtaining stem cells from human embryos cannot be ethical because it necessarily involves destroying those embryos.

- **Defending Against Bioterrorism** - Bioterrorism means the use of infectious agents or other harmful biological or biochemical substances as weapons of terrorism. Security is hugely important, and public fears over terrorism are unlikely to diminish. Economic losses caused by a successful bioterror attack in a densely populated area could be massive. Also at a time when deficits are growing, generous funding for bioterrorism research suggests that funding for other public health priorities - such as diseases that are becoming more prevalent - may suffer. There is an inextricably linked, synergistic relationship between research and development efforts needed to protect against both naturally occurring infections and bioterrorism agents.

## Clinical Applications of whole Genome Sequencing

### About DNA

- ❑ DeoxyriboNucleic Acid (DNA) is a molecule that encodes the genetic instructions used in the development and functioning of all known living organisms.
- ❑ DNA is made of chemical building blocks called nucleotides. These building blocks are made of three parts: a phosphate group, a sugar group and one of four types of nitrogen bases. To form a strand of DNA, nucleotides are linked into chains, with the phosphate and sugar groups alternating.
- ❑ The four types of nitrogen bases found in nucleotides are adenine (A), thymine (T), guanine (G) and cytosine (C).
- ❑ Genomic information present in the DNA has been instrumental in identifying inherited disorders, characterizing the mutations that drive cancer progression, and tracking disease outbreaks.
- ❑ The process of getting this genomic information is known as Whole genome sequencing.

### About Whole genome sequencing

- ❑ Whole genome sequencing is a laboratory process that determines the complete DNA sequence of an organism's genome at a single time. This entails sequencing all of an organism's chromosomal DNA as well as DNA contained in the mitochondria and, for plants, in the chloroplast.
- ❑ Whole genome sequencing should not be confused with DNA profiling, which only determines the likelihood that genetic material came from a particular individual or group, and does not contain additional information on genetic relationships, origin or susceptibility to specific diseases. It also unlike full genome sequencing, SNP genotyping covers less than 0.1% of the genome. Almost all truly complete genomes are of microbes; the term "full genome" is thus sometimes used loosely to mean "greater than 95%".
- ❑ Recently a team of scientists in Bengaluru has decoded the genome of *Candida auris*, a fungus that has caused disease outbreaks in India, Pakistan, South Korea, Kuwait, South Africa, Colombia, Venezuela, USA and United Kingdom.

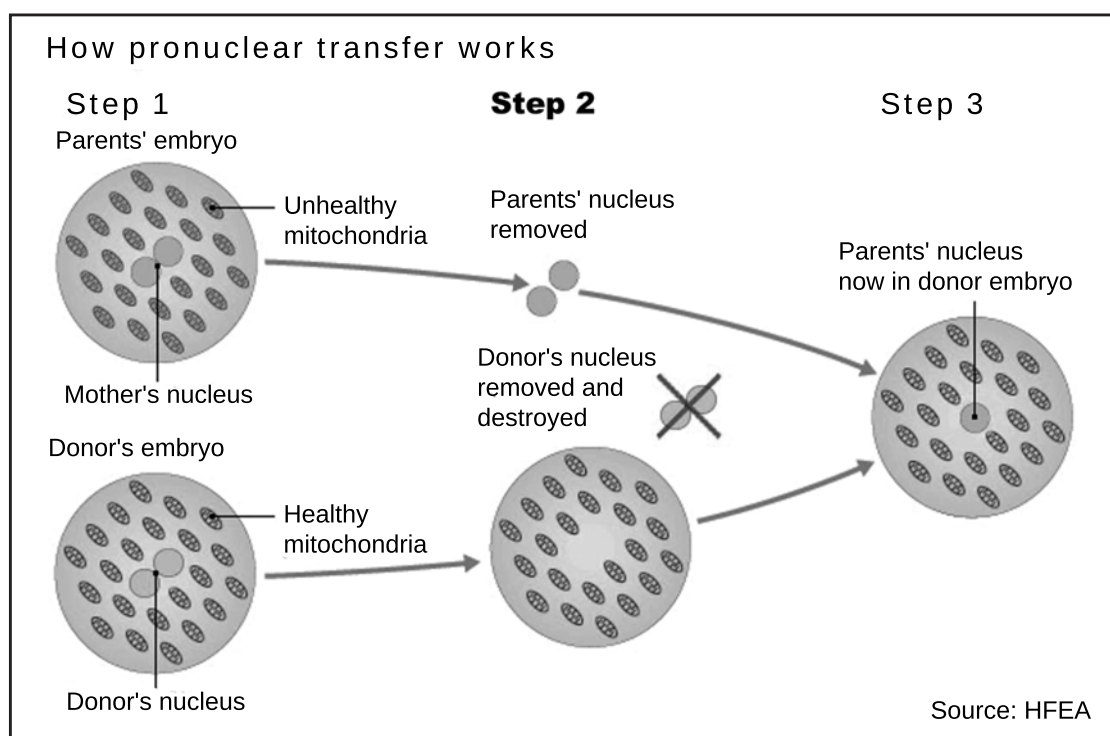
## Benefits of conducting whole-genome sequencing

- The advantage of genome sequencing techniques is the greater potential to identify the genetic component of health problems, and probably, in the near future, at a lower cost than that of the current techniques. The sheer mass of data generated can reveal disease-causing alleles that could not be detected otherwise. Moreover, affordable technology that generates more genomic information may aid the translation of applications to further improve health care.
- It's estimated that one in four people with serious but undiagnosed medical conditions who undergo whole genome sequencing receive a diagnosis as a result of the sequencing. In addition, sequencing can identify which cancer patients are more likely to respond to a particular treatment. It is also being used to diagnose sepsis, allowing affected patients to get started with the right treatment more quickly
- However, there are barriers to broader adoption of this technology, including the cost of the service, limited insurance coverage and physicians' lack of knowledge and training of genomic data.

## Three-Parent Babies Permitted in U.K.

- In a move aimed at preventing the passage of incurable genetic diseases from mothers to offsprings, authorities in the UK have permitted doctors to create the country's first three-parent babies.
- The babies are still conceived from two parents, but genetic material from one woman is inserted into another's egg to prevent the child from being born with an inherited disease.
- The procedure will use mitochondrial donation therapy for the women, who know that any children they have could inherit a neurodegenerative disorder, which causes problems with movement or mental functioning.

### About Three-Parent Babies



- ❑ A number of children each year are born with faults in their mitochondrial DNA which can cause diseases. Due to it, the parts of the body that need most energy are worst affected: The brain, muscles, heart, and liver. Faulty mitochondria have also been linked to more common medical problems, including Parkinson's, deafness, failing eyesight, epilepsy, and diabetes. Thus 3-parent babies' mechanism has been evolved to decrease the number of children born with diseases.
- ❑ 3-parent babies are human offspring with 3 genetic parents. The procedure replaces a small amount of faulty DNA in a mother's egg with healthy DNA from a second woman, so that the baby would inherit genes from 2 mothers and 1 father.
- ❑ The procedure is intended to prevent mitochondrial diseases including diabetes, mellitus and deafness and some heart and liver conditions.
- ❑ The world's first three-parent baby has been born in Mexico, second in Ukraine.

#### ❑ **Pros of Three-Parent Babies**

- Reduces the risk of genetic diseases.
- Reduces the risk of inherited medical conditions.
- Better chance the child will succeed in life.
- A better understanding of genetics.
- Increased life span.
- It can give, the child genes that the parents do not carry.
- Prevent the next generation of the family from getting characteristics/diseases.

#### ❑ **Cons of Three-Parent Babies**

- Termination of embryos.
- Could create a gap in society
- Possibility of damage to the gene pool.
- Baby has no choice in the matter.
- Genes often have more than one use.
- Geneticists are not perfect.
- Loss of Individuality.
- Other children in the family could be affected by a parent's decision.
- Only the rich can afford it

## **Mass Embryo Transfer**

- ❑ Department of Animal husbandry, Dairying, and Fisheries in co-operation with 12 States have undertaken a Mass Embryo Transfer programme in Indigenous Breeds under the scheme, National Mission on Bovine Productivity.
- ❑ The programme is implemented with the objective of conservation and development of indigenous breeds under Rashtriya Gokul Mission.
- ❑ Through the use of ETT, (i) a farmer can get a 5-6 fold increase in a number of off-springs, (ii) the calves so born will be of high genetic merit and (iii) the off-springs born will be free from diseases.

- ❑ Under this programme, embryos of higher genetic merit **indigenous bovines such as Sahiwal, Gir, Red Sindhi, Ongole, Deoni, and Vechur** were transferred into surrogate cows. These cows were identified by UID and are under observation.
- ❑ **Embryo transfer Technology:** Embryo transfer is a specialized technique of breeding. A sexually mature female referred to as the donor is injected with exogenous hormones to produce. Ova (the female reproductive cell or gamete of animals, which is capable of developing, into a new individual) are fertilized inside her either by natural or artificial service. These are then removed prior to their implantation and transfer to the reproductive tracts of synchronized surrogate mothers of the same species referred to as the recipients. The fertilized ova, thus are developed in the recipient body and resulting offspring derive their genes from the donor and from the male to which donor was bred.
- ❑ **Steps for improving cattle population:** Steps undertaken by the Government for the development of cattle population in the country is as under:
  - ❑ RashtriyaGokul Mission has been launched December 2014 for the development and conservation of indigenous bovine breeds thereby enhancing milk production and productivity. The framework of the scheme is to enhance milk production & productivity through induction of high genetic merit bulls for semen production; field performance recording; strengthening of bulls mother farms; setting up of Gokul Grams, etc.
  - ❑ National Programme for Bovine Breeding is being implemented for enhancing the productivity of milch animals through the extension of Artificial Insemination (AI) coverage. This is done through the establishment of Multi-Purpose AI Technicians in Rural India (MAITRIs); strengthening of existing AI centers; monitoring of AI, etc.
  - ❑ National Mission on Bovine Productivity has been launched in November 2016 with the aim of enhancing milk production and productivity and thereby making dairying more remunerative to the farmers. The scheme is being implemented with the following components a) PashuSanjivni- this component includes identification of animals in milk using UID, issuing health cards to all animals in milk and uploading data on INAPH database; b) Advance reproductive Technique- under the component sex-sorted semen production facility is being created at 10 A graded semen stations and 50 Embryo Transfer Technology Labs with IVF facilities are being created in the country; c) Creation of E PashuHaat Portal- The e-pashuhaat portal has been launched in November 2016 for linking farmers and breeders of indigenous breeds and d) Establishment of National Bovine Genomic Centre for Indigenous Breeds(NBGC-IB): The NBGC-IB is being established for enhancing milk production and productivity through genomic selection among indigenous breeds.
  - ❑ Two National Kamdhenu Breeding Centres are being established one in the State of Andhra Pradesh for the southern region and other in Madhya Pradesh for the northern region of the country with the aim of development and conservation of indigenous breeds in a scientific manner and thereby enhancing milk production and productivity.
  - ❑ National Dairy Plan-I a World Bank assisted project being implemented in 18 major dairy States with aim of enhancing milk production and productivity in order to meet the demand of milk in the country through the strengthening of semen stations; bull production programme (progeny testing and pedigree selection), ration balancing programme, etc.
  - ❑ Government has also established three subordinate organizations namely (i) Central Cattle Breeding Farms (CCBFs) (ii) Central Herd registration Scheme and (iii) Central Frozen Semen Production & Training Institute. These organizations are also undertaking genetic upgradation of milch animals through the supply of disease-free high genetic merit bulls for semen production and natural service for use in the breeding programme being implemented by the States.

## Issues Related to GM Food

- With the rapid advances in biotechnology, a number of Genetically Modified (GM) crops or transgenic crops carrying novel traits have been developed and released for commercial agriculture production.
- Recently the Genetic Engineering Appraisal Committee has cleared GM mustard for environmental release and uses in farmer fields for four years subject to certain field conditions.

### ■ What are Genetically Modified Mustard (GM Mustard)?

- A Genetically Modified Organism (GMO) is an organism in which one or more genes (called transgenes) have been introduced into its genetic material from another organism using recombinant DNA technology.
- Foods produced from or using GM organisms are often referred to as GM foods.
- Dhara Mustard Hybrid-11 or DMH-11 is a genetically modified variety of mustard.
- It has been developed by the Delhi University's Centre for Genetic Manipulation of Crop Plants under a government-funded project.

### ■ The recent approval by GEAC

- On May 11, 2017, the Genetic Engineering Appraisal Committee (GEAC) has cleared GM mustard for environmental release and use in farmer fields for four years subject to certain field conditions
- According to GEAC Chairperson, "It was a unanimous decision with no dissent and all safety concerns were discussed with experts".
- However, the approval is contingent on a final nod from Environment Minister, who can say no.
- In the past also, the environment ministry has blocked the crops approved by GEAC. In 2010, GEAC

## Arguments for GM Crops

The arguments that have been put forward for the use of GMOs in agriculture include:

### ■ Potential benefits for agricultural productivity:

- **Better resistance to stress:** If crops can be made more resistant to pest outbreaks and severe weather (such as frost, extreme heat or drought), then it would reduce the danger of crop failure.
- **More nutritious staple foods:** By inserting genes into crops such as rice and wheat, we can increase their nutritious value which can solve the problem of malnutrition.
- **More productive farm animals:** By inserting Genes into cattle we can opt for more, production of milk, for example, raise their milk yield, capacity.
- **Longer shelf lives:** The genetic modification of fruits and vegetables can make them less likely to spoil in storage or on the way to market. This could expand trade opportunities as well as reduce massive wastage incurred in transport and supply.
- **More food from less land:** Improved productivity from GMOs might mean that farmers in the next century won't have to bring so much marginal land into cultivation.

### ■ Potential benefits for the environment:

- **GMOs might reduce the environmental impact of food production and industrial processes:** Genetically engineered resistance to pests and diseases could greatly reduce the use of pesticides

and insecticides needed for crop protection. This could not only reduce environmental impact - but they could also improve the health of farm and industrial workers.

- **Rehabilitation of damaged or less-fertile land:** Large areas of cropland in the developing world have become saline by unsustainable irrigation practices. Genetic modification could produce salt-tolerant varieties.
- **Bioremediation:** Rehabilitation of damaged land may also become possible through organisms bred to restore nutrients and soil structure.
- **Biofuels:** Plant material fuel, or biomass, has enormous energy potential. For example, the waste from sugar cane or sorghum can provide energy, especially in rural areas. It may be possible to breed plants specifically for this purpose.

#### □ **Potential benefits for human health:**

- **Pharming (Vaccines and Medicines):** Plants are being engineered to produce vaccines, proteins, and other pharmaceutical products not only for humans but also for farm animals. This process is called “Pharming”.
- **Hunger:** According to data from the World Food Programme, around 795 million people do not have enough food to live a healthy life. So many people are still suffering from starvation and malnutrition. And this can become even worse as the populations continue to grow, conflicts devastate regions and the effects of global warming take effect.

## Arguments against GM crops

The main arguments that have been put forward against the use of GMOs in agriculture include:

#### □ **Potential negative effects on the environment:**

- **Genes can end up in unexpected places:**
  - ▶ Through “gene escape” they can pass on to other members of the same species and perhaps other species.
- **Genes can mutate with harmful effect:**
  - ▶ Artificial insertion of genes could destabilize an organism by encouraging mutations.
  - ▶ Interaction with wild and native populations:
  - ▶ GMOs could compete or breed with wild species.
  - ▶ GM crops could pose a threat to crop biodiversity, especially if grown in areas that are centers of origin of that crop.
  - ▶ In addition, GM crops could compete with and substitute traditional farmers’ varieties and wild relatives that have been bred, or evolved, to cope with local stresses. If genetically modified crop varieties substitute them, they could be lost.
- **Impact on birds, insects and soil biota:**
  - ▶ Potential risks to non-target species, such as birds, pollinators and micro-organisms, is another important issue.
  - ▶ Besides, it is feared that widespread use of GM crops could lead to the development of resistance in insect populations exposed to the GM crops.

### ❑ Potential negative effects on human health:

- **Allergenicity (Transfer of allergenic genes):** These could be accidentally transferred to other species, causing dangerous reactions in people with allergies.
- **Outcrossing:** The migration of genes from GM plants into conventional crops or related species in the wild (referred to as “outcrossing”), as well as the mixing of crops derived from conventional seeds with GM crops, may have an indirect effect on food safety and food security. Cases have been reported where GM crops approved for animal feed or industrial use were detected at low levels in the products intended for human consumption.
- Studies in the U.S. have shown a strong correlation between the growth of GM crops, and diseases such as acute kidney injury, diabetes, autism, Alzheimer’s and cancers in the past 20 years in the U.S.

### ❑ Potential socio-economic effects:

- **Loss of farmers’ access to plant material:**
  - ▶ Biotechnology research is carried out predominantly by the private sector and there are concerns about market dominance in the agricultural sector by a few powerful companies.
  - ▶ This could have a negative impact on small-scale farmers all over the world.
  - ▶ Farmers fear that they might even have to pay for crop varieties bred from genetic material that originally came from their own fields when they buy seeds from “**companies holding patents**” on specific genetic modification “events”.
- **Intellectual property rights could slow research:** The proprietary nature of biotechnology products and processes may prevent their access for public-sector research.

## Arguments Related to GM Mustard

- ❑ Introduction of GM crop may reduce dependence on edible oil:
- ❑ The increased yields will help lessen India’s dependence on the rising imports of edible oil.
- ❑ India is the world’s second-largest consumer of edible oil after China, and 14.5-15.5 million tonnes of the total 20-21 mt annual consumption is imported.

### ❑ Counter-arguments to GM mustard’s high yield

- **Yields claims are not reliable:** The yield claims on which GM mustard has been cleared are not reliable. They are based on comparisons with 30-year-old cultivars, and not on more recent high-yielding hybrids.
- **Top producers do not use GM mustard:** According to data provided by FAO, the highest yields in mustard are from the five countries which do not grow GM mustard — U.K., France, Poland, Germany, and the Czech Republic — and not from the GM-growing U.S. or Canada.
- **An alternative to GM mustard exists:** If India wants to increase mustard production yield rapidly and safely, then the government can adopt the practice of “System of Mustard Intensification”, for which successful trials have been done in Bihar through a World Bank project. Results showed higher yields and better income. And all of this was done without the spraying of any toxic herbicides.

# Genetic Testing

## Introduction

- Most diseases involve complex interactions of the involved genes, in addition to environmental stimuli. It is possible that a healthy-born individual runs a high risk of acquiring a deadly disease. This is known as genetic predisposition or susceptibility. Even though genetically predisposed individuals may lead a healthy lifestyle, they have an inherent risk of contracting a disease, independent of environmental factor, unless the risk factors are properly addressed. Advancement in genetic research and testing have aided our understanding and helped us in mapping the disease at the molecular level through genetic associations.
- Genetic testing is a type of medical test that identifies changes in chromosomes, genes, or proteins. The results of a genetic test can confirm or rule out a suspected genetic condition or help determine a person's chance of developing or passing on a genetic disorder. More than 1,000 genetic tests are currently in use, and more are being developed.

## ■ Methods can be used for Genetic testing

- Molecular genetic tests (or gene tests) study single genes or short lengths of DNA to identify variations or mutations that lead to a genetic disorder.
- Chromosomal genetic tests analyze whole chromosomes or long lengths of DNA to see if there are large genetic changes, such as an extra copy of a chromosome, that cause a genetic condition.
- Biochemical genetic tests study the amount or activity level of proteins; abnormalities in either can indicate changes to the DNA that result in a genetic disorder.

## ■ The Importance of Genetic Testing

- Genetic testing has potential benefits whether the results are positive or negative for a gene mutation. Test results can provide a sense of relief from uncertainty and help people make informed decisions about managing their health care.
- “Genetic testing has potential benefits whether the results are positive or negative for a gene mutation. Test results can provide a sense of relief from uncertainty and help people make informed decisions about managing their health care. A negative result can eliminate the need for unnecessary checkups and screening tests in some cases. A positive result can direct a person toward available prevention, monitoring, and treatment options.
- Genetic mapping has proved to be effective in disease-risk prediction. It is a stepping stone to advanced diagnostics and targeted treatments.
- **Epigenetic changes are responsible for normal development and health, and many diseases, too.** Epigenetics is the study of the effect of environmental factors on the modification of gene expression and the subsequent changes in organisms. It describes the factors controlling genetic expression, apart from an individual's DNA sequence. Genetic testing helps in its identification.
- Genetic test results can also help people make decisions about having children. Newborn screening can identify genetic disorders early in life so treatment can be started as early as possible.
- Genetic testing can provide important information for diagnosing, treating and preventing illness, with limitations. For example, if you're a healthy person, a positive result from genetic testing doesn't always mean that you will not develop a disease.
- The result of a genetic test uniquely identifies an individual. As a result, there are many criminal cases that can be solved by placing the subject at the crime scene. First, forensic investigators get samples of blood, hair or tissue from the crime scene. Secondly, laboratory technicians can easily verify the identity of the person who is involved in the crime.

## ❑ Risks and Limitations Associated with Genetic Testing

- The physical risks associated with most genetic tests are very small, particularly for those tests that require only a blood sample or buccal smear (a procedure that samples cells from the inside surface of the cheek).
- The procedures used for prenatal testing carry a small but non-negligible risk of losing the pregnancy (miscarriage) because they require a sample of amniotic fluid or tissue from around the fetus.
- Many of the risks associated with genetic testing involve the emotional, social, or financial consequences of the test results. People may feel angry, depressed, anxious, or guilty about their results.
- The potential negative impact of genetic testing has led to increasing recognition of a “right not to know”. In some cases, genetic testing creates tension within a family because the results can reveal information about other family members in addition to the person who is tested.
- Some individuals avoid genetic testing out of fear that it will affect their ability to purchase insurance or find a job.
- Genetic testing can provide only limited information about an inherited condition. The test often can’t determine if a person will show symptoms of a disorder, how severe the symptoms will be, or whether the disorder will progress over time.
- Another major limitation is the lack of treatment strategies for many genetic disorders once they are diagnosed.
- Another limitation of genetic testing for hereditary linked cancer is the variants of unknown clinical significance. Because the human genome has over 22,000 genes, there are 3.5 million variants in the average person’s genome. These variants of unknown clinical significance mean there is a change in the DNA sequence, however, the increase for cancer is unclear because it is unknown if the change affects the gene’s function.
- For some conditions, even though a changed gene or chromosome is found, it is not possible to tell how severely a person will be affected.

## Conclusion

Numerous disease conditions still cannot be properly diagnosed with contemporary methods. With genetic analysis, a person can benefit from timely interventions and gene-targeted treatments. Precision medicine is also emerging to provide better and effective treatment. Further, reducing the trial-and-error in lifestyle choices—nutrition plans and fitness regimes—are among the key benefits of genetic assessments.

# Health Geo-Mapping Project

A geo-map helps to visualize, question, analyze, and interpret data to understand relationships, patterns, and trends.

## ❑ Health Geo-Mapping Project:

- Up to 2019, a database of almost all health establishments approximately 30 lakhs – whether it is private or government sector or be it allopathic or Indian traditional medical system spread across the country will be available online with interactive maps.

- Aiming to improve health outcomes and create health database a two-year long massive exercise to map all public and private healthcare establishment at a district level in a country. This is the first ever healthcare establishment census, using paperless technology.
- It will comprise of the data on health Infrastructure and availability and types of medical facilities such as allopathy, Ayurveda, Unani, Siddha and homeopathy (excluding Yoga, Naturopathy and Sowa-Rigpa) in each establishment in the country.
- The importance of health mapping lies in the production of interactive and published maps that would link the geography of communities with other dimensions such as availability and accessibility of health services or disease prevention and control services particularly in rural areas.
- The NRSC has a well-demonstrated platform (“BhuvanGeoportal”) to support such programs.

### □ Why geo-mapping required in the health sector?

- Public health, being a geographic issue, finds many solutions in geospatial technology and epidemiology.
- Mapping of the description and analysis of communicable and chronic diseases with respect to the demographic, environmental, behavioral, socioeconomic and genetic risk factors is needed for better implementation of programmes and policies related to health.
- Generally, there has been a lack of authentic data on healthcare resources has long been one of the biggest impediments to health planning in India. It is universally acknowledged that doctors and health facilities are far more easily available in urban than in rural areas but there has never been an attempt in the past to quantify the gap in density and to plan accordingly.

### □ About the project

- For the first time, the government will map health facilities, doctors and specialists available in all districts of the country. The health geo-mapping project has already been completed in four districts chosen as a pilot. When the entire country is covered, the project will cost around Rs 100 crore.
- The Bill and Melinda Gates Foundation is partnering the project.
- The four districts that have been covered by the Bill and Melinda Gates Foundation are Hazaribagh (Jharkhand), Vellore (Tamil Nadu), Dungarpur (Rajasthan) and Dimapur (Nagaland). Both government and private health facilities will be mapped, as will be the availability and distribution of chemists.
- In the first phase, the government is looking at covering eight states through the names are yet to be finalized.

### □ Proposed benefits

- The mapping of specialists would also ensure that in future planning for medical education, the skewed distribution of seats — specialties such as oncology have very few doctors passing out every year because of the low number of seats — could be addressed keeping in mind the health profile of the country.

## Policy on Synthetic Biology

### Introduction

- Synthetic Biology is the application of science, technology and engineering to facilitate and accelerate the design, manufacture and/or modification of genetic materials in living organisms. Unlike traditional genetic engineering, which typically involves the transfer of individual genes between cells, SB involves the assembly of new sequences of DNA and even entire genome.

- It goes far beyond the modification of existing cells by inserting or deleting small numbers of genes. Cells can be equipped with new functions and entire biological systems can be designed. Compared to traditional GMOs therefore, synthetic organisms involve much larger-scale interventions.
- SB provides tools to better understand biological systems and can also produce valuable products, such as drugs, fuels, or raw materials for industrial processes or food. By reducing the time, cost and complexity of developing these products, the field represents opportunities for a range of industries and has been linked to future economic growth and job creation. One report (McKinsey Global Institute, 2013) suggests that the field could be worth \$100 billion by 2025.

## Application and Benefits

- Synthetic Biology is still an emerging field but there are growing numbers of applications in the pharmaceutical, chemical, agricultural and energy sectors.
- Commercial applications of SB tend to focus on creating microorganisms (such as *E. coli*, baker's yeast and microalgae) that can synthesize valuable products, such as fuels, food and pharmaceuticals. A notable example is the engineering of yeast cells that synthesize artemisinin, a drug used to treat malaria. Other medical applications of synthetic biology include engineering bacteria to attack cancer cells and designing new antibiotics.
- It is also possible to develop organisms that can process waste and purify water (and therefore restore damaged sites) by removing contaminants such as heavy metals and pesticides. *E. coli* able to degrade methyl mercury, a toxic metal that can accumulate up the food chain
- Biofuels produced by engineered organisms such as algae could be a more sustainable alternative to fossil fuels, as they can be farmed without using arable land. As photosynthetic organisms, algae also remove CO<sub>2</sub> from the air, reducing it into energy rich hydrocarbons
- SB has for some time been hailed as a potent contributor to food security, by developing new crop varieties that are resistant to pests or that have enhanced nutritional value.
- It reduce the impact of human land use on biodiversity, by, for example, reducing the need for pesticide use
- Engineering biosynthetic pathways provides an alternative and cost-effective method of producing drugs of natural origin, such as morphine and aspirin.
- It could be used to engineer solutions to other threats to biodiversity, including infectious diseases like white nose syndrome, a fungal disease that affects hibernating bats.
- It is also possible to use SB for control of disease vectors. Using gene drive systems, it is possible to change the genomes of populations of mosquitoes to make them less dangerous.

## India and the Synthetic Biology

- India is taking its first steps to evolve a policy on Synthetic Biology (**SB**), an emerging science through which new life forms can potentially be made in labs and existing life forms, such as bacteria and other microbes, tweaked to produce specific proteins or chemically useful products. The Environment Ministry will be convening a group of experts on biodiversity and biotechnology, to assess synthetic biology work pursued in Indian labs, potential benefits and risks, and the implications of the trans-boundary movement of such life forms.
- Synthetic biology in microbial systems holds promise for production of drugs, vaccines, fuel components and other chemicals. There are assorted labs in India that work on synthetic biology. Last December, government officials participated in the United Nations Biodiversity Conference of the Convention on Biological Diversity (**CBD**) at Cancun, Mexico, where about 8,000 delegates from 180 countries discussed matters related to biodiversity.

- India, so far, has no policy on synthetic biology, and according to a presentation made at the venue, it has promised to “put in place a Synthetic Biology Team for articulating India’s view” at a forthcoming meeting.

## Challenges

Although synthetic biology may have benefits for society, there are many scientific uncertainties surrounding the development of synthetic life, cells and genomes, especially in terms of their impact on the environment.

- Transfer of genetic materials-** The escape or release of novel organisms into the environment could radically and detrimentally change ecosystems. The transfer of genetic material to wild populations is a major risk. Genes could be transferred through horizontal or vertical gene transfer, which could lead to toxic effects on other organisms, spread of harmful characteristics and loss of genetic diversity.
- Disrupt conservation projects and displace small-scale farmers-** while replacing natural products with synthetic ones could reduce pressure on natural habitats, it could also disrupt conservation projects and displace small-scale farmers. Saffron for example is usually picked from crocus flowers but, now, it can be synthetically produced by yeast. Each hectare of natural saffron growing (in Iran) provides jobs for around 270 people a day - replacing that with synthetic versions therefore threatens livelihoods.
- Raises serious and complex issues of global justice** -A growing range of products (such as palm oil, rubber and Artemisinin) are beginning to be provided by synthetic biology, which may deprive farmers of their only source of income and raises serious and complex issues of global justice.
- Large-scale increase in the use of biomass** -Another major concern relates to the large-scale increase in the use of biomass. A large number of synthetic biology applications involve organisms that convert biomass into valuable products. Although use of feedstock could benefit the environment by representing a shift away from non-renewable resources, increased demand for biomass could also lead to increased extraction of biomass from agricultural land.
- Soil Fertility and Structure-** Fuel production may require particularly large amounts of biomass, which could reduce soil fertility and structure and contribute to biodiversity loss due to the conversion of natural land
- Food and security challenges-** These land-use changes may also have adverse impacts on food and livelihood security. The increased production of biomass could reduce access to local natural resources and cause small, self-sufficient farms to be replaced by large-scale commercial farming.
- Temporary Solution** - Finally, there are deeper concerns that synthetic biology may act as a ‘sticking plaster’ rather than providing a profound solution to biodiversity loss. In other words, synthetic biology may distract policymakers, scientists and industry from the deeper underlying causes of biodiversity loss.

# Law Commission Report on Human DNA Profiling

## Introduction

- DNA fingerprinting has been very useful for law enforcement, as it has been used to exonerate the innocent. Unlike blood found at a crime scene, DNA material remains usable for an endless period of time. DNA technology can be used even on decomposed human remains to identify the victims.

- ❑ Such tests relating to a party would definitely constitute corroborative evidence. Appreciating the use and regulation of DNA based technology in judicial proceedings, particularly, identification of persons accused of offences under the Indian Penal Code 1860 (IPC) and other laws, identification of missing persons and disaster victims apart from its use in medical sciences; a need has long been felt to have special legislation to regulate human DNA profiling.
- ❑ DNA analysis offers substantial information which if misused or used improperly may cause serious harm to individuals and society as a whole.

### ❑ **Constitutional and Legal Aspects of DNA Profiling**

- The Constitution under Article 51A(h) and (j) casts a duty on every citizen of India “to develop the scientific temper, humanism and the spirit of inquiry and reform and to strive towards excellence in all spheres of individual and collective activity”. Parliament is competent to undertake legislation which encourages various technological and scientific methods to detect crimes, speed up the investigation and determine standards in institutions for higher education and development in technical institutions (Entry 65 & 66 of the Union List). The other relevant provisions of the Constitution are, (i) Article 20(3) which guarantees a right against the self-incrimination; and (ii) Article 21 which guarantees the protection of life and liberty of every person.
- The right to privacy is implicit in the right to life and liberty guaranteed to the citizens of this country by Article 21. It is a “right to be let alone”. A citizen has a right to safeguard the privacy of his own, his family, marriage, procreation, motherhood, child-bearing and education among other matters.

## **Critical analysis of the Human DNA Profiling Bill 2016**

- ❑ The Bill seeks to set up two new institutions — a DNA Profiling Board and a DNA Data Bank. The Board, with 11 members, is supposed to be the regulatory authority that will grant accreditation to DNA laboratories and lay down guidelines, standards, and procedures for their functioning.
- ❑ It will advise central and state governments on “all issues relating to DNA laboratories”. It will also be the authority to make recommendations on ethical and human rights, including privacy, issues related to DNA testing.
- ❑ A national databank of DNA profiles is proposed to be set up, along with regional databanks in every state, or one for two or more states, as required.
- ❑ The new draft does not specify the location of the national databank. All regional DNA databanks will be mandated to share their information with the national databank.
- ❑ Certain DNA Profiling Board-accredited labs would be authorized to carry out DNA testing and analysis. These are the only places to which DNA samples, picked up from a crime scene, for example, by police, can be referred for analysis. Data from the analyses will need to be shared with the nearest regional DNA databank which will store it and share it with the national databank.
- ❑ The databanks will maintain five sets of databases — for DNA samples picked up from crime scenes, for suspects or undertrials, and for offenders, missing persons, and unidentified dead bodies.
- ❑ The Bill was criticized for not addressing the concerns of privacy by a large number of organizations and public-spirited persons on similar grounds and made various representations to the statutory authorities. The Bill did not make special provisions in respect of funding of the Board and how the required funds will be made available to the investigating agencies to collect proper reports of samples. Moreover, the Bill did not specifically provide as to on what stage the samples could be collected.

## ❑ Recommendations of the Law Commission

Following are some of the salient features of the recommendations:

- Constitution of a DNA Profiling Board, a statutory body to undertake functions such as laying down procedures and standards to establish DNA laboratories and granting accreditation to such laboratories; and advising the concerned Ministries / Departments of the Central and State Governments on issues relating to DNA laboratories. The Board shall also be responsible to supervise, monitor, inspect and assess the laboratories. The Board will frame guidelines for training of the Police and other investigating agencies dealing with DNA related matters. Advising on all ethical and human rights issues relating to DNA testing in consonance with international guidelines will be another function of the Board. It will recommend research and development activities in DNA testing and related issues, etc.
- DNA profiling would be undertaken exclusively for the identification of a person and would not be used to extract any other information.
- There shall be a National DNA Data Bank, and Regional DNA Data Banks for the States, to be established by the Central Government. The Data Banks will be responsible for storing DNA profiles received from the accredited laboratories and maintaining certain indices for various categories of data, like crime scene index, suspects' index, offenders' index, missing persons' index and unknown deceased persons' index.
- With a view to assisting the kith and kin of missing persons, provisions have been made for proper identification of missing persons on the basis of their bodily samples/substances.
- Appropriate regulations may be notified by the Board for entry, retention, and expunction of DNA profiles.
- Maintenance of strict confidentiality with regard to the keeping of records of DNA profiles and their use.
- Sharing of DNA profiles with and by foreign Government or Government organization or Government institutions or any of its agencies, for the purpose of this Act.
- The violators of the provisions would be liable for punishment of imprisonment, which may extend up to three years and also fine which may extend up to Rs.2 lakhs.
- The undertrial may request the trial court for another DNA testing if s/he satisfies the court that the previous DNA sample(s)/bodily substance(s) stood contaminated and hence could not be relied upon.
- The DNA experts may be specified as Government Scientific Experts and be notified as such under clause (g) of sub-section (4) of section 293 of Cr. P.C.

## Conclusion

- ❑ DNA Profiling, an accurate and well established scientific technique is used for disaster victim identification, investigation of crimes, identification of missing persons and human remains, and for medical research purposes.
- ❑ DNA Profiling and use thereof involves various legal and ethical issues and concerns are raised and apprehensions exist in the minds of the common man about its misuse which unless protected may result in disclosure of personal information, such as health-related data capable of being misused by persons having prejudicial interests, adversely affecting the privacy of the person.

# The DNA Technology (Use and Application) Regulation Bill, 2018

## □ The DNA Technology (Use and Application) Regulation Bill, 2019

- The DNA Technology (Use and Application) Regulation Bill, 2019 was introduced in Lok Sabha by the Minister for Science and Technology, in July, 2019. The Bill provides for the regulation of use of DNA technology for establishing the identity of certain persons. Note that the same Bill had been previously introduced in Lok Sabha in August 2018, but lapsed.
- **Use of DNA Data:** Under the Bill, DNA testing is allowed only in respect of matters listed in the Schedule to the Bill. These include offences under the Indian Penal Code, 1860, and for civil matters such as paternity suits. Further, the Schedule includes DNA testing for matters related to establishment of individual identity.
- **Collection of DNA:** While preparing a DNA profile, bodily substances of persons may be collected by the investigating authorities. Authorities are required to obtain consent for collection in certain situations. For arrested persons, authorities are required to obtain written consent if the offence carries a punishment of up to seven years. If the offence carries more than seven years of imprisonment or death, consent is not required. Further, if the person is a victim, or relative of a missing person, or a minor or disabled person, the authorities are required to obtain the written consent of such victim, or relative, or parent or guardian of the minor or disabled person. If consent is not given in these cases, the authorities can approach a Magistrate who may order the taking of bodily substances of such persons.
- **DNA Data Bank:** The Bill provides for the establishment of a National DNA Data Bank and Regional DNA Data Banks, for every state, or two or more states. DNA laboratories are required to share DNA data prepared by them with the National and Regional DNA Data Banks. Every Data Bank will be required to maintain indices for the following categories of data: (i) a crime scene index, (ii) a suspects' or under trials' index, (iii) an offenders' index, (iv) a missing persons' index, and (v) an unknown deceased persons' index.
- **Removal of DNA profiles:** The Bill states that the criteria for entry, retention, or removal of the DNA profile will be specified by regulations. However, the Bill provides for removal of the DNA profiles of the following persons: (i) of a suspect if a police report is filed or court order given, (ii) of an under trial if a court order is given, and (iii) on written request, for persons who are not a suspect, offender or under trial, from the crime scene or missing persons' index.
- **DNA Regulatory Board:** The Bill provides for the establishment of a DNA Regulatory Board, which will supervise the DNA Data Banks and DNA laboratories. The Secretary, Department of Biotechnology, will be the ex officio Chairperson of the Board. The Board will comprise additional members including: (i) experts in the field of biological sciences, and (ii) Director General of the National Investigation Agency and the Director of the Central Bureau of Investigation.
- **Functions of the Board:** The functions of the Board include: (i) advising governments on all issues related to establishing DNA laboratories or Data Banks, and (ii) granting accreditation to DNA laboratories. Further, the Board is required to ensure that all information relating to DNA profiles with the Data Banks, laboratories, and other persons are kept confidential.
- **DNA laboratories:** Any laboratory undertaking DNA testing is required to obtain accreditation from the Board. The Board may revoke the accreditation for reasons including, failure to: (i) undertake DNA testing, or (ii) comply with the conditions attached to the accreditation. If the accreditation is revoked, an appeal will lie before the central government or any other authority notified by the central government. Further, every DNA laboratory is required to follow standards for quality assurance in collection, storing, and analysis of DNA samples. After depositing the DNA profile for

criminal cases, the laboratory is required to return the biological sample to the investigating officer. In all other cases, the sample must be destroyed.

- **Offences:** The Bill specifies penalties for various offences, including: (i) for disclosure of DNA information, or (ii) using DNA sample without authorization. For instance, disclosure of DNA information will be punishable with imprisonment of up to three years and fine of up to one lakh rupees.

## Law against Genetic Discrimination

### □ What is Genetic Discrimination?

- Genetic discrimination occurs when people are treated differently, for example by their employer or insurance company, because they have or are perceived to have a gene mutation that causes or increases the risk of an inherited disorder. A country which is already suffering from caste, religion, sex, color discrimination, this is another discrimination bomb waiting to explode.
- Every person has dozens of DNA differences that could increase or decrease his or her chance of getting a disease such as diabetes, heart disease, cancer or Alzheimer's disease. More and more tests are being developed to find DNA differences that affect our health. These tests will become a routine part of health care in the future. Health care providers will use information about each person's DNA to develop more individualized ways of detecting, treating and preventing disease. But unless this DNA information is protected, it could be used to discriminate against people especially in the insurance sector to decrease the benefits.

### □ The methodology of Accessing Genetic

- Genetic testing is a type of medical test that identifies changes in chromosomes, genes, or proteins. The results of a genetic test can confirm or rule out a suspected genetic condition or help determine a person's chance of developing or passing on a genetic disorder.
- Genetic tests are performed on a sample of blood, hair, skin, amniotic fluid (the fluid that surrounds a fetus during pregnancy), or other tissue.

### □ Advantages of Genetic Testing

- For a lot of disorders, **genetic testing is the only way to make an accurate diagnosis** and help **avoid additional unnecessary clinical investigations**.
- Genetic testing can guide the clinician in choosing the **most suitable therapy and support for the patient**.
- A **definite diagnosis can be of great relief to patients and families**, especially if they have been searching for the answer for a long time.
- In some genetic diseases, **good surveillance and early intervention can save the patient's life** (e.g. early diagnosis of hereditary cancer).
- The results of genetic testing may be **useful for future family planning**.
- However, the expansion of genetic tests means that discrimination will likely increase.
- During the past ten years, there has been an explosion in the number of available tests for genetic conditions. Ten years ago we had only a handful of genetic tests; today we have hundreds.

- As these tests become simpler to administer and their use expands, the employers and insurers will continue to use genetic information in a discriminatory manner and that a growing number of people will be stigmatized on the basis of their genetic makeup.

## □ Employment Discrimination

- The tragedies of race and sex discrimination illustrate the dangers of basing employment decisions on inborn characteristics. Like these, discrimination on the basis of genetics ignores the present abilities and health status of workers and substitutes questionable stereotypes about future performance.
- Basing employment decisions on genetic status opens the door to unfounded generalizations about employee performance and increases acceptance of the notion that employers need to exercise such discrimination in order to lower labor costs. Indeed, without countervailing equitable forces, employers face economic pressures to identify workers who are likely to remain healthy. Less absenteeism, reduced life, and health insurance costs and longer returns on investments in employee training all reduce the costs of labor. To the extent that employers believe that genetic information can help identify workers who have a “healthy constitution,” they have strong economic incentives to screen applicants and workers.
- **Such policies victimize all workers.** Discrimination against individuals with particular genetic characteristics harms all workers by diverting attention from the need to improve and, if possible, eliminate workplace and environmental conditions that contribute to ill health for everyone. Moreover, such genetic discrimination masks the fundamental need for adequate leave policies and insurance coverage as well as for reasonable workplace accommodation for all workers who experience temporary or permanent disabilities, for whatever reasons.

## □ Insurance Discrimination

- In the case of health insurance, the goal is to ensure access to health care by providing adequate financing mechanisms. In the case of life and disability insurance, the goal is to provide families some measure of economic security following a tragic death or disability.
- Genetic information is potentially discriminating factor that cannot be fairly included in insurance underwriting practices.
- Recent developments in human genetic science and the technology of testing are not identifying new costly diseases that were not previously accounted for by the insurance industry’s actuarial data. Rather, these developments are only facilitating the identification of those individuals who carry disease-associated genes at earlier times; many of these people will never have a related illness or will experience a lifetime of the asymptomatic, presymptomatic or minimally symptomatic phases of the condition. It is not, therefore, the cost of financing the care of genetic conditions which is driving the call for access and inclusion of genetic information in insurance practices. There is no reason for insurers to begin to use this new predictive information now, merely because it is available.

## □ International Rules

### ◦ Canada

- ▶ Canadian lawmakers passed the Genetic Non-Discrimination Act on March 8, 2017. This law would make it illegal for employers or insurance companies in Canada to discriminate against people based on their genetic information.

### ◦ United States of America

- ▶ The Genetic Information Nondiscrimination Act of 2008, also referred to as GINA, is a new federal law that protects Americans from being treated unfairly because of differences in their DNA that may affect their health. The new law prevents discrimination from health insurers and employers.

- ▶ GINA protects a person's genetic information when seeking genetic testing or participating in a research study. It also protects a person's family medical history, including a family member's genetic information. For example, an employer cannot legally ask an employee if Huntington's disease runs in his or her family. This law provides a path of legal recourse for people who believe that they have experienced genetic discrimination.
- ▶ India too needs a law that prevents genetic discrimination. In this era of rampant genetic testing, we need to prevent discrimination and uphold "equal treatment under the law".

## Conclusion

- Any effort to address genetic discrimination inevitably implicates broader and extremely contentious issues, such as the right to health care. If we wish to eliminate genetic discrimination in health insurance without creating questionable distinctions between genetic and other conditions, and without risking system collapse through adverse selection, we need to work toward mandatory participation, guaranteed issue, and renewal, community-rated health insurance. If we wish to eliminate genetic discrimination in employment, without endorsing questionable distinctions, and without risking a system in which protections against discrimination are vitiated by the ease of access to information and the difficulties involved in policing its use, we need to prohibit employers from obtaining all non-job-related medical information.
- There should, therefore, be no discrimination based on genetic information. Only universal health care can, therefore, be a viable solution.

# Genome Editing

## Context

- Recently, a Chinese scientist has claimed to have created the world's first genetically edited babies using CRISPR-Cas9 technology, in a potentially ground-breaking and controversial medical first.
- If true, it would be a profound leap in science and ethics. This kind of gene editing is banned in most countries as the technology is still experimental and DNA changes can pass to future generations, potentially with unforeseen side-effects.

## Background

- CRISPRs were first discovered in archaea (and later in bacteria) by Francisco Mojica. He proposed that CRISPRs serve as part of the bacterial immune system, defending against invading viruses. They consist of repeating sequences of the genetic code, interrupted by "spacer" sequences – remnants of genetic code from past invaders.
- The system serves as a genetic memory that helps the cell detect and destroy invaders (called "bacteriophage") when they return.

## How does it work?

- The CRISPR-Cas9 system consists of two key molecules that introduce a change (mutation) into the DNA. These are:
- An enzyme called Cas9. This acts as a pair of 'molecular scissors' that can cut the two strands of DNA at a specific location in the genome so that bits of DNA can then be added or removed.

- ❑ A piece of RNA called guide RNA (gRNA). This consists of a small piece of pre-designed RNA sequence (about 20 bases long) located within a longer RNA scaffold. The scaffold part binds to DNA and the pre-designed sequence 'guides' Cas9 to the right part of the genome. This makes sure that the Cas9 enzyme cuts at the right point in the genome.
- ❑ The guide RNA is designed to find and bind to a specific sequence in the DNA. The guide RNA has RNA bases that are complementary to those of the target DNA sequence in the genome. This means that the guide RNA will only bind to the target sequence and no other regions of the genome.
- ❑ The Cas9 follows the guide RNA to the same location in the DNA sequence and makes a cut across both strands of the DNA.
- ❑ At this stage, the cell recognizes that the DNA is damaged and tries to repair it.
- ❑ Scientists can use the DNA repair machinery to introduce changes to one or more genes in the genome of a cell of interest.

## Applications and Implications

- ❑ Genome editing is of great interest in the prevention and treatment of human diseases. Currently, most research on genome editing is done to understand diseases using cells and animal models.
- ❑ The technology is being explored in research on a wide variety of diseases, including single-gene disorders such as cystic fibrosis, hemophilia, and sickle cell disease.
- ❑ It also holds promise for the treatment and prevention of more complex diseases, such as cancer, heart disease, mental illness, and human immunodeficiency virus (HIV) infection.
- ❑ CRISPR-Cas9 has a lot of potential as a tool for treating a range of medical conditions that have a genetic component, including cancer, hepatitis B or even high cholesterol.
- ❑ Many of the proposed applications involve editing the genomes of somatic (non-reproductive) cells but there has been a lot of interest and debate about the potential to edit germline (reproductive) cells.

## Implications

### ❑ The Ethical dilemma

- Making genetic modifications to human embryos and reproductive cells such as sperm and eggs are known as germline editing. Since any changes made in germline cells using CRISPR-Cas9 technology will be passed on from generation to generation. It has raised a number of ethical concerns.
- Another ethical challenge germline cell and embryo genome editing brings up includes whether it would be permissible to use this technology to enhance normal human traits (such as height or intelligence).
- There are growing concerns about trying to produce "designer" babies or altered human beings.
- Based on concerns about ethics and safety, germline cell and embryo genome editing are currently illegal in many countries.
- Other Concerns
- Variable efficacy: CRISPR technology is not hundred percent efficient. The genome-editing efficiencies can vary.
- Off-target effects and imprecise edits: There is also the phenomenon of "off-target effects," where DNA is cut at sites other than the intended target. This can lead to the introduction of unintended mutations. Furthermore, even when the system cuts on target, there is a chance of not getting a precise edit. This is called as "genome vandalism."

- There is also a potential ecological impact of using gene drives. An introduced trait could spread beyond the target population to other organisms through crossbreeding. Gene drives could also reduce the genetic diversity of the target population.

## Way Forward

- ❑ Experts recommend that germline editing should be done only on genes that lead to serious diseases and when no other reasonable treatment alternatives exist.
- ❑ Among other criteria, they stress the need to have data on the health risks and benefits and the need for continuous oversight during clinical trials. They also recommend following up on families for multiple generations.
- ❑ CRISPR technology is indeed a path-breaking technology, to alter genes in order to tackle a number of conventional and unconventional problems. The most promising use of CRISPR technology is in the treatment of diseases. For example, sickle cell anemia.
- ❑ However, experiments and tests to validate its use must be subjected to appropriate scrutiny by the regulators, and their use must be controlled to prevent commercial misuse.
- ❑ Scientists across the world are still working to determine whether the CRISPR technology is safe and effective for use in people.

## Biotechnology programme for Societal Development

- ❑ Biotechnology based programme for societal development was initiated in 1990 to benefit the vulnerable section of the society particularly the farmers, women and SC/ST population. The emphasis was on diffusion of proven and field tested interventions with an approach to reach the unreached through various means like field demonstrations, trainings, education campaigns etc.
- ❑ These programmes were undertaken with the funding mechanism of department.
- ❑ The programme aims to promote dissemination of biotech interventions in agriculture and allied sector including animal husbandry, dairy and fisheries, integrated farming system, health & nutrition, environment & biodiversity conservation, product / process development and value addition etc. for the benefit of the underprivileged section of the society.

## Aim/ Objectives of the Programme

- ❑ **Aim:** Socio-economic upliftment of the underprivileged section of the society.
- ❑ **Objectives**
  - To promote the use of biotechnological processes and tools for the benefit of under privileged section of the society comprising of women, rural, SC/ST population and weaker section.
  - To develop programs on agriculture and allied areas; health, hygiene and nutrition; biodiversity conservation and sustainable utilization of resources for societal benefit.
  - To create a platform for livelihood, self-employment generation and entrepreneurial activities among the target population by diffusion of proven and field-tested technologies through demonstration, training and extension activities.
  - Science outreach & public engagement.

## Genomics for Public Health in India (IndiGen) Programme

- The First Indian Genome was announced on 8th of December 2009.
  - The project called IndiGen was implemented by Delhi-based Institute of Genomics and Integrative Biology (IGIB) and Hyderabad-based Centre for Cellular and Molecular Biology (CCMB). The whole genome sequencing of individuals drawn from across the country has been completed, enabling benchmarking the scalability of genome sequencing and computational analysis at population scale.
  - IndiGen programme aims to undertake whole genome sequencing of thousands of individuals representing diverse ethnic groups from India. The objective is to enable genetic epidemiology and develop public health technologies applications using population genome data.
- **Genome Sequence benefits**
- Research laboratories working under the Council of Scientific and Industrial Research (CSIR) on announced completion of whole genome sequencing of 1008 Indian individuals representing diverse ethnic groups in the country.
  - The data will act as baseline information for developing various applications in predictive and preventive medicine.
  - It will further lead to cost-effective genetic tests, carrier screening applications for expectant couples, enabling efficient diagnosis of heritable cancers and pharmacogenetic tests to prevent adverse drug reactions are some of the other benefits of this initiative.
  - IndiGenome card and mobile application for researchers and clinicians to access clinically actionable information has also been developed. It would ensure privacy and data security, which is vital for personal genomics to be implemented at large scale.
  - 'Indian Genome Variation' has made major contributions in understanding genetic makeup of Indian population. It has also pioneered the application of genomics in clinical settings in the area of rare genetic diseases by means of DNA and genome based diagnostics and interaction with large number of clinical collaborators.

## Stem cells–potential and challenges

### Application of stem cell:

- Increase understanding of how diseases occur. By watching stem cells mature into cells in bones, heart muscle, nerves, and other organs and tissue, researchers may better understand how diseases and conditions develop.
- Generate healthy cells to replace cells affected by disease (regenerative medicine). Stem cells can be guided into becoming specific cells that can be used in people to regenerate and repair tissues that have been damaged or affected by disease.
- People who might benefit from stem cell therapies include those with spinal cord injuries, type 1 diabetes, Parkinson's disease, amyotrophic lateral sclerosis, Alzheimer's disease, heart disease, stroke, burns, cancer and osteoarthritis.
- Stem cells may have the potential to be grown to become new tissue for use in transplant and regenerative medicine. Researchers continue to advance the knowledge on stem cells and their applications in transplant and regenerative medicine.

- ❑ Test new drugs for safety and effectiveness. Before using investigational drugs in people, researchers can use some types of stem cells to test the drugs for safety and quality. This type of testing will most likely first have a direct impact on drug development for cardiac toxicity testing.
- ❑ New areas of study include the effectiveness of using human stem cells that have been programmed into tissue-specific cells to test new drugs. For the testing of new drugs to be accurate, the cells must be programmed to acquire properties of the type of cells targeted by the drug. Techniques to program cells into specific cells are under study.
- ❑ For instance, nerve cells could be generated to test a new drug for a nerve disease. Tests could show whether the new drug had any effect on the cells and whether the cells were harmed.

## Where do stem cells come from?

### ❑ There are several sources of stem cells:

- **Embryonic stem cells:** These stem cells come from embryos that are 3 to 5 days old. At this stage, an embryo is called a blastocyst and has about 150 cells.
- These are pluripotent (ploo-RIP-uh-tunt) stem cells, meaning they can divide into more stem cells or can become any type of cell in the body. This versatility allows embryonic stem cells to be used to regenerate or repair diseased tissue and organs.
- **Adult stem cells:** These stem cells are found in small numbers in most adult tissues, such as bone marrow or fat. Compared with embryonic stem cells, adult stem cells have a more limited ability to give rise to various cells of the body.
- Until recently, researchers thought adult stem cells could create only similar types of cells. For instance, researchers thought that stem cells residing in the bone marrow could give rise only to blood cells.
- However, emerging evidence suggests that adult stem cells may be able to create various types of cells. For instance, bone marrow stem cells may be able to create bone or heart muscle cells.
- This research has led to early-stage clinical trials to test usefulness and safety in people. For example, adult stem cells are currently being tested in people with neurological or heart disease.
- **Adult cells altered to have properties of embryonic stem cells:** Scientists have successfully transformed regular adult cells into stem cells using genetic reprogramming. By altering the genes in the adult cells, researchers can reprogram the cells to act similarly to embryonic stem cells.
- This new technique may allow use of reprogrammed cells instead of embryonic stem cells and prevent immune system rejection of the new stem cells. However, scientists don't yet know whether using altered adult cells will cause adverse effects in humans.
- Researchers have been able to take regular connective tissue cells and reprogram them to become functional heart cells. In studies, animals with heart failure that were injected with new heart cells experienced improved heart function and survival time.
- **Perinatal stem cells:** Researchers have discovered stem cells in amniotic fluid as well as umbilical cord blood. These stem cells have the ability to change into specialized cells.
- Amniotic fluid fills the sac that surrounds and protects a developing fetus in the uterus. Researchers have identified stem cells in samples of amniotic fluid drawn from pregnant women for testing or treatment — a procedure called amniocentesis.

### ❑ Controversy about using embryonic stem cells

- Embryonic stem cells are obtained from early-stage embryos — a group of cells that forms when eggs are fertilized with sperm at an in vitro fertilization clinic. Because human embryonic stem cells are

extracted from human embryos, several questions and issues have been raised about the ethics of embryonic stem cell research.

- The National Institutes of Health created guidelines for human stem cell research in 2009. The guidelines define embryonic stem cells and how they may be used in research, and include recommendations for the donation of embryonic stem cells. Also, the guidelines state that embryonic stem cells from embryos created by in vitro fertilization can be used only when the embryo is no longer needed.

#### □ **Stem cell therapy (regenerative medicine)**

- Stem cell therapy, also known as regenerative medicine, promotes the repair response of diseased, dysfunctional or injured tissue using stem cells or their derivatives. It is the next chapter in organ transplantation and uses cells instead of donor organs, which are limited in supply.
- Researchers grow stem cells in a lab. These stem cells are manipulated to specialize into specific types of cells, such as heart muscle cells, blood cells or nerve cells.
- The specialized cells can then be implanted into a person. For example, if the person has heart disease, the cells could be injected into the heart muscle. The healthy transplanted heart muscle cells could then contribute to repairing the injured heart muscle.
- Researchers have already shown that adult bone marrow cells guided to become heart-like cells can repair heart tissue in people, and more research is ongoing.

#### □ **Have stem cells already been used to treat diseases?**

- Doctors have performed stem cell transplants, also known as bone marrow transplants. In stem cell transplants, stem cells replace cells damaged by chemotherapy or disease or serve as a way for the donor's immune system to fight some types of cancer and blood-related diseases, such as leukemia, lymphoma, neuroblastoma and multiple myeloma. These transplants use adult stem cells or umbilical cord blood.
- Researchers are testing adult stem cells to treat other conditions, including a number of degenerative diseases such as heart failure.

#### □ **Potential problems with using embryonic stem cells in humans**

- For embryonic stem cells to be useful, researchers must be certain that the stem cells will differentiate into the specific cell types desired.
- Researchers have discovered ways to direct stem cells to become specific types of cells, such as directing embryonic stem cells to become heart cells. Research is ongoing in this area.
- Embryonic stem cells can also grow irregularly or specialize in different cell types spontaneously. Researchers are studying how to control the growth and differentiation of embryonic stem cells.
- Embryonic stem cells might also trigger an immune response in which the recipient's body attacks the stem cells as foreign invaders, or the stem cells might simply fail to function as expected, with unknown consequences. Researchers continue to study how to avoid these possible complications.

#### □ **Therapeutic cloning**

- Therapeutic cloning, also called somatic cell nuclear transfer, is a technique to create versatile stem cells independent of fertilized eggs. In this technique, the nucleus is removed from an unfertilized egg. This nucleus contains the genetic material. The nucleus is also removed from the cell of a donor.

- This donor nucleus is then injected into the egg, replacing the nucleus that was removed, in a process called nuclear transfer. The egg is allowed to divide and soon forms a blastocyst. This process creates a line of stem cells that is genetically identical to the donor's cells — in essence, a clone.
- Some researchers believe that stem cells derived from therapeutic cloning may offer benefits over those from fertilized eggs because cloned cells are less likely to be rejected once transplanted back into the donor and may allow researchers to see exactly how a disease develops.

#### □ **Has therapeutic cloning in people been successful?**

- Researchers haven't been able to successfully perform therapeutic cloning with humans despite success in a number of other species.
- However, in recent studies, researchers have created human pluripotent stem cells by modifying the therapeutic cloning process. Researchers continue to study the potential of therapeutic cloning in people.

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## Chapter

# 3

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# DISEASES IN NEWS

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## Need for Public Health Surveillance

Public health surveillance is the ongoing systematic collection, analysis, and interpretation of data, closely integrated with the timely dissemination of these data to those responsible for preventing and controlling disease and injury.

### Need for Public Health Surveillance

- ❑ The purpose for conducting public health surveillance is to learn the **ongoing pattern of disease** occurrence and the potential for disease in a population so that we can be effective in **investigating, controlling, and preventing disease** in that population.
- ❑ Through surveillance we can learn more about the natural history, clinical spectrum, and **epidemiology of a disease**
- ❑ Surveillance will provide us with a baseline of data which we can use to **assess prevention and control measures** when they are developed and implemented.

### Fault Lines in India's Public Health Surveillance System

- ❑ **Patchy surveillance, not comprehensive:** There is a lack of uniformity in outbreak investigation and reporting and there are limitations in geographic coverage within states.
- ❑ **Surveillance functions in vertical silos of programs and institutions:** Vertical programs such as the National AIDS Control Program and the National TB Elimination Program have achieved significant success. However, surveillance data from these vertical programs are not yet fully integrated within a single unified surveillance platform.
- ❑ **Private sector involvement in surveillance is limited**
- ❑ **Inadequate linkage of morbidity with mortality data**
- ❑ **Human resource challenges:** The recruitment of human resources for State and District Level Surveillance Units has been devolved to states, however, the response of States to address these human resource gaps is varied.

- ❑ Limited use of digital, social and print media in surveillance

### Measures that can be taken:

- ❑ A **governance framework** that is inclusive of political, policy, technical, and managerial leadership at the national and state level.
- ❑ **Identify broad disease categories** that will be included under Public Health Surveillance.
- ❑ **Enhance surveillance of non-communicable diseases** and conditions in a stepwise manner.
- ❑ **Prioritize diseases** that can be targeted for elimination as a public health problem, regularly.
- ❑ **Improve core support functions**, core functions, and system attributes for surveillance at all levels; national, state, district, and block.
- ❑ Establish mechanisms to **streamline data sharing, capture, analysis, and dissemination for action**. These could include the use of situation-aware real-time signals from social media, mobile sensor networks, and participatory surveillance systems for event based epidemic intelligence.
- ❑ **Encourage innovations** at every step-in surveillance activity.

### Conclusion

Vision 2035 on Public Health Surveillance by NITI Aayog aims to build India as a global leader in Public Health Surveillance. This will provide the citizens of India a healthier life where they can reflect on their health choices based on the data collected and disseminated by the Government. And healthier citizens will eventually lead to a prosperous country.

## Corona virus & Vaccine Development

Corona viruses are a large family of viruses which may cause illness in animals or humans. In humans, several coronaviruses are known to cause respiratory infections ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). The most recently discovered coronavirus causes coronavirus disease COVID-19.

### What is COVID-19?

COVID-19 is the infectious disease caused by the most recently discovered corona virus. This new virus and disease were unknown before the outbreak began in Wuhan, China, in December 2019.

### Symptoms

The most common symptoms of COVID-19 are fever, tiredness, and dry cough. Some patients may have aches and pains, nasal congestion, runny nose, sore throat or diarrhea. These symptoms are usually mild and begin gradually. Some people become infected but don't develop any symptoms and don't feel unwell.

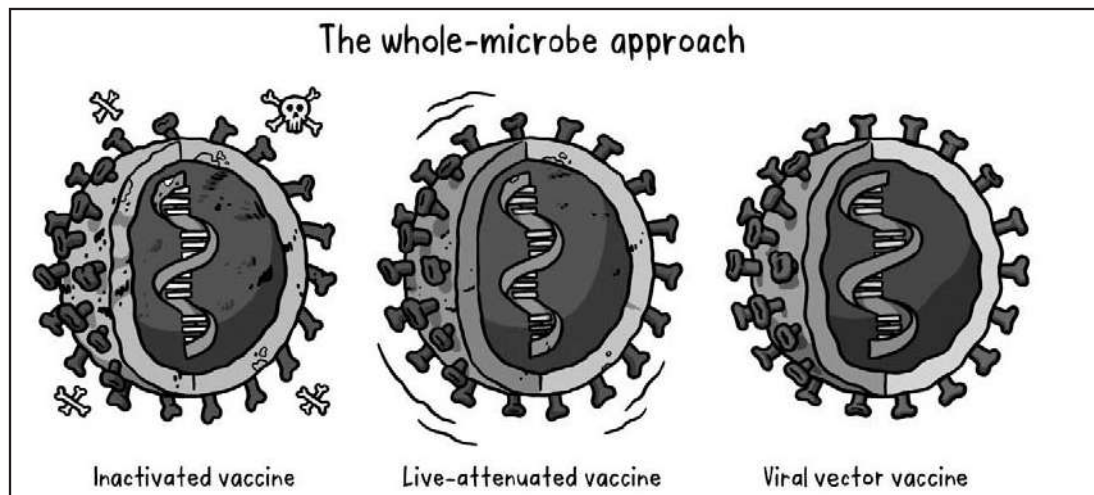
### The different types of vaccines

There are three main approaches to designing a vaccine. Their differences lie in whether they use a **whole** virus or bacterium; just the **parts** of the germ that triggers the immune system; or just the **genetic material** that provides the instructions for making specific proteins and not the whole virus.

## The whole-microbe approach

### ❑ Inactivated vaccine

- The first way to make a vaccine is to take the disease-carrying virus or bacterium, or one very similar to it, and inactivate or kill it using chemicals, heat or radiation. This approach uses technology that's been proven to work in people – this is the way the flu and polio vaccines are made – and vaccines can be manufactured on a reasonable scale.



- However, it requires special laboratory facilities to grow the virus or bacterium safely, can have a relatively long production time, and will likely require two or three doses to be administered.

### ❑ Live-attenuated vaccine

- A live-attenuated vaccine uses a living but weakened version of the virus or one that's very similar. The measles, mumps and rubella (MMR) vaccine and the chickenpox and shingles vaccine are examples of this type of vaccine. This approach uses similar technology to the inactivated vaccine and can be manufactured at scale. However, vaccines like this may not be suitable for people with compromised immune systems.

### ❑ Viral vector vaccine

- This type of vaccine uses a safe virus to deliver specific sub-parts – called proteins – of the germ of interest so that it can trigger an immune response without causing disease. To do this, the instructions for making particular parts of the pathogen of interest are inserted into a safe virus. The safe virus then serves as a platform or vector to deliver the protein into the body. The protein triggers the immune response. The Ebola vaccine is a viral vector vaccine and this type can be developed rapidly.

## The subunit approach

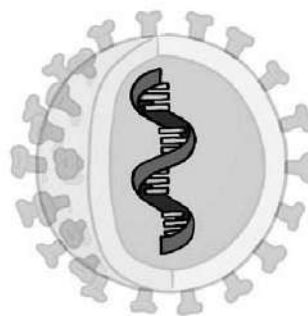
- ❑ A subunit vaccine is one that only uses the very specific parts (the subunits) of a virus or bacterium that the immune system needs to recognize. It doesn't contain the whole microbe or use a safe virus as a vector. The subunits may be proteins or sugars. Most of the vaccines on the childhood schedule are subunit vaccines, protecting people from diseases such as whooping cough, tetanus, diphtheria and meningococcal meningitis.

### The subunit approach



Only uses the very specific parts (the subunits) of a virus or bacterium that the immune system needs to recognize.

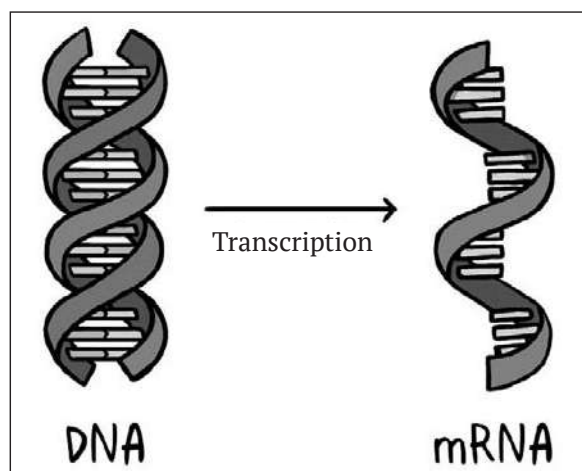
### The genetic approach (nucleic acid vaccine)



Uses the genetic material for specific proteins - the DNA or RNA.

## The genetic approach (nucleic acid vaccine)

- Unlike vaccine approaches that use either a weakened or dead whole microbe or parts of one, a nucleic acid vaccine just uses a section of genetic material that provides the instructions for specific proteins, not the whole microbe. DNA and RNA are the instructions our cells use to make proteins. In our cells, DNA is first turned into messenger RNA, which is then used as the blueprint to make specific proteins.



A nucleic acid vaccine delivers a specific set of instructions to our cells, either as DNA or mRNA, for them to make the specific protein that we want our immune system to recognize and respond to.

### Vaccine diplomacy

- It is the use of vaccines to improve a country's diplomatic relationship and influence of other countries.
- It also "means a set of diplomatic measures taken to ensure access to the best practices in the development of potential vaccines, to enhance bilateral and/or multilateral cooperation between countries in conducting joint R&D, and, in the case of the announcement of production, to ensure the signing of a contract for the purchase of the vaccine at the shortest term."
- Although primary discussed in the context of the supply of COVID-19 vaccines, it also played a part in the distribution of the smallpox vaccine.

## India and Vaccine Diplomacy

- For over two decades, India has acquired the reputation of being the “pharmacy of the world” as its strong generic pharmaceutical industry has been supplying affordable medicines conforming to quality standards to the global markets.
- In keeping with its historical role as a provider of affordable medicines, India has taken two significant initiatives to overcome the scourge of the COVID-pandemic.
- The first is to make vaccines widely available, which is in response to the growing evidence of the criticality of making COVID-19 vaccines accessible to all. The second initiative is a joint proposal tabled along with South Africa in the World Trade Organization (WTO), which seeks temporary waiver from the implementation and enforcement of four forms of intellectual property rights (IPRs).
- The objective is to ensure that COVID-19 vaccines, medicines and other medical products are freed from the encumbrances of these IPRs, thus making them affordable.
- India has decided to supply 10 million doses of the vaccine to Africa and 1 million to UN health workers India under the COVID-19 Vaccines Global Access (COVAX) facility of the Global Alliance for Vaccines and Immunizations (GAVI).
- Among the individual countries, Bangladesh is the largest beneficiary having received 7 million doses of “Covishield” vaccine, of which 2 million doses are in the form of grant, while Nepal has received 1 million.
- Bhutan and Maldives have received 150,000 doses and 100,000 doses respectively, while Sri Lanka and Afghanistan have both received 500,000 doses.
- Other than its South Asian neighbors, Government of India has supplied 1.5 million doses of “Covaxin” vaccine to Myanmar.
- Mauritius and Seychelles have been sent 100,000 doses and 50,000 doses of “Covishield,” respectively.
- Vaccine supplies to the aforementioned countries should be seen as a part of the development partnership initiative that the Government of India has been pursuing since the early 1950s.
- This initiative was formalized in 2012 with the establishment of the “Development Partnership Administration”, which, while extending support to other developing countries, recognizes that the “most fundamental principle in cooperation is respecting development partners and be guided by their development priorities”.

## What are the different types of Covid-19 test?

- Polymerase chain reaction (PCR) tests - PCR tests are used to directly screen for the presence of viral RNA, which will be detectable in the body before antibodies form or symptoms of the disease are present.
- Lateral flow tests (LFTs) - LFTs are similar to PCR tests, in that they’re both types of antigen test, designed to pick up active Covid-19 infection rather than antibodies to the disease.
  - The major benefit of LFTs over PCRs is that they do not need to be sent away for confirmation, and instead provide results within 15 to 30 minutes.
- Antibody (or serology) tests – The samples are tested for the presence of specific type of antibody against the antigen.

## COVAXIN

It is India’s indigenous COVID-19 vaccine by Bharat Biotech.

- It is developed in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV).

- The indigenous, inactivated vaccine is developed and manufactured in Bharat Biotech's BSL-3 (Bio-Safety Level 3) high containment facility.
- The vaccine is developed using Whole-Virion Inactivated Vero Cell derived platform technology. Inactivated vaccines do not replicate and are therefore unlikely to revert and cause pathological effects. They contain dead virus, incapable of infecting people but still able to instruct the immune system to mount a defensive reaction against an infection.
- Conventionally, inactivated vaccines have been around for decades. Numerous vaccines for diseases such as Seasonal Influenza, Polio, Pertussis, Rabies, and Japanese Encephalitis use the same technology to develop inactivated vaccines.

## Ind-CEPI MISSION

- CEPI (Coalition for Epidemic Preparedness Innovations) has already conducted a prioritization exercise in the past based on which it issued RFPs for Lassa, Nipah, MERS, RFV and Chikungunya vaccine candidates.
- The IndCEPI Mission was approved on 27th March 2019.
- The Ind-CEPI Mission will facilitate the studies through the provision of clearly defined criteria and pathways for vaccine assessment, which will be developed in consultation with CEPI.
- The Mission aims to strengthen the development of vaccines for the diseases of epidemic potential in India as well as build coordinated preparedness in the Indian public health system and vaccine industry to address existing and emergent infectious threats in India.

## Mission Implementation:

- The Department of Biotechnology, Ministry of Science and Technology, Government of India is supporting the implementation of the Ind-CEPIs mission.
- The mission is being implemented through a dedicated Program Management Unit (PMU) at Biotechnology Industry Research Assistance Council (BIRAC).

## Ind-CEPI OBJECTIVES:

- Supporting the development of at least 2-3 new vaccines for potential outbreak threats up to phase 2 testing in five years.
- Strengthening of infrastructure to support the needs of the vaccine development through an academia-industry interface.
- Supporting capacity building and skill development.
- Strengthening internal inter-ministerial co-ordination for rapid vaccine development and testing to address known and unknown infectious disease threats.
- Strengthening of development frameworks, surveillance and logistics for use of new vaccines.

# Mucormycosis

- Mucormycosis (previously called zygomycosis) is a serious but rare fungal infection caused by a group of molds called mucormycetes. These molds live throughout the environment.

- ❑ Mucormycosis mainly affects people who have health problems or take medicines that lower the body's ability to fight germs and sickness. It most commonly affects the sinuses or the lungs after inhaling fungal spores from the air. It can also occur on the skin after a cut, burn, or other type of skin injury.
- ❑ It is caused by the Rhizopus species, Mucor species, Rhizomucor species, Lichtheimia etc.

## Types of mucormycosis

- ❑ Rhinocerebral (sinus and brain) mucormycosis is an infection in the sinuses that can spread to the brain. This form of mucormycosis is most common in people with uncontrolled diabetes and in people who have had a kidney transplant. 7-8
- ❑ Pulmonary (lung) mucormycosis is the most common type of mucormycosis in people with cancer and in people who have had an organ transplant or a stem cell transplant.
- ❑ Gastrointestinal mucormycosis is more common among young children than adults, especially premature and low birth weight infants less than 1 month of age, who have had antibiotics, surgery, or medications that lower the body's ability to fight germs and sickness. 9-10
- ❑ Cutaneous (skin) mucormycosis: occurs after the fungi enter the body through a break in the skin (for example, after surgery, a burn, or other type of skin trauma). This is the most common form of mucormycosis among people who do not have weakened immune systems.
- ❑ Disseminated mucormycosis occurs when the infection spreads through the bloodstream to affect another part of the body. The infection most commonly affects the brain, but also can affect other organs such as the spleen, heart, and skin.

## Symptoms of Mucormycosis

- ❑ The symptoms of mucormycosis depend on where in the body the fungus is growing. 1,4 Contact your healthcare provider if you have symptoms that you think are related to mucormycosis. Symptoms of rhinocerebral (sinus and brain) mucormycosis include:
  - One-sided facial swelling
  - Headache
  - Nasal or sinus congestion
  - Black lesions on nasal bridge or upper inside of mouth that quickly become more severe
  - Fever
- ❑ Symptoms of **pulmonary (lung) mucormycosis** include:
  - Fever
  - Cough
  - Chest pain
  - Shortness of breath
- ❑ **Cutaneous (skin) mucormycosis** can look like blisters or ulcers, and the infected area may turn black. Other symptoms include pain, warmth, excessive redness, or swelling around a wound. Symptoms of **gastrointestinal mucormycosis** include:
  - Abdominal pain
  - Nausea and vomiting
  - Gastrointestinal bleeding

- ❑ **Disseminated mucormycosis** typically occurs in people who are already sick from other medical conditions, so it can be difficult to know which symptoms are related to mucormycosis. Patients with disseminated infection in the brain can develop mental status changes or coma.

## Mother-to-Child Transmission of HIV

- ❑ **HIV can pass from an HIV-positive mother to her child:**
  - During pregnancy – The foetus is infected by HIV crossing the placenta.
  - During childbirth – The baby is infected by HIV in the mother’s cervical secretions or blood.
  - During breastfeeding – The baby is infected by HIV in the mother’s breast milk (or blood).
- ❑ Because of this, efforts to prevent HIV transmission need to incorporate strategies which cover the entire period from pregnancy to infant feeding.
- ❑ **Symptoms of HIV infection:**
  - Symptoms of HIV infection vary by age and individual child, but the **following are some of the more common symptoms:**
    - Failure to thrive, which is the failure to gain weight or grow according to standardised growth charts used by health visitors and doctors.
    - Failure to reach developmental milestones during the expected time frame.
    - Brain or nervous system problems, characterized by seizures, difficulty with walking or poor performance in school
    - Frequent childhood illnesses such as ear infections, colds, upset stomach and diarrhoea.
  - As HIV infection becomes more advanced, children start to develop **Opportunistic Infections**. These are infections that rarely affect healthy people but can be deadly for people whose immune systems aren’t working properly. **Common opportunistic infections related to HIV include:**
    - Pneumocystis pneumonia - a fungal infection of the lungs.
    - Severe infection due to cytomegalovirus (CMV).
    - A condition of lung scarring called Lymphocytic Interstitial Pneumonitis (LIP).
    - Oral thrush or severe nappy rash due to Candida, a yeast infection.
- ❑ **Treatment offered in India:**
  - Indian health providers offered ‘**Single Dose Therapy**’, which involved administering the antiretroviral drug, nevirapine, to pregnant HIV-positive women two hours before delivery and to newborns within 72 hours of birth.
  - In 2014, the country moved on to follow the **World Health Organisation**(WHO) recommended ‘multidrug therapy’, which is a combination of three drugs — tenofovir, lamivudine and efavirenz (TLE).
  - Affected women need to take it all their lives and nevirapine syrup for six weeks only for their babies. “Nevirapine is known to cause drug-resistant HIV in mothers.

In 2015, Cuba became the first country in the world to receive validation from WHO that it had eliminated mother-to-child transmission of HIV and syphilis, followed by Thailand and Belarus. Among African countries, Uganda claims to be in the pre-elimination stage. “The enormous population in India makes it challenging for health-care workers to reach out to every pregnant woman.

## □ Challenges

### ◉ Population:

- ▶ The enormous population in India makes it challenging for health-care workers to reach out to every pregnant woman. On the other hand, pregnant women too often delay registering for antenatal care.

### ◉ Medicine stockpiles:

- ▶ There have been instances of a shortage of medicines related to HIV/AIDS. Eg. Children friendly Lopinavir Syrup production was stopped by CIPLA since the government failed to clear its dues.
- ▶ **Ignorance and lack of information** perpetuate wrong conceptions of these diseases and associated stigmatization.
- ▶ Many of the infections tend to be asymptomatic or otherwise unrecognized until complications and sequela develop, especially in women.
- ▶ **The stigmatization** associated with infection (and clinics that provide services) constitutes an ongoing and powerful barrier to the implementation of prevention and care interventions.
- ▶ The reluctance of patients to seek early treatment.
- ▶ Difficulty in notifying and treating infections in sexual partners.

## □ Solutions

### ◉ Medicines

- ▶ Consistent availability of appropriate medicines is essential for a successful sexually transmitted infection control programme.
- ▶ A streamlined process of procurement and storage of medicines related to HIV/AIDS. Eg. Tamil Nadu model of direct procurement from manufacturers prevents any leakages and also reduces drug prices.
- ▶ A focus on injectable drug users needs to increase to prevent the transmission of

### ◉ Cooperation:

- ▶ Centre and States would have to cooperate and set targets within specified timelines.

### ◉ Surveillance:

- ▶ Better HIV surveillance and targeted interventions are needed for these risk groups.
- ▶ Surveillance of sexually transmitted infections at the national, regional and global levels needs to be enhanced for the purposes of advocacy, programme design, monitoring and evaluation, and patient care.

### ◉ Awareness:

- ▶ Increasing geographical coverage and the number of people served within a particular target population, extending a programme to reach additional target populations, and broadening the scope of interventions provided by a programme.

### ◉ Monitoring and evaluation:

- ▶ Progress of programme implementation needs to be monitored in order to ensure that activities are performed as planned, on time and within budgeted resources and determine whether the activities are producing the expected outcome or impact.

### ❑ **Government Measures for preventing HIV/AIDS transmission from mother to child:**

- Prevention from Parent to Child Transmission (PPTCT) programme has been integrated with the RCH programme.
- PALS (PPTCT ART Linkages Software) System has also been launched to maintain details of all HIV positive pregnant and breastfeeding women and their newborn babies.
- NACO has been conducting regular thematic **Mass Media campaigns** on TV and Radio to cover issues of condom promotion, ICTC/PPTCT, STI treatment and services, stigma and discrimination, the vulnerability of youth to HIV, ART, HIV-TB and blood safety.

### ❑ **90:90:90 Strategy:**

- It is a new HIV treatment that lays the groundwork to end the AIDS epidemic.
- 90% of all people living with HIV will know their HIV status (90% diagnosed).
- 90% of all people with diagnosed HIV infection will receive sustained antiretroviral therapy (90% on HIV treatment).
- 90% of all people receiving antiretroviral therapy will have viral suppression (90% suppressed).

## **Way Forward**

- ❑ Increase the commitment of national governments and national and international development partners for prevention and control.
- ❑ Gender inequalities must be addressed through interventions that influence political will as well as societal norms and attitudes concerning sexual behavior and the status of women. Active promotion of male responsibility and the empowerment of women in the prevention and control of sexually transmitted infections are crucial elements of an effective gender-sensitive response.
- ❑ There should be a seamless continuum between prevention interventions and care. The balance and variety of activities will depend on the local determinants of epidemiology, patterns of infections and resources available. In each setting, the availability of and access to condoms and medicines for the treatment of sexually transmitted infections will constitute elements of a fully effective response?
- ❑ Cooperation between prevention and care programs for sexually transmitted infections and those for HIV is vital for the response, as not only are the risk behaviors that lead to infection with HIV and other sexually.

## **Nipah Virus Infection**

- ❑ Nipah virus (NiV) infection is a newly emerging zoonosis that causes severe disease in both animals and humans. The natural host of the virus are fruit bats of the Pteropodidae Family, Pteropus genus.
- ❑ The Nipah virus is a newly emerging disease that can be transmitted from its natural host, the fruit bat, to animals and humans alike. It takes its name from Sungai Nipah, the Malaysian village where it was first identified in 1998. An outbreak there among pigs left approximately 300 people infected and more than 100 people dead within a year. In an attempt to stop the outbreak, millions of pigs were euthanized, resulting in a tremendous trade loss for Malaysia at the time.

### □ How is the Nipah virus transmitted?

- Recent outbreaks have shown that the Nipah virus is transmitted through direct contact with infected humans or domesticated animals, such as cattle, pigs and cows. It is also passed on through the consumption of contaminated fruits.
- The recent outbreak in Kerala is thought to have been caused by dead bats found in a well of a family's home in the village of Changaroath. The infection reportedly spread among family members and was passed on to others who had been in contact with the family.

### □ What are the symptoms?

- Infection by the Nipah virus can result in an aggressive inflammation of the brain, called encephalitis. According to the US Centers for Disease Control and Prevention, the incubation period spans five to 14 days, with the first signs of infection appearing after three to 14 days.
- Initial symptoms include fever, vomiting and severe headaches, and some patients experience acute respiratory syndrome. These initial symptoms are followed by disorientation, drowsiness and mental confusion. Within one to two days the disease can result in coma and death. The Nipah virus has a mortality rate of 70 percent.

### □ Prevention and control

- There is no effective treatment for Nipah virus disease, but ribavarin may alleviate the symptoms of nausea, vomiting, and convulsions. Treatment is mostly focused on managing fever and the neurological symptoms. Severely ill individuals need to be hospitalized and may require the use of a ventilator.
- Human-to-human transmission of NiV has been reported in recent outbreaks demonstrating a risk of transmission of the virus from infected patients to healthcare workers through contact with infected secretions, excretions, blood or tissues. Healthcare workers caring for patients with suspected or confirmed NiV should implement Standard Precautions when caring for patients and handling specimens from them.
- Prevention and control measures should focus on immediate eradication by mass culling of infected and in-contact pigs and on antibody surveillance of high risk farms to prevent future outbreaks. After culling, the burial sites are disinfected with chlorinated lime. It is also recommended to use sodium hypochlorite (bleach) to disinfect the contaminated areas and equipment. Other important control measures have been a ban on transporting pigs within the countries affected, a temporary ban on pig production in the regions affected, as well as improvement of biosecurity practices.
- Education and use of personal protective equipment (PPE) by persons exposed to potentially infected pigs is highly recommended. Also, improved hygiene at pig operations is suggested. One of the most important biosecurity measures for affected areas is to decrease the likelihood of the bat reservoir coming into contact with pig production facilities.

## Avian Influenza or Bird Flu

- Avian Influenza known as avian flu or bird flu refers to influenza caused by viruses adapted to birds.
- These viruses occur naturally among wild aquatic birds worldwide and can infect domestic poultry and other bird and animal species.

- ❑ Avian flu viruses do not normally infect humans, infected birds shed avian influenza virus in their saliva, mucous and feces.
- ❑ Human infections with bird flu viruses can happen when enough viruses get into a person's eyes, nose or mouth, or are inhaled.
- ❑ This can happen when virus is in the air and a person breathes it in, or when a person touches something that has virus on it then touches their mouth, eyes or nose.

### ❑ Recent update

- India has declared itself free from Avian Influenza (H5N8 and H5N1) from 6th June, 2017 and notified the same to World Organization for Animal Health (OIE).
- All the outbreaks of Avian Influenza (HPAI) were notified to OIE and the control and containment operations were carried out as per the Action Plan on Preparedness, Control and Containment of Avian Influenza.
- Surveillance was carried out throughout the country and around the areas of the outbreaks since completion of the operation (including culling, disinfection and clean-up). These surveillance in the states showed no evidence of presence of Avian Influenza Virus.
- The move will help it resume export of poultry products to the countries which had banned trade in such items early this year.
- The countries which banned Indian poultry products include United Arab Emirates (UAE) and Hong Kong.

### ❑ What does World Organization for Animal Health do?

- The World Organization for Animal Health is recognized as **a reference body by the World Trade Organization**. It has 181 countries as its members. This global body keeps tab on animal health issues and advises countries on best practices to be followed during such outbreaks.
- This Organization **also supports countries to help them control animal diseases that cause livestock losses and pose a risk to public health**. Under its norms, ban can be lifted after 90 days of surveillance.

## Bovine TB

- ❑ The first-ever road map to combat animal **tuberculosis** (bovine TB) and its transmission to humans, referred to as zoonotic TB.
- ❑ Bovine TB, caused by *Mycobacterium bovis*, affects cattle, threatens people's livelihoods and results in major economic and trade barriers, as well as posing a major risk to food safety and human health.
- ❑ Zoonotic TB spreads through consumption of contaminated untreated meat or dairy products from diseased animals. New data released by the WHO estimates that over 140,000 people fall ill and more than 12,000 people lose their lives each year to zoonotic TB — mostly in Africa and Southeast Asia.
- ❑ There is no cure for bovine TB and it threatens animal welfare and those with livelihoods based on livestock.
- ❑ Bovine TB is most often communicated to humans through food consumption, usually non-heat-treated dairy products or raw, or improperly cooked meat from diseased animals. Direct transmission from infected animals or animal products to people can also occur. Experts maintain that for countries to achieve the global TB elimination targets, interventions addressing zoonotic TB must be introduced in the national programmes.

- ❑ The priorities outlined in this road map highlight the need for multi-sectoral action to tackle this neglected form of TB and achieve the targets of the UN Sustainable Development Goals and WHO's End TB Strategy.

## Encephalitis

- ❑ Encephalitis is an inflammation of the brain tissue. The most common cause is viral infections. In rare cases it can be caused by bacteria or even fungi.
- ❑ There are **two main types of encephalitis**: primary and secondary. Primary encephalitis occurs when a virus directly infects the brain and spinal cord. **Secondary encephalitis occurs** when an infection starts elsewhere in the body and then travels to your brain.
- ❑ The symptoms of encephalitis can range from mild to severe. Mild symptoms include: fever, headache, vomiting, stiff neck, lethargy (exhaustion). Severe symptoms include: fever of 103°F (39.4°C) or higher; drowsiness; hallucinations; slower movements; coma; sensitivity to light, etc.

## Kyasanur Forest Disease (Monkey Fever)

- ❑ **Kyasanur Forest Disease (KFD)** is caused by **Kyasanur Forest Disease Virus (KFDV)**, a member of the virus family Flaviviridae. KFDV was identified in 1957 when it was isolated from a sick monkey from the Kyasanur forest in the Karnataka (formerly Mysore) State, India. Since then, between 400-500 humans cases per year have been reported.
- ❑ Hard ticks (*Hemaphysalis spinigera*) are the reservoir of the KFD virus and once infected, remain so for life.
- ❑ Rodents, shrews, and monkeys are common hosts for KFDV after being bitten by an infected tick, KFDV can cause epizootics with high fatality in primates.
- ❑ Transmission to humans may occur after a tick bite or contact with an infected animal, most importantly a sick or recently dead monkey.
- ❑ No person-to-person transmission has been described.
- ❑ Disease as of now was stated to be transmitted through monkeys.
- ❑ Large animals such as goats, cows, and sheep may become infected with KFD but play a limited role in the transmission of the disease.
- ❑ These animals provide the blood meals for ticks and it is possible for infected animals with viremia to infect other ticks, but transmission of KFDV to humans from these larger animals is extremely rare.
- ❑ There is no evidence of disease transmission via the unpasteurised milk of any of these animals.
- ❑ **What are the symptoms of Kyasanur forest disease?**
  - After an incubation period of 3-8 days, the symptoms of KFD begin suddenly with fever, headache, severe muscle pain, cough, dehydration, gastrointestinal symptoms and bleeding problems.
  - Patients may experience abnormally low blood pressure, and low platelet, red blood cell, and white blood cell counts.

- After 1-2 weeks of symptoms, some patients recover without complication. However, in most patients, the illness is biphasic and the patient begins experiencing a second wave of symptoms at the beginning of the third week. These symptoms include fever and signs of encephalitis (inflammation of the brain).
- **Who is at risk for the disease?**
  - People with recreational or occupational exposure to rural or outdoor settings (e.g., hunters, herders, forest workers, farmers) are potentially at risk for infection by contact with infected ticks. Seasonality is another important risk factor as more cases are reported during the dry season, from November through June.
- **How is Kyasanur forest disease prevented?**
  - There is no specific treatment for KFD, but early hospitalisation and supportive therapy is important. Supportive therapy includes the maintenance of hydration and the usual precautions for patients with bleeding disorders.
  - A vaccine does exist for KFD and is used in endemic areas of India. Additional preventative measures include insect repellents and wearing protective clothing in areas where ticks are endemic.
  - Tick repellents such as DEET, DMP, DBP provide 90-100% protection against tick bite.
  - One or 2 treatments of forest floor with the insecticide Lindane was highly effective in killing ticks. This was particularly useful to clear infection following detection of monkey deaths
- **Biosafety concerns**
  - Internationally, KFD virus is ranked as one of the highest risk categories of pathogens belonging to Bio Safety Level-4.
  - During investigations, over 100 laboratory persons got infected and suffered with the disease. Majority of the infections occurred in field during investigations on etiological agent, arthropods and mammals in nature.

## Hospital Acquired Infection

- Hospital-acquired infections are caused by viral, bacterial, and fungal pathogens; the most common types are bloodstream infection (BSI), pneumonia (eg, ventilator-associated pneumonia [VAP]), urinary tract infection (UTI), and surgical site infection (SSI).
- Such an infection can be acquired in hospital, nursing home, rehabilitation facility, outpatient clinic, or other clinical settings. Infection is spread to the susceptible patient in the clinical setting by various means.
- Symptoms of HAIs will vary by type. The most common types of HAIs are: urinary tract infections (UTIs); surgical site infections; gastroenteritis; meningitis and pneumonia.
- **The symptoms for these infections may include:** discharge from a wound; fever; cough, shortness of breathing; burning with urination or difficulty urinating; headache and nausea, vomiting, diarrhea.

## Rotavirus

- ❑ Rotavirus is a virus that infects the bowels.
- ❑ Children under five years of age, especially those between 6 months and two years are most vulnerable to this disease.
- ❑ Rotavirus affects populations in all socio-economic groups and is equally prevalent in industrialized and developing countries.
- ❑ The new vaccine **ROTAVAC** has been developed under an innovative public-private partnership model. It involved partnership between the Ministry of Science and Technology, the institutions of the US Government, various government institutions and NGOs in India, supported by the Bill and Melinda Gates Foundation.
- ❑ ROTAVAC is an oral vaccine and is administered to infants in a three-dose course at the ages of 6, 10, and 14 weeks. It is given alongside routine immunizations in the UIP vaccines recommended at these ages.
- ❑ It is on the World Health Organization's List of Essential Medicines, a list of the most important medication needed in a basic health system.

## Middle East Respiratory Syndrome Virus

- ❑ It's a **coronavirus** - a family of viruses that usually cause common colds and that can infect both animals and people.
- ❑ Typical MERS symptoms include fever, cough and shortness of breath. Pneumonia is common, but not always present. Gastrointestinal symptoms, including diarrhoea, have also been reported.
- ❑ Although the majority of human cases of MERS have been attributed to human-to-human infections, camels are likely to be a major reservoir host for MERS-CoV and an animal source of MERS infection in humans. However, the exact role of camels in transmission of the virus and the exact route(s) of transmission are unknown.
- ❑ The virus does not seem to pass easily from person to person unless there is close contact, such as occurs when providing unprotected care to a patient.

## Swine Flu

- ❑ Swine flu (swine influenza) is a **respiratory disease caused by viruses (influenza viruses)** that infect the respiratory tract of pigs and result in nasal secretions, a barking cough, decreased appetite, and listless behaviour.
- ❑ The virus spreads by tiny droplets that are released when a person coughs or sneezes. The droplets reach a distance of about one metre (3ft). These droplets remain suspended in the air for a short duration, and then settle on a surface. The virus suspended in airborne droplets can infect a person, if the person inhales the contaminated droplet.
- ❑ Common objects such as door handles, remote control, hand rails and computer keyboards can get contaminated with the virus when the droplet settles on these surfaces. If a person touches these surfaces and places the contaminated hands on their mouth or nose he or she can get the infection.

- ❑ Symptoms of swine flu are similar to most influenza infections: fever (100 °F or greater), cough, nasal secretions, fatigue, and headache, with fatigue being reported in most infected individuals. Some patients also get nausea, vomiting, and diarrhea.
- ❑ H1N1 swine flu virus is sensitive to the antiviral drugs Tamiflu and Relenza. These antiviral drugs are most effective when taken within 48 hours of the start of flu symptoms. It's resistant to older flu drugs. A third antiviral drug, peramivir, can be used only in hospitalized patients with severe flu.

## Chikanguniya

- ❑ Chikungunya is a viral disease transmitted to humans by infected mosquitoes. It causes fever and severe joint pain. Other symptoms include muscle pain, headache, nausea, fatigue and rash.
- ❑ The joint pain is often very debilitating, but usually lasts for a few days or may be prolonged to weeks. Hence the virus can cause acute, subacute or chronic disease.
- ❑ The virus is transmitted from human to human by the bites of infected female mosquitoes. Most commonly, the mosquitoes involved are *Aedes aegypti* and *Aedes albopictus*, two species which can also transmit other mosquito-borne viruses, including dengue. These mosquitoes can be found biting throughout daylight hours, though there may be peaks of activity in the early morning and late afternoon. Both species are found biting outdoors, but *Ae. aegypti* will also readily feed indoors.
- ❑ Serological tests, such as enzyme-linked immunosorbent assays (ELISA) is used for detection.

## Tuberculosis

- ❑ TB is an infectious disease caused by the *Mycobacterium tuberculosis*. It typically affects the lungs (pulmonary TB) but can also affect other sites (extra pulmonary TB). The disease spreads when people who are sick with pulmonary TB exhale bacteria into the air, for example by coughing. Overall, a relatively small proportion (5–15%) of the estimated 1.7 billion people infected with *M. tuberculosis* will develop TB disease during their lifetime. However, the probability of developing TB disease is much higher among people infected with HIV, and also higher among people affected by risk factors such as under-nutrition, diabetes, smoking and alcohol consumption.

### Zoonotic TB

- ❑ Zoonotic TB is predominantly caused by *M. bovis*, which belongs to the *M. tuberculosis* complex. In humans, there were an estimated 147,000 new cases of Zoonotic TB and 12,500 deaths due to the disease in 2016. This burden of disease cannot be reduced without improving standards of food safety and controlling bovine TB in the animal reservoir.
- ❑ The organism is host-adapted to cattle, where it is referred to as bovine TB; it also causes TB in other animal species, including wildlife. Bovine TB has an important economic impact and threatens livelihoods.
- ❑ In 2016–2017, a roadmap for zoonotic TB was developed by the tripartite of WHO, the World Organisation for Animal Health (OIE) and the Food and Agricultural Organization of the United Nations (FAO), together with the International Union Against Tuberculosis and Lung Disease. The roadmap calls for a multidisciplinary “One Health” approach that includes a more comprehensive analysis of risks, better coverage of interventions, more efficient use of resources, reduced costs and, ultimately, improved health of human and animal populations.

## Drug-resistant TB

- Drug-resistant TB threatens global TB care and prevention, and remains a major public health concern in many countries. Three major categories are used for global surveillance and treatment. MDR-TB is TB that is resistant to both rifampicin and isoniazid, the two most powerful anti-TB drugs; it requires treatment with a second-line regimen. RR-TB also requires treatment with second-line drugs. With increasing use of Xpert MTB/RIF for simultaneous detection of TB and resistance to rifampicin, a growing number of RR-TB cases (without further testing for isoniazid resistance) are being detected and notified.

### Steps taken in India

- In India, for decades, the majority of patients diagnosed and treated by private health care providers were not reported to the country's national TB programme, resulting in underreporting of TB cases. To address this, the Indian government implemented a policy of mandatory TB notification in 2012 and created a national web-based reporting system called Nikshay. This facilitated the reporting of TB cases, including those detected in the private sector. As a result, reporting from the private sector grew considerably. In 2015, the number of notified TB cases was 34% higher than in 2013 thanks to Nikshay.
- Innovative models for private sector engagement have been introduced in three districts – Mehsana in Gujarat, Mumbai in Maharashtra and Patna in Bihar, and later expanded to one more district - Nagpur also in Maharashtra. These include the introduction of vouchers for free diagnosis and free drugs for patients in private clinics through links with private laboratories and pharmacies in the neighbourhoods, and tiered referrals to access these services. These models have produced impressive results.
- New drugs to treat MDR-TB have been introduced as well as the new shorter MDR-TB regimen, which cuts the duration of treatment in half - from two years to less than one year.
- India TB Research and Development Corporation” (ITRDC), a flagship initiative by ICMR, aims to bring together all major national and international stakeholders to develop new tools (drug, diagnostics, vaccines) for TB. The vision of the corporation is “To achieve Elimination of TB from India by investing in new tools (drugs, diagnostics, and vaccines) as well as provide these solutions to the world.
- Government of India is implementing the Revised National Tuberculosis Control Programme in the country. Under this programme, diagnosis and treatment facilities including anti-TB drugs are provided free of cost to all TB patients.
- India has signed a ‘call for action’ pledging to scale-up efforts and implement adequately funded, innovative, multi-sectoral and comprehensive measures to achieve the global target to end the disease by 2030.

## Issues related to TB treatment in India

- Inadequate diagnostics:** India is still heavily dependent on smear microscopy, one of the oldest ways of diagnosing tuberculosis. This technique can detect tuberculosis in only 70% of cases, and is not a very sensitive test for pediatric tuberculosis, tuberculosis in HIV patients and extra-pulmonary tuberculosis.
- As per WHO guidelines, all patients suspected of having tuberculosis infections should be screened using the cartridge-based nucleic acid amplification test or CB-NAAT, which can pick tuberculosis bacteria even in small samples or when there are only smaller amounts of bacteria. The machine also picks out bacteria that are resistant to the tuberculosis drug rifampicin. The results are ready in two hours' time.

- ❑ Many countries such as Indonesia, Brazil, Kenya, and Zimbabwe, offer CB-NAAT testing as an initial test for all suspected tuberculosis cases.
- ❑ **Disruption in medicine supply:** Every year, some parts of India are affected by medicine shortages. State TB officers of Odisha, Jharkhand and Uttar Pradesh have confirmed stock-outs of different TB drugs at different points of time.
- ❑ The government program is supposed to ensure that TB patients all over India get their daily regimen of drugs and is phasing out the intermittent regimen, which consists of three doses every week. The intermittent regimen triples drug resistance as opposed to daily treatment. Currently, India and China are the only countries among the 29 studied which follow intermittent dosing.
- ❑ Moreover, two new drugs – bedaquiline and delamanid – that have been approved by the World Health Organisation for treatment especially of drug-resistant tuberculosis, are not being used extensively in India. While access to bedaquiline is limited to six centers including Delhi, Mumbai, Chennai, Ahmedabad, and Guwahati, delamanid has not yet been registered as a drug in the country.
- ❑ **Lack of counseling:** Counseling is an important part of the WHO's tuberculosis control strategy and, on paper, India's tuberculosis programme provides for counselors for MDR-TB patients at the district level. However, many of these positions lie vacant, say, health activists.
  - While India's HIV control program has Integrated Counseling and Testing Centres where counselors explain the disease, how drugs should be taken and how the spread of the disease can be prevented, there is very little infrastructure for a similar service in the tuberculosis programme. The National Strategic Plan had aimed to appoint treatment counselors at every health facility by 2017.

### Some persistent barriers to TB control in the SEA Region include:

- ❑ Absence of universal health coverage, as well as limited access to quality health services and fully subsidized treatment for chronic diseases;
- ❑ Widespread shortage and uneven distribution of well-trained, well equipped and motivated health workers;
- ❑ Insufficient data collection capacity, leading to gross neglect of TB monitoring and under-reporting of incidence;
- ❑ Failure to address poverty, under-nutrition and risk factors that adversely influence exposure to tuberculosis;
- ❑ Insufficient strategies to address populations at risk, including targeted screening and investigation;
- ❑ Lack of regulatory systems and weak accountability mechanisms, as well as poor governance in public health management; and
- ❑ Insufficient long-term strategies to address the socio-economic factors that germinate tuberculosis – poverty reduction, better nutrition, better living, and work conditions, as well as strategies to mitigate the impact of migration.

### New initiatives for TB control

- ❑ **NIKSHAY- A web-based solution for monitoring of TB patients:** To monitor Revised National Tuberculosis Programme (RNTCP) effectively, web enabled and case-based monitoring application called NIKSHAY has been developed by National Informatics Centre (NIC). This is used by health functionaries at various levels across the country in association with Central TB Division (CTD), Ministry of Health & Family Welfare. NIKSHAY covers various aspects of controlling TB using technological innovations. Apart from web-based technology, SMS services have been used effectively for communication with patients and monitoring the program on day to day basis.

- ❑ **National Health Policy, 2017:** The policy acknowledges HIV and TB co-infection and increased incidence of drug-resistant tuberculosis as key challenges in control of Tuberculosis. The policy calls for more active case detection, with a greater involvement of private sector supplemented by preventive and promotive action in the workplace and in living conditions. Access to free drugs would need to be complemented by affirmative action to ensure that the treatment is carried out, dropouts reduced and transmission of resistant strains is contained.

## Way forward

- ❑ Ending TB by 2030 would require a 90% reduction in TB deaths and an 80% reduction in annual TB cases, yet since 2000 the mortality rate has only declined by 37%. TB remains the leading infectious killer, responsible for 1.3 million deaths among HIV-negative individuals (down from 1.7 million in 2000). A further 374,000 deaths were reported among people living with HIV, for whom the disease is still the leading killer.
- ❑ People living with HIV have an estimated 26 to 31-fold greater risk of contracting TB, particularly when they are not on antiretroviral treatment (ART) as their immune systems are weakened making them more susceptible to co-infection. Yet thankfully, ART can reduce the risk of TB infection in people living with HIV by 65%.
- ❑ But efforts to provide preventative TB treatment have so far been uneven and insufficient. In 2016, 18 of the 30 countries with the highest burden of HIV-associated TB offered no preventative TB treatment for patients diagnosed with HIV, despite WHO recommendations.
- ❑ Recognizing the need to accelerate the response, the WHO is calling for a radical new approach to tackle TB. The social and economic drivers of the epidemic mean that TB cannot be beaten by the health sector alone; instead “a dynamic, global, multi-sectoral approach” is needed.

# Coronavirus outbreak

Coronavirus was declared global health emergency by WHO. World Health Organization (WHO) declared COVID-19 an official name for coronavirus disease.

## Background

- ❑ It is also called the Wuhan Virus.
- ❑ The first cases emerged in Wuhan in central China's Hubei province.
- ❑ A large number of patients with unexplained pneumonia were observed.
- ❑ A coronavirus is a kind of common virus that causes an infection in your nose, sinuses, or upper throat. Most coronaviruses are not dangerous.
- ❑ Often a coronavirus causes upper respiratory infection symptoms like a stuffy nose, cough, and sore throat.
- ❑ The coronavirus can also cause middle ear infections in children.
- ❑ Coronavirus can infect both animals and humans.

## Human Coronavirus Types

- ❑ Coronaviruses are named for the crown-like spikes on their surface.
- ❑ There are four main sub-groupings of coronaviruses, known as alpha, beta, gamma, and delta.

- Coronaviruses are a large family of viruses that can cause diseases ranging from the common cold to Severe Acute Respiratory Syndrome (SARS).

## Major types

- Middle East respiratory syndrome coronavirus (MERS-CoV):** caused by a novel coronavirus that was first identified in Saudi Arabia in 2012. MERS-CoV is a zoonotic virus, which means it is a virus that is transmitted between animals and people. Studies have shown that humans are infected through direct or indirect contact with infected dromedary camels. MERS-CoV has been identified in dromedaries in several countries in the Middle East, Africa and South Asia.
- SARS (Severe Acute Respiratory Syndrome):** SARS-CoV is thought to be an animal virus from an as-yet-uncertain animal reservoir, perhaps bats, that spread to other animals (civet cats) and first infected humans in the Guangdong province of southern China in 2002.

## What are the symptoms of coronavirus infection?

- Common signs include fever, cough, and shortness of breath. Serious infections can lead to pneumonia, kidney failure, and death.
- Human-to-human transmission has now been confirmed.
- Animals are the outbreak's likely primary source.
- Direct contact with farm or wild animals should be avoided.

## Why is there concern around the world?

- People see a similarity with the SARS outbreak that infected over 8,000 people and killed around 775 in more than 35 countries worldwide in 2002-03.
- The source of the virus was traced back to a colony of horseshoe bats living in remote cave in Yunnan province. The virus was carried by civet cats which are sold in markets in China.

## Global economic and financial market impact

- The outbreak has sent shivers through world financial markets, with investors drawing comparisons to the 2003 SARS (Severe Acute Respiratory Syndrome) outbreak in order to assess its potential economic impact.
- Expected annual losses from pandemic risk to be about \$500 billion — or 0.6% of global income — per year, accounting for both lost income and the intrinsic cost of elevated mortality.
- Another study by the Commission on a Global Health Risk Framework for the Future estimated that pandemic disease events would cost the global economy over 6trillioninthe21stcentury—over6trillioninthe21stcentury—over60 billion per year.
- Despite the disruption to the wider economy, virus outbreaks have tended to benefit pharmaceutical stocks, while tourism and travel-related stocks — hotels, airlines and luxury and consumer goods — tend to get punished.
- During the SARS outbreak, retail sales figures in China showed a marked drop-off as consumer spending took a hit.

## Why China has emerged as the epicentre of global outbreaks of disease

- With a population of nearly 1.4 billion and 50% of the world's livestock, China's ecology poses a risk for emerging, re-emerging, and novel diseases that could threaten China and the rest of the world.

- ❑ The reason could lie in the busy food markets dotting cities across the country — where fruits, vegetables, hairy crabs and butchered meat are often sold next to bamboo rats, snakes, turtles, and palm civets.
- ❑ The Chinese taste for exotic meats, and the high population density of cities create the conditions for the spread of zoonotic infections.
- ❑ Wherever there is close mixing of humans and animals, especially the unregulated handling of blood and other body products, as happens for example in China's animal markets, there are greater chances of transmission of a virus from animals to humans, and its mutation to adapt to the human body.
- ❑ Ebola outbreak in Africa where wild chimpanzees had the disease. It came into humans after these were killed and consumed. Animal markets are breeding grounds because there is free interchange of pathogens between species and mutations.

## Plasma Bank

- ❑ Delhi Chief Minister Arvind Kejriwal has inaugurated India's first plasma bank at the Institute of Liver and Biliary Sciences (ILBS) to ease access to plasma that is being used as a trial to treat Covid-19 patients.
- ❑ A healthy person between the age group of 18-60 years with no co-morbidities could be a donor.
- ❑ The reason for setting plasma bank is that people were finding it really difficult to get plasma and the situation in Delhi was turning chaotic.
- ❑ The therapy is still at a trial stage and only seven hospitals, like Lok Nayak Hospital and Max Super Specialty, Saket, have the permission to administer it.

## Similar trends

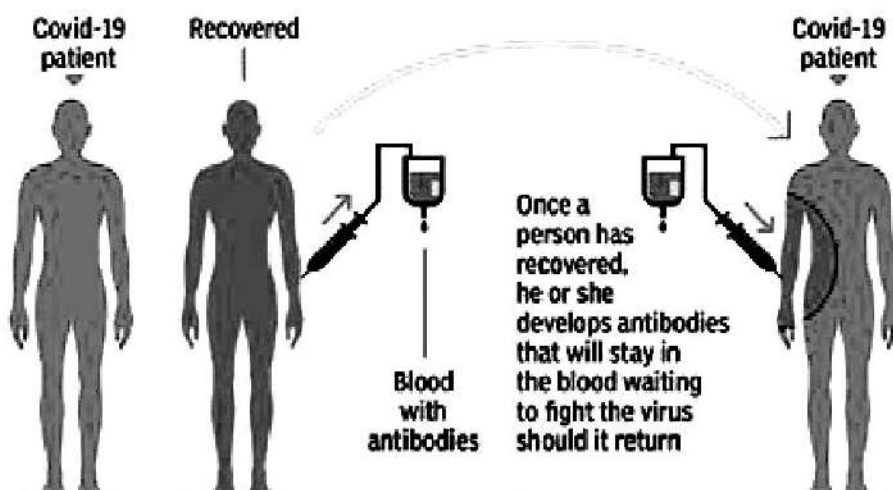
- ❑ Maharashtra has launched 'Project Platina' for plasma therapy trial.
- ❑ Similarly, states like Kerala and Punjab have similar plans to set up plasma bank.
- ❑ Countries such as China, South Korea, US and UK have been trying convalescent plasma therapy (CPT).

## WHAT IS CONVALESCENT PLASMA THERAPY?

It involves transfusing plasma retrieved from the blood of people who have recovered from Covid-19 into people suffering from the disease

### How does it work?

As people fight the Covid-19 virus, they produce antibodies that attack the virus. These antibodies are secreted by immune cells known as B lymphocytes, found in plasma or liquid part of blood, which helps the blood clot when needed and supports immunity



### □ Significance of plasma therapy

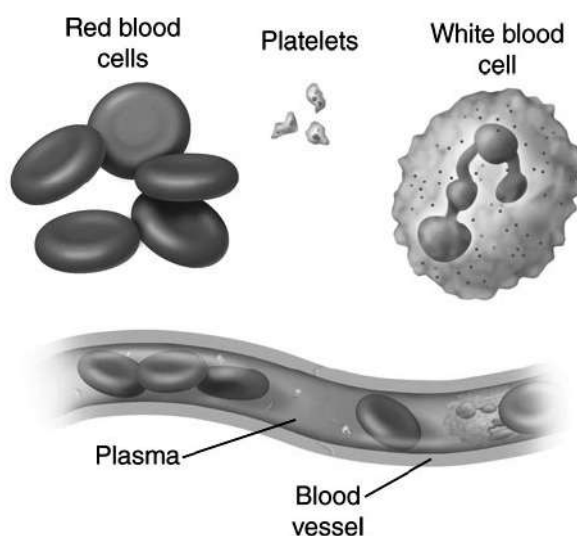
- Convalescent plasma therapy may be helpful for people with COVID-19 who are not helped by other treatments. Some people with COVID-19 become very sick and do not respond to other treatments or drugs. These people often develop acute respiratory distress syndrome (ARDS) — a severe lung condition. They often require mechanical assistance, such as a ventilator, to breathe. These people also are in danger of developing organ failure.
- It could also help other people who may have a higher risk of serious illness, such as people with chronic medical conditions, for example, heart disease or diabetes, or those who have weakened immune systems. Convalescent plasma could help these people from getting sicker if they get COVID-19.
- Convalescent plasma might also be considered for family members or health care workers who have been exposed to someone with COVID-19 to potentially prevent them from getting COVID-19.
- Plasma donation does not cause any weakness in an individual. A person can donate plasma again in a gap of 10 days.
- Trials with Plasma Therapy conducted to date have shown positive results. The patients suffering from the virus at the second stage have either a decline in oxygen levels or the respiration levels have increased.

### □ Risks associated with plasma therapy

- Blood and plasma have been used to treat many other conditions, and they're usually very safe. The risk of contracting COVID-19 infection from receiving convalescent plasma therapy has not been tested yet.
- The risk of these infections is very low, because donated blood must meet certain requirements outlined by the health authority. Before donated blood can be used, it must be tested for safety. It then goes through a process to separate out blood cells so that all that's left is plasma with antibodies. However, convalescent plasma therapy carries the risk of:
  - Allergic reactions
  - Lung damage and difficulty breathing
  - Transmission of infections, including HIV and hepatitis B and C

#### What Is Plasma?

- Blood plasma is a 'yellowish liquid' component of blood that holds the blood cells of whole blood in suspension. It is the liquid part of the blood that carries cells and proteins throughout the body.
- Plasma is the largest part of blood. It makes up more than half (about 55%) of its overall content. When separated from the rest of the blood, plasma is a light yellow liquid. Plasma carries water, salts and enzymes.



- The main role of plasma is to take nutrients, hormones, and proteins to the parts of the body that need it. Cells also put their waste products into the plasma. The plasma then helps remove this waste from the body. Blood plasma also carries all parts of the blood through your circulatory system.

### **How does plasma keep a person healthy?**

- Plasma is a critical part of the treatment for many serious health problems. This is why there are blood drives asking people to donate blood plasma.
- Along with water, salt, and enzymes, plasma also contains important components. These include antibodies, clotting factors, and the proteins albumin and fibrinogen. When a person donates blood, healthcare providers can separate these vital parts from plasma. These parts can then be concentrated into various products. These products are then used as treatments that can help save the lives of people suffering from burns, shock, trauma, and other medical emergencies.
- The proteins and antibodies in plasma are also used in therapies for rare chronic conditions. These include autoimmune disorders and hemophilia. People with these conditions can live long and productive lives because of the treatments. In fact, some health organizations call plasma “the gift of life.”

### **□ Herd immunity**

- Concerns has been raised about a phenomenon known as “herd immunity” and whether it might play a role in how the COVID -19 pandemic progresses.
- UK’s Government Science community hinted at a strategy that would allow the novel corona virus to infect 60% of the country’s population so that a degree of “Herd immunity” could be achieved.
- Following widespread criticism, and with Imperial College London projecting a dire scenario if the pandemic remains uncontrolled, the UK has now retracted — and is looking at self -isolation for the elderly.

### **□ What is Herd Immunity?**

- Herd immunity refers to preventing an infectious disease from spreading by immunising a certain percentage of the population. While the concept is most commonly used in the context of vaccination, herd community can also be achieved after enough people have become immune after being infected.
- The premise is that if a certain percentage of the population is immune, members of that group can no longer infect another person. This breaks the chain of infection through the community (“herd”), and prevents it from reaching those who are the most vulnerable.

### **□ How does Herd Immunity work?**

- The scientific principle is that the presence of a large number of immune persons in the community, who will interrupt the transmission, provides indirect protection to those who are not immune.
- To estimate the extent of spread and immunity, epidemiologists use a measure called the ‘basic reproductive number’ ( $R_0$ ). This indicates how many persons will be infected when exposed to a single case; an  $R_0$  of more than 1 indicates one person can spread the infection to multiple persons.
- Scientific evidence shows that a person with measles can infect around 12-18 persons; and a person with influenza can infect around 1.2-4.5 persons, depending on the season. On the basis of the available evidence from China, and according to various experts,  $R_0$  COVID-19 range between 2 and 3.
- There are three ways in which an infection can spread in a community.

- The first scenario looks at a community that is not immunised. When two infectious cases, both with an  $R_0$  value of 1, are introduced, there is a possibility of the entire community being infected, with a few exceptions.
- In the second scenario, there may be some persons who have been immunised; and only these immunised persons will not be infected when at least two infectious cases are introduced in the community.
- The third scenario is when the majority of the community is immunised. So, when two infectious cases are introduced, the spread can take place only in exceptional cases, like in the elderly or other vulnerable persons. Even in such a situation, the immunised persons protect the non-immunised by acting as a barrier — which is herd immunity.

### □ When do we achieve Herd Immunity?

- It depends on multiple factors: how effective the vaccine for a given disease is, how long-lasting immunity is from both vaccination and infection, and which population forms critical links in transmission of the disease.
- Mathematically, it is defined on the basis of a number called “herd immunity threshold”, which is the number of immune individuals above which a disease may no longer circulate.
- The higher the  $R_0$ , the higher the percentage of the population that has to be immunised to achieve herd immunity.
- Polio has a threshold of 80% to 85%, while measles has 95%. With the current data for COVID-19, experts have estimated a threshold of over 60%. That means more than 60% of the population needs to develop immunity to reach the stage of herd immunity.

### □ Why is herd immunity not safe against COVID-19?

- It is very risky to seek herd immunity by allowing a large proportion of the population to get infected. Such a strategy at this stage, experts have underlined, would be based on many unknowns and variables.
- To begin with, much about the behaviour of the pathogen is still unclear. There isn't enough statistically significant data to estimate conclusively how many persons can get the virus from a single infected person.
- Second, it can take months, or even longer, to build group immunity to COVID-19. During that time, the need is to protect people who are at greater risk; the numbers so far indicate that people above 55, especially those with co-morbidities like cardiovascular disease and hypertension, are the most vulnerable.
- Third, while herd immunity may come about from a pandemic because the people who survive may develop immunity — they also may not — it is important to note that for COVID-19, we still don't know whether one can become immune to the virus. Nor is it clear whether a person who develops immunity will remain permanently immune.

## Generic Drugs in India

- A generic medicine is a medicine that is similar to an original, brand-name medicine.
  - It has the same active ingredient as the original medicine, and
  - It is made to the same standard to make sure it is as safe and effective.

## ❑ Significance of generic drugs

- Although generic drug active ingredients are chemically identical to their branded counterparts, they are typically sold at a cheaper price than the brand-name drug. Generics are less expensive because the drug manufacturer does not have to duplicate the original clinical trials for effectiveness and safety, which lowers the cost to bring the drug to market. Generics are not less expensive because they are lower in quality.
- Health care costs are the second most frequent reason for rural indebtedness. A major component of health care cost is medicines. Studies show that in India the cost of medicines is anything between 50 to 80 percent of the total cost of treatment. Currently, many of the patients seeking care in Public Health Facilities have to buy medicines from retail shops and these medicines are very costly for a variety of reasons. To meet these generic drugs can play an important role in reducing the cost of health issues.

## Rules in India related to the Pharma sector

### ❑ In India, the approval, production, and marketing of quality drugs at reasonable prices are ensured by the following regulatory bodies:

#### ◦ The Central Drug Standards and Control Organization (CDSCO):

- ▶ It functions under the Ministry of Health and Family Welfare.
- ▶ It prescribes standards and measures for ensuring the safety, efficacy, and quality of drugs, cosmetics, diagnostics and devices in the country.
- ▶ Regulates the market authorization of new drugs and clinical trials standards.
- ▶ Supervises drug imports and approves licenses to manufacture the products.

#### ◦ The National Pharmaceutical Pricing Authority (NPPA), 1997:

- ▶ It functions under the Department of Chemicals and Petrochemicals.
- ▶ It fixes or revises the prices of decontrolled bulk drugs and formulations periodically.
- ▶ Updates the list under price control through inclusion and exclusion of drugs in line with prescribed guidelines periodically.
- ▶ Maintains data on production, exports and imports and market share of pharmaceutical firms.
- ▶ Monitors the shortage of medicines in addition to providing inputs to Parliament in issues pertaining to drug pricing.

**All the drugs and pharmaceuticals, unless specifically allotted to any other department, would come under the purview of the Department of Pharmaceuticals.**

#### ◦ Department of Pharmaceuticals:

- ▶ Under the Ministry of Chemicals and Fertilisers.
- ▶ The objective of giving greater focus and thrust on the development of Pharmaceutical Sector in India and to regulate various complex issues related to pricing and availability of affordable medicines, research & development, protection of intellectual property rights and international commitments related to the pharmaceutical sector which require integration of work with other ministries.

#### ◦ The Patent Act, 1970:

- ▶ The Patents Act removed composition patents for foods and drugs, and though it kept process patents, these were shortened to a period of five to seven years.

- ▶ The resulting lack of patent protection created a niche in both the Indian and global markets that Indian companies filled by reverse-engineering new processes for manufacturing low-cost drugs
- **Pricing and tax policies through DPCO and NPPA:**
  - ▶ Price control on medicines was first introduced in India in 1962 and has subsequently undergone evolution through the Drug Price Control Order (DPCO).
  - ▶ As per the directive of NPPA, the criterion for price regulation is based on the nature of the drug in terms of whether it enjoys mass consumption and in terms of whether there is lack of adequate competition for the drug.
  - ▶ Drugs with high sales and a market share of more than 50% are part of the price regulation exercise. These drugs are referred to as scheduled drugs. Historically the NPPA would intervene only if the annual price increases were more than 20%.
  - ▶ However, post-2007, the NPPA intervenes in cases where drugs have significant sales and where the annual price increases by 10%.
  - ▶ The National Pharmaceuticals Policy 2006, proposed various measures such as increasing the number of bulk drugs under regulation from 74 to 354, regulating trade margins and instituting a new framework for drug price negotiations so as to make drugs more affordable for the Indian masses, to name a few.

## Way Forward

- The government may resort for bulk procurement of medicines directly from manufacturers, quality generic medicines through a transparent bidding process. Same as case of Tamil Nadu.
- In Tamil Nadu, since 1995 all patients visiting Public Health Facilities (which in Tamil Nadu, constitute 40% of the total number of patients per as NSSO 60th round figures) get all medicines free. This has been possible because of setting up of an autonomous corporation in the Public Sector, the Tamil Nadu Medical Services Corporation (TNMSC), which procures in bulk directly from manufacturers, quality generic medicines through a transparent bidding process. TNMSC then supplies these to the Public Health Facilities (PHFs) through a demand sensitive passbook system instead of the traditional 'supply driven' inflexible system of distribution. It supplies about 260 drugs to Public Health Facilities as per its Essential Drug List and 192 'specialty' drugs for secondary and tertiary care as per need. The TNMSC procurement prices of quality generic medicines are very low; for many medicines, they are one-tenth and sometimes even one-fiftieth of the retail prices. Hence Tamil Nadu is able to provide free medicines to all indoor and outdoor patients in all PHFs (from all PHCs to all secondary and tertiary care hospitals under the State Government). The Government of Kerala has adapted the TNMSC model.
- Proper implementation of Jan Aushidhi campaign. A key initiative under the campaign would involve the opening of Jan Aushadhi stores where unbranded quality generic medicines would be sold which are available at lower prices but are equivalent in potency to branded expensive drugs.
- The challenge for the government is to balance its policy objectives of taking the power of the doctor away to prescribe brand name drugs with the reality that generic drugs in India are of questionable quality. The solution does not lie in more laws, but in providing more information to the consumer. Drug regulators in India have a vast trove of information on substandard drugs which they need to release into a searchable database.

## Stent Implants

A stent is a tiny wire mesh tube. It props open an artery and is left there permanently. When a coronary artery (an artery feeding the heart muscle) is narrowed by a buildup of fatty deposits called plaque, it can

reduce blood flow. If blood flow is reduced to the heart muscle, chest pain can result. If a clot forms and completely blocks the blood flow to part of the heart muscle, a heart attack results. Stents help keep coronary arteries open and reduce the possibility of a heart attack.

#### □ How does it work?

- Most commonly, it is used to increase the passage of blood by its placement in a blood vessel that has undergone narrowing or occlusion due to atherosclerosis (a disease in which there is deposition of plaques inside the blood vessels causing their occlusion or narrowing). It thus provides relief by improving the blood supply to the respective organ or tissue in the body.
- During an angioplasty, a stent is permanently inserted into the coronary artery. The balloon is placed inside the stent and inflated, which opens the stent and pushes it into place against the artery wall to keep the narrowed artery open. Because the stent is like woven mesh, the cells lining the blood vessel grow through and around the stent to help secure it. **“Stent is basically a scaffolding device”.**
- When the balloon inflates, the stent pops open and reinforces the artery walls. The balloon and catheter are then withdrawn and the stent remains permanently. In a few weeks, tissues from the artery lining grow over the stent.

#### □ Risk Involved in Stenting?

- The greatest risk with stent implantation is the formation of clots within the stent. Aspirin and oral anti-clotting medications are usually given after stent placement to minimize this risk, which has been reported to occur in about 1-1.5% of patients undergoing endovascular stent surgeries. There has been no evidence of long-term complications from stent implantation, according to the American Heart Association.
- A variety of complications can occur with stent grafting for emergency aneurysm repair. Movement of the stent within the vessel can occur in up to 10% of cases, requiring repeat surgery.
- Clots can occur in the vessel and migrate to other areas of the body, causing a heart attack or stroke. About 2% of patients will require an additional open surgical procedure to correct the aneurysm or complications that occur after emergency endovascular repair.

#### □ Stenting in India

- Recently several senior cardiologists in India have raised concern over the rise in the cases of the unnecessary implant of stents in India. If an audit of stent implant cases was done, over a third of the elective procedures could turn out to be needless.
- There are cases of stents being used in absolutely normal patients.
- In our country, the major gap is in the counseling which the doctor provides. Normally the patients go by the doctor's advice. In the absence of any monitoring, patients in India have no protection from unnecessary use of a stent.
- As per the study in the US, a few years ago, only half the non-emergency cardiac stenting procedures were appropriate. And the patients insist on angioplasty because they have a feeling that angioplasty will improve their long-term survival.
- Currently valued at Rs. 1,400 crores, India's stent industry is heavily import-based, which has also added to the higher procedure costs.
- There is no regulation and the Drug Controller is not capable of regulating domestic stent

manufacturers. There have been cases where the stent manufacturers have been found making stents in garages.

- There is no regulation of hospitals in India, especially in the private sector where a majority of urban Indians seek healthcare. At least 25-30% of the stenting done in this country is inappropriate.
- In the absence of any monitoring or oversight, patients in India have no protection from unnecessary use of a stent.

#### □ **Government's Initiative and Implementation of the Rules**

- In July 2016, the health ministry had announced their decision to include all kinds of **stents in the National List of Essential Medicines** in order to bring down the prices of the product. In view of this regards, the public interest litigation was filed because earlier drug manufacturing companies did not mention the maximum retail price on the stent packaging and neither did the hospitals mention the price of the stents in the bill.
- The government has included two categories of stents in the National List of Essential Medicines (NLEM), a step expected to lead to a steep drop in the prices of the device.
- The health ministry added Drug-Eluting Stents (DES) and Bare Metal Stents (BMS) to the NLEM 2015.
- The decision was based on recommendations of a sub-committee of expert cardiologists that examined whether coronary stents should be included in the NLEM and will be implemented immediately.
- In 2017, the National Pharmaceutical Pricing Authority (NPPA) has announced a ceiling on the prices of stents. The bare metal stent was capped at Rs. 7,260 while all drug-eluting stents were capped at Rs. 29,600. Previously, the price of stents ranged anything between Rs 23,000 and Rs 2.5 lakh per piece. (The above measures were the direct outcome of the public interest litigation, filed by an advocate BirenderSanghwan. The petition was filed because earlier drug manufacturing companies did not mention the maximum retail price on the stent packaging and neither did the hospitals mention the price of the stents in the bill.)
- The National Pharmaceutical Pricing Authority has directed all hospitals to issue detailed bills to patients, specifically and separately mentioning the cost of the coronary stents, along with the brand name of the manufacturer, importer, batch number and other details.
- Hospitals across the country are closely being watched by the NPPA and the State Food and Drug Administration authorities on their pattern of billing after the capping of stent prices.

## **Digital Health Technology Eco-System**

- Digital Health Technology is the convergence of Digital and Genomic Technologies with health, healthcare, living, and society to enhance the efficiency of healthcare delivery and make medicines more personalized and precise.
- The discipline involves the use of information and communication technologies to help address the health problems and challenges faced by patients. These technologies include both hardware and software solutions and services, including telemedicine, web-based analysis, email, mobile phones and applications, text messages, and clinic or remote monitoring sensors.
- In other words, generally, digital health is concerned about the development of interconnected health systems to improve the use of computational technologies, smart devices, computational analysis techniques, and communication media to aid healthcare professionals and patients manage illnesses and health risks, as well as promote health and wellbeing.

## Technology and Healthcare

### □ ICT can be used to improve healthcare services by providing:

- Information access to doctors, patients, researchers, healthcare professionals, and others to get desired changes in behaviors and outcomes of all the stakeholders.
- Design less expensive, robust and more realistic methods of testing the effectiveness of alternative clinical practices.
- Construct better measures of healthcare outcomes, delivery system characteristics, and other variables that may affect outcomes.
- By developing an electronic patient database must be developed which provides easy and quick access to large databases and data can be easily accessed and transmitted through a communication medium.
- By providing decision support systems are required to facilitate the physicians and doctors in decision making.

### □ India's initiatives towards Digitalization of Health

- The Indian government has started ambitious initiatives like Digital India and Internet of Things that intend to bridge the digital divide in India on the one hand and enabling e-delivery of services in India on the other. There are many segments of Digital India projects and e-health is one of them.
- E-health initiatives of the Indian government aimed at providing timely, effective and economical healthcare services to the Indian population. E-health is particularly relevant for masses that have little access to healthcare services in India.
- The National Health Policy of India envisions prevention of diseases and promotion of good health through cross-sectoral actions, access to technologies, developing human resources, encouraging medical pluralism, building a knowledge base, developing better financial protection strategies, strengthening regulation and health assurance.
- The National Health Policy of India also envisions Health Management Information by:
  - Ensuring district-level electronic database of information on health system components by 2020.
  - Strengthening the health surveillance system and establish registries for diseases of public health importance by 2020.
  - Establishing federated integrated health information architecture, Health Information Exchanges and National Health Information Network by 2025.

### □ Some of the initiatives are:

- **National e-Health Authority:** National eHealth Authority (NeHA) is a proposed body as a promotional, regulatory and standards-setting organization to guide and support India's journey in e-Health and consequent realization of benefits of ICT (Information and Communication Technology) intervention in Health sector in an orderly way.
- **Health Management Information System:** To monitor the performance and quality of the health services being provided under the NHM, it is important to introduce mechanisms that would strengthen the monitoring and evaluation systems, through performance statistics, surveys, community monitoring, quality assurance, etc.
- The Health Statistics Information Portal facilitates the flow of physical and financial performance from the District level to the State HQ and the Centre using a web-based Health Management

Information System (HMIS) interface. The portal will provide periodic reports on the status of the health sector.

- ◉ **Electronic Health Records:** An Electronic Health Record (EHR) is a digital version of a patient's paper chart.
- ◉ EHRs are real-time, patient-centered records that make information available instantly and securely to authorized users.
- ◉ While an EHR does contain the medical and treatment histories of patients, an EHR system is built to go beyond standard clinical data collected in a provider's office and can be inclusive of a broader view of a patient's care.
- ◉ Introducing and streamlining EHR in Indian health care would help the government address Health care from a futuristic approach than a causal one.
- ◉ **SEHAT:** To provide healthcare facilities in rural areas, the government today launched a telemedicine initiative in collaboration with Apollo Hospitals under which people can consult doctors through video link.
- ◉ The CSC will also provide diagnostic services and promote the sale of generic drugs through collaboration with the Ministry of Health, by setting up Jan Aasudhi Stores.

#### □ **Advantages of Information and Communication Technology in Health Care**

- ◉ Improved timeliness (better quality of healthcare delivery)
- ◉ Effectiveness (right intervention/audit trails for adverse events)
- ◉ Efficiency (less resources in terms of manpower, time and cost)
- ◉ Informed patients and their caregivers
- ◉ Better access
- ◉ Diagnostic accuracy
- ◉ Reduced waiting times
- ◉ Better referral management

## Health effect of Trans fat

### Context:

- The Food Safety and Standards Authority of India (FSSAI) has capped the amount of trans fatty acids (TFA) in oils and fats to 3% for 2021 and 2% by 2022 from the current permissible limit of 5% through an amendment to the Food Safety and Standards (Prohibition and Restriction on Sales) Regulations.

### Formation of Trans fat:

- These are formed during the hydrogenation of vegetable oils (adding hydrogen to liquid vegetable oils to make them more solid) to increase the shelf life of foods, and other processes

such as heating of oil at high temperature.

- ❑ Industrial trans fats are largely present in partially hydrogenated fats such as margarine, and bakery shortenings used in preparation of bakery products, and in vanaspati that is used to prepare sweets and deep fried items.

### **Harmful effects of Trans fat:**

- ❑ Trans fats are associated with increased risk of heart attacks and death from coronary heart disease.
- ❑ As per the World Health Organisation (WHO), approximately 5.4 lakh deaths take place each year globally because of intake of industrially produced trans fatty acids.
- ❑ The WHO has also called for global elimination of trans fats by 2023.
- ❑ Cardiovascular disease risk: Trans fats raise your LDL (bad) cholesterol. They also lower your HDL (good) cholesterol. High LDL along with low HDL levels can cause cholesterol to build up in your arteries (blood vessels). This increases your risk for heart disease and stroke.
- ❑ Weight gain and diabetes risk: Many high-fat foods such as baked goods and fried foods have a lot of trans fat. Eating too much trans-fat can cause you to gain weight. It may also increase your risk for type 2 diabetes. Staying at a healthy weight can reduce your risk for diabetes, heart disease, and other health problems.

## **Sustained rise in antimicrobial resistance in India**

### **Context:**

- ❑ A big chunk of patients in India may no longer benefit from carbapenem, a powerful antibiotic administered mainly in ICU settings to treat pneumonia and septicemia, as they have developed antimicrobial resistance to it, an ICMR study has found.
- ❑ The data analysis done between January 1 and December 31, 2021, pointed towards a sustained increase in drug-resistant pathogens, resulting in difficulty to treat certain infections with available medicines.

### **Meaning of AMR**

- ❑ The World Health Organisation (WHO) defines AMR as “the ability of a microorganism (like bacteria, viruses, and some parasites) to stop an antimicrobial (such as antibiotics, antivirals and antimalarial) from working against it. As a result, standard treatments become ineffective, infections persist and may spread to others.”
- ❑ One of the sources of antibiotic resistance development is the presence of antibiotics in the environment, which generates foci of resistant bacteria through bacterial exposure to antibiotics.

### **Causes of AMR:**

- ❑ Misuse of antibiotics in humans, animals, aquaculture, hospital effluents and antibiotic use in livestock and poultry contributes to AMR.

- ❑ **Poor management of waste from farms, factories, healthcare settings and households adds to this problem.**
- ❑ **The vast scale and diversity of the country in terms of population, food animal sectors (for instance, commercial and backyard farming), extent of antibiotic use adds to the challenges of addressing this multi-sectoral issue.**
- ❑ **Impact of increasing AMR:**
  - With rising AMR, antibiotics are increasingly becoming ineffective for treating diseases in humans.
  - If there is no timely containment, AMR is likely to cause nearly 10 million deaths by 2050 and result in significant global economic losses.
  - It would impact nutrition security, livelihood and hinder the attainment of the Sustainable Development Goals.
- ❑ **Challenges in preventing AMR**
  - The resistance rates reported by the hospitals and laboratories do not automatically translate to disease burden unless each resistant isolate is correlated with the clinical outcomes in the patients from whom they were isolated.
  - This has to do with inadequate hospital information systems in most public sector funded healthcare facilities in India and many low-middle income countries.
  - No new classes of antibiotics have made it to the market in the last three decades, largely on account of inadequate incentives for their development and production.
  - Lack of an urgent action is leading towards an antibiotic apocalypse – a future with bacteria becoming completely resistant to treatment.
  - In India, current effluent standards do not include antibiotic residues, and thus they are not monitored in the pharmaceutical industry effluents.
  - The National Action Plan for AMR, approved in 2017, completes its official duration this year. The progress under the plan has been far from satisfactory.
  - Too many players, missing governance mechanisms and absence of funding are the key impediments to the effective rollout of the scheme.
  - Only a fraction of the Indian data, available through the WHO-GLASS portal, has been included in the GRAM report.
  - India has been reporting high levels of resistance to fluoroquinolones, cephalosporins and carbapenems across the Gram-negative pathogens that cause almost 70% of infections in communities and hospitals.
- ❑ **Methods of controlling the spread of AMR:**
  - Tracking antibiotic use in humans, animals, fisheries, crops.
  - Ensuring effective infection prevention and control in human and animal health, community and environment.
  - Optimised use of antimicrobial agents in the health, animal and food sectors.
  - Promoting investments for AMR activities, research and innovations for AMR containment.

### □ Step taken by the government

- ICMR along with the Research Council of Norway (RCN) initiated a joint call for research in antimicrobial resistance in 2017.
- The government gathered data trend in 2015 from tertiary care Centres. This data showcased high resistance to commonly used antibiotics for treatment of bacterial infections.
- Through various national, sub-national studies conducted in various institutions in India, it was observed that over/ mis-use of antimicrobial drugs are responsible for rising antimicrobial resistance in human, animal and food sectors. Other factors are inadequate sanitation and infection control practices in health care settings and also in the community.
- Government of India has launched the 'National Programme on Containment of Antimicrobial Resistance (AMR)' under the 12th Five Year Plan under which a surveillance lab network of ten labs has been established to monitor trends of AMR in the country.
- The Schedule H1 notification of the Government of India as an amendment to the Drugs and Cosmetics Rules of 1945, came into force from Mar 1, 2014 to control the misuse of 24 antibiotics (falling under third and fourth generation) through over-the-counter (OTC) dispensing of antibiotics in India.
- The packaging of these drugs will have mandatory Schedule H1 warning printed on the label in a box with red border and the Rx symbol in red. They can be sold by pharmaceutical chemists only on production of a valid prescription. Government drug inspectors can conduct surprise checks on these registers.

## Rare Disease

### □ What is Rare Disease?

- A rare disease also referred to as an orphan disease, is any disease that affects a small percentage of the population.
- Over 300 million people are living with one or more of over 6,000 identified rare diseases around the world.
- Over 6000 rare diseases are characterised by a broad diversity of disorders and symptoms that vary not only from disease to disease but also from patient to patient suffering from the same disease.
- Relatively common symptoms can hide underlying rare diseases leading to misdiagnosis and delaying treatment.
- Quintessentially disabling, the patients quality of life is affected by the lack or loss of autonomy due to the chronic, progressive, degenerative, and frequently life-threatening aspects of the disease.
- Each rare disease may only affect a handful of people, scattered around the world, but taken together with the number of people directly affected is equivalent to the population of the world's third-largest country.

### □ What causes rare diseases?

- There are many different causes of rare diseases. The majority are thought to be genetic, directly caused by changes in genes or chromosomes.
- In some cases, genetic changes that cause disease are passed from one generation to the next.
- In other cases, they occur randomly in a person who is the first in a family to be diagnosed.

- Many rare diseases, including infections, some rare cancers, and some autoimmune diseases, are not inherited.
- The most common rare diseases identified in India are Haemophilia, Thalassemia, Sickle-cell Anaemia, Primary Immuno Deficiency, Lysosomal Storage Disorders such as Gaucher Disease, Fabry Disease, Hunter Syndrome and Pompe's Disease.

#### □ Challenges:

- **Lack of knowledge:** The lack of scientific knowledge and quality information on the disease often results in a delay in diagnosis.
- **Misdiagnosis:** As mentioned, due to the broad diversity of disorders and relatively common symptoms which can hide underlying rare diseases, initial misdiagnosis is common. In addition, symptoms differ not only from disease to disease but also from patient to patient suffering from the same disease.
- **Social and financial burden:** Also the need for appropriate quality health care engenders inequalities and difficulties in access to treatment and care. This often results in heavy social and financial burdens on patients.

#### Conclusion:

- Building awareness of rare diseases is so important because 1 in 20 people will live with a rare disease at some point in their life. Rare Disease Day improves knowledge amongst the general public of rare diseases while encouraging researchers and decision-makers to address the needs of those living with rare diseases.

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# RENEWABLE ENERGY

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## Ocean Thermal Energy Conversion (OTEC)

- ❑ Ocean Thermal Energy Conversion is an energy technology that converts solar radiation to electric power. OTEC systems use the ocean's natural thermal gradient, consequently the temperature difference between the warm surface water and the cold deep water below 600 meters by about 20 degree C, an OTEC system can produce a significant amount of power. The oceans are thus a vast renewable resource, with the potential to help us produce billions of watts of electric power.
- ❑ The cold seawater used in the OTEC process is also rich in nutrients and it can be used to culture both marine organisms and plant life near the shore or on land.
- ❑ OTEC seems most suitable, and economically viable for island countries and remote island states in tropical seas where generation can be combined with other functions, as e.g., air-conditioning and fresh water production. Several countries are actively pursuing large-scale deployment of OTEC.

### ❑ Basic Principle

- Warm water is collected on the surface of the tropical ocean and pumped by a warm water pump. The water is pumped through the boiler, where some of the water is used to heat the working fluid, usually propane or some similar material. The propane vapour expands through a turbine which is coupled to a generator that generating electric power. Cold water from the bottom is pumped through the condensers, where the vapour returns to the liquid state. The fluid is pumped back into the boiler. Some small fraction of the power from the turbine is used to pump the water through the system and to power other internal operations, but most of it is available as net power.

### ❑ Advantages of OTEC

- OTEC uses clean, renewable, natural resources. Warm surface seawater and cold water from the ocean depths replace fossil fuels to produce electricity.
- Suitably designed OTEC plants will produce little or no carbon dioxide or other polluting chemicals.
- OTEC systems can produce fresh water as well as electricity. This is a significant advantage in island areas where fresh water is limited.

- There is enough solar energy received and stored in the warm tropical ocean surface layer to provide most of present human energy needs.
- The use of OTEC as a source of electricity will help reduce the state's almost complete dependence on imported fossil fuels.

#### ❑ Disadvantages of OTEC

- OTEC-produced electricity at present would cost more than electricity generated from fossil fuels at their current costs.
- OTEC plants must be located where a difference of about 20° C occurs year round.
- Ocean depths must be available fairly close to shore-based facilities for economic operation.
- Construction of OTEC plants and laying of pipes in coastal waters may cause localised damage to reefs and near-shore marine ecosystems.
- Discharging the cold water at the oceans' surface could change local concentrations of nutrients and dissolved gases.

#### ❑ Effect of OTEC on Environment

- OTEC is unique among all energy generation technologies in that not only does it generate no carbon dioxide whatsoever, but it actually counteracts the effects of fossil fuel use. OTEC involves bringing up mineral-rich water from the depths of the oceans.
- This water will promote growth of photosynthetic phytoplankton. These organisms will absorb carbon dioxide from the atmosphere into their bodies, and when they die, or when the animals, which eat them, die, the carbon dioxide will be sequestered in the depths of the oceans. The effect is not small. Each 100-megawatt OTEC plant will cause the absorption of an amount of carbon dioxide equivalent to that produced by fossil fuel power plant of roughly the same capacity. No other energy technology ever imagined can do this. OTEC plants construction, with laying pipes in coastal waters may cause localized damage to reefs and near-shore marine ecosystems.

## Fuel Cell

- Fuel cells are electrochemical devices that convert chemical energy in fuels into electrical energy directly, promising power generation with high efficiency and low environmental impact.
- A fuel cell produces electricity, water, and heat using fuel and oxygen in the air. Water is the only emission when hydrogen is the fuel.
- As hydrogen flows into the fuel cell on the anode side, a platinum catalyst facilitates the separation of the hydrogen gas into electrons and protons (hydrogen ions). The hydrogen ions pass through the membrane (the center of the fuel cell) and, again with the help of a platinum catalyst, combine with oxygen and electrons on the cathode side, producing water. The electrons, which cannot pass through the membrane, flow from the anode to the cathode through an external circuit containing a motor or other electric load, which consumes the power generated by the cell.
- The voltage from one single cell is about 0.7 volts - just about enough for a light bulb - much less a car. When the cells are stacked in series, the operating voltage increases to 0.7 volts, multiplied by the number of cells stacked.

❑ **Most fuel cell power systems comprise a number of components:**

- **Unit cells**, in which the electrochemical reactions take place
  - **Stacks**, in which individual cells are modularly combined by electrically connecting the cells to form units with the desired output capacity.
  - **Balance of plant** which comprises components that provide feed stream conditioning (including a fuel processor if needed), thermal management, and electric power conditioning among other ancillary and interface functions.
- In a typical fuel cell, fuel is fed continuously to the anode (negative electrode) and an oxidant (often oxygen from air) is fed continuously to the cathode (positive electrode). The electrochemical reactions take place at the electrodes to produce an electric current through the electrolyte, while driving a complementary electric current that performs work on the load.

❑ **Benefits of fuel cell**

- **Low emission:** A fuel cell operating on pure hydrogen emits zero emissions at the source. Fuel cells also reduce noise emissions. Since fuel cells do not rely on combustion and have few moving parts, they are very quiet - about 60 decibels, the volume of a typical conversation. And since noise pollution is all but eliminated, fuel cells can be sited indoors or outdoors without being obtrusive.
- **High Efficiency:** As fuel cells create energy electrochemically, and do not burn fuel, they are fundamentally more efficient than combustion systems. Fuel cell systems today achieve 40-50 percent fuel-to-electricity efficiency using hydrocarbon fuels such as natural gas.
- **Energy Security:** Hydrogen can be produced from domestic resources, eliminating the need to import foreign oil.
- Because fuel cells do not have to be connected to the electrical grid, they are a form of distributed generation that allows the country to move away from reliance on high voltage central power generation, which is vulnerable to attacks and natural disasters.
- **Durability:** Whether in rough terrain or extreme climates, fuel cells can be sited wherever power is needed.
- **Scalability:** Fuel cells are modular, and can be scaled up depending on the power needs of a facility. Larger fuel cells can be linked together to achieve multi-megawatt outputs, while smaller ones can satisfy specific power needs at residential, telecommunications, or small commercial facilities.
- **Lightweight and Long Lasting:** Fuel cells are being developed for portable electronic devices such as laptops and cell phones. Fuel cells provide a much longer operating life than a battery, and since fuel cells have a higher energy density, they are lighter than an equivalent battery system. Fuel cells do not require recharging; as long as fuel is present, the system will continuously generate electricity.

❑ **Applications of Fuel Cell**

- Fuel cell applications may be classified as being either mobile or stationary applications. The mobile applications primarily include transportation systems and portable electronic equipment while stationary applications primarily include combined heat and power systems for both residential and commercial needs.
- **Transportation Applications:** All the world leading car manufacturers have designed at least one prototype vehicle using fuel cells. Some of the car manufacturers (Toyota, Ford) have chosen to feed the fuel cell with methanol, while others have preferred to use pure hydrogen (Opel has used liquid hydrogen, General Motors has stored hydrogen in hydride form).

- **Military Applications:** Fuel cells offer military advantages that can reduce the burden on soldiers and save lives in the field. As military equipment has become increasingly electronic, the power demand of soldiers in the field has increased dramatically. Unmanned aerial, ground, and underwater vehicles can all use fuel cell power to extend their range significantly while reducing heat and noise signatures.
- Other advantages afforded by fuel cells include fuel flexibility and elimination of the need to charge batteries.
- **Portable Electronic Equipment:** In addition to large-scale power production, miniature fuel cells could replace batteries that power consumer electronic products such as cellular telephones, portable computers, and video cameras. Small fuel cells could be used to power telecommunications satellites, replacing or augmenting solar panels.
- **As Backup Power:** Backup power systems provide power when the primary power source is disrupted. Fuel cells used for backup power come in many sizes and types and typically use hydrogen as their fuel. Backup fuel cells can be commercialized more quickly than other fuel cells because they do not depend on upon the implementation of a hydrogen infrastructure. Some backup power applications include computer systems, manufacturing facilities, homes, and utility substations.

## Hydroelectricity Energy

- ❑ Hydroelectricity is produced when moving water rotates a turbine shaft; this movement is converted to electricity with an electrical generator.
- ❑ **Advantages of hydroelectric power:**
  - Fuel is not burned so there is minimal pollution
  - Water to run the power plant is provided free by nature
  - Hydropower plays a major role in reducing greenhouse gas emissions
  - Relatively low operations and maintenance costs
  - The technology is reliable and proven over time
  - It's renewable - rainfall renews the water in the reservoir, so the fuel is almost always there
- ❑ **Disadvantages of power plants that use coal, oil, and gas fuel:**
  - They use up valuable and limited natural resources
  - They can produce a lot of pollution
  - Companies have to dig up the Earth or drill wells to get the coal, oil, and gas
  - For nuclear power plants there are waste-disposal problems
- ❑ **Hydroelectric power is not perfect, though, and does have some disadvantages:**
  - High investment costs
  - Hydrology dependent (precipitation)
  - In some cases, inundation of land and wildlife habitat
  - In some cases, loss or modification of fish habitat

- Fish entrainment or passage restriction
- In some cases, changes in reservoir and stream water quality
- In some cases, displacement of local populations

□ **Hydropower is non-polluting, but does have environmental impacts**

- Hydropower does not pollute the water or the air. However, hydropower facilities can have large environmental impacts by changing the environment and affecting land use, homes, and natural habitats in the dam area.
- Most hydroelectric power plants have a dam and a reservoir. These structures may obstruct fish migration and affect their populations. Operating a hydroelectric power plant may also change the water temperature and the river's flow. These changes may harm native plants and animals in the river and on land. Reservoirs may cover people's homes, important natural areas, agricultural land, and archaeological sites. So building dams can require relocating people. Methane, a strong greenhouse gas, may also form in some reservoirs and be emitted to the atmosphere.
- The land acquisition for hydroelectric projects is also a time consuming lengthy process in India. Land is required for various purposes like building dams, power house, Switch yard, etc. Constraints in infrastructure development and Land availability and acquisition are other issues of land. The various protests while acquiring land for projects are Tata Nano Project at Singur in West Bengal, Posco project in Odisha, Reliance Power's Dadri project in Uttar Pradesh, etc.
- Hydropower projects involve submergence causing the displacement of project area people. The rehabilitation of project affected people is also a major issue which is more pronounced in the case of storage-based hydropower projects, as was evident during the development of the Tehri dam. The project met with mass protests and public outcry on the issue of safety, environment and rehabilitation, resulting in unusual delays (e.g. the Tehri dam was commissioned more than 25 years after it was started). Progress of many projects has been affected on account of delay and non-clearance on environment and forest aspects.
- These factors have resulted in negative public perception about hydropower projects resulting in sustained opposition to project construction in many cases often resulting in time and cost over-runs

## Solar Energy

- The source of all energy on the earth is the sun. The sun acts as a great engine that drives winds, ocean currents, exo-genetic or denudation processes and sustains life on the earth. The energy radiated from the sun comes from the nuclear fusion process taking place in its core, where the temperature is about 15,000,000°C. The solar energy is transmitted in the form of short wave electromagnetic radiations. They travel at the speed of light (about 2, 98,000 km per second).

□ **Solar Technology**

- Solar Photovoltaic
  - ▶ Solar photovoltaic (SPV) cells convert solar radiation (sunlight) into electricity. A solar cell is a semi-conducting device made of silicon and/or other materials, which, when exposed to sunlight, generates electricity. Solar cells are connected in series and parallel combinations to form modules that provide the required power.
    - ◆ Crystalline Silicon solar cells (C-Si): Monocrystalline and Polycrystalline

- ◆ Thin-film solar cells: Amorphous Silicon Solar cells (A-Si), CIGS, CdTe
- ▶ PV modules are manufactured by assembling the solar cells after stringing, tabbing and providing other interconnections.

## □ PV System Applications

### ● PV applications include:

- ▶ Water pumping for small-scale remote irrigation, stock watering, residential uses, remote villages, and marine sump pumps;
- ▶ Lighting for residential needs, billboards, security, highway signs, streets and parking lots, pathways, recreational vehicles, remote villages and schools, and marine navigational buoys;
- ▶ Communications by remote relay stations, emergency radios, orbiting satellites, and cellular telephones;
- ▶ Refrigeration for medical and recreational uses;
- ▶ Corrosion protection for pipelines and docks, petroleum and water wells, and underground tanks;
- ▶ Utility grids that produce utility- or commercial-scale electricity; and
- ▶ Household appliances such as ventilation fans, swamp coolers, televisions, blenders, stereos, and other appliances.

### ● Advantages:

- ▶ The fuel for photovoltaic, sunlight, is practically infinite, free, and easily accessible.
- ▶ Photovoltaic panels are extremely reliable and require low maintenance even in harsh conditions.
- ▶ Photovoltaic systems are very versatile as they are suitable for loads of any size; they can provide a couple of watts for small loads like lanterns or electronic gadgets, a couple of kilowatts for loads like heavy machinery and households, or a couple of megawatts for solar power stations.
- ▶ Photovoltaic systems are versatile also in the sense that they can be stand-alone, local grid, central grid-connected or even hybrid (in conjunction with other technologies like wind or hydro) systems.
- ▶ Photovoltaic systems are an ideal choice and turn out to be cheaper for remote applications away from the grid as infrastructure costs of electricity transmission can be avoided.
- ▶ Photovoltaic systems are modular, where additional power generating capacity can readily be added.
- ▶ Photovoltaic systems last at least thirty years as typically there are no moving parts involved in electricity generation; consequently, they don't create any noise pollution.
- ▶ Photovoltaic conversion does not involve any polluting emissions, combustion, radioactivity, high temperature and pressure process or disposal or raw materials.
- ▶ Photovoltaic systems have a very short lead time for installation.
- ▶ Photovoltaic has a high rate of public acceptance and an excellent safety record.
- ▶ Photovoltaic is a green technology and has the potential to play a major role in controlling greenhouse gases and global warming.
- ▶ Photovoltaic industries create jobs in addition to energy, and help the economic development of societies.

- **Disadvantages:**

- ▶ The main disadvantage of photovoltaics is its relatively high cost compared to many other large-scale electricity generating sources. However, the cost of solar electricity has dramatically reduced over the last couple of years with advances in technology. Moreover, the cost of photovoltaics will further reduce as more and more systems will be deployed (economies of scale) and an infrastructure starts revolving around it.
- ▶ Even though the sunlight reaching earth carries 6,000 times greater energy than the global requirement, the power density of sunlight is relatively low. This means that photovoltaics tend to be less suited for applications that are physically small compared to the energy they require.
- ▶ The output of photovoltaic systems is variable depending on the availability of solar radiation. Areas with greater cloud cover and shorter days will experience lower power generations, and such systems have to be designed accordingly.
- ▶ Photovoltaic energy is typically stored in batteries, which increases the costs and maintenance of such systems. However, there is a tremendous thrust to improve energy storage technologies such as solar-hydrogen systems.
- ▶ Photovoltaic modules are typically only 13-18% efficient; this low efficiency is one of the dominant causes for the high cost. Again, this technology is aggressively pursued to further photovoltaic cell and system efficiency.

- **Solar Thermal**

- ▶ Solar Thermal Power systems, also known as Concentrating Solar Power systems, use concentrated solar radiation as a high temperature energy source to produce electricity using thermal route. High temperature solar energy collectors are basically of **three types**:
- ▶ Parabolic trough system: at the receiver can reach 400°C and produce steam for generating electricity.
- ▶ Power tower system: The reflected rays of the sun are always aimed at the receiver, where temperatures well above 1000°C can be reached.
- ▶ Parabolic dish systems: Parabolic dish systems can reach 1000° C at the receiver, and achieve the highest efficiencies for converting solar energy to electricity.

- **Solar Water Heater**

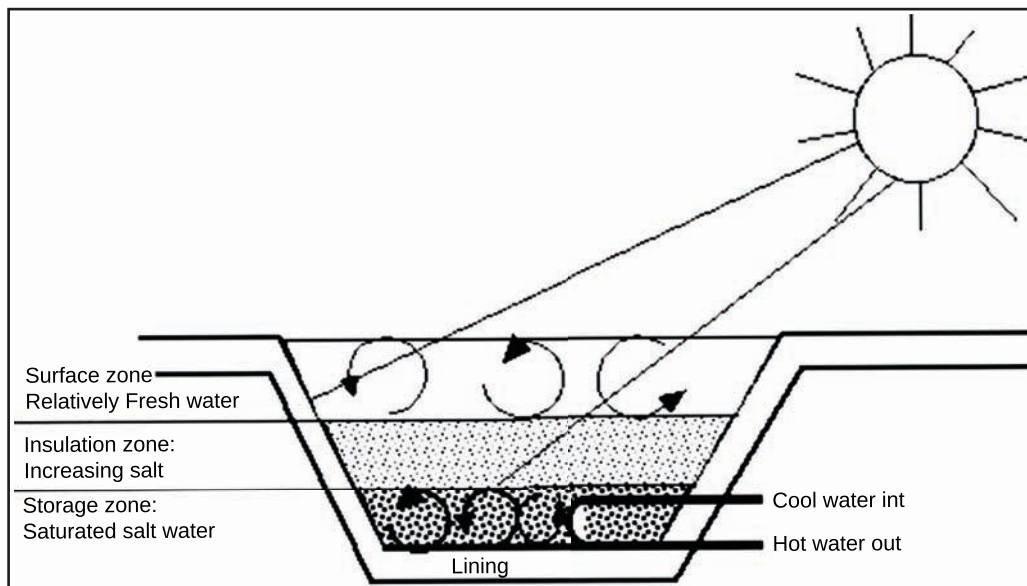
- ▶ Solar Water Heater is a device that helps in heating water by using the energy from the Sun. This energy is totally free. Solar energy (sun rays) is used for heating water. Water is easily heated to a temperature of 60-80°C. **Solar Water Heaters (SWHs)** of 100-300 litres capacity are suited for domestic use. Larger systems can be used in restaurants, canteens, guest houses, hotels, hospitals etc.
- ▶ A 100 litres capacity SWH can replace an electric geyser for residential use and may save upto 1500 units of electricity annually. The use of 1000 SWHs of 100 litres capacity each can contribute to a peak load saving of approximately 1 MW. A SWH of 100 litres capacity can prevent emission of 1.5 tonnes of carbon dioxide per year.

- **Working**

- ▶ The Sun's rays fall on the Collector Panel (a component of Solar Water Heater). A black absorbing surface (absorber) inside the collectors absorbs solar radiation and transfers the heat energy to water flowing through it. Heated water is collected in a tank which is insulated to prevent heat loss. Circulation of water from the tank through the collectors and back to the tank continues automatically due to thermo siphon principle.

## □ Solar Lantern Programme

- Objectives
  - ▶ To reduce the consumption of kerosene for lighting purposes by replacing the kerosene lanterns and wick lamps by Solar Lantern.



- ▶ To improve the quality of life in rural areas through the use of environment friendly solar lighting systems, which do not need any fossil fuels, do not emit any pollutants and are free from health and fire hazards; and
- ▶ To provide an alternative for meeting small lighting requirements
- **Programme Implementing Organizations**
  - ▶ The Solar lantern programme is implemented only through the **state nodal agencies/ Departments (SNAs)** and the AkshayaUrja shops. Shops opened / managed by manufacturers or their associations will not be eligible under the scheme. The SNAs will not be allowed to allocate targets to the manufacturers to market the lanterns on their behalf. Further, the Ministry will not allocate targets for direct marketing by the manufacturers, their associations or NGOs etc.

## □ Solar Pond

- A solar pond is a pool of saltwater which acts as a large-scale solar thermal energy collector with integral heat storage for supplying thermal energy. A solar pond can be used for various applications, such as process heating, desalination, refrigeration, drying and solar power generation.
- **Basic principle**
  - ▶ In a SS.5, and 1 m respectively.
- **Major advantages:**
  - ▶ The heat storage is massive, so energy can be extracted day and night - hence it is a source of 'base load' solar power - no batteries or other storage needed.
  - ▶ Solar ponds can have very large heat collection area at low cost.
  - ▶ The major production potential is during peak electrical power demand (and price) in mid-summer

- ▶ The technology and scientific principles for collection and extraction of heat and its conversion to electricity are well understood and well documented in scientific papers.

- ▶ Any qualified engineer would be able to build one of these systems (being a refrigeration specialist would be useful if you wanted to build a Rankine engine)

The first solar pond in India was built at the Central Salt and Marine Chemicals Research Institute in Bhavnagar, Gujarat, in 1970. This solar pond was based on bittern, which is a waste product during the production of sodium chloride from sea water.

The largest operative solar pond project in the world is located in Bhuj, in the state of Gujarat.

#### ◉ Challenges

- ▶ **Efficiency issue:** Despite huge breakthrough in technology, the efficiency of conversion is still very low. Example crystalline silicon PV cell (14-16%).
- ▶ **Power grid integration:** Variable output and lack of grid convertibility makes transmission and distribution expensive.
- ▶ **Location dependency:** Remote location of solar plants (away from main centers of consumption), incurs huge transmission infrastructure cost. It also makes it prone to regional politics.
- ▶ **Storage:** There is an immediate need to increase the storage capacity and reduce storage expenses, to keep up with production.
- ▶ **Maintenance:** Huge cost of maintenance (dust cleaning, installation of RO to soften water for cleaning panels) makes it economically unviable. The total life cycle cost to energy production is far more than conventional sources.
- ▶ **Funding:** In a volatile policy environment (India lost in WTO over the domestic content provision) and unfriendly tax policy, funding becomes a problem as clean energy projects have a long gestation period.

#### □ Solar Initiatives

- ◉ Capacity of the scheme for “Development of Solar Parks and Ultra Mega Solar Power Projects” has been enhanced from 20,000 MW to 40,000 MW. **35 solar parks of aggregate capacity 20,514 MW have been approved in 21 States.**
- ◉ Kurnool Solar Park in Andhra Pradesh with 1000 MW capacity has already been commissioned and is operational. With commissioning of **1000 MW** capacity at single location, **Kurnool Solar Park has emerged as the World’s Largest Solar Park.**
- ◉ **3 new solar parks have been approved** in this year at Rajasthan (1000 MW), Gujarat (500 MW) and Mizoram (23 MW) after issue of Guidelines for Enhancement of capacity from 20, 000 MW to 40, 000 MW under Solar Park Scheme.
- ◉ **Solar tariff has declined to lowest level of Rs 2.44 /kWh.**
- ◉ Several schemes namely (i) Defence scheme (ii) Central Public Sector Undertakings (CPSUs) scheme (iii) Bundling scheme (iv) Canal Bank/ Canal Top scheme (v) VGF Scheme (vi) Solar Park scheme (vii) Solar rooftops, have been initiated/launched by the Ministry under National Solar Mission which are under implementation.
- ◉ Under **Defence scheme** against a target of 300 MW, 357.50 MW has been sanctioned; under **Central Public Sector Undertakings (CPSUs) scheme** against a target of 1000 MW, entire capacity sanctioned; under **3000 MW Bundling scheme**, Tranch-I: 3000 MW has been tendered; under **100 MW Canal Bank/ Canal Top scheme**, all capacity sanctioned; under **2000 MW & 5000 MW VGF Scheme**; and under **20,000 MW Solar Park scheme**, 35 Solar parks have been approved in 21 States with aggregate capacity of 20,514 MW.

- Ministry is implementing Grid Connected Rooftop and Small Solar Power Plants Programme which provides for installation of 2100 MW capacity through CFA/ incentive in the residential, social, Government/PSU and Institutional sectors.
- Under the programme, central financial assistance upto 30% of bench mark is being provided for such projects in Residential, Institutional and Social sectors in General Category States and upto 70% of the benchmark cost in Special Category States. For Government sector, achievement linked incentives are being provided. Subsidy/CFA is not applicable for commercial and industrial establishments in private sector.
- **Suryamitra programme** has been launched for creation of a qualified technical workforce and over **11 thousand persons have been trained** under the programme.
- Launched **mobile app ARUN (Atal Rooftop Solar User Navigator)** for ease of access of beneficiaries for request submission and awareness.
- The Government of India is in the process of formulating a Scheme '**Kisan Urja Suraksha evam Utthaan Mahabhiyan (KUSUM)**' which, inter alia, provides for:
  - ▶ installation of grid-connected solar power plants each of capacity up to 2 MW in the rural areas;
  - ▶ installation of standalone off-grid solar water pumps to fulfill irrigation needs of farmers not connected to grid;
  - ▶ solarization of existing grid-connected agriculture pumps to make farmers independent of grid supply and **also enable them to sell surplus solar power generated to DISCOM and get extra income**; and
  - ▶ solarization of tube-wells and lift irrigation projects of Government sector.
- The Solar Water Purifier is an important S&T innovation that can deliver 300-400 litres of drinking water everyday. This water purifier is ideally suited for village schools, primary health centers and tourist lodges where conventional electricity is very erratic or not available. The solar water purifier removes iron and other sediments and kills all bacteria through ultra-filtration and UV. The operational power of the system comes from sun. Two days storage capacity is inbuilt in the purifier with unique system called "Storing of Solar Energy in the form of Purified Water". Water is the mostly affected part of human life in Indian rural areas. The unavailability of safe potable drinking water and the use of contaminated water lead to cause waterborne diseases affecting millions of citizens. Approximately 4.7 million hours are lost each year due to illnesses caused by consuming contaminated water. Solar water purifier is a pro-people green technology device developed first time in the country with the support of DST. **Technological innovations under this project:**
  - ▶ Solar energy is saved as treated water
  - ▶ No inverter is used
  - ▶ No pollution is caused
  - ▶ Low maintenance required
  - ▶ No batteries are required
  - ▶ Development of special DC-DC converter.
- Solar jacket is a mobile energy source, especially needed for the defence personnel, forest dwellers, or other people working in far-flung areas. The jacket will have proper insulating material for use in cold regions. **The jacket provides these facilities at present:**
  - ▶ Torch with beam facilities.
  - ▶ Identification code (Illuminated).
  - ▶ Mobile Phone Charging facilities.

- ▶ GPS (optional)
- ▶ Pocket Solar Fan (optional).
- ◉ **International Solar Alliance:** India and France launched International solar alliance in COP 21 to boost solar energy production in developing countries. For India, the objective is clear, by normalizing the techniques and promoting large scale purchases worldwide, it wants to bring down the price of the technology to help accelerate development especially in less developed and developing nations. It has also been agreed to contribute \$ 30 million along with the land for building the future headquarters for The Alliance. The new body is to function from the National Institute of Solar Energy in Gurgaon, India. India will also support the Alliance for next 5 years.

## Wind Energy

- Wind energy is the kinetic energy associated with the movement of atmospheric air. Wind energy systems convert this kinetic energy to more useful forms of power.
- **Advantages of Wind Energy**
  - ◉ Wind power has far less environment impacts, there is no gas or water emissions, no radiations or solid waste production. Apart from these environmental benefits there are various operational benefits to Wind Energy like
  - ◉ The short gestation periods for installing wind turbines, and the increasing reliability and performance of wind energy machines has made wind power a favoured choice for capacity addition in India.
  - ◉ Wind power plants need very less land (less than one acre/MW for tower foundation) compared to other power generation technologies. It uses air space without effecting vegetation on the ground
  - ◉ Can be used for both distributed generation or grid interactive power generation using on-shore or off shore technologies.
  - ◉ Ranges of power producing turbines are available. Micro-turbines are capable of producing 300W to 1MW and large wind turbines have typical size of 35kW-3MW.
  - ◉ Wind turbine is suitable to install in remote rural area, water pumping and grinding mills
  - ◉ The irrigation potential and efficiency can be increased by using wind driven irrigation pumps.
- **Introduce a defining LiDAR**
  - ◉ LiDAR which stands for light detection and ranging is a remote sensing method that uses light in the form of a pulsed laser to measure range (variable distances) to the earth.
  - ◉ It can be said that wind energy can suitably aid government's programmes like electricity to every home through decentralized production, Rurban mission, Make in India Mission, Skill India Mission etc. It will help in rural development and rural employment.
- **Initiatives in Wind Sector**
  - ◉ The present wind power installed capacity in the country is around 32.75 GW. Now, in terms of wind power installed capacity India is globally placed at 4th position after China, USA and Germany.

- India has long coastline where there is a good possibility for developing offshore wind power projects. The cabinet has cleared the National Offshore Wind Energy Policy. Certain blocks near Gujarat and Tamil Nadu coast line have been identified. First LiDAR installed and commissioned off Gujarat coast for gathering wind resource data.
- Wind Forecasting:** Based on wind forecasting experience of Tamil Nadu with NIWE, MoUs for forecasting done with Gujarat and Rajasthan.
- Meso scale map** prepared for wind resource at 120 meter height, as most of turbine hub heights being installed are more than 100 meters. Total assessed wind resource of India would go up from 302 GW at 100 m to about 600 GW at 120 m); MESO scale map also prepared for Offshore wind. However for actual use these would have to be correlated with actual site specific measurements.

### □ Challenges faced

- Delay in signing of power purchase agreements by DISCOMs puts developers in quandary about the future of the projects.
- 70% of wind generation is during the five months duration from May to September coinciding with Southwest monsoon duration. This is the season when rivers usually flood with water generating cheaper secondary hydro power. Therefore generating hydroelectricity becomes economical than wind energy.
- Initial cost for wind turbines is greater than that of conventional fossil fuel generators and capacity expansion of existing hydro power plants with pumped storage hydro units.
- Wind power generation is intermittent. This creates scheduling problems.
- Accelerated depreciation and associated problem of non-operational plants is another major concern. As many of the plants were started to seek economic benefits rather than produce electricity.
- When large wind power plants are located away from the load centers, laying dedicated transmission lines to evacuate the unreliable secondary wind power is additional cost liability.
- Some other minor problems like bird kills, turbines make noise and affect TV receptions nearby.

## Concept of Green Building

- A green building uses minimum amount of energy, consumes less water, conserves natural resources, generates less waste and creates space for healthy and comfortable living.

### □ Efforts in direction of green buildings in India

- The **Indian Green Building Council**, part of the Confederation of Indian Industry (CII) was formed in the year 2001. The council offers a wide array of services which include developing new green building rating programmes, certification services and green building training programmes.
- GRIHA (Green Rating for Integrated Habitat Assessment):** The system has been developed to help 'design and evaluate' new buildings (buildings that are still at the inception stages). A building is assessed based on its predicted performance over its entire life cycle - inception through operation.
- The Indian Bureau of Energy Efficiency (BEE)** launched the Energy Conservation Building Code (ECBC). The code is set for energy efficiency standards for design and construction with any building of minimum conditioned area of 1000 Sqmts and a connected demand of power of 500 KW or 600 KVA.

### ❑ What should be done to increase share of green buildings?

- The city corporations should make these climate responsive techniques invariably a part of its bye-laws, to tame the impact of changing climate to a pronounced extent.
- Green building components should be monitored and regulated irrespective of any rating systems in cities, especially for new construction.
- The city corporations should retain the ecologically sensitive zones, like salt pans, mangroves, wetlands, lakes especially in the cities like Bangalore, Mumbai, and Delhi, where development is rampant.
- Needless to say, the youth, citizens and policy makers should be positively made aware of the urgent need of environmental issues on the sustainable development and relevant measures.
- The city and local governments can play a significant role in mainstreaming the mitigation actions into the developmental process.

### ❑ Indigenous Fuel Cell System

- The President of India, Shri Ram Nath Kovind, unveiled the first Indigenous High Temperature Fuel Cell System developed by Council of Scientific and Industrial Research (CSIR) in partnership with Indian industries under India's flagship program named "New Millennium Indian Technology Leadership Initiative (NMITLI).
- **About:**
  - ▶ A unique example of Public-Private Partnership (PPP) among CSIR's three Laboratories. The 5.0 kW fuel cell system generates power in a green manner using methanol / bio-methane, with heat and water as bi-products for further use; amounting to greater than 70% efficiency, which otherwise may not be possible by other energy sources.
  - ▶ The Fuel Cells developed are based on High Temperature Proton Exchange Membrane (HTPEM) Technology. The development is most suitable for distributed stationary power applications like; for small offices, commercial units, data centers etc.; where highly reliable power is essential with simultaneous requirement for air-conditioning.
  - ▶ This system will also meet the requirement of efficient, clean and reliable backup power generator for telecom towers, remote locations and strategic applications as well. This development would replace Diesel Generating (DG) sets and help reduce India's dependence on crude oil.
  - ▶ The developed technology is world class and the development has placed India in the league of developed nations which are in possession of such a knowledgebase. CSIR has an impressive portfolio of global patents on these developments. In the field of clean energy, Fuel Cell distributed power generation systems are emerging as promising alternative to grid power.
  - ▶ The Fuel Cells fit well in India's mission of replacing diesel with green and alternate fuels. The development of fuel cell technology is indigenous and carries immense national importance in terms of non-grid energy security.

### ❑ Hydrothermal Carbonisation

IIT Kharagpur has developed Hydrothermal Carbonisation technology which can generate energy from solid waste with high moisture content.

- **About:**
  - ▶ Hydrothermal carbonization (HTC) (also referred to as "aqueous carbonization at elevated temperature and pressure") is a chemical process for the conversion of organic compounds to structured carbons.

- ▶ It can be used to make a wide variety of nanostructured carbons, simple production of brown coal substitute, synthesis gas, liquid petroleum precursors and humus from biomass with release of energy.
- ▶ Technically the process imitates, within a few hours, the brown coal formation process (German “Inkohlung” literally “to coal process”) which takes place in nature over enormously longer geological time periods of 50,000 to 50 million years. It was investigated by Friedrich Bergius and first described in 1913.

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# **POLICIES & REPORTS RELATED TO SCIENCE**

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## **Technology Vision Document 2035**

### **Introduction**

- ❑ Technology is one of the key drivers for empowering individuals, societies and countries. Technologies that facilitate development in all its dimensions and enhance human capabilities are of particular importance.
- ❑ The role of technology in the economic progress of a nation is well recognized and appreciated, efforts are being made globally to develop technology strengths and make the industries competitive, for well-rounded development of the society.

### **About the Vision document**

- ❑ Changes in the global economic scenario, growing aspirations of Indian population for better living Technology Vision Document 2035 has been prepared for India.
- ❑ The document foresees the Indians of 2035, and technologies required for fulfilling their needs. It is not a visualization of technologies that will be available in 2035, but a vision of where country and its citizens should be in 2035 and how technology should bring this vision to fruition.
- ❑ The Aim of this 'Technology Vision Document 2035' is to ensure the Security, Enhancing of Prosperity, and Enhancing Identity of every Indian, which is stated in the document as "Our Aspiration" or "Vision Statement" in all languages of the 8th Schedule of the Constitution.
- ❑ The Technology Vision 2035 would take into account our capabilities and competitiveness, accommodate regional aspirations, priorities & disparities and placed as a referential document.
- ❑ The 12 identified sectors of Vision Document are: Education; Medical Sciences & Healthcare; Food and Agriculture; Water; Energy; Environment; Habitat; Transportation; Infrastructure; Manufacturing; Materials and Information and Communication Technology.

### **Prerogatives of the vision document**

- ❑ The Vision documents also identifies 12 prerogatives- (6 for meeting individual needs and 6 for the collective needs) that should be available to each and every Indian. These are:

- ❑ **Individual Prerogatives:-** Clean air and potable water; Food and nutritional security; Universal healthcare and public hygiene; 24x7 energy; Decent habitat and Quality education, livelihood and creative opportunities.
- ❑ **Collective Prerogatives:** - Safe and speedy mobility; Public safety and national security; Cultural diversity and vibrancy; Transparent and effective governance; Disaster and climate resilience and Eco-friendly conservation of natural resources.
- ❑ **It categorizes technologies into a 5-fold classification from an Indian perspective which is as follows:**
- ❑ **Technology Leadership** - Niche technologies in which we have core competencies, skilled manpower, infrastructure and a traditional knowledge base e.g., Nuclear Energy, Space Science.
- ❑ **Technology Independence** - Strategic technologies that we would have to develop on our own as they may not be obtainable from elsewhere e.g., Defence sector.
- ❑ **Technology Innovation** - Linking disparate technologies together or making a breakthrough in one technology and applying it to another eg., solar cells patterned on chlorophyll based synthetic pathway are a potent future source of renewable energy.
- ❑ **Technology Adoption** - Obtain technologies from elsewhere, modify them according to local needs and reduce dependence on other sources e.g., foreign collaboration in the sectors of rainwater harvesting, agri-biotech, desalination, energy efficient buildings.
- ❑ **Technology Constraints** - Areas where technology is threatening and problematic i.e. having a negative social or environmental impact because of serious legal and ethical issues e.g., Genetically Modified(GM) Crops.

## National Intellectual Property Rights Policy

### Introduction

- ❑ **Intellectual Property Rights (IPR)** refer to rights provided to individuals or organizations pertaining to specific innovation or invention in products or processes for a certain period of time. They exist in the form of patents, trademarks, Geographical Indicators (GIs), copyrights, etc. IPR intends to spur and incentivize creativity and innovation and facilitate access to knowledge in order to achieve social and economic welfare.
- ❑ India became a member of World Intellectual Property Organization (**WIPO**) in 1975.
- ❑ Department of Industrial Policy and Promotion (**DIPP**) is the nodal agency for IPR and related policy issues in India.
- ❑ India amended its Indian Patents Act, 1970 in 2005 to bring its laws in line with the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).
- ❑ **The Major Needs of Intellectual Property Rights:**
  - Prevent plagiarism.
  - Prevent others using it.
  - Prevent using it for financial gains.
  - Fulfill obligation to funding agency.
  - Support income generation strategy.

## Objectives:

A draft IPR policy developed by the government's think tank points out the following objectives:

- Proposes the establishing of an IP Promotion and Development Council (**IPPDC**), which would open IP Promotion and Development Units in all states in order to create a single window system for promotion, awareness and utilization of IP in the country.
- Calls for the creation of a Multi-Agency Task Force to coordinate between different agencies and strengthen the enforcement mechanism so as to ensure better IPR protection.
- Recommends designation of specialized patent bench in the Bombay, Calcutta, Delhi & Madras High Court for ensuring speedy disposal of patents cases; setting up branches of the Intellectual Property Appellate Board (IPAB) in the 5 regions, Ahmedabad, Bombay, Calcutta, Delhi & Madras, where Indian Patent Offices (IPOs) are functioning.
- Stresses on the need to augment the capacity and resources at the disposal of IPOs to deal with the increasing number and complexity of IPR filings in the country in a time-bound and effective manner.
- Suggests the enactment of a law to bring utility models under the IPR legal regime (to tap into the ingenuity of local innovation); introducing a first time patent fee waiver and developing a support system for Micro, Small and Medium Enterprises (MSMEs) to spur innovation.

### ● Intellectual Property:

- Intellectual property (IP) refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce.

### ● IPR:

- Intellectual property rights are the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time. These rights can include copyrights, patents, trademarks, and trade secrets.
- These rights may be enforced by a court via a lawsuit.
- The reasoning for intellectual property is to encourage innovation without the fear that a competitor will steal the idea and / or take the credit for it.

### ● What is a Trademark?

- A trademark is a sign that individualizes the goods or services of a given enterprise and distinguishes them from those of competitors. To fall under law protection, a trademark must be distinctive, and not deceptive, illegal or immoral.

### ● What is a Geographical Indication?

- A geographical indication is basically a notice stating that a given product originates in a given geographical area.

### ● What is an Industrial Design or Model?

- It is the aesthetics and ergonomics of a product. It consists of three-dimensional elements, such as the creation of the product's shape, or two-dimensional ones, such as graphics, patterns and colors.

### ● What is a Patent?

- Patent is an exclusive right granted by law to an inventor or assignee to prevent others from commercially benefiting from his/her patented invention without permission, for a limited period of time in exchange for detailed public disclosure of patented invention.

- **What is a Trade Secret?**
  - ▶ A trade secret is any information of commercial value concerning production or sales operations which is not generally known. The owner of a trade secret must take reasonable measures to maintain its confidentiality.
- **What is a Copyright?**
  - ▶ Copyright is a form of IPR concerned with protecting works of human intellect. The domain of copyright is literary and artistic works, might that be writings, musicals and works of fine arts, such as paintings and sculptures, as well as technology-based works such as computer programs and electronic databases.
- **What is a Related Right?**
  - ▶ Related Rights or Neighboring Rights are rights that in certain respects resemble copyright. The purpose of related rights is to protect the legal interests of certain individuals, namely performers, producers and broadcasters, and to help them deliver their message to the public.
- **Why Countries Care for IPR and Seek to Promote and Protect it?**
  - ▶ New innovations in all IPR domains lead to Human progress and advancement.
  - ▶ Legal protection of new innovations encourages safe spending on other innovations.
  - ▶ Caring for and protecting IPR contribute to achieving economic and social development.

## STI Policy 2013 of India: Analysis

India's new Science, Technology, and Innovation (STI) Policy was released in January 2013. It envisions placing India among the top five global scientific powers by 2020. It proposes to use STI for faster, sustainable and more inclusive growth with a focus both on STI for people and people for STI. It plans to boost innovation through research and development (R&D) driven by private sector participation, publishing more research papers, achieving gender parity in S&T and global cooperation.

### The Key Features of the STI Policy 2013 are:

- ❑ **Budget:** Increasing the R&D spending to 2% in the next five years' time through PPP; creating a conducive environment for encouraging private sector investment in R&D.
- ❑ **Manpower:** Promotion of spread of scientific temper amongst all sections of society; attracting talented and bright minds towards careers in science, research and innovation; increasing the number of R&D personnel by 66% in next five years; creating environment for women to enter in R&D field; and setting up inter-university centers, bringing together different disciplines of humanities and science together.
- ❑ **Business:** Identifying 10 sectors of high potential and putting more resources into them for STI; increasing by two folds the global share of high tech products; increasing R&D intensity in service sector, small and medium scale enterprises; sharing the risk on R&D investments with private sector; providing new financing mechanisms for entrepreneurs; creating a public procurement policy that favors indigenous innovations; achieving synergy between R&D policy for agriculture vs. STI policy.
- ❑ **Climate Change:** Active role in the implementation of the National Action Plan for Climate Change (NAPCC); and providing incentives for green manufacturing.
- ❑ **PPP:** Setting up of a National Science, Technology and Innovation Fund to facilitate investments in S&T projects under PPP mode and large scale R&D facilities under PPP mode; establishing technology business incubators and science-led entrepreneurship; and treating private sector R&D institutions at par with public sector institutions for giving public funds.

- ❑ **IPR:** Modification of Intellectual Property Rights (IPR) for social goods and IPR generated under PPP; setting up of a regulatory and legal framework for sharing IPRs between Investors and inventors.
- ❑ **Participation:** Encouraging participation of all STI stakeholders including - a) Women and differently-abled and disadvantaged sections of society; b) NGO's who would play pivotal role for delivery science-tech-innovation outputs especially related with rural / grassroots level; c) State Governments by setting up state-specific plans and strengthening the State Sci-Tech Councils / Boards and fine-tuning five-year plan schemes in response to rapid changes in S&T; d) International partners by forging strategic alliances both bilateral and multilateral.
- ❑ **Public awareness:** Releasing white papers on new science projects to generate public awareness about the ethical/social/ economic implications of science-tech-R&D initiatives.

## Critical Analysis of Policy

- ❑ Unfortunately, the Policy adopts a '**one-size, fit-all**' approach towards STI. Though the basic policy tools may remain the same across the board, customized policy tools may be required for each sector. For instance, the policy framework The Policy has also totally overlooked Traditional Knowledge ("TK") especially when the potential is untapped. There is ample scope for leveraging our TK for achieving the larger objectives of the Policy. The Policy fails to integrate the aforesaid aspect into its framework.
- ❑ It is to be noted that the Policy seeks to "**vertically integrate all dimensions of STI into the socio-economic processes**" and promote "**inclusive innovation**". The Policy, further, states that the focus is on "both people for science and science for people". Perceived in this context, its muted approach towards leveraging TK is perturbing. Further the good and bad of Indian policy initiatives for scientific research and innovation', several forthcoming initiatives of the government are stalled either at Parliament or in Ministry of S&T.
- ❑ There exists **regulatory deficit** in Indian science which is a debilitating factor for any forthcoming wholesome and sustainable progress in STI. The Policy should have called for a **quick review and implementation** of the same as these delays dent the objectives stated to be achieved.
- ❑ The Policy does not clearly put forward its approach vis-à-vis IPR. It also does not explore the linkage between traditional IP protection and innovation. The Policy states that it will modify "IPR policy to provide for marching rights for social good when supported by public funds and for co-sharing, IPRs generated under PPP." It does not define the expression "marching rights". Considering the context, it is likely to mean that where public funds are used, IPRs will be modified to direct the benefits of the innovation towards social good. The aforesaid objective is couched in abstract terms and the Policy does not set out or at least provide an outline for achieving the aforesaid objective. Further, the Policy merely puts forward mechanisms such as "Small Idea-Small Money" and "Risky Idea Fund" for supporting innovation incubators without elaborating upon them.
- ❑ Further rather than focusing on enhancing the R&D facilities in universities (which should have received the primary focus), it intends to multiply inter-university centers "to enable a wide cross-section of university researchers to access advanced research facilities and equipment which are otherwise not available in university environments."

## National Science Technology and Innovation Policy (STIP 2020)

The **Office of the Principal Scientific Adviser** to the Government of India (Office of PSA) and the **Department of Science and Technology (DST)** have jointly initiated a decentralized, bottom-up, and inclusive process for the formulation of a new '**national Science Technology and Innovation Policy (STIP 2020)**'.

## About

### □ About S & T Policy

- The fifth S&T policy of India is being formulated at a crucial juncture when India and the world are tackling the COVID-19 pandemic.
- This is only the latest among the many important changes in the past decade that have necessitated formulation of a new outlook and strategy for Science, Technology, and Innovation (STI).
- As the crisis changes the world, the new policy with its decentralized manner of formation will reorient STI in terms of priorities, sectoral focus, the way research is done, and technologies are developed and deployed for larger socio-economic welfare.
- The STI Policy for the new India will also integrate the lessons of COVID-19 including building of an Atmanirbhar Bharat (self-reliance) through ST&I by leveraging our strengths in R&D, Design, S&T workforce and institutions, huge markets, demographic dividend, diversity and data.

### □ The formulation process

- The STIP 2020 formulation process will be six-months long.
- It is organised into 4 highly interlinked tracks, which will reach out to around 15000 stakeholders for consultation in the policy formulation.
- **Track I** involves an extensive public and expert consultation process through Science Policy Forum- a dedicated platform for soliciting inputs from larger public and expert pool during and after the policy drafting process.
- **Track II** comprises experts-driven thematic consultations to feed evidence-informed recommendations into the policy drafting process. Twenty-one (21) focused thematic groups have been constituted for this purpose.
- **Track III** involves consultations with Ministries and States
- **Track IV** constitutes apex level multi-stakeholder consultation

### □ About the Organisations

- **Office of the Principal Scientific Adviser**
- India has had a Principal Scientific Adviser (PSA) since 1999.
- A. P. J. Abdul Kalam was the first PSA from 1999–2001
- R. Chidambaram succeeded Dr. Kalam and was the PSA from 2001-2018.
- Professor K. Vijay Raghavan succeeded Dr. Chidambaram on April 3, 2018 and is the current PSA.
- The Office aims to help enable and empower all spheres of science and technology so that the execution of programmes is effective for society and the economy.
- **Department of Science and Technology (DST)**
- Department of Science & Technology (DST) were established in May 1971.
- The organisation aims to promote new areas of Science & Technology and to play the role of a nodal department for organising, coordinating and promoting S&T activities in the country.

### ❑ Previous S&T policies in India

- ◉ **Scientific Policy Resolution 1958:** India's first major science policy can be traced back to the year 1958. SPR1958 laid the foundation of scientific enterprise and scientific temper in India.
- ◉ **Technology Policy Statement 1983:** The primary feature of TPS1983 was technological self-reliance through promotion and development of indigenous technologies. Adoption of indigenous technology would reduce vulnerabilities in critical areas and would help maximise the utilisation of local (human and material) resources.
- ◉ **Science and Technology Policy 2003:** Aim was to keep pace with science and technology, to stay competitive in an increasingly globalised world, and to meet the primary goal of equitable and sustainable development. It called to invest heavily into the R&D sector with an aim of increasing investment to 2% of GDP.
- ◉ **Science Technology Innovation Policy 2013:** The decade of 2010 to 2020 was declared as a decade of innovation. It was acknowledged that in order to stay globally competitive, it was necessary to make a transition into a knowledge-based economy. This policy document was a step in the direction towards building a robust national innovation ecosystem.

## The Paradox of Innovation

- ❑ The World Intellectual Property Organisation (WIPO) released the rankings as part of its Global Innovation Index 2018.
- ❑ WIPO ranked India the world's top exporter of information, computer and telecom services, and also the 57th most innovative nation. Global Innovation Index ranks countries on an annual basis for their contribution to successful innovations based on their capacity.

### ❑ Innovation Defined

- ◉ Why do some nations prosper while others struggle? The reason is the urge for innovation. Innovation is increasingly seen as the key to unlocking competitive advantage, as much for countries as for companies.
- ◉ Innovation involves thinking differently, creatively and insightfully to create solutions that have an impact in terms of social and economic value.
- ◉ Innovation is critical for creating competitive or collaborative advantage, problem-solving to address the challenges of our times, improving governance, and generating intellectual value.

### ❑ Significance of innovation

- ◉ Innovation has a critical role to play in the processes of India's economic and social growth and development. Innovation can make a difference in addressing urgent developmental challenges such as providing access to drinking water, eradicating neglected diseases or reducing hunger.
- ◉ At the grass-root level, it often involves local communities, utilizing locally owned knowledge to create innovations which can then be disseminated to other communities and transferred to other activities. Innovation has gone beyond the confines of traditional research and development (R&D) and is providing solutions across sectors, and has become vital for driving productivity and competitiveness.

### ❑ Rising Innovation in India

- Some sections of the society are claiming that innovation in India is happening both in large corporations as well as at the grassroots level in remote villages. Their argument is based on the following developments:
- Improvement in Global Innovation Index:** India has moved up three ranks to 57th in the 2018 Global Innovation Index compared to 2017. It's a significant improvement from the 81st position out of 140-odd countries in 2016. Even countries such as Trinidad and Tobago, Bosnia and Herzegovina, and Morocco were ahead of India that year.
- Increase in international patent applications:** International patent applications filed by a country are used to assess the innovative activity of that country. Now, according to figures released by the Geneva-based World Intellectual Property Organisation, international patent applications filed from India rose 8.3 percent to 1,529 (1,423 last year).

### ❑ Real Situation

- In The Times Higher Education World Reputation Rankings 2017, no Indian university made it to the top-100 list, though Asian universities improved their performance, with 28 of them making to the list.
- Last year, The IITs ranked 71 on the Reuters Top 75 — Asia's Most Innovative Universities list that identifies institutions doing the most to advance science, invent new technologies and help drive the global economy. The Indian Institute of Science in Bengaluru, the only other Indian institute in the list, was ranked 72.
- Over 70 percent of the patents filed in the country are by multinational companies; Indian companies and academia share the remaining 30 percent.
- In the last 60 years or more, India has failed to produce a single groundbreaking innovative idea that made a notable economic impact. No Indian citizen has won a Nobel in any tech discipline since independence. The only resident Indian to have won Nobel was CV Raman, in 1930.
- The country has become the third-largest start-up ecosystem, but it lacks successful innovation. That's why 90 percent of Indian start-ups fail within the first five years.
- India has only two research organizations of repute – the Indian Institute of Science and the Indian Space Research Organisation.

### ❑ What are the Reasons behind Poor Innovation in our Higher Education Systems?

- Less number of researchers:** Most Indian universities lack focus on research, which in effect reduces them to **teaching shops**. This has happened because the number of researchers in the country is just about 15 per 100,000 people.
- Fewer Tax incentives:** India lags in other areas such as collaborative R&D tax credits (offered on expenditures made to support research at universities, national labs, and research consortia), and encouragement to commercialize innovation, rather than just for the research.
- Obsession with jugaad:** Many say real Indian innovation continues to be low-cost tweaks at the bottom of the pyramid, or, to use a word Indians love, jugaad. Celebrating jugaad is also the reason why there is hardly any incentive for a small business to invest in new technologies. The collective obsession for "more for less" can hardly develop an ecosystem for real innovation.
- Less spending on R&D by companies:** India Inc's miserly spend (less than 1 percent of sales) on research and development. Just one out of five Indian manufacturing firms offer in-service training, compared with 92 percent in China and 42 percent in Korea.

- **Fragmented policy and policy implementation:** There has been no comprehensive policy focusing on innovation and entrepreneurship so far. Also, the mechanisms to operate existing, fragmented policies are not uniform, which resulted in gaps in understanding and failure to achieve the desired effects of such policies.
- **Difficult and lengthy funding procedures:** Although funding is available from banks and public sources the procedures for accessing such funding are often complex, cumbersome, lengthy, and bureaucratic, in other words, not conducive to innovation and entrepreneurship. Moreover, despite these difficult and lengthy procedures, the system seeks immediate returns. However, the returns from innovation are often uncertain, late, or not quantifiable immediately.
- **Weak linkages between stakeholders:** The linkages between industry, especially medium and small-scale enterprises and R&D or academic institutions are weak.
- **Non-conductive education system:** The general education system is still too focused on grades and careers and is not oriented toward innovation and entrepreneurship. This situation is further worsened by the inherent problems of lack of infrastructure and good facilities in the educational institutions; delays in the funding system; and delays in the funds or other support reaching innovation projects.

## □ Strategies for Innovation

Overcoming these challenges will not be easy. Yet the need for action is clear. Here are some strategies for action:

- **First**, it is important to articulate a national vision of innovation. This can only be done as a successful collaboration across the government and other key stakeholders including the private sector and academia. In this context, while it is heartening to see that the NITI Aayog has formed the Atal Innovation Mission, a cohesive national strategy for innovation is yet to be articulated.
- **Second**, choices have to be made and supported. A strategy of letting private venture capital firms decide which firms or sectors to support may not be the best approach for India. The government in partnership with industry and academics should seek to identify areas of focus—areas where India seeks to innovate with appropriate technologies and create solutions for India and the world. India and Indians face a myriad of problems and challenges—ranging from health to sanitation and from transportation to the environment.
- **Third**, Encouraging innovation in the private and public sectors of the economy is critical, especially if these companies are to become more competitive globally. Clear incentives should be provided to firms to invest in research and development. Effective regulatory regimes should be encouraged to support intellectual property and the longer term investments of firms.
- **Finally**, the government should make itself the showcase of digital transformation and innovation. Government services touch the lives of hundreds of millions within India, in all parts of the country ranging from remote villages to large cities. By embracing digital technologies, and redesigning processes, the government can lower costs, create the capacity to invest in critical growth areas and help improve the quality of lives of all Indians.

# Analysis of INSPIRE Scheme

## About INSPIRE Scheme

### □ The basic objective of INSPIRE:

- To communicate to the youth population of the country the excitements of creative pursuit of science and attract talent to the study of science at an early stage and build the required critical

human resource pool for strengthening and expanding the Science & Technology system and R&D base in the country. It is a program with a long term foresight.

- A striking feature of the programme is that **it does not believe in conducting competitive exams for identification of talent** at any level. It believes in and relies on the efficacy of the existing educational structure for the identification of talent.

### □ Three components of Programme:

- **Scheme for Early Attraction of Talent (SEATS) for Science:** It aims at attracting talented youth to study science by providing INSPIRE Award, to experience the joy of innovations, of Rs.5,000 to **one million young learners** in the **age group 10-15 years**. There shall be annual Summer/Winter Camps for about 50,000 youth at more than 100 locations, for toppers in Class X board examinations for exposure with global leaders in Science, through INSPIRE Internship.
- **Scholarship for Higher Education (SHE):** It aims at attracting talented youth into undertaking higher education in science-intensive programmes, by providing scholarships and mentoring through '**summer attachment**' to performing researchers. The scheme offers 10,000 scholarships every year of Rs 0.80 lakh per year to talented youth in the age group 17-22 years, for undertaking Bachelor and Masters level education in Natural and Basic Sciences.
- The main feature of the scheme is mentorship support being planned for every scholar through INSPIRE scholarship.
- **Assured Opportunity for Research Careers (AORC):** It aims at attracting, attaching, retaining and nourishing talented young scientific Human Resource to strengthen the R&D foundation and base by offering doctoral INSPIRE Fellowship in the age group 22-27 years, in both Basic and Applied sciences (including engineering and medicine).
  - ▶ It also aims at assuring opportunities for post-doctoral researchers through a scheme (similar to the New Blood programme of the Royal Society of UK) through contractual and tenure track positions for five years in both Basic and Applied sciences areas through an INSPIRE Faculty Scheme.
- **INSPIRE Award- MANAK (Million Minds Augmenting National Aspiration and Knowledge):** In order to seed and experience the joy of innovation, every year two lakh school children in the age group of 10 to 15 years i.e., 6th to 10th standards are being identified for the INSPIRE Award. Each INSPIRE Award envisions an investment of INR 5,000 per child. The scheme plans to reach at least two students per secondary school during the next five years.
- **INSPIRE Faculty Scheme:** It is expected to augment high-quality scientific manpower in scientific and educational institutions. It provides attractive opportunities to young achievers for developing independent scientific profiles and intends helping them emerge as S&T leaders in the long term. The Scheme offers contractual research positions. It provides career opportunities, but it is not a guarantee for tenure positions after 5 years.

### □ The need for such Programme

- There is urgent need to curtail the popular fact that people pursuing engineering, management, banking jobs are much better off than their counterparts in research, hence aiming to retain talented students in the field of science.
- Lack of innovative research in various streams has made the Indian industries dependent on technology purchase and technology transfers.
- The Indian universities and research facilities are unable to retain the brilliant minds hence increasing the 'brain drain' phenomenon and reducing the country's tally of international awards like the Nobel Prize.

- It provided five-year employment at the University of the research scholar's choice with a handsome salary and annual research grant.

### ❑ Critical Analysis

- The scheme was conceived in 2008 amid concerns that not enough talented students were opting for research careers in basic sciences and were being lured away by higher salaries in banking, information technology, and management jobs.
- But scientists allege that they are never treated "on par" with peers, denied opportunities to compete for faculty positions and were repeatedly asked to clear out their work-station by senior department members.
- DST releases the salary and research funds so late every year, because of it, it became impossible to spend the money before the close of the financial year.

### ❑ Steps Needed

- The Academies and the Panel should play a role so that INSPIRE complements and enhances existing mechanisms for pre- and postdoctoral support.
- The scale of INSPIRE is very large and this is what makes it seem worthwhile. The Academies should help overcome the mismatch between the enormity of INSPIRE targets and the number of individuals with necessary time and competence. Academies should convince the scientific community to collectively invest time and resources to make the programme a success.
- DST level Panels to set up and manage the Tree Structure:
- Nodal centers such as IISER's, IIT's, Central Universities with sizeable expertise to cover all disciplines be identified to coordinate with schools and colleges over two/three states to run summer and winter camps; DST to support INSPIRE cells at Nodal centers to draw in faculty.
- INSPIRE centers to coordinate activities in local schools and colleges for age groups 10-17 and 17-22, drawing upon SCERT's (State Councils for Education Research and Training), formulate proposals for running camps and to provide assistance for student selections.
- Nodal officer for every three or four districts, located at INSPIRE Centers, should be able to handle about 100-250 students.

### Way Forward

- The strength of the innovation infrastructure of a nation has enormous significance in the competition among emerging knowledge economies. The realization of Vision 2020 calls for action and well-designed innovation infrastructure.
- Generation of pre-competitive technologies desired from the first principles of science will form a differentiating element in knowledge-based economies. India enjoys a natural competitive advantage by virtue of demography and inherited knowledge system. The only need is the conversion of competitive advantage into a competitive strength. This can be done through such programs.

## Organ Donation Rules in India

- In India every year nearly 500,000 people die because of non-availability of organs, 200,000 people die of liver disease, 50,000 people die from heart disease, 150,000 people await a kidney transplant but only 5,000 get one, 1,000,000 lakh people suffer from corneal blindness and await a transplant. Almost 1.5

lakh people in India need a kidney, however, only 3000 of them receive one. Only 1 out of 30 people who need a kidney receive one 90% of people in the waiting list die without getting an organ.

- Nationally, with a population of 1.2 billion people in India, the statistic stands at 0.08 persons as organ donors Per Million Populations (PMP). This is an incredibly small and insignificant number compared to the statistics around the world.
- Due to lack of awareness, there are myths and fears in peoples' mind about organ donation. Thus the government has organized Indian Organ Donation Week to motivate normal human beings to pledge to donate organs after death and to spread awareness about the importance of organ donation.

### ■ What are Organ donation and organ transplantation?

- **Organ donation** is the process of removing tissues or organs from a live, or recently dead, person to be used in another. Kidneys, Eyes (cornea), Heart, Lungs, Liver, Pancreas, small bowel and Skin can be donated.
- The blood group should be non-interfering. If the recipient is blood group 'O' – only 'O' can be a donor; if the blood group is AB - any blood group O, A, B & AB can be a donor. This is for live kidney donation. Healthy organs should be transplanted as soon as possible after brain death from the donor to the recipient.
- Whereas, **Organ Transplant** is a medical procedure where one person's dysfunctional organ or tissue is replaced by that of a healthy person, thus restoring its function. Transplants drastically improve the quality of life of the patient and give them another chance to live.

### ■ Advantages

- The biggest advantage to organ donation is it saves lives that would otherwise be lost. A single organ donor has the chance to save the lives or improve the quality of life for several people. Families of organ donors may be able to correspond with the recipients of their loved one's organs, which may give them the sense that some good came out of tragedy, particularly if the donor were very young. Those who donate the whole body often are making contributions to medical advancement, as cadavers may be used for the education of medical students. There is no cost to organ donors or their families, and the body will not be disfigured for funeral services.

### ■ Disadvantages

- A disadvantage to organ donation is the donor or his family has no say in who receives the donated organs. Organs may be donated to recipients who have very different religious or political views or to people the donor may not have considered deserving. For this reason, donors have to believe all life is sacred and one recipient isn't more valuable than another.

### ■ The legality of Organ Donation in India

- The Indian government enacted the Transplantation of Human Organs Act (THOA), 1994, allows organ donation, and legalized the concept of 'brain death'.
- In India, matters related to health are governed by each state.
- The Act was initiated at the request of Maharashtra, Himachal Pradesh and Goa (who therefore adopted it by default) and was subsequently adopted by all states except Andhra Pradesh and Jammu & Kashmir.
- An amendment to the act was proposed by the states of Goa, Himachal Pradesh and West Bengal in 2009 to address inadequacies in the efficacy, relevance, and impact of the Act.

- The amendment to the Act was passed by the parliament in 2011, and the rules were notified in 2014.
- The same is adopted by the proposing states and union territories by default and may be adopted by other states by passing a resolution.

□ **The main provisions of the Act (including the amendments and rules of 2014) are as follows:**

- Brain death identified as a form of death. Process and criteria for brain death certification defined. It is the irreversible and permanent cessation of all brain functions. In situations of brain death, a person cannot sustain his own life, but vital body functions may be maintained in an ‘intensive care unit’ for a short period of time. Organs of such patients can be transplanted to terminally ill patients.
- It allowed transplantation of human organs and tissues from living donors and cadavers (after cardiac or brain death).
- Regulatory and advisory bodies for monitoring transplantation activity and their constitution has also been defined.
- Organs can either be retrieved from cadavers or from brain dead patients with family consent or may be donated by living donors.

□ **Donation from living donors:**

- The law recognizes three types of living donors.
- Near relatives like parents, siblings, grandparents, grandchildren or spouses
- Others who can donate for “affection and attachment” or for a special reason but not for financial considerations
- Swap donors where near relative donors are swapped between patients whose own family members are incompatible.

□ **Responsible Bodies:**

- According to Indian law, Organ Transplantation is a State subject and is under the direct control of the respective State Governments.
- However, the Union Health Ministry is responsible for making amendments to the Transplantation of Human Organs Act, so that the organ transplantation system in the country runs effectively.
- Two separate committees for related and unrelated donors evaluate and clear cases.
- The committee that looks at procedures involving related donors comprises hospital staff, but people who are not part of the treating team.
- For unrelated donors, there are, in addition, two nominees of the government who evaluate the cases.
- In November last year, a national registry for organs and tissue donations — currently limited to hospitals in Delhi and NCR — was launched to make the process transparent.
- Patients need to register there and would be given an organ depending on availability regardless of their financial or social status.
- As health is a state subject, each region has its own registry to aid the process of transplantation through living donors.

### □ Challenges

- The huge disparity between a number of recipients requiring kidney and other organ transplant and availability of donor organs.
- For end-stage renal disease, maintenance analysis is an acceptable and reasonably good alternate therapy; so far the majority of such patients, transplant is not considered an emergency procedure.
- A provision that allows an unrelated person to donate out of love and affection has been a major reason behind the commodification of organs.
- The success of black market lies in bypassing norms mostly by fake documentation and arranging donors (mostly poor) for patients who were willing to pay for the organs. As doctors go by the documents that have been placed before them these racquets survive easily. The basic problem behind the success of these racquets is in the perpetual shortage of organs. The huge demand-supply gap has fueled a black market in organs trade.

## Maharashtra's Public Cloud Policy

Maharashtra becomes the first state in India to unveil public cloud policy

### □ Key Information about the Policy

- The policy virtually mandating its departments to shift their data storage onto the cloud, which intends to make them available for free to the general public.
- Under the framework, the government will make it mandatory for the data to be stored within the country.
- Enhanced security features are in place for private and sensitive data
- The objectives of the policy are to attract ₹5,000 crore investment in the development of incubation and start-ups.
- Provide ₹2,500 crore for youth entrepreneurship activities (one percent of State Budget). Establish an average of three incubators in each of the 12 designated sectors and develop at least 2,000 start-ups in the next five years. The wants to develop at least 10 lakh sqft of incubation space within the state over the next five years.
- An establishment up to five years from the date of its registration shall be considered as a start-up. The annual turnover of the establishment should be up to ₹25 crore. The establishment should be based on an innovative concept, innovative commercialization of products and services or it could be based on innovative production methods and processes.

### □ Impact

- This will accelerate e-governance.
- Open new areas for private sector investments.
- Government is the biggest data creator and consumer. This policy will take new technologies to all the departments.
- It will create a \$2 Billion opportunity for the industry.
- Enable more transparency where citizens can access the government data directly. Hence giving a push to Good Governance.

## □ Challenges

- **Data Breaches:** it is consistently a serious concern for cloud computers.
- **Human Error:** Experts say that through 2020, 95% of cloud security failures will be the customer's fault
- **Data Loss with no Backup:** An accident or catastrophe can lead to the permanent loss of customer data unless there are measures in place to back up the data
- **DDoS attacks:** Distributed Denial-of-Service attacks pose a significant risk to cloud customers and providers, including lengthy service outages, reputational damage, and exposure of customer data
- **Insecure APIs:** Just like the home's entry door, an API is likely to be the initial entry point for attackers.
- **Account Hijacking:** Using stolen credentials, attackers may gain access to critical areas of cloud computing services, compromising the confidentiality and integrity of those services.

# National Policy on Electronics 2019

## Policy Summary

- The Policy envisions positioning India as a global hub for Electronics System Design and Manufacturing – (ESDM) by encouraging and driving capabilities in the country for developing core components, including chipsets, and creating an enabling environment for the industry to compete globally.
- The policy aims to achieve a turnover of \$ 400 Billion for the electronics sector by the year 2025.
- Also, to generate employment opportunities for 1 crore people.
- To produce 1 billion mobile handsets by the year 2025.

## Salient Features of NPE 2019:

- Create eco-system for globally competitive ESDM sector: Promoting domestic manufacturing and export in the entire value-chain of ESDM.
- Provide incentives and support for manufacturing of core electronic components.
- Provide a special package of incentives for mega projects which are extremely high-tech and entail huge investments, such as semiconductor facilities display fabrication, etc.
- Formulate suitable schemes and incentive mechanisms to encourage new units and expansion of existing units.
- Promote Industry-led R&D and innovation in all sub-sectors of electronics, including grass root level innovations and early stage Start-ups in emerging technology areas such as 5G, IoT/ Sensors, Artificial Intelligence (AI), Machine Learning, Virtual Reality (VR), Drones, Robotics, Additive Manufacturing, Photonics, Nano-based devices, etc.
- Provide incentives and support for significantly enhancing the availability of skilled manpower, including re-skilling.
- Special thrust on Fabless Chip Design Industry, Medical Electronic Devices Industry, Automotive Electronics Industry and Power Electronics for Mobility and Strategic Electronics Industry.

- Create a Sovereign Patent Fund (SPF) to promote the development and acquisition of IPs in the ESDM sector.
- Promote trusted electronics value chain initiatives to improve national cyber-security profile.

### Major Impact:

- The NPE 2019, when implemented, will lead to the formulation of several schemes, initiatives, projects, etc., in consultation with the concerned Ministries/ Departments, for the development of ESDM sector in the country.
- It will enable the flow of investment and technology, leading to higher value addition in the domestically manufactured electronic products, increased electronics hardware manufacturing in the country and their export while generating substantial employment opportunities.
- It will also improve the cyber-security situation in India because now we will have the know-how of the microchips embedded in the systems.

### □ Suggestions:

- India needs to increase the share of investment in electronics research in Universities.
- Young entrepreneurs must be encouraged to develop innovative electronic hardware solutions to solve the prevailing problems in India
- India should try to bring the whole supply chain process of mobile manufacturing in India rather than only the assembly line process.
- We need to develop microchips which could be embedded with multiple electronic devices.

## Roadmap for Drones

### □ Need for Drone Policy in India

- The Unmanned Aircraft System (“UAS”) market in India is projected to touch US\$ 886 million by 2021, while the global market is likely touching US\$ 21.47 billion. In order to tap into the opportunities in this space, India must regularly guide technology standards and upgrade its policy framework accordingly.

### □ Highlights of First Drone Policy of India

- The drone policy has been made keeping in mind several parameters such as the **height** at which a drone can travel, the **area** in which it can be used, **registration** of the drone and more.
- **Owners and pilots** of the drone need to be registered with the ministry.
- **Permission** for flying a drone needs to be applied via an app.
- As per the ministry, during daytimes, a drone can be flown up to a height of **400 ft.**
- There will be special ‘**No Drone Areas**’ such as airports, near international borders and especially in some areas of vital military installations and such.
- It is mandated for obtaining a **Unique Identification Number (UIN)** and Unmanned Aircraft Operator Permit (UAOP) for flying of drones, with exemptions in certain cases.

- Although private operators can use drones across various sectors like health, agriculture, disaster relief, the current policy clearly bars the delivery of items by drones for now.
- An all-digital process for registering and operating drones.
- It is called the **Digital Sky Platform** and is “first-of-its-kind national unmanned traffic management (UTM) platform that implements ‘no permission, no takeoff’ (NPNT).”
- This UTM will be in close contact with the defense and civilian air traffic controllers (ATCs) so that the drones remain on the correct course.

## Significance

- India is one of the largest importers of drones.
- The Drone Policy is aimed at regulating the practice of civilians flying drones in India.
- The drone market in India holds the potential of hitting over \$1 trillion.
- The guidelines would help foster technology and innovation in the development of drones.
- The regulations will encourage a vast Made in India drone industry.

## □ Advantages

- While drones have historically been used in military operations, their application for peaceful purposes has risen steeply in recent years.
- Drones have an extensive range of applications like disaster relief, GIS mapping, Crowd Monitoring, Traffic management, and detection of suspicious activities, etc.
- In recent times, Drones have been recognized as an effective tool for planning, management, and decision-making, locally and globally.
- Aerial surveillance of crops, precision agriculture, and targeted pesticide spraying.
- In Madagascar, drones are being used to deliver medical supplies and equipment to remote areas.
- Drones can also provide accurate, detailed maps of key resources present.
- Show the demographic distribution which can help in identifying how social groups are segregated and distributed within a region

## □ Recommendations for the purpose of CAR 2.0 may include:

- **BVLOS Operations:** Expansion of operational airspace for UAS operating beyond the visual line of sight and above the current limit of 400 ft.
- **Drone Corridor:** A segregated airspace denied by the appropriate authorities in consultation with the airspace designers to keep commercial UAS operations out of the non-segregated airspace in which manned aircraft operate.
- **Autonomous Operations:** Use of algorithms for piloting may be permitted, but only if adequate safety, security, and privacy principles are demonstrated in the design of operations.
- **Airworthiness:** New principles of airworthiness can be introduced to include safety by design, security by design and privacy by design.
- **UAS Traffic Management:** UAS Traffic Management should be responsible for managing UAS induced traffic, especially in the Drone Corridor.
- **Digital Sky Service Providers:** DSPs may engage in providing enabled services to the UAS Operators, DigitalSky Platform, relevant law enforcement authorities and/or any other stakeholders.

- **Pilot Training:** Improved and advance pilot training methods should be introduced to meet the professional requirements under CAR 2.0.
- **Drone-ports:** Designated areas dedicated to facilitating take-off and landing of the UAS.
- **Make in India:** 100% FDI in UAS and RPAS-based commercial civil aviation services would provide a boost to the make in India initiative in this industry.
- **Insurance:** Considering the increased exposure due to commercial operations, it becomes important for UAS operators to have professional liability insurance to cover the cost of legal fees and damages awarded against such operators.
- **Payload / Cargo:** Commercial UAS operations will foster various new forms of air freight capabilities.

## Conclusion

Flying drones safely in India will require research and development to understand how they can be best used in India's unique landscape. Such R&D occurs best in a market-oriented environment, which will not happen unless civilian drone use is permitted. Building profitable companies around drone use can be complicated when the core business model is illegal.

# National Wind-Solar Hybrid Policy

India has set an ambitious target of reaching 175 GW of installed capacity from renewable energy sources by the year 2022, which includes 100 GW of solar and 60 GW of wind power capacity. Various policy initiatives have been taken to achieve this target. At the end of the 2017-18, the total renewable power installed capacity in the country was almost 70 GW.

## □ Need for this policy

- The existing wind farms have a scope of adding solar PV capacity and similarly, there may be wind potential in the vicinity of the existing solar PV plant.

## □ The objective of the Policy

- To provide a framework for the promotion of large grid-connected wind-solar PV hybrid system
- To encourage new technologies, methods and way outs involving the combined operation of wind and solar PV plants.

## □ Key Highlights of the Policy

- Wind Turbine Generators (WTGs) and Solar PV systems will be configured to operate at the same point of grid connection.
- The size of the solar PVs capacity to be added as the solar-hybrid component could be relatively smaller for optimal and efficient utilization of transmission infrastructure.
- a wind-solar plant will be recognized as a hybrid plant if the rated power capacity of one resource is at least 25% of the rated power capacity of another resource.
- New wind-solar hybrid projects shall be encouraged
- Battery storage may be added to the hybrid project (i) to reduce the variability of output power from wind solar hybrid plant; (ii) providing higher energy output for a given capacity (bid/ sanctioned

capacity) at delivery point, by installing additional capacity of wind and solar power in a wind-solar hybrid plant; and (iii) ensuring availability of firm power for a particular period.

- The Central Electricity Authority and CERC shall formulate necessary standards and regulations including metering methodology and standards, forecasting and scheduling regulations, REC mechanism, the grant of connectivity and sharing of transmission lines, etc. for wind-solar hybrid systems
- For wind turbines, solar modules and balance of systems, the technical guidelines issued by the Ministry from time to time for grid-connected systems will be followed.
- The government will support technology development projects in the field of wind-solar hybrid systems. Besides, support will be provided for the development of standards for hybrid systems.

### Way Forward:

With significant capacity additions in renewables in recent years and with Hybrid Policy aiming at better utilization of resources, it is envisaged that the Hybrid Policy will open-up a new area for availability of renewable power at competitive prices along with reduced variability.

## Draft Rules for E-Pharmacies

### Introduction:

- ❑ The increasing popularity of e-commerce, including e-pharmacies, is undeniable.
  - ❑ E-Pharmacies, operate through websites or smartphone apps on the Internet. E-pharmacies offer the comfort of shopping from home, privacy, and price discounts. It also allows access to drugs, not available locally.
  - ❑ They offer medicines for sale at a discount of at least 20%, when compared to traditional pharmacies.
  - ❑ For scheduled drugs, patients can submit photographs of prescriptions, while placing orders.
  - ❑ In India, in the absence of any legislative framework, the existence of e – pharmacies are per-se illegal. The Drugs Controller General of India (DCGI) banned sale through e – pharmacies on 30th December 2015.
  - ❑ Yet, e-pharmacies have grown rapidly as against the traditional “brick-and-mortar” or offline pharmacies.
  - ❑ On Dec.12 2018, the Delhi high court ordered a complete ban on online pharmacies across the country with immediate effect, asking the central government to implement the order
  - ❑ The court order is in response to a petition which stated that the sale of drugs and prescription medicines online was illegal and without any mandate of law and, therefore, a health risk.
- ❑ **Opponents to E-Pharmacies:**
- The fiercest opponents of e-pharmacies are trade associations of existing pharmacists and chemists.
  - They argue that their livelihoods are threatened by venture capital-backed e-pharmacies and that jobs of thousands are on the line.

- There is enough evidence on record to demonstrate how existing pharmacies contribute generously to drug abuse and sale of sub-standard medicine. There is no reason to suspect that e-pharmacies are going to worsen the situation in any way.

#### ❑ Defects in Brick-and-Mortar Pharmacies:

- The history of India's trade associations of pharmacists is one of rampant, unabashed cartelization that has resulted in artificial inflation of medicine prices.
- This practice of two competitors colluding to fix the sale price and area of operation is called cartelization and is illegal under India's Competition Act.
- The premise of this law is that a free market is efficient only if all sellers are competing with each other to offer the lowest price to the customer.
- A second, more insidious strategy is the practice of requiring pharmaceutical companies to apply for a no-objection-certificate (NOC) from the regional trade association before they appoint new stockists in a region to sell a particular drug.
- This has the effect of artificially restricting competition in certain markets because more stockists mean more competition.
- By creating such artificial, extra-legal barriers to the free trade of medicines within India, these trade associations create huge distortions in the Indian market. It is suspected that these practices continue despite multiple restraining orders by the Competition Commission of India.

#### ❑ Risks Associated with E-Pharmacies:

- India's pharmacy laws are derived from the Drugs and Cosmetics Act, 1940, Drugs and Cosmetics Rule, 1945, and the Pharmacy Act, 1948.
- These laws predate the advent of online commerce in India, leaving the business out of the purview.
- Unlike common items, drugs are highly potent and its misuse or abuse can have serious consequences on human health, not just for the one person consuming it but for humanity at large as some drugs can be addictive, habit-forming and harmful to the body.
- A large number of children/minor or people from uneducated rural background use the internet and can be victims of wrong medication while ordering medicines online.

#### ❑ The risks exist in buying drugs online:

- Supply of fake and illegal drugs;
- Abuse on account of fake or forged or no prescriptions;
- Lack of verification of the ultimate user;
- Unhealthy competition;
- Abuse of critical health data generated online; and
- Mishandling during transport; are some of them.

#### ❑ Making draft guidelines is the need of the hour:

- E-pharmacies market is \$18 billion and will grow to \$55 billion by 2020.
- Industry experts estimate the market to be generating 3,000-4,000 orders on a daily basis.

- According to the draft guidelines that are yet to be formalized, e-pharmacies have to register for a license with the Drug Controller General of India (DCGI), which will be valid for three years.
- They do not allow e-pharmacies to sell narcotic drugs, tranquilizers, and Schedule X drugs, and neither are they allowed to advertise.
- These draft guidelines are along the lines of laws in the US, where the regulators monitor e-drug sales.
- The National Association of Boards of Pharmacy (NABP), the apex pharmacy body in the US, gives registration and certification for e-pharmacies and they have to display the certification logo on their website.

## Conclusion:

- ▣ Specific and clear-cut rules should be made for selling, prescribing, dispensing, and delivering prescription drugs through e-pharmacies.
- ▣ In its recent policy note on “Making markets work for affordable healthcare”, the CCI noted, “One major factor that contributes to high drug prices in India is the unreasonably high trade margins.”
- ▣ One of the culprits for this phenomenon identified by the CCI was “self-regulation by trade associations also contributes towards high margins as these trade associations control the entire drug distribution system in a manner that mutes competition”.
- ▣ One of the solutions proposed by the CCI was encouraging more e-pharmacies.
- ▣ As stated by the CCI in its policy note, “Electronic trading of medicines via online platforms, with appropriate regulatory safeguards, can bring in transparency and spur price competition among platforms and among retailers, as has been witnessed in other product segments.”
- ▣ The fact that the government has come out with draft regulations means it is not keen on killing it. It is a regular course of evolution of an industry which is very nascent. It is important to weed out the unruly players.

# National Digital Communications Policy

## ▣ National Digital Communications Policy, 2018:

- The National Digital Communications Policy, 2018 seeks to unlock the transformative power of digital communications networks to achieve the goal of digital empowerment and well-being of the people of India; and towards this end, attempts to outline a set of goals, initiatives, strategies, and intended policy outcomes.

## ▣ The National Communications Policy aims to accomplish the following Strategic Objectives by 2022:

- Provisioning of Broadband for All
- Creating 4 Million additional jobs in the Digital Communications sector
- Propelling India to the Top 50 Nations in the ICT Development Index of ITU from 134 in 2017
- Enhancing India's contribution to Global Value Chains
- Ensuring Digital Sovereignty

- Time to make Digitally Empowered India:
  - The task before India's policymakers is to ensure that the advantages of the new technologies are accessible to all equitably and affordable while securing them against existing and emerging threats.
  - India needs to particularly ensure that its communications infrastructure supports the entire population, whose demographic profiles vary widely across various indices such as literacy, economic conditions, and urbanization.
  - It is important for India to remain sensitive to these factors and promote policies that increase opportunities for their social and economic development
  - Digital infrastructure and services are increasingly emerging as the key enablers and critical determinants of a country's growth and well-being
  - India's digital profile and footprint are one of the fastest growing in the world. With over a billion mobile phones and digital identities and half a billion internet users, India's mobile data consumption is already the highest in the world.
  - Over 200 million Indians regularly use social media and in the last year alone, over 200 million Indians took to mobile banking and digital payments. At the current pace of digitization and digitalization, it is estimated that India's digital economy has the potential to reach one trillion USD by 2025.
  - The objective of National Digital Communications Policy, 2018:
  - The objective of this document is to lay out a policy and principles framework that will enable the creation of a vibrant competitive telecom market to strengthen India's long term competitiveness and serve the needs of our aspiring nation.
  - It has been broadly estimated that a 10% increase in broadband penetration in a country could potentially lead to an over 1% increase in GDP.
  - However, studies in India estimate that the impact could be significantly higher for the country, given the increased productivity and efficiency gains that are likely to accrue to the economy.
  - It is necessary to explore and utilize the opportunities presented by next generation-networks like 5G and other pioneering network access technologies including satellite communications.
  - It would be critical to focus on fixed infrastructure development initiatives related to fiber deployment and Right of Way clearances that will form the bedrock of next-generation technologies.
  - Implementing a 'Fibre First Initiative' to take fiber to the home, to enterprises and to key development institutions in Tier I, II and III towns and to rural clusters.
- ❑ **Implementation of the broadband initiatives, to be funded through USOF and Public-Private Partnerships:**
- BharatNet – Providing 1 Gbps to Gram Panchayats upgradeable to 10 Gbps
  - GramNet – Connecting all key rural development institutions with 10 Mbps upgradeable to 100 Mbps
  - NagarNet – Establishing 1 Million public Wi-Fi Hotspots in urban areas
  - JanWiFi – Establishing 2 Million Wi-Fi Hotspots in rural areas
- ❑ **Secure India: Ensuring Digital Sovereignty, Safety, and Security of Digital Communications 2022 Goals:**
- Establish a comprehensive data protection regime for digital communications that safeguards the privacy, autonomy, and choice of individuals and facilitates India's effective participation in the global digital economy.

- Ensure that net neutrality principles are upheld and aligned with service requirements, bandwidth availability and network capabilities including next-generation access technologies.
- Develop and deploy robust digital communication network security frameworks.
- Build capacity for security testing and establish appropriate security standards.
- Address security issues relating to encryption and security clearances.
- Enforce accountability through appropriate institutional mechanisms to assure citizens of safe and secure digital communications infrastructure and services.

## Conclusion

- ▣ The job of a national policy on digital communications is to prepare the country and its citizens for the future.
- ▣ Achieving these goals would require that the key stakeholders – namely the Centre, the States, local governments, Telecom Service Providers, Internet Service Providers, handset and equipment manufacturers, the academic community, the innovators and start-ups come together to forge a coalition to deliver this national policy and missions.
- ▣ It is hoped that this policy will facilitate the unleashing of the creative energies of citizens, enterprises, and institutions in India and play a seminal role in fulfilling the aspirations of all Indians for a better quality of life.

## Empowered Technology Group

Cabinet approved constitution of a 12-Member Technology Group with the Principal Scientific Adviser to Government of India as its Chair. This Group is mandated to render timely policy advice on latest technologies; mapping of technology and technology products; commercialisation of dual use technologies developed in national laboratories and government R&D organisations; developing an indigenisation road map for selected key technologies; and selection of appropriate R&D programs leading to technology development.

## Major Impact

- ▣ **The Technology Group will:-**
  - render the best possible advice on technology to be developed for a technology supplier and the technology procurement strategy;
  - develop in-house expertise in aspects of policy and use of emerging technologies; and
  - ensure sustainability of public sector technology developed/being developed at PSUs, national labs and research organisations.

## Implementation strategy and targets

- ▣ **The three pillars of the work of the Technology Group include:**
  - Policy Support;
  - Procurement Support; and
  - Support on Research and Development proposals.

### ❑ The Technology Group intends to ensure:-

- that India has appropriate policies and strategies for effective, secure and context-sensitive exploitation of the latest technologies for economic growth and sustainable development of Indian Industry, in all sectors;
- to advise the Government on priorities and strategies for research on emerging technologies across sectors;
- to maintain an updated map of technology and technology products available, and being developed, across India;
- to develop indigenization roadmap for selected key technologies;
- to advise the Government on its technology supplier and procurement strategy;
- to encourage all Ministries and Departments as well as State Governments to develop in-house expertise in policy and use aspects of emerging technologies such as data science and artificial intelligence, and to this end develop an approach to training and capacity building
- to formulate policies for sustainability of public sector technology at PSUs/Labs while encouraging cross-sector collaborations and research alliances with Universities and Private Companies; and
- to formulate standards and common vocabulary to apply in vetting of proposals for R&D.

## Accelerate Vigyan' (AV)

To provide a single platform for research internships, capacity building programs, and workshops across the country, the Science and Engineering Research Board (SERB) has launched a new scheme called 'Accelerate Vigyan' (AV).

### About

- ❑ The primary objective of this inter-ministerial scheme is to give more thrust on encouraging high-end scientific research and preparing scientific manpower, which can lead to research careers and knowledge-based economy.
- ❑ The vision is to expand the research base, with three broad goals, namely-
- ❑ consolidation/aggregation of all scientific programs
- ❑ initiating high-end orientation workshops
- ❑ creating opportunities for research internships for those who do not have access to such resources/facilities

### How will it work?

- ❑ The AV will work on mission mode, particularly with respect to its component dealing with consolidation/aggregation of all major scientific events in the country.
- ❑ Thus, an Inter-Ministerial Overseeing Committee (IMOC) involving all the scientific ministries/departments and a few others have been constituted for the purpose of supporting SERB in implementing the AV scheme in a successful manner.
- ❑ The database of skilled manpower developed across different disciplines so generated and the final outcomes captured in the process through all the sub-components of the AV will serve the cause of all stakeholders in respect of capacity building in the country.

- The scheme also seeks to garner the social responsibility of the scientific community in the country.

## Major Components under the Scheme

### □ 'ABHYAAS' programme

- 'ABHYAAS' programme is an attempt to boost research and development in the country by enabling and grooming potential PG/PhD students by means of developing their research skills in selected areas across different disciplines or fields.
- It has two components:
- High-End Workshops ('KARYASHALA')
- Research Internships ('VRITIKA')

### □ SAMMOHAN

- Another new component under AV is 'SAMMOHAN' that has been sub-divided into 'SAYONJIKA' and 'SANGOSHTI'.
- SAYONJIKA is an open-ended program to catalogue the capacity building activities in science and technology supported by all government funding agencies in the country.
- SANGOSHTI is a pre-existing program of SERB.

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# Chapter 6

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## MISCELLENEOUS

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### Innovation and the Innovation Wars

- ❑ Since the early days of the Cold War, the **United States** has led the world in **technology**, and conquered **space**, spearheaded the **Internet**, and brought the world the **iPhone**. However, in the recent past, **China** has undertaken an impressive effort to claim the mantle of technological leadership, investing billions of dollars in **robotics, artificial intelligence, microelectronics, green energy**, and much more.
- ❑ The competition has shifted to selling **5G wireless infrastructures** around the world, harnessing synthetic biology to bolster food supplies, and racing to build smaller and faster microchips, all in a bid to grow in power.
- ❑ Policymakers have called for greater government action to protect the lead in innovation: **boost R & D spending, ease visa restrictions and develop more domestic talent, and build new partnerships** with industry at home and with friends and allies abroad. However, there is a flawed understanding of which technologies matter and of how to foster their development.
- ❑ In such a scenario, countries like the U.S. need to broaden their horizons and support a **wider range of technologies - hypersonic flight, quantum computing, artificial intelligence, microelectronics and biotechnology**.

### Innovation Basics

- ❑ Innovation could be described as the development and application of ideas and technologies that improve goods and services and make their production more efficient.

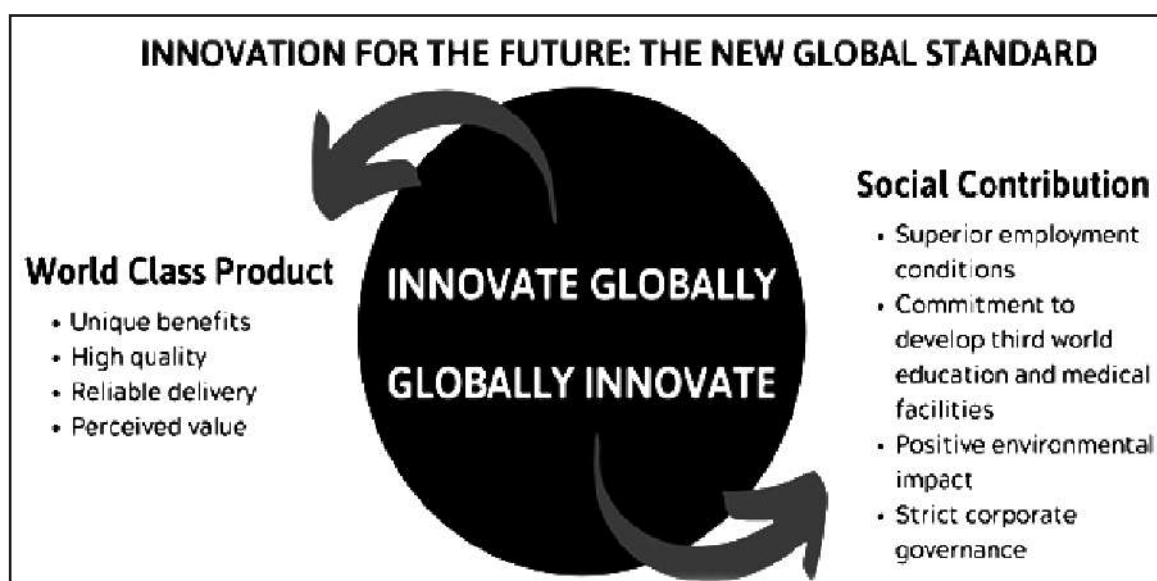
### Innovation Wars

- ❑ It is the battle between countries or corporate operation groups, responsible for on-going operations and support of existing products and services.
- ❑ The teams formed for new initiatives are usually given names like innovation team. Special teams dedicated to innovation initiatives inevitably run into conflict with the rest of the organization.

- ❑ The key to avoiding conflict is incorporating an innovation leader who can collaborate well with the performance engine and a senior executive who supports the dedicated team, prioritizes the company's long-term interests, and adjudicates contests for resources.

## Importance of innovation

- ❑ **Creation of new products and services** in response to unmet needs and demands of people and the country.
- ❑ **Innovation contributes to economic growth** - Innovation creates jobs and these economic opportunities uplift and support communities through increasing the quality of life and overall standard of living.
- ❑ **Socio - Economic empowerment** of people who are at margins of society - e.g. innovations like Smokeless Chulha can help in reducing the Indoor air pollution which improves health of women. Innovative products like Water ATMs help in reducing the burden on women in areas where accessibility of safe drinking water is a problem.
- ❑ **Policy Innovations** - they can improve socio-economic status of targeted beneficiaries. Policy innovations like Accredited Social Health Activist (ASHA), a trained female community health activist have been credited with task of improving social indicators like Infant Mortality Rate and Mother Mortality Rate. Innovative products like Kisan Credit Cards help farmers to avoid informal lending which have usurious interest rates.
- ❑ **Innovation promotes efficiency** - Use of innovative mobile technology and biometric authentication can improve efficiency in service delivery; reducing leakage, reducing chances of fake beneficiary etc.



## Intellectual Property Rights: Issues & Concerns

- ❑ Intellectual Property is a general term covering patents, copyright, trademark, industrial designs, geographical indications, protection of layout design of integrated circuits and protection of undisclosed information (trade secrets).
- ❑ IPRs refers to the legal ownership by a person or business of an invention/discovery attached to a particular product or processes which protects the owner against unauthorized copying or imitation.

### □ Types of Intellectual Property

- **Copyright:** It's an exclusive privilege to authors to reproduce, distribute, perform, or display their creative works. Copyright includes literary, Artistic works, Computer programs, Musical works, etc.
- **Trade and Service Marks:** A trademark is a sign used in connection with the marketing of goods or services. It commonly appears on container or wrapper of the products. A service mark identifies and distinguishes the source of service rather than a product.
- **Industrial Design:** Industrial Design is an ornamental or aesthetic aspect of a useful article of industry. It gives a special appearance to a product of industry.
- **Geographical Indications:** It refers to an indication which identified such goods as agricultural goods, natural goods or manufactured goods as originating, or manufactured in the territory of a country, or a region or locality in that territory, where a given quality, reputation or other characteristics of such goods is essentially attributable to its geographical origin.
- **Patents:** A patent describes an invention for which the inventor claims the exclusive right to make, use and sell an invention for a specific period. The invention is a new solution to the "technical" problem. (Product, process and new use)

### □ Need of IPR

- Legal characterization of the new invention.
- To protect the rights of an individual to enjoy their creations and invention.
- To ensure protection against unfair trade practices.
- To assure the world flow of useful, informative and intellectual works.
- To encourage the continuing innovativeness and creativity of owners of IP.
- Monetary profit

### □ Issues relating to Intellectual Property Rights

- Insufficiency of the regulations.
- IPR has encouraged monopolies as many corporate take overs' have been motivated by access to an IPR.
- It may adversely affect biological diversity and ecological balance.
- Adversely affects the livelihood of the poor in developing countries.
- Private sector drove international norm setting
- Nontransparent and non-participatory international lawmaking
- Trade in pirated and counterfeited goods threaten health, safety, and security of consumers worldwide, particularly in poor countries.
- Entry barriers

### □ New IPR Policy

- India's National Intellectual Property Rights (IPR) Policy is in compliance with WTO's (World Trade Organisation) agreement on TRIPS (Trade-Related aspects of IPRs) which aims to sustain entrepreneurship and boost Government's 'Make in India' scheme. The highlights of IPR policy:
- The Policy aims to push IPRs as a marketable financial asset, promote innovation and entrepreneurship while protecting the public interest.

- Periodic review of existing IP laws — to update and improve them or to remove anomalies and inconsistencies.
- Special thrust on awareness generation and effective enforcement of IPR
- It suggests making the Department of Industrial Policy and Promotion (DIPP) the nodal agency for all IPR issues.
- Copyrights related issues will also come under DIPP's ambit from that of the Human Resource Development (HRD) Ministry.
- Films, music, industrial drawings will be all covered by copyright.
- The policy left the country's patent laws intact and specifically did not open up Section 3(d) of the Patents Act for reinterpretation.

## Issues & Concerns

- ❑ With the advent of hybrid and genetically modified plants, it is possible to create different quality of plants of the same genus or species. There has been the unending quest of developing plant varieties that are more productive, more fortified with nutrients, more resistant to vagaries of nature and are reasonably priced. Such development demands a lot of expenditure and time just like any other patentable invention.
- ❑ TRIPS agreement says that either a member should cover plant variety in domestic patent law or it should be provided a sui- generis protection. Accordingly, India's patent law doesn't cover plant varieties and POPVFR act provides a sui-generis protection
- ❑ In order to provide for the establishment of an effective system for the protection of plant varieties, the rights of farmers and plant breeders and to encourage the development of new varieties of plants it has been considered necessary to recognize and to protect the rights of the farmers the Govt. of India enacted "The Protection of Plant Varieties and Farmers' Rights (PPV&FR) Act, 2001" adopting sui generis system.
- ❑ Indian legislation is not only in conformity with International Union for the Protection of New Varieties of Plants (UPOV), 1978, but also have sufficient provisions to protect the interests of public/private sector breeding institutions and the farmers.
- ❑ Also, the Protection of Plant Varieties and Farmers Right Authority has been created under the act.
- ❑ Indian law, not only provides for the right of breeders' and researchers', but it also provides the right to seed to farmers and village community. Registering the variety under the authority offers certain protection to its growers under the law.
- ❑ As such, plant varieties present in the wilderness cannot be registered, under PPV&FR Authority. However, any traditionally cultivated plant variety which has undergone the process of domestication / improvement through human interventions can be registered and protected subjected to fulfillment of the eligible criteria.
- ❑ The Central Government has notified 57 crops with their genera and species eligible for registration as new varieties.
- ❑ Patenting of Traditional Knowledge - Yoga Asanas
- ❑ Traditional Knowledge Digital Library (TKDL) is in the process of documenting over 1500 yoga postures in order to stop patenting of these postures by foreign parties.
- ❑ TKDL believes that as many as 2,000 applications were being made internationally every year for patents on Indian systems of medicine including yoga postures, which was nothing but misappropriation of traditional Indian knowledge.

- ❑ But with India providing evidence to the contrary, Patent applications have had to be withdrawn in countries as varied as USA, Japan, UK, Italy, Germany, Australia, China, Cyprus, Kenya, Spain, South Korea, Bulgaria, the Netherlands, and New Zealand.
- ❑ It is estimated that up to 300 million people practice yoga across the globe, with the US being the world's largest yoga industry worth over \$27 billion. Yet more than half of global yoga enthusiasts are Indians.
- ❑ News sources indicate that a mind-boggling 249 patents were taken on yoga in 2004 and 2,300 in 2005 at various international Patent offices, thus implying the urgent need to incorporate these Yoga Aasanas into TKDL.

CSIR-TKDL unit till date has achieved success in about 200 cases and more. Besides major companies like Colgate-Palmolive and Pangaia, the other big players who have been hit by the TKDL include Nestle, L'Oreal, Avasthagen, Ranbaxy, BASF and Unilever.

## Misuse of Secondary Patent Methodology

### Introduction

- ❑ A patent is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application.
- ❑ Items fall under four classes:
  - ❑ **The machine:** Apparatus or device with interrelated parts that work together to perform the invention's designed or intended functions,
  - ❑ **Manufacture:** All manufactured or fabricated items,
  - ❑ **Process: Chemical**, mechanical, electrical or another process that produces a chemical or physical change in the condition or character of an item, and
  - ❑ **Composition of matter:** Chemical compounds or mixtures having properties different from their constituent ingredients.
- What are the Primary and Secondary Patents?
- Patents play a crucial role in the pharmaceutical industry. Patents are usually filed already during the research phase in the development of a new drug. These early patents are filed to protect potential active ingredients that form the basis of the new drug.
- Patents on active ingredients are referred to as primary patents. In later phases of the drug development, patents are filed on other aspects of active ingredients such as different dosage forms, formulations, production methods, etc.
- These patents are referred to as secondary patents. Secondary patents also emerge from changes to formulations and dosages or applications in new therapeutic classes, discovered during clinical trials.
- The secondary patents are taken before the expiry of a primary patent thereby stretching the exclusivity beyond 20 years, a practice that is called "ever-greening".

- Generally **blockbuster medicines**, which reap annual revenues exceeding \$1 billion are made evergreen to continue profit.

#### □ What is 'Blockbuster Drug'

- It is an essential and popular drug that generates annual sales of at least \$1 billion for the company that sells it. Examples of blockbuster drugs include Humira and Lipitor. Blockbuster drugs are commonly used to treat common medical problems like high cholesterol, diabetes, high blood pressure, asthma, and cancer.

#### □ Take for example

- The drug, **Humira**, continues to grow even after the expiry of the patent over its main ingredient, **adalimumab**, a biologic used for the treatment of arthritis.
- By 2020, a company called AbbVie Inc, makers of Humira, expects its sales to touch \$21 billion.

#### □ What is meant by Ever-greening?

- Patents offer their owners market exclusivity for a limited period of time, typically 20 years. The end of patent exclusivity will reduce the drug prices drastically.
- However, pharmaceutical companies find new ways to postpone their exclusivity by filing secondary patents making small changes to an original drug with a new formulation, a dosage regime, or a new method of administering the medicine. This practice is called ever-greening.

#### □ The stand of India over Ever-greening

- India's patent law does not accept Ever-greening of drugs.
- For example Swiss company Novartis filed a new patent on its drug Glivec, a drug used to fight leukemia. But Supreme Court refused to grant Novartis a patent for a new version of its cancer drug as the drug was not substantially different from the original one.
- Spiriva, a medicine for asthma, enjoys patent protection until 2021 in the U.S., largely due to secondary patents. All of these secondary patents were rejected in India.
- Indian Patent Act provisions also extend to biologics.
- In developing countries, secondary patents may have played a particularly important role for multinational originator companies during the years following the introduction of pharmaceutical patents. When developing countries began to allow the granting of pharmaceutical product patents, in many instances originator companies were unable to obtain patent protection for drugs that had already been patented abroad.
- Despite the widespread use of secondary patents and the contentious policy debate, there is little evidence on the use of primary and secondary patents in developing countries.
- In India secondary patents are not provided. The rejection of a secondary patent for Novartis' Glivec, a crucial leukemia cure, was famously upheld by the Supreme Court of India in 2013, while the same was granted in the U.S. Consequently, the cost of a monthly dose of the medicine in the U.S. was Rs. 1.6 lakh, while the cost of the generic was Rs. 11,100 in India. Likewise, Spiriva, a medicine for

asthma, enjoys patent protection until 2021 in the U.S., largely due to secondary patents. All of these secondary patents were rejected in India. As a result, while the monthly cost of the medicine in the U.S. is over Rs. 19,100, and it costs a mere Rs. 250 in India.

## Way Forward

- ❑ The result of the check on evergreening is low and affordable prices for life-saving drugs. This will ensure India's universal health coverage.
- ❑ Along with punishing errant through the patent regime, India should invest largely in innovation for affordable medicines.
- ❑ Along with deterrence, manufacturing in drugs to be boost though policy changes and ease of doing business.

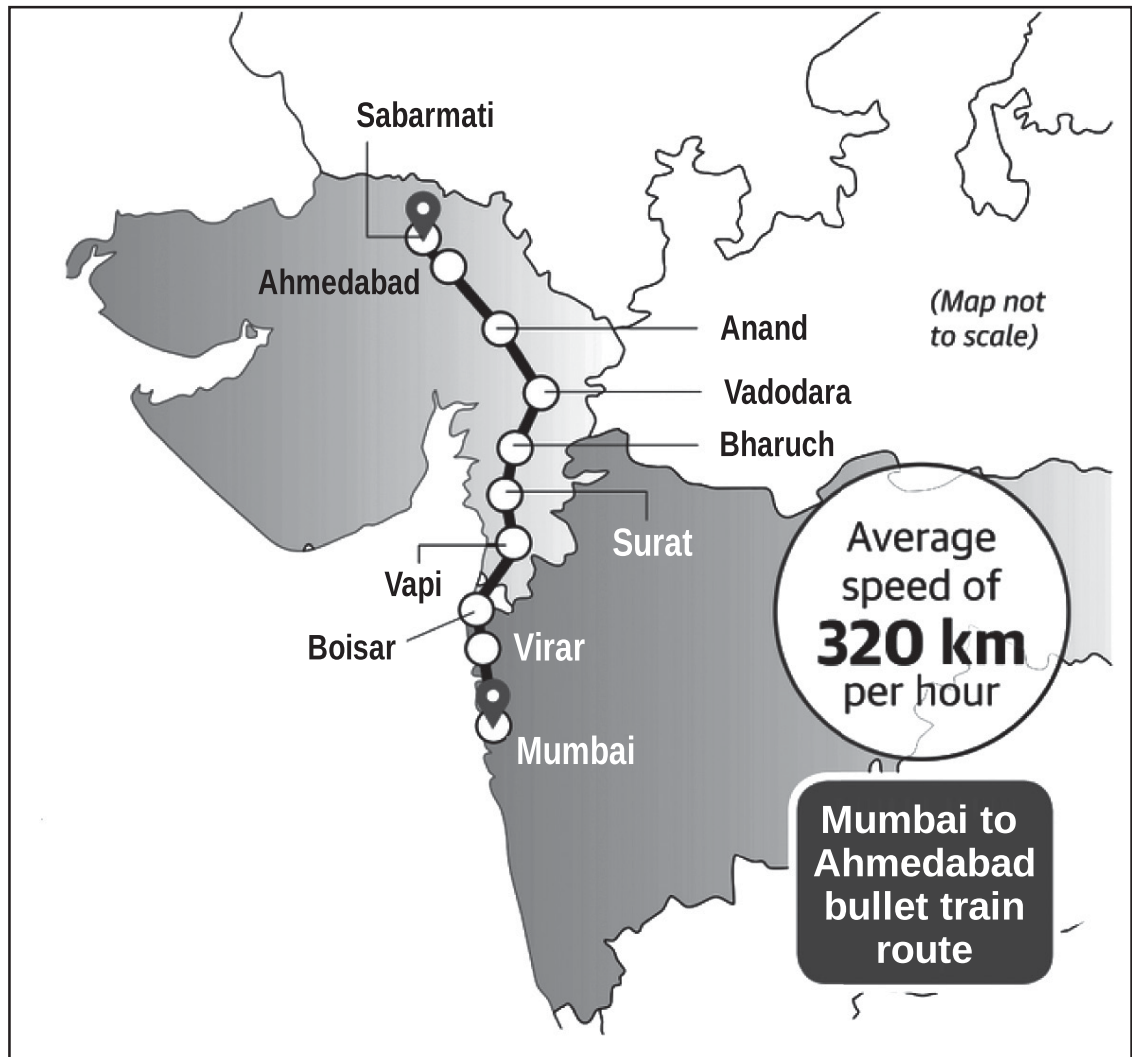
# Bullet Train

## Introduction

- ❑ Prime Minister Narendra Modi laid the foundation stone in Ahmedabad for the country's first Rs. 1,10,000 crore, 508 km high-speed rail project between Mumbai and Ahmedabad.

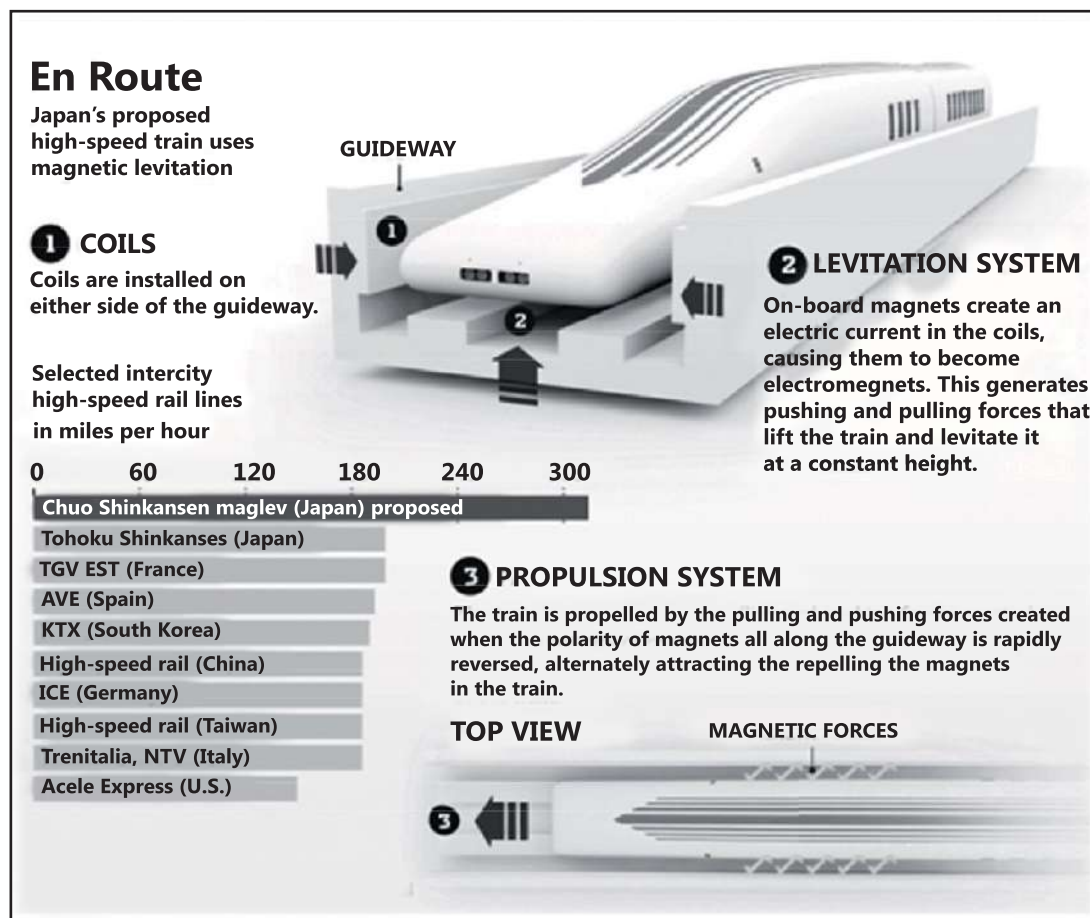
## Key Project features:

- ❑ **Length 508 kms double line.** Mumbai Ahmedabad High-Speed Rail will be passing through two states, Maharashtra 155.642 KMs and Gujarat 350.530 KMs and one Union Territory of Dadra and Nagar Haveli 2 KMs.
- ❑ **12 stations:** Mumbai, Thane, Virar, Boisar, Vapi, Bilimora, Surat, Bharuch, Vadodara, Anand, Ahmedabad, Sabarmati. Except for Mumbai, all other stations will be elevated.
- ❑ **Maximum Design Speed:** 350 kmph while Maximum Operating speed of 320 kmph.
- ❑ **Journey time:** - 2.07 hrs (limited stops), 2.58 hrs (stopping at all stations).
- ❑ **Maintenance of Trains** – Sabarmati (Depot & Workshop) and Thane Depot.
- ❑ **Operations Control Centre (OCC)** at Sabarmati. High-Speed Railway training Centre which was earlier planned at Gandhinagar will now be located at Vadodara.
- ❑ The Railways will only require around 825 hectares of land for the project as 92 percent of the route will be elevated, six percent will go through tunnels and only the remaining two percent will be on the ground.
  - ❖ **Cost of the Project:** The project is estimated to cost Rs. 1.1 lakh crore (US\$17 billion). The cost includes interest during construction and import duties. Japanese International Cooperation Agency (JICA) agreed to fund 81% of the total project cost Rs. 88,087 crore (US\$14 billion), through a 50-year loan at an interest rate of 0.1% with a moratorium on repayments up to 15 years and the remaining cost will be borne by the state governments of Maharashtra and Gujarat.



### Scientific principle

- ❑ Bullet trains are outfitted with electromagnets along their undercarriages. The track, meanwhile, is equipped with coils. Electrical current supplied to the electromagnets and monitored by computers constantly changes the polarity of the coils, which allows the magnetic fields system to push and pull the train along the track.
- ❑ Electrodynamic suspension operates with repulsion magnets. Through this method, the magnetic levitation force keeps the train in a stable position by balancing its weight. This method works with electromagnetic coils on the track and super-cooled superconducting magnets on the train cars. When the trains approach the coils, a current is generated. This current allows the train to levitate roughly 1 inch above the track and center itself.
- ❑ Bullet trains are capable of speeds of 300 miles per hour or more. Each train carries a battery power supply that operators can engage in the event of a power outage to prevent a sudden stop in levitation that results in a crash.
- ❑ A big benefit of the Maglev train is safety. Maglev trains are “driven” by the powered guideway. Any two trains traveling the same route cannot catch up and crash into one another because they’re all being powered to move at the same speed. Similarly, traditional train derailments that occur because of cornering too quickly can’t happen with Maglev. The further a Maglev train gets from its normal position between the guideway walls, the stronger the magnetic force pushing it back into place becomes.



## Technology and Food Security

### Introduction

- ❑ “Food security exists when all people, at all times, have physical, social and economic access to sufficient, safe and nutritious food which meets their dietary needs and food preferences for an active and healthy life”.
- ❑ In India, the Central Government, through Food Corporation of India (FCI), has assumed the responsibility for procurement, storage, transportation and bulk allocation of food grains to the State Governments. The operational responsibility including allocation within State, identification of eligible families, issue of Ration Cards and supervision of the functioning of Fair Price Shops (FPSs), etc., rest with the State Governments.
- ❑ **Reasons for the existing food insecurity in India:**
  - Poverty is a major cause as it limits the amount of food available to the vulnerable sector.
  - Overpopulation is linked to competition for food and can lead to malnutrition amongst children, especially in rural areas where access to food is limited.
  - Lack of adequate knowledge amongst mothers regarding nutrition, breastfeeding, and parenting is another area of concern.

- Gender inequality places the female child at a disadvantage compared to males and causes them to suffer more because they are last to eat and considered less important.
- Inadequate distribution of food through public distribution mechanisms (PDS i.e. Public Distribution System) is also a reason for growing food insecurity in the country.
- Lack of coherent food and nutrition policies along with the absence of inter-sectoral coordination between various ministries of government such as Ministry of Women and Child Health, Ministry of Health and Family Welfare, Ministry of Agriculture, Ministry of Finance, etc have added to the problem.
- Climate change too has an impact on agricultural productivity, which affects the availability of food items and thus, food security.
- Rural-to-urban migration

### □ Role of Technology

- IT supports new methods for precision agriculture like computerized farm machinery that applies to fertilizers and pesticides. Farm animals are fed and monitored by electronic sensors and identification systems. Selling or buying online began to become popular in the world.

### □ Benefits of using technology:

- **May attract Youth:** High-tech agriculture technology could attract the educated youth to agriculture, helping create skilled jobs in rural areas. Farming should be made profitable for farmers with remunerative prices for their produce. With the investment in agriculture, modern technologies agricultural productivity will increase thus food security.
- **Improved Prediction:**
  - ▶ From satellites circling the earth to ground-based remote sensors in the oceans, rivers, and farms, we can forecast the drivers of food insecurity with increasingly higher degrees of accuracy.
  - ▶ For example, the agriculture technology firm where has created a global agronomic weather database with 1.6 million 'virtual weather stations' that can predict current and future weather events at 9km intervals. aWhere can also highlight "pocket droughts" where small geographical areas might be experiencing severe water access issues, even when the larger region has plenty of rainfall.
- **Better planning**
  - ▶ IT has paved the way to come up with farming software which can keep better track of crops, predict yields, when to best plant and what to plant, to intercrop or focus on just one product, or determine the current need of the crops—just about everything needed to improve production and income. By adjusting to the modern farming methodologies, farmers can have better control of their crops. Gaining information from their farm is essential in sustaining its success and fuelling further growth.
  - ▶ Big data and the Internet of things can be harnessed for a number of agricultural applications, including farmer decision support, precision farming, and insurance.
- **Precision agriculture (PA):**
  - ▶ Satellite farming or site-specific crop management (SSCM) is a farming management concept based on observing, measuring and responding to inter and intra-field variability in crops.
  - ▶ This technique focuses on utilizing resources optimally to improve the quality and quantity of crops while lowering the cost of production. It reduces fertilizer and pesticide use, prevents soil degradation, utilizes water optimally and raises productivity.

- **Increase food accessibility:**
- A key aspect of accessing food is minimizing food losses during production, storage and transport, and waste of food by retailers and consumers. Such agricultural losses are attributable to a number of factors, including lack of access to ready markets, adequate storage facilities, affordable refrigeration, and local crop-processing facilities.
- Nanotechnology is being used in a number of projects to improve the preservation of crops. Similarly, radiation technology can be used for sterilization of the bacteria and to increase the shelf life of food.
- **Increase food utilization:**
  - ▶ Biofortification – or the breeding of critical micronutrients and vitamins into staple crops – has emerged as an effective approach to combat malnutrition, especially in developing countries.
- **Decrease the impact of climate change:**
  - ▶ Soil carbon losses can be reduced by protecting existing permanent grassland, and soil carbon sequestration can be increased in arable land by the application of organic fertilizers, minimal soil disturbance, agroforestry, mixed cropping and the planting of legumes.
  - ▶ In addition, locally adapted breeding for drought or heat-tolerant crop varieties, with a focus on underutilized crops, has great potential to support climate change adaptation in agriculture.

## Challenges

- ❑ **India is a poignant example of how food sufficiency at the aggregate level has not translated into food security at the household level.**
- ❑ While India's scientific community has been working on technologies to advance domestic agriculture, policymakers have been timid and inept and have blocked the maturation of new products and technologies.
- ❑ **Long gestation periods:** It takes 10-12 years on average to bring any new crop biotechnology from the research labs to commercialization. With such long gestation periods, the industry cannot survive in perennial uncertainty over whether their research will eventually culminate in commercial products.
- ❑ **Brain-drain:** India's farmers are yearning for innovative technologies to boost their yields, provide resilience against pests, drought, and other challenges, and enhance their income. However, uncertain regulatory policy and other sorts of governmental interference will not only lead to the flight of much-needed capital for research and development in agriculture but also a brain-drain of promising and talented intellectual capital.
- ❑ The reach of the technology is still a very poor and large chunk of farmers are still **ignorant** about such advancements. The distribution of technologies is not uniform throughout the country. Farmers of prosperous states are at the receiving end like- Punjab, Haryana, Maharashtra and the farmers of backward states still practice their age-old techniques and knowledge.
- ❑ The use of technology is being used by the already rich farmers and utilizing these services they are further prospering. The small and marginal farmers are again being left out in the process of development.
- ❑ Due to the low literacy rate among farmers and the digital divide, there is a rise of a new class of middle man, who provide ICT services to farmers. They are also believed to distort the information for their own benefit.
- ❑ The rural infrastructure for the use of ICT is also not uniform and a lot of regional disparity persists.

## Solutions

- ❑ To harness science and technology for the various dimensions of food security, it is necessary to make the food system itself more innovative.

- ❑ Designing and strengthening an agricultural innovation system involves promoting research and development, investing in infrastructure, building human capacity, creating an enabling environment and strengthening knowledge flows, particularly among scientists and farmers. Because women account for a significant share of agricultural labor, a gender-sensitive lens to agricultural innovation should be applied. Regional and international collaboration can address research priorities, while international technology assessment and foresight can help countries evaluate the immediate and long-term implications of innovations for food security.
- ❑ The establishment of new education and research programmes and institutions can help create a knowledge base and pool of experts to develop the capacity to innovate within agriculture. E-education platform can be utilized.

## Government Initiatives

### Food Legumes Research Platform:

- ❑ The establishment of FLRP in India will enable India to harness the best of international science in meeting the emerging food security challenges.
- ❑ India would be able to rapidly and effectively absorb the research output achieved in the country by FLRP.

### Kisan credit card:

- ❑ The Kisan Credit Card allows farmers to have cash credit facilities without going through time-consuming bank credit screening processes repeatedly.

### Kisan SMS Portal:

- ❑ Here farmer keeps getting SMS messages providing information or delivering service or giving advisories on his mobile from experts, scientists and officers at various levels after once opting for messages on agricultural practices/crops of his interest.

### Kisan Call center:

- ❑ An expert advisory system and the farmers need to call the toll free number 1800-180-1551 to seek expert advice on different matters related to agriculture and allied sectors.
- ❑ For farm credit, service of ICT is being harnessed like Smart Cards, Internet Kiosks and cell phone messaging. And also disbursement of all social security benefits through electronic benefit transfer to all rural areas. Mobile-enabled Kisan card system to help the agricultural community engage in cashless transactions.

### Moisture sensors:

- ❑ These in the ground are able to communicate information about the level of the moisture present at a certain depth of the soil. This gives more precise control of water and other inputs like fertilizer that are applied by irrigation pivot.

## Village Knowledge Centre (VKC):

- These serve as information dissemination center providing instant access to farmers to latest information/ knowledge available in the field of agriculture, starting from crop production to marketing.

## Conclusion

- ICTs can improve the quality, reach and efficiency of extension services. The potential benefits of ICTs do not necessarily depend on the sophistication of the ICT device, with deployments involving mobile phones, locally produced how-to videos for farmers and participatory radio campaigns.
- Public investment in breeding programs and support for local seed systems that allow the diffusion of locally adapted genetic material, which farmers would have the right to freely save, exchange and market, is a good example of the need for public investment in research and technology diffusion.

# Boosting Horticulture through Remote Sensing

Horticulture is a boon of nature which is refined by human skill as a science to obtaining more and more benefits. It involves rigorous cropping expertise, including the improvement, production, distribution, and use of vegetables, fruits, woody landscape, and greenhouse plants. Horticulture is now one of the fastest growing industries with striking professional opportunities.

## Data: Horticulture sector in India

- Horticulture accounts for about **30% of India's agricultural GDP** from 13.08% of the cropped area.
- Provides about 37% of the total exports of agricultural commodities.
- Horticulture production is significant, despite its comparatively lower productivity. Both in the case of fruits & vegetable productivity of India (11.7 & 17.3 tons per hectare respectively) is about half of the productivity of the USA.
- Another positive for horticulture is that fruits and vegetables are mostly grown by marginal and small farmers (with less than 2 hectares of land). This means that resource-poor farmers are likely to have benefitted most from the growth in the horticulture sector. More so, because the value of the horticulture output grew more than double compared with all other crops put together in the four years between 2008-09 and 2012-13. Fruits and vegetables are grown in less than 5% of the country's gross cropped area, compared to over 63% of the area used to grow foodgrains.

## Government initiatives for Horticulture Development

### Use of Biotechnology in Horticulture:

- Biotechnology is an innovative science in which the living systems and organisms are used to develop new and useful products.
- Biotechnological tools have revolutionized the entire crop improvement programmes by providing new strains of plants, the supply of planting material, more efficient and selective pesticides and improved fertilizers.
- Many genetically modified fruits and vegetables are already in the market in developed countries.
- The major areas of biotechnology which can be adopted for the improvement of horticultural crops are:

- ❑ **Tissue Culture:** It is economical in time and space, provides greater output, disease free and elite offsprings. Another aspect of plant tissue culture is to produce somaclonal variation which means to generate genetic variations that may be needed in the breeding program
- ❑ **Embryo Rescue** is another area where plant breeders are able to rescue their crosses which would otherwise abort.

## ❑ Genetic Engineering.

- **Molecular Diagnostics and Molecular Markers.**
- Development of **Beneficial Microbes.**
- **GM Crops.**

### ➤ **Role of Government:**

- ◆ Under a scheme called Small Business Innovation Research Initiative (SBIRI), the private tissue culture units are entitled to expansion of existing units.
- ◆ Department of Agriculture and Cooperation provides financial assistance up to Rs. 21 lakhs for setting up tissue culture units (in public sector) and Rs 10 lakhs in private sector, subject to a maximum of 20% of the project cost under Integrated Development of Fruits Scheme, financial assistance in the form of subsidy up to 50 per cent is provided for purchase of tissue-cultured banana plants by various State Governments.

### ➤ **CHAMAN Project:**

- ◆ In 2015, the Modi government started project CHAMAN, an acronym for **Coordinated Horticulture Assessment and Management using geo-informatics** to prepare a comprehensive horticultural plan.
- ◆ Using remote sensing technology to study soil conditions, land use, weather, and cropping pattern, the Centre has chosen 185 districts across the country where seven selected crops are being promoted.
- ◆ Once complete, the findings of the project would be shared with all states to give a boost to the cultivation of horticultural crops.
- ◆ Under CHAMAN, Tamil Nadu, Andhra Pradesh, Karnataka, Gujarat, and Maharashtra have been identified as the major banana-growing states. Mango cultivation is being promoted in Andhra, Bihar, Uttar Pradesh, Karnataka, and Telangana, while the onion is the focus for Maharashtra, Gujarat, Karnataka, and Madhya Pradesh.
- ◆ The idea is to use space technology to identify crops suitable for different areas and raise the production of horticulture crops.
- ◆ The scheme is part of the government's ambitious target for doubling farmers' income by 2022. The second phase of the project envisages complete horticulture mapping of the country with two to three major districts for every state.
- ◆ Remote sensing can significantly contribute to providing a timely and accurate picture of the agricultural sector, as it is very suitable for gathering information over large areas with high revisit frequency.
- ◆ Reliable information on crop acreages, timely forecasts, and estimates of production and yields can improve domestic and foreign trade as well as various downstream and upstream activities.

## Challenges

- ❑ The country still has some distance to cover in terms of exports as post-harvest wastage of produce in India is high.

- ❑ The lack of good planting material like seeds and technologies hinders the production of this sector. For example, in India, the average mango production is 3-4 tons per acre as against 8-10 tons per acre in developed countries.
- ❑ As most of the horticultural products are perishable the lack of suitable post-harvest technologies and value addition facilities at the grass root level de-incentivize the farming community to take horticulture as a primary profession.
- ❑ Lack of regulated markets and multiplicity of intermediaries in marketing makes the price higher in the consumer end and lower in the production end.
- ❑ Improper knowledge about the climate and irrigation facilities makes the production fluctuate.

## Hyperloop Transportation Technology

Hyperloop is a new way to move people and things at airline speeds for the price of a bus ticket. Currently, at a conceptual level, the new transport system can ferry passengers through a low-pressure vacuum tube at a speed of 700mph. A one-way trip for instance, between Delhi and Mumbai on this transit system, could take about 1 hour and 14 minutes.

### Technology

- ❑ HTT uses a technology called hyperloop that essentially transports passengers in special capsules, or pods, propelled by magnets through steel tubes at a supersonic speed of 760 miles per hour (1,223 kilometers per hour).
- ❑ HTT utilizes a magnetic technology that allows its capsules to levitate and move. It is currently in negotiations for 20 projects across the world, including the U.S., Chile, Botswana, Egypt, the U.A.E, Indonesia, Malaysia, China, Russia, and Australia.

### Comparison with High-Speed Train

- Hyperloop transportation is two to three times faster than the fastest high-speed rail.
- High-speed rail requires power along the entire track. Thus, the track costs more to build and more to operate whereas HTT's track is electrified, its transport system consumes tiny amounts of energy.
- In the context of India, using such technology, as has been proposed for the railways, recently, can bring about significant transformation in the following ways:
- A tremendous saving in traveling times, both for passengers as well as in the case of freight transport.
- A significant reduction in cost if the technology is adopted, especially when compared with alternatives such as bullet trains.
- Significant reduction in energy consumption, and also reduce pollution.
- Has the potential to revolutionize the entire transport sector.
- A boost to economic productivity and GDP growth.
- The hyperloop technology is without a doubt a significant technological breakthrough and has tremendous potential for providing numerous spillover benefits in various sectors.

## Cloud Seeding Experiment in Maharashtra

- ❑ Cloud seeding involves introducing dry ice or silver iodide into clouds to aid precipitation and rainfall.
- ❑ Cloud seeding is a form of weather modification, is a way of changing the amount or type of precipitation that falls from clouds, by dispersing substances into the air that serve as cloud condensation or ice nuclei, which alter the microphysical processes within the cloud. The usual intent is to increase precipitation (rain or snow).

### Cloud Seeding Experiment

- ❑ Maharashtra Government has approved Rs.250 crore Cloud Seeding Programme during 2017 monsoon season to produce sufficient rain.
- ❑ Under this programme, weather scientists using aircraft will spray chemicals (silver iodide) over clouds hovering above Solapur district, a rain shadow region of the Western Ghats in the state.
- ❑ The aircraft will be based at Aurangabad, which will cover parched areas like Solapur, Sangli, Satara, Latur, Osmanabad and Beed, and the radar would help indicate “the accurate movement of clouds with their depth and moisture content”.
- ❑ This will be the first controlled experiment to quantify the extent to which clouds form water drops large enough to make rain.
- ❑ This programme, coordinated by the Indian Institute of Tropical Meteorology, will be the first controlled experiment to quantify the extent to which clouds form water drops large enough to make rain.

## Hydrogen Bomb

- ❑ Atombombs release energy by fission, or breaking apart, of heavy atomic nuclei like uranium and plutonium, while a hydrogen bomb releases energy by fusing together light nuclei like tritium or deuterium, converting even more matter into energy.

### Nuclear fusion

- ❑ Fusion powers the Sun and stars as hydrogen atoms fuse together to form helium, and the matter is converted into energy. Hydrogen, heated to very high temperatures changes from a gas to a plasma in which the negatively-charged electrons are separated from the positively-charged atomic nuclei (ions).
- ❑ Normally, fusion is not possible because the strongly repulsive electrostatic forces between the positively charged nuclei prevent them from getting close enough together to collide and for fusion to occur. However, if the conditions are such that the nuclei can overcome the electrostatic forces to the extent that they can come within a very close range of each other, then the attractive nuclear force (which binds protons and neutrons together in atomic nuclei) between the nuclei will outweigh the repulsive (electrostatic) force, allowing the nuclei to fuse together. Such conditions can occur when the temperature increases, causing the ions to move faster and eventually reach speeds high enough to bring the ions close enough together. The nuclei can then fuse, causing a release of energy.

### ❑ Basics of Hydrogen Bomb

- ❖ First, the stages of the weapon are separated into a triggering, primary explosive and a much more powerful secondary explosive.

- After this, the secondary explosive is compressed by X-rays coming from the nuclear fission of the primary explosive. This process is called the “radiation implosion” of the secondary explosive.
- Finally, the secondary explosive is heated, after cold compression, by a second fission explosion that occurs inside the secondary explosive.

#### ❑ Differences between the Hydrogen bomb and Atom bomb:

- ❑ A Hydrogen bomb is a much more powerful atomic weapon.
- ❑ The energy released in a Hydrogen bomb is several magnitudes higher than an Atom bomb. Hydrogen bombs can devastate whole cities in one explosion.
- ❑ A Hydrogen bomb derives its energy through the fusion of atoms. An Atom bomb derives its energy from fission.
- ❑ Nuclear fusion and nuclear fission are different types of reactions that release energy. In fission, an atom is split into 2 or smaller, lighter atoms. Fusion, in contrast, occurs when 2 or more atoms fuse together, creating a larger, heavier atom.
- ❑ A fusion bomb is more sophisticated and difficult to make since it requires a much higher temperature in the order of millions of degrees centigrade. So fission is carried out first to produce more energy, which is then used to initiate fusion. In a fusion bomb, a fission device has to be triggered first.
- ❑ It is easier to make Hydrogen bombs in small size, so it is easier to place them in missiles.
- ❑ Hiroshima and Nagasaki both were atomic bombs and till date Hydrogen bombs have never been used in war.
- ❑ This is the fourth atomic test by North Korea and the first test of a fusion bomb.

## Ear Tagging In Cattle

- ❑ Animal identification verification and tracking are usually done for verification of ownership, biosecurity control, identification and tracking for research, tracking the health of animals, as well as agricultural purposes.
- ❑ There are a variety of methods to identify are leg rings, tags, microchip (parrots), telemetry (falconry birds), collar, earmarking, ear tags (electronic and non-electronic), Semi-permanent paint, tattoo, microchip implants, lip tattoo, anklets, Rumen bolus (electronic), cowbell.
- ❑ Ear tagging is the process of applying a plastic or metal tag to the ear of an animal for identification. Information that is included on an ear tag are details such as ownership of the herd and record of dates that medical and other treatments were administered. Ear tags may also contain chemicals that are dispersed to treat insects or combat infection. Electronic ear tags are equipped with RFID chips for electronic data storage and retrieval of information contained on the tag.

#### ❑ About RFID Technology:

- Radio Frequency Identification (RFID) uses radio waves to communicate between two objects: a reader and a tag. RFID communication is the same as two-way radio communication in the sense that information is transmitted or received via a radio wave at a specific frequency.
- RFID tagging is an ID system that uses small radio frequency identification devices for identification and tracking purposes. An RFID tagging system includes the tag itself, a read/write device, and a host

system application for data collection, processing, and transmission. An RFID tag (sometimes called an RFID transponder) consists of a chip, some memory, and an antenna.

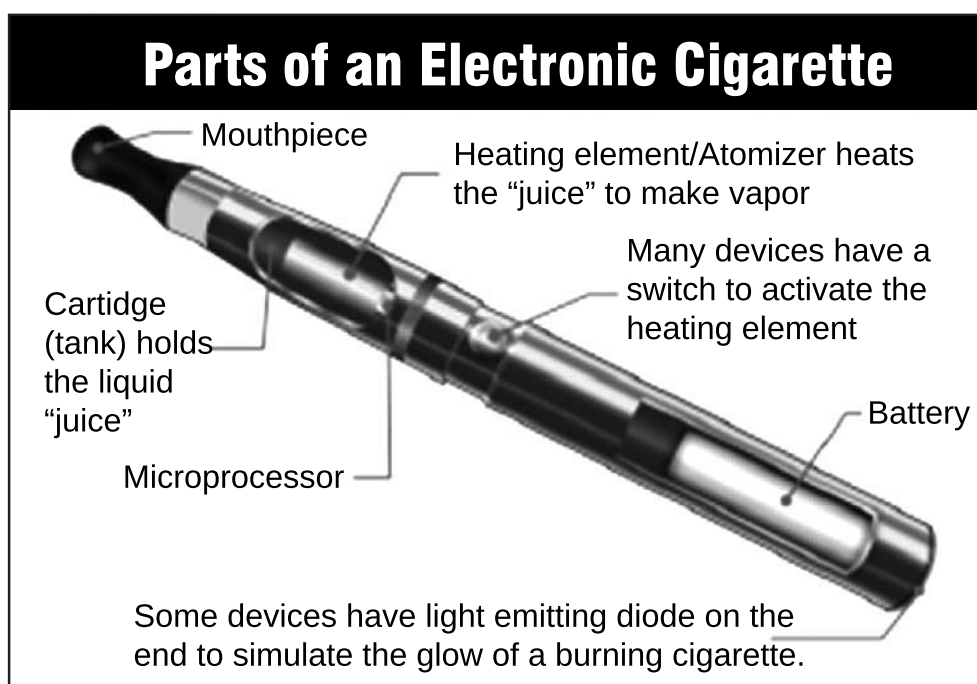
- RFID tags that contain their own power source are known as active tags. Those without a power source are known as passive tags. A passive tag is briefly activated by the Radio Frequency (RF) scan of the reader.

□ **Fundamentally they comprise two main elements:**

- **Electronics Circuitry:** The electronics within an RFID tag are kept to the minimum to ensure that cost is minimized and power levels are kept as low as possible.
- **Antenna:** The antenna within the RFID tag is the element that takes the largest amount of space. It must be able to operate satisfactorily at the frequency of operation. With wavelengths being smaller at higher frequencies (especially UHF and microwave), this makes antennas for these frequencies much more efficient.

□ **Ear Tagging benefits:**

- It helps in storing the information of each and every animal with breeding, feeding and yield data.
- Milking and egg laying database and monitoring can be easily recorded and maintained, enabling classification, individual preventive measures or maintaining group health improvement.
- Tagging helps us to improve agro-management through increased efficiencies, controlled and monitored feed as well as reduced feed and labor costs, enhanced outcomes and exponentially improved group health of animals.
- Identification and recording of animals using Radio Frequency Identification [RFID] chips have a lot of merit for reducing malpractices related to the implementation of government programs in the animal husbandry sector and insurance and also in recording the breed, yield and behavior of animals.



- The necessity for proof of ownership and identification help keepers to maintain records of origin, identity, and destination of animals. It will help to keep up-to-date records of all animal births,

deaths, movements, treatment, vaccination, castration, pregnancy, insemination, accident and other information with dates.

- By collecting Secure, authentic and real-time data, one can get correct statistical analysis and on time information which helps to take decision making.
- It will also help in to provide proper and timely treatment to the cattle with a health-related case history and improving management, sales of breeding animals and genetic improvement.
- RFID tagging will help to get constructed data will help to achieve the goal for the better breed, more productivity which helps for better production.
- Scientific intervention can be made resulting in better breeding and an increase in quality milk production.
- The tag is tamper-proof, cannot be opened by a wrench and is designed to last for years.
- It offers the advantage of being more easily adapted to computerized tracking and scanning systems for recording and storing animal records as compared to visual systems.

## e-Cigarette

Tobacco use, especially through cigarettes, is a risk factor for many diseases, especially those affecting the heart, liver, and lungs, as well as many cancers. In 2008, the World Health Organization (WHO) named tobacco as the world's single greatest cause of preventable death.

### □ The burden of Tobacco Use (India)

- Nearly 8-9 lakh person die in India due to tobacco use every year.
- 30% of cancer deaths, the majority of cardiovascular and lung disorders.
- 40% of TB and other related diseases are attributed to tobacco consumption.
- Over 80% of oral cancers are caused due to tobacco use. As per the WHO Global Report on "Tobacco Attributable Mortality" in 2012, 7% of all deaths (for ages 30 and over) in India are attributable to tobacco.
- Within the non-communicable diseases group, 9% of deaths are attributable to tobacco, of which 58% of deaths due to trachea, bronchus, and lung cancers caused due to tobacco use.
- In addition, 25% of deaths caused by respiratory diseases and 28% of deaths caused by Chronic Obstructive Pulmonary Disease (COPD) are attributable to tobacco.

### □ Why was it in the news recently?

- The Karnataka government imposed a ban on sale (including online) and use of e-cigarettes in the State, based on the recommendations of the State high powered committee on tobacco control. But recently, teachers in Karnataka are discovering that many schools and college students are switching over to e-cigarettes, which are officially banned for sale but available in a variety of shops.

### □ What are e-Cigarettes?

- Electronic cigarettes, or e-cigarettes, include e-pens, e-pipes, e-hookah, and e-cigars are known collectively as ENDS – Electronic Nicotine Delivery Systems. E-cigarettes are devices that allow users to inhale aerosol (vapor) containing nicotine or other substances. Unlike traditional cigarettes,

e-cigarettes are generally battery-operated and use a heating element to heat e-liquid from a refillable cartridge, releasing a chemical-filled aerosol.

#### ❑ **Components of E-cigarettes:**

- The main component of e-cigarettes is the e-liquid contained in cartridges. To create an e-liquid, nicotine is extracted from tobacco and mixed with a base (usually propylene glycol), and may also include flavorings, colorings, and other chemicals.

#### ❑ **Disadvantages of E-Cigarette**

There are various disadvantages of E-Cigarettes:

- An e-cigarette is endless in nature due to the higher number of puffs per filling, which leads to higher consumption.
- It does not emit tar but metals such as tin, lead, nickel, and chromium have been found in e-cigarette liquids and vapor, which is injurious to health and have the potential to cause cancer.
- E-cigarettes deliver high levels of nanoparticles, which can trigger inflammation (asthma), stroke, heart disease, and diabetes.
- The cartridge of E-Cigarette contains nicotine (a highly addictive chemical) and leakage of liquid can cause toxic exposure to nicotine.
- There are several cases of E-Cigarette explosion have been reported around the world and due to proximity to the human face, it can cause serious injuries as in a case of explosion, it burnt cornea of a boy in Florida.
- It does not contain tobacco and due to this, it does not come under the ambit of existing laws. In the absence of a legal framework, manufacturers are not accountable and do not hesitate to add inappropriate (toxic) substances on the name of flavor.

#### ❑ **WHO cautions India over E-Cigarettes**

- The World Health Organisation (WHO) has red flagged the growing market for e-cigarettes in India, underlining that the use of the devices is no less harmful than traditional cigarettes.
- In the absence of a regulation the use of e-cigarettes has grown; they are easily accessible to even the nonsmokers. In many countries these e-cigarettes are available in candy flavors, giving an impression they are not harmful. We have sought a regulation on their use to protect public health. There should be a ban on smoking of e-cigarettes in public as well and a restriction on their use. From the current \$ 3 billion, the market for e-cigarettes is expected to grow 17 times.
- The WHO has also expressed concern over the notion that e-cigarettes aid in kicking the habit; it has cautioned that there is not enough evidence to conclude that e-cigarettes help users quit smoking.

## **Geo-Tagging the Assets in MGNREGA**

- ❑ Mahatma Gandhi National Rural Employment Guarantee Act (MGNREGA) enacted in 2005, aims to enhance the livelihood security of rural people by guaranteeing 100 days of wages in a financial year for adults willing to take up unskilled manual work.
- ❑ This initiative is unique of its kind across the globe in poverty alleviation. Around 30 lakh (3 million) assets are created annually across the country under the rural job scheme, which involves water

harvesting, drought relief and flood control as preferred activities. Convergence with other schemes necessitates further transparency in database creation of MGNREGA assets.

### Geo-tagging of Assets:

- ❑ A Memorandum of Understanding (MoU) was signed between the Department of Rural Development (DoRD), Ministry of Rural Development (MoRD), New Delhi and National Remote Sensing Centre (NRSC), ISRO, Hyderabad, for geo-tagging of the assets created under MGNREGA.
- ❑ NRSC will be developing the geospatial solutions on 'Bhuvan Geo-portal' and also the mobile-based geo-tagging applications for Mahatma Gandhi NREGA scheme.
- ❑ The entire implementation is planned in three phases and the memorandum addresses the first phase of implementation.
- ❑ Next phases aim to enable citizen-based reporting as well as national level MGNREGA planning framework using geo-information.
- ❑ Geo-tagging exercise is a national level initiative involving linking ISRO-Bhuvan with "NREGA-Soft" interface operated under DoRD by National Informatics Centre (NIC). This has to be established within a very limited timeline, which will enable access to all state implementing departments.
- ❑ Database of completed assets residing on "NREGA-Soft" will be pushed to Bhuvan, which in turn will be served to each data collector under Gram Panchayats.
- ❑ Collected data will be moderated for quality level through approved authorities at the block level to ensure the precise information for online visualization. Bhuvan can facilitate complete geographic information storage, retrieval, analysis and reporting for completed assets, with a high-resolution backdrop of Indian Remote-sensing Satellite (IRS) natural color images. DoRD and NRSC are closely working out the modalities of design, integration, and rollout based on intensive schedules seeking compliance of high rigor.

### What is Geo-tagging?

- ❑ Geotagging is the process of adding geographical information to various media in the form of metadata. The data usually consists of coordinates like latitude and longitude, but may even include bearing, altitude, distance and place names. Geotagging is most commonly used for photographs and can help people get a lot of specific information about where the picture was taken.
- ❑ Geotagging location services can be used to find location-specific websites, news, and other information. It is based on positions and coordinates and is often directly taken from a Global Positioning System (GPS). It is conducive for biotechnology and may differ from that of software which in turn may differ from that of electronics. It is understandable that a master policy document may not be able to set out all the sector-specific policies.

## India & World Collaboration in Science Projects

- ❑ In the last six decades, a rash of scientists had left India for better opportunities and, over the years, gained vital exposure to the best global research labs. After years of experimenting and collaborating with some of the top scientists in the world, they have now chosen to return to their homeland.
- ❑ Recently, India's participation in frontier mega-projects provides an excellent opportunity for the country's scientific community to showcase its prowess on the global stage. At the same time, next-generation experiments on Indian soil also offer challenging career options in science and technology. This step can be significant in encouraging India's top talents, who are working in foreign organizations and laboratories, to return and work in India.

## Mega Science Projects:

- Global Mega Science Projects often involve cross-border cooperation between teams of competent researchers. While the scientific goals of these projects are significant, their worldly benefits are equally important. By collaborating, participating and delivering components for these giant projects, India will place itself as a major player in fundamental science. In addition, these projects have the potential to create new avenues for science-industry collaborations and to popularize science in the country.

## List of six major science projects:

- LIGO – Gravitational Wave Analysis
- LHC – The God Particle
- Thirty Metre Telescope – World's Most Advanced Telescope
- ITER – Fusion Energy
- FAIR – Facility for Antiproton and Ion Research
- SKA – World's Largest Radio Telescope

## LIGO – Gravitational Wave Analysis

- LIGO or Laser Interferometer Gravitational-Wave Observatory is a large-scale physics experiment that detects cosmic gravitational waves and develops them as an astronomical tool.
- There are two LIGO observatories in the USA (at Livingston and Richland) that are operated by Caltech and MIT. The Indian team in the global LIGO collaboration, which is involved in analyzing the data collected by LIGO observatories, has 60 members.

## LHC – The God Particle

- There is an intrinsic Indian connection to the discovery of Higgs Boson at CERN – SatyendraNath Bose, the Indian scientist after whom the sub-atomic particle is named. Over the years, CERN, the world's largest particle physics laboratory, has seen Indian scientists make quite a mark with their work.
- Indian scientists have helped build the Large Hadron Collider (LHC), the largest single machine and the most powerful particle collider in the world. They are also collaborating on two significant CERN experiments, CMS and ALICE. CMS is one of the two experiments that discovered the Higgs Boson (also called God Particle) and ALICE studies matter under extreme conditions of density and temperature that may have existed at the birth of the universe.
- India is also poised to become an associate member of CERN by the end of 2016, which would entitle it to attend even the restricted sessions of the organization. And this is all thanks to our brilliant scientists.

## Thirty Metre Telescope – World's Most Advanced Telescope

- The Thirty Meter Telescope (TMT) will be the world's most advanced and capable ground-based telescope. At the heart of the telescope will be a mirror made up of 492 individual segments. Precisely aligned, these segments will work together as a single reflective surface with a diameter of 30 meters.
- The TMT- India project will propel India into a special league of deep space research. The main Indian institutes working on this unique project are Aryabhatta Research Institute for Observational Sciences (ARIES), the Indian Institute of Astrophysics (IIA), and the Inter-University Center for Astronomy and Astrophysics (IUCAA).

## ITER – Fusion Energy

- ITER (International Thermonuclear Experimental Reactor) is an experimental nuclear fusion reactor that is being built at Cadarache in the south of France. It's the core of a nuclear fusion research megaproject that will also be the world's largest plasma physics experiment.
- The ITER project aims to make the long-awaited transition from experimental plasma physics to full-scale electricity-producing fusion power stations.

## FAIR – Facility for Antiproton and Ion Research

- The Facility for Antiproton and Ion Research (FAIR) is an international accelerator facility that will be used to study the building blocks of the universe. Situated in Darmstadt in Germany, FAIR will use intense beams of antiprotons and ions for research in the fields of nuclear, particle, plasma and anti-matter physics.
- In India, the project is being coordinated by the Indo-FAIR Coordination Centre (IFCC) at Bose Institute, Kolkata and is jointly implemented by the Department of Science and Technology and the Department of Atomic Energy. Several Indian industries are also involved in building advanced equipment for the FAIR accelerator.

## SKA – World's Largest Radio Telescope

- The Square Kilometre Array (SKA) project is an international effort to build the world's largest radio telescope that is currently scheduled for completion in 2024. With an unprecedented large collecting area of over a square kilometer, the SKA will be 50 times more sensitive and 10,000 times faster than any imaging radio telescope array previously built.

## Benefits of indulging in collaboration

- Academic and research collaboration is a very valuable tool that not only accelerates the progress but also enhances the quality of the work and extends the repertoire of the partners. Academic collaboration is beneficial to the faculty in learning new teaching tools, and to the students in increasing the breadth of their knowledge and learning different approaches to solving a problem.

These opportunities include:

- Enhancing scientific capabilities,
- Enhancing the stability of science goals and funding
- Supporting foreign policy
- Addressing global science and technology issues.

## Carbon Capture and Utilisation Technologies

- Carbon Capture, Utilization, and Storage (CCUS) involves sophisticated methods and technologies to remove CO<sub>2</sub> from the flue gas and from the atmosphere, followed by recycling the CO<sub>2</sub> for utilization and determining safe and permanent storage options.
- The CO<sub>2</sub> captured using this way is converted into fuel (methane and methanol), refrigerants and building materials.
- The captured gas has multiple applications.
- It is used directly in fire extinguishers, pharma, food and beverage industries as well as the agricultural sector.

- ❑ CCUS technologies can play an important role in meeting net zero targets, including as one of few solutions to tackle emissions from heavy industry and to remove carbon from the atmosphere.
- ❑ CCUS is considered an important tool to help countries halve their emissions by 2030 and reach net-zero by 2050.
- ❑ These goals are crucial to meet the Paris Agreement targets for restricting global warming to 2 degrees Celsius (°C), and preferable to 1.5°C, over pre-industrial levels.

## Applications

- ❑ Mitigating Climate Change: Despite the adoption of alternative energy sources and energy efficient systems to reduce the rate of CO<sub>2</sub> emissions, the cumulative amount of CO<sub>2</sub> in the atmosphere needs to be reduced to limit the detrimental impacts of climate change.
- ❑ Agriculture: Capturing CO<sub>2</sub> from biogenic sources such as plants and soil to boost crop growth in a greenhouse could work.
- ❑ Industrial Use: Combining CO<sub>2</sub> with steel slag - an industrial byproduct of the steel manufacturing process — to make construction materials compatible with the Paris Agreement goals.
- ❑ Enhanced Oil Recovery: CCU is already making inroads into India. For instance, Oil and Natural Gas Corporation signed a MoU with Indian Oil Corporation Limited (IOCL) for Enhanced Oil Recovery (EOR) by injecting CO<sub>2</sub>.

## Challenges

- ❑ Expensive: Carbon capture involves the development of sorbents that can effectively bind to the CO<sub>2</sub> present in flue gas or the atmosphere, which is expensive.
- ❑ Lesser Demand for Recycled CO<sub>2</sub>: Converting CO<sub>2</sub> into useful chemicals of commercial importance, or utilizing CO<sub>2</sub> for oil extraction or remediation of alkaline industrial wastes, would add economic value to this greenhouse gas.
- ❑ However, the demand for CO<sub>2</sub> is limited compared to the vast amount of CO<sub>2</sub> that needs to be removed from the atmosphere, to reduce the detrimental environmental impacts of climate change.

## Semiconductor Shortage

- ❑ Semiconductors are materials which have a conductivity between conductors (generally metals) and non-conductors or insulators (such as most ceramics). Semiconductors can be pure elements, such as silicon or germanium, or compounds such as gallium arsenide or cadmium selenide.
- ❑ Conductivity is the measure of the ease at which an electric charge or heat can pass through a material.
- ❑ They are also known as integrated circuits or more commonly just chips, they may be the tiniest yet most exacting product ever manufactured on a global scale.
- ❑ It's an electric circuit with many components such as transistors and wiring formed on a semiconductor wafer. An electronic device comprising numerous of these components is called Integrated Circuit (IC), and can be found in electronic devices such as computers, smartphones, appliances, gaming hardware and medical equipment.
- ❑ These devices find widespread use in almost all industries, especially in the automobile industry.
- ❑ Electronic parts and components today account for 40% of the cost of a new internal combustion engine car, up from less than 20% two decades ago.
- ❑ Semiconductor Chips account for a bulk of this increase.

## Reasons for the Shortage:

- ❑ **Work from Home due to Covid:** Lockdowns increased the growth in sales of laptops to the highest in a decade. Home networking gear, webcams and monitors were snapped up as office work moved out of the office, and laptops were in demand for a while as schools shut.
- ❑ **False Forecasts:** Automakers that cut back drastically early in the pandemic underestimated how quickly car sales would rebound. They rushed to re-up orders late in 2020, only to get turned away because chipmakers were stretched supplying computing and smartphone giants.
- ❑ **Stockpiling:** Computer makers began warning about tight supplies early in 2020. Then around the middle of that year, Huawei Technologies Co. — the Chinese smartphone maker that also dominates the global market for 5G networking gear — began building up inventory to ensure it could survive US sanctions that were set to cut it off from its primary suppliers. Other companies followed suit, hoping to grab share from Huawei, and China's chip imports climbed to almost USD 380 billion in 2020, up from about USD 330 billion the previous year.
- ❑ **Disasters:** Production plants in the US were affected by the cold and in Japan by wildfire.
- ❑ **Difficult Production:** Manufacturing advanced logic chips requires extraordinary precision, along with huge long-term bets in a field subject to rapid change. Plants cost billions of dollars to build and equip, and they have to run flat-out 24/7 to recoup the investment.

## Impact:

- ❑ Countless industries have been affected as global demand for semiconductor chips continues to outstrip supply.
- ❑ Chip shortages are expected to wipe out USD 210 billion of sales for carmakers this year, with production of 7.7 million vehicles lost.
- ❑ The semiconductor shortage will severely disrupt the supply chain and will constrain the production of many electronic equipment types.
- ❑ The chip shortage directly impacts consumers as prices of everyday appliances and electronic goods — from TV to smartphones — have increased due to the global supply chain disruption.

## National Digital Health Mission

- ❑ The NDHM is a complete digital health ecosystem. The digital platform will have four key features — health ID, personal health records, Digi Doctor and health facility registry.
- ❑ At a later stage, it will also include e-pharmacy and telemedicine services, regulatory guidelines for which are being framed.
- ❑ The Prime Minister of India announced the launch of National Digital Health Mission (NDHM) on 74th Independence Day. This is a part of three digital announcements by the Prime Minister including a new cyber security policy and optical fibre connectivity to six lakh villages in the country.
- ❑ The NDHM is implemented by the National Health Authority (NHA) under the Ministry of Health and Family Welfare. The National Health Authority (NHA), is also the implementing agency for Ayushman Bharat.
- ❑ The platform will be available in the form of an app and website.
- ❑ The Digi Doctor option will allow doctors from across the country to enrol and their details, including their contact numbers if they want to provide them, will be available.
- ❑ These doctors will also be assigned digital signatures for free which can be used for writing prescriptions.
- ❑ It will be voluntary for the hospitals and doctors to provide details for the app.

## Health ID

- ❑ The national health ID will be a repository of all health-related information of every Indian.
- ❑ Various healthcare providers — such as hospitals, laboratories, insurance companies, online pharmacies, telemedicine firms — will be expected to participate in the health ID system.
- ❑ Every patient who wishes to have their health records available digitally must create a unique Health ID, using their basic details and mobile or Aadhaar number.
- ❑ Each Health ID will be linked to a health data consent manager, which will be used to seek the patient's consent and allow for seamless flow of health information from the Personal Health Records module.
- ❑ The Health ID will be voluntary and applicable across states, hospitals, diagnostic laboratories and pharmacies.

## Background

- ❑ The National Health Policy 2017 had envisaged creation of a digital health technology eco-system aiming at developing an integrated health information system that serves the needs of all stakeholders and improves efficiency, transparency and citizens' experience with linkage across public and private healthcare.
- ❑ A Digital Health ID was proposed to “greatly reduce the risk of preventable medical errors and significantly increase quality of care”.
- ❑ In the context of this, the central government's think-tank NITI Aayog, in June 2018, floated a consultation of a digital backbone for India's health system — National Health Stack (NHS).
- ❑ NHS was intended to be a digital infrastructure built with the aim of making the health insurance system more transparent and robust, while factoring in the uniqueness of India's health sector, and the political realities of federalism.
- ❑ A committee headed by former Unique Identification Authority of India (UIDAI) chairman released the National Digital Health Blueprint in July 2019.
- ❑ NDHB recognised the need to establish a specialised organisation, called the National Digital Health Mission (NDHM), to facilitate the evolution of the National Digital Health Ecosystem.
- ❑ On 7th August 2020, National Digital Health Mission (NDHM) released its latest strategic document, outlining the envisioned digital registries of doctors, hospitals, pharmacies, and insurance companies, digital personal health records, and digital clinical decision systems.

## Use of Technology in Agriculture

- ❑ Technology in agriculture can be used in different aspects of agriculture such as the application of herbicide, pesticide, fertilizer, and improved seed.
- ❑ Over the years, technology has proved to be extremely useful in the agricultural sector.
- ❑ Presently, farmers are able to grow crops in areas where they were thought could not grow, but this is only possible through agricultural biotechnology.
- ❑ For example, genetic engineering has made it possible to introduce certain strains into other genes of crops or animals.
- ❑ Such engineering boosts the resistance of the crops to pests (e.g. Bt Cotton) and droughts. Through technology, farmers are in a position to electrify every process for efficiency and improved production.

## How using Technology can be Beneficial in Agriculture?

- ❑ Increases agriculture productivity.
- ❑ Prevents soil degradation.

- ❑ Reduces chemical application in crop production.
- ❑ Efficient use of water resources.
- ❑ Disseminates modern farm practices to improve the quality, quantity and reduced cost of production.
- ❑ Changes the socio-economic status of farmers.

## What are the Related Challenges?

### ❑ Education and Training Related:

- Lack of knowledge
- Inadequate skills
- Lack of improved skills

### ❑ Technology and Infrastructure:

- Poor infrastructure
- Lack of storage
- Lack of transport

### ❑ Economic and Policy issues:

- Lack of Money
- Access to credit
- Lack of access to Bank Loans

### ❑ Climate and Environmental Issues:

- Poor soils,
- Soil fertility
- Unreliable rainfall
- Natural disasters such as floods, frost, hail storm
- Psycho-Social Issues:
  - Workers have no interest in agriculture, farm works are not preferred over ipelegeng projects (self-reliance works), and farm jobs are time consuming.

## Steps taken by the Government in the Direction

- ❑ **AgriStack:** The Ministry of Agriculture and Farmers Welfare has planned creating 'AgriStack' - a collection of technology-based interventions in agriculture.
- ❑ **Digital Agriculture Mission:** This has been initiated for 2021 -2025 by the government for projects based on new technologies like artificial intelligence, block chain, remote sensing and GIS technology, use of drones and robots etc.
- ❑ **Unified Farmer Service Platform (UFSP):** UFSP is a combination of Core Infrastructure, Data, Applications and Tools that enable seamless interoperability of various public and private IT systems in the agriculture ecosystem across the country.

- ❑ **National e-Governance Plan in Agriculture (NeGP-A):** A Centrally Sponsored Scheme, it was initially launched in 2010-11 in 7 pilot States, which aims to achieve rapid development in India through use of ICT for timely access to agriculture related information to the farmers. In 2014-15, the scheme was further extended for all the remaining States and 2 UTs.

### **Sub-Mission on Agricultural Mechanization (SMAM):**

- ❑ Under this Scheme, subsidies are provided for purchase of various types of agricultural equipment and machinery.
- ❑ Other Digital Initiatives: Kisan Call Centres, Kisan Suvidha App, Agri Market App, Soil Health Card (SHC) Portal, etc.

### **Antimicrobial Resistance**

- ❑ Antimicrobial Resistance is the resistance acquired by any microorganism (bacteria, viruses, fungi, parasite, etc.) against antimicrobial drugs that are used to treat infections.
- ❑ It occurs when a microorganism changes over time and no longer responds to medicines making infections harder to treat and increasing the risk of disease spread, severe illness and death.
- ❑ The World Health Organisation (WHO) has identified AMR as one of the top ten threats to global health.
- ❑ Microorganisms that develop antimicrobial resistance are sometimes referred to as “superbugs”.
- ❑ In India, over 56,000 newborn deaths each year due to sepsis caused by organisms that are resistant to first line antibiotics.
- ❑ A study reported by ICMR (Indian Council of Medical Research) from 10 hospitals showed that when Covid patients acquire drug-resistant infections in hospitals, the mortality is almost 50-60%.
- ❑ The multi-drug resistance determinant, New Delhi Metallo-beta-lactamase-1 (NDM-1), emerged from this region.
- ❑ Africa, Europe and other parts of Asia have also been affected by multi-drug resistant typhoid originating from South Asia.

### **What are the Concerns Regarding AMR?**

- ❑ **Life-threatening Condition:** The growth of AMR has proved to be a major challenge in the treatment of sepsis, which is a life-threatening condition and, unfortunately, the failure of antibiotics is leading to deaths which are preventable.
- ❑ **Reduction in Medical Advances:** AMR is also undermining and undoing medical advances made over decades, especially for high-burden diseases like tuberculosis and various cancers.
- ❑ **Achievements of Goals:** It is putting the gains of the Millennium Development Goals at risk and endangers achievement of the Sustainable Development Goals.
- ❑ **Increase in Superbugs:** Untreated wastewater from medical facilities is awash with chemical compounds that promote superbugs.
- ❑ **Expanding with Time:** The concoction of self-medication and over the counter (OTC) antibiotic availability has led to one of the highest rates of antibiotic resistance in the world.

### **What are the Reasons for the Spread of AMR?**

- ❑ **Antibiotic consumption in humans**

- Unnecessary and injudicious use of antibiotic fixed dose combinations could lead to emergence of bacterial strains resistant to multiple antibiotics.

## Social factors

- Include self-medication.
- Access to antibiotics without prescription.
- Lack of knowledge about when to use antibiotics.

## ❑ Cultural Activities

- Mass bathing in rivers as part of religious mass gathering occasions.

## ❑ Antibiotic Consumption in Food Animals

- Antibiotics which are critical to human health are commonly used for growth promotion in poultry.

## ❑ Pharmaceutical Industry Pollution

- The wastewater effluents from the antibiotic manufacturing units contain a substantial amount of antibiotics, leading to contamination of rivers and lakes.

## ❑ Environmental Sanitation

- Untreated disposal of sewage water bodies - leading to contamination of rivers with antibiotic residues and antibiotic-resistant organisms.

## ❑ Infection Control Practices in Healthcare Settings

- A report on hand-washing practices of nurses and doctors found that only 31.8% of them washed hands after contact with patients.

## AMR in India: What's the Scenario?

- ❑ AMR is of particular concern in developing nations, including India, where the burden of infectious disease is high and healthcare spending is low.
- ❑ India is among the nations with the highest burden of bacterial infections.
- ❑ Consequently, the impact of AMR is likely to be higher in the Indian setting.
- ❑ The National Health Policy 2017 highlights the problem of antimicrobial resistance and calls for effective action to address it.
- ❑ The Ministry of Health & Family Welfare (MoHFW) identified AMR as one of the top 10 priorities for the ministry's collaborative work with the World Health Organisation (WHO).
- ❑ India has instituted surveillance of the emergence of drug resistance in disease causing microbes in programmes on Tuberculosis, Vector Borne diseases, AIDS, etc.
- ❑ Since March 2014 a separate Schedule H-1 has been incorporated in Drug and Cosmetic rules to regulate the sale of antimicrobials in the country.
- ❑ The Food Safety and Standards Authority of India (FSSAI) banned the use of antibiotics and several pharmacologically active substances in fisheries.

- ❑ The government has also capped the maximum levels of drugs that can be used for growth promotion in meat and meat products.
- ❑ India, with its combination of large population, rising incomes that facilitate purchase of antibiotics, high burden of infectious diseases and easy over-the-counter access to antibiotics, is an important locus for the generation of resistance genes (such genes help bacteria in surviving on being exposed to antibiotics).

## Autonomous vehicle

- ❑ An autonomous vehicle is one that can sense its surroundings and operate without the need for human intervention. A human passenger is not obliged to assume control of the car at any moment, nor is he or she required to be in the vehicle at all times.
- ❑ In recent years, the race to develop autonomous vehicles (AVs) or self-driving cars has accelerated, with major automotive and IT giants investing significant resources in the field.

The autonomous vehicles work on the foundational process of **sense-plan-act architecture**:

- ❑ **Sense** - The use of a combination of sensors (cameras, radars, Lidar, etc.), navigation, and communication systems aids in the detection of numerous cues from the environment, such as roadways, other vehicles, traffic lights, and sign boards.
- ❑ **Plan** - The autonomous automobiles are outfitted with AI-based data processing tools that aid in the interpretation of sensor data. Furthermore, electronic control systems give signals to actuators instructing them to slow down, speed up, or halt, among other things.
- ❑ **Act** - Actuators are electromechanical mechanisms that control autonomous vehicles. In other words, the controllers' decisions are converted into actions through actuators.

## Obstacles

While autonomous cars are said to revolutionize sustainable urban mobility, the following obstacles must be overcome before they can be widely used.

- ❖ **Reliability** - They are based on AI-based systems that require a vast amount of data to learn from. AI-based solutions may not be dependable because to the unpredictable driving circumstances on Indian roads, which are characterised by tiny lanes and tough terrain. Unpredictability caused by severe rainfall must also be considered.
- ❖ **Infrastructure issues** - Communication with things such as traffic signals, parking lots, sign boards, and other items is required for autonomous vehicles to sense cues from the environment. As a result, the environment's infrastructure must be modified (Vehicle to Infrastructure Technology), which is both costly and time-consuming.
- ❖ **Safety** - Failure of any system in the sense-plan-act architecture could result in incidents that endanger public safety.
- ❖ **Acceptance** - Because self-driving cars are still in their infancy, there is no consumer approval.
- ❖ **Eroding public trust in AVs** - In addition to checks and balances, the AV industry's transparency is a critical component in establishing and maintaining public trust in the technology.
- ❖ **Legal and regulatory standards**: Indian motor vehicle legislation would pose a hurdle for AVs, as the Indian Motor Vehicles Act, 1988 currently prohibits the use of fully automated systems in the country. Strict legal and regulatory criteria should be in place before we move forward with autonomous vehicles. Given the intricacy of the technology utilised in these cars, as well as the privacy and lawsuit issues involved, designing proper regulations is a challenge.
- ❖ **Risks of unemployment** - There are 40 lakh drivers in the country, with a deficit of 25 lakh, and driving skills can give employment, putting the careers of 1 crore people at risk.

- **Responsibility distribution** - The allocation of liability is the most important part of enabling AVs who is responsible if a self-driving automobile collides with a pedestrian or another vehicle.
- **Privacy** - AVs will also introduce new and more complex privacy concerns. Automated cars operate on a massive amount of personal data and preferences that require protection under privacy rules – which, given the subtleties of the technology, may be insufficient at the moment.
- **IPR protection** - The protection and ring-fencing of intellectual property will be another crucial factor for automotive companies.
- **Changes in auto insurance:** Automobile insurance trends are also anticipated to change as a result of AVs. The focus will shift away from accountability for driver error and toward liability for automobile makers or technology providers. Perhaps car insurance for drivers will become obsolete. There will be several hazards that require insurance, such as algorithm failure or cyber-attacks involving driverless automobiles.

## Conclusion:

Without the complete support of government authorities, autonomous technology will not advance. The government of India appears to be most concerned about job losses and unemployment as a result of allowing the usage of AVs in India. On the contrary, one may expect this to result in more skilled jobs being created in India's IT/ITES, engineering, artificial intelligence/robotics, automotive, software development, and related sectors. It is necessary to improve road safety and reduce traffic accidents, pollution and carbon emissions, fuel consumption, and traffic congestion, as well as to make transportation accessible to all people, including the disabled. More study should be done to properly assess the potential costs and benefits of the technology, as well as who will benefit from them.

# Food Fortification

Fortification is the addition of key vitamins and minerals such as Iron, Iodine, Zinc, and Vitamins A & D to staple foods such as rice, wheat, oil, milk and salt to improve their nutritional content. These nutrients may or may not have been originally present in the food before processing or may have been lost during processing.

## □ Need for the Fortification of Food

- Deficiency of micronutrients or micronutrient malnutrition, also known as hidden hunger which is a serious health risk. Access to safe and nutritious food is a must and sometimes due to lack of consumption of a balanced diet, lack variety in the diet or unavailability of food one does not get adequate micronutrients. Often, there is considerable loss of nutrients during the processing of food as well. One of the strategies to address this problem is fortification of food. This method complements other ways to improve nutrition such as such as diversification of diet and supplementation of food.
- India has a very high burden of micronutrient deficiencies caused by Vitamin A, Iodine, Iron and Folic Acid leading to Night Blindness, Goitre, Anaemia and various birth defects. According to the National Family Health Survey (NFHS-4).

## □ Benefits of Food Fortification

Following are the various benefits of fortification of foods:

- Nutrients are added to staple foods since they are widely consumed. Thus, this is an excellent method to improve the health of a large section of the population, all at once.

- ◉ It is a safe method of improving nutrition among people. The addition of micronutrients to food does not pose a health risk to people. The quantity added is small and well under the Recommended Daily Allowances (RDA) and are well regulated as per prescribed standards for safe consumption.
  - ◉ It is a cost-effective intervention and does not require any changes in eating patterns or food habits of people. It is a socio-culturally acceptable way to deliver nutrients to people.
  - ◉ It does not alter the characteristics of the food like the taste, aroma or the texture of the food.
- **WHO Recommendations for rice fortification**
- ◉ Fortification of rice with iron is recommended as a public health strategy to improve the iron status of populations, in settings where rice is a staple food.
  - ◉ Fortification of rice with vitamin A may be used as a public health strategy to improve the iron status and vitamin A nutrition of populations.
  - ◉ Fortification of rice with folic acid may be used as a public health strategy to improve the folate nutritional status of populations.

## Carbon Capture TWechnologies

### About Carbon Capture, Utilization and Storage (CCUS)

- ▣ Carbon capture and storage, also known as CCS or carbon sequestration, describes the technologies designed to tackle global warming by capturing CO<sub>2</sub> at power stations, industrial sites or even directly from the air and permanently storing it underground.
- ▣ Carbon sequestration describes long-term storage of carbon dioxide or other forms of carbon to either mitigate or defer global warming.
- ▣ It has been proposed as a way to slow the atmospheric and marine accumulation of greenhouse gases, which are released by burning fossil fuels.
- ▣ There are number of technologies under investigation for sequestering carbon from the atmosphere. Some of these are:
- ▣ **Ocean Sequestration:** Carbon stored in oceans through direct injection or fertilization.
- ▣ **Geologic Sequestration:** Natural pore spaces in geologic formations serve as reservoirs for long-term carbon dioxide storage.
- ▣ **Terrestrial Sequestration:** A large amount of carbon is stored in soils and vegetation, which are our natural carbon sinks. Increasing carbon fixation through photosynthesis, slowing down or reducing decomposition of organic matter, and changing land use practices can enhance carbon uptake in these natural sinks.

### Geologic Sequestration trapping mechanisms

- ▣ Geologic Sequestration is thought to have the largest potential for near-term application. Geologic Sequestration trapping mechanisms include:
- ▣ **Hydrodynamic Trapping:** Carbon dioxide can be trapped as a gas under low-permeability cap rock (much like natural gas is stored in gas reservoirs).
- ▣ **Solubility Trapping:** Carbon dioxide can be dissolved into a liquid, such as water or oil.

- ❑ **Mineral Carbonation:** Carbon dioxide can react with the minerals, fluids, and organic matter in a geologic formation to form stable compounds/minerals; largely calcium, iron, and magnesium carbonates.

### Status of the Technology:

- ❑ As of 2021, 27 carbon capture, utilization and storage facilities are operating worldwide, and five others are under construction. Many are in the research and development phase, with 67 in the advanced stage and seven in the early stage.
- ❑ Typically, a technology takes 20-30 years to progress from the research and development stage to being available in the market.
- ❑ The authors of the report rated CCU on their technology readiness level (TRL) – ranging from the basic concept (TRL 1) to successful, real-life operation (TRL 9).
- ❑ For a CCU technology to be ready and make a difference on the ground in 2030, it must have reached at least TRL 6 by 2020, according to the study.

### Boon or bane?

- ❑ Replacing a conventional fuel with a synthetic fuel like methanol produced via CCU is likely to be a successful mitigation strategy only if clean energy is used to capture CO<sub>2</sub> and convert it into synthetic fuel.
- ❑ This raises the question: Can this clean energy not be used more easily and efficiently to directly replace the use of conventional fuel?
- ❑ The researchers warned that most CCU techs might divert attention from more effective emission reduction options like carbon capture and permanent storage and reducing consumption.

### Promising technologies:

- ❑ CO<sub>2</sub> captured using CCU technologies are converted into fuel (methane and methanol), refrigerants and building materials.
- ❑ The captured gas is used directly in fire extinguishers, pharma, food and beverage industries as well as the agricultural sector.
- ❑ Using CO<sub>2</sub> to improve crop yields in agricultural greenhouses and enhanced oil recovery are two examples of mature CCU technologies.
- ❑ Combining CO<sub>2</sub> with steel slag (an industrial by-product of the steel manufacturing process) to make construction materials are compatible with the Paris Agreement goals.
- ❑ Taking stock of the current CCU technologies in meeting the Paris goals can help nations redirect funding to technologies that are more likely to reduce emissions drastically.

### Progress in India:

- ❑ Keeping pace with the global developments to building CCU capacity, the Indian government announced that it would establish two CCU centres:
- ❑ The National Centre of Excellence in Carbon Capture and Utilization at IIT, Bombay and

- ❑ The National Centre in Carbon Capture and Utilization at Bengaluru's Jawaharlal Nehru Centre for Advanced Scientific Research.
- ❑ The technology is attractive to industries that lack effective clean energy alternatives, especially carbon-intensive sectors that manufacture cement, iron and steel or chemicals.
- ❑ Oil and Natural Gas Corporation (ONGC) signed a MoU with Indian Oil Corporation Limited (IOCL) for enhanced oil recovery (EOR) by injecting CO<sub>2</sub> captured from IOCL's Koyali refinery, Gujarat.
- ❑ Countries like India would need more construction material in the future, and climate-compatible construction blocks could be a game-changer.

### Way Forward:

- ❑ The country is in a very early stage of adopting these nascent technologies. Over the next couple of years, India should invest in building and strengthening research and development work on CCU technologies. Demonstrating their capabilities will increase stakeholders' confidence in the technology while also helping them understand its uncertainties.

## Significance of Semiconducting Devices in Indian Economy

### Context

- ❑ Recently 1st Semicon India 2022 Conference has been unveiled the Ministry of Electronics and Information Technology as a component of India's Semiconductor Mission.
- ❑ The conference was organised to make India a leader in electronics production, semiconductor layout, production and innovation.

### Background

- ❑ The Semicon India Programme was cleared by the Union Cabinet in December 2021, with a financial outlay of INR 76,000 crore for the development of semiconductors and display manufacturing ecosystems over the next six years.
- ❑ A specialised and dedicated "India Semiconductor Mission (ISM)" has been set up within Digital India Corporation to drive India's strategies for developing semiconductors and display ecosystem.
- ❑ The scheme has been aimed at making India a global electronics hub as a shortage of microchips hurts industrial production.

### Need of Semiconductor Mission

- ❑ India Semiconductor Mission (ISM) is a specialised and independent business division within the Digital India Corporation (a not for profit company set up by the Ministry of Electronics and Information Technology).
- ❑ The aim of the mission is to build a vibrant semiconductor and display ecosystem to enable India's emergence as a global hub for electronics manufacturing and design.
- ❑ The mission is authorised to negotiate with the applicants under the semiconductor fab scheme and the display fab scheme.

- ❑ This mission has been given the autonomy to decide the appropriate technology mix, applications, node generation, capacity and propose the structure and quantum of fiscal support for the selected applicants.

## What are semiconductors?

- Semiconductors are crystalline or amorphous solids that have electrical conductivity opposite at temperatures to those of metal, higher electrical resistance than typical resistant materials, but still of much lower resistance than insulators.
- There are two basic groups or classifications that can be used to define the different semiconductor types:
- Intrinsic material: An intrinsic type of semiconductor material made to be very pure chemically.
- Extrinsic material: Extrinsic types of semiconductor are those where a small amount of impurity has been added to the basic intrinsic material.

## Need of Promoting Indigenous Semiconductor Industry

- **Employment:** Promotion of semiconductor industry will create highly skilled employment opportunities and help India harness its demographic dividend.
- **Reducing Imports Dependency:** As the demand increases, electronics imports are expected to overtake crude oil as India's largest import commodity.
- **Disruption in Global Supply Chains:** Pandemic induced lockdown and restriction followed by Russia-Ukraine war has led to the shortage of semiconducting devices. It has a cascading effect on other industries as well leading to slowdown in many sectors of the economy.
- **Promoting Make in India:** Indigenous manufacturing of semiconductor devices will give push to the Make in India program and will help in attracting investment.
- **Atmanirbhar Bharat:** Local semiconductor manufacturing will pave the way for India's technological leadership in areas of strategic importance and economic self-reliance.
- **National Security:** India imports most of electronic components used in its communication and critical systems. There is a risk of programming backdoors in the manufacturing process and thus hampering national security and sovereignty of India.
- **Capital intensive:** Semiconductor manufacturing is a highly capital-intensive industry which needs developed ecosystem to thrive.
- **Shortage of process engineers:** Despite having large talent pool of chip designers, India lacks process engineers who can run a front-end chip factory.
- **Dominance of Few Countries:** Taiwan and South Korea dominated the semiconductor manufacturing space. 75% of the semiconductor manufacturing capacity is concentrated in East Asia and China. Any disruption in supply chain due to conflict or restriction poses many challenges for the importing country.
- **Pursuing Western Companies:** India needs to attract foreign investment to built-up chip fab capacity by overcoming the intense competition from other countries.

## Required measures

- ❑ **Supporting startups:** India has a huge talent of entrepreneurial engineers and hand-holding of Indian engineers by the government can produce large payoffs.

- ❑ **Budgetary support:** Semiconductor manufacturing is a capital intensive process and will require government's support to reach its full potential.
- ❑ **Focus on back-end of manufacturing:** Semiconductor foundries accounts for 65% of industry capital expenditure but only 25% of the value addition. Therefore, to lower the risks of investment, India should especially look at back-end of manufacturing such as assembly, packaging and testing. Once it stabilises and an ecosystem develops, front-end of manufacturing will follow.
- ❑ **Cooperation of states:** Semiconductor industry requires stable power, large quantities of pure water and land. These are state subjects, and state governments' proactive cooperation is needed to create the right climate for easy implementation of semiconductor projects.
- ❑ **Transport logistics:** Roads, railway and air connectivity to the site are also critical.

## Conclusion

- ❑ Semiconductors are foundation for the next Industrial Revolution. While, India ramps up its semiconductor manufacturing capabilities, need of the hour is to look for trusted partners and diversify supply chains to meet the growing need.

## Women in STEM

- ❑ STEM refers to -Science, Technology, Engineering, and Mathematics. India is one of the countries that produce the highest number of scientists and engineers, the growth of STEM has picked up significantly over the last few years. Women make up nearly 43 per cent of the total graduates in Science, Technology, Engineering and Mathematics (STEM) in India - one of the highest in the world. However women face various constraints
- ❑ **Household Responsibility:** Responsibility related to running of households and elder care sets women back at the early stages of their careers.
- ❑ In some institutes, to ensure their safety, women are advised to work only during official hours, while men can access labs any time. The outcome of this measure is contrary to the intention.
- ❑ Despite the ground breaking research and performance, women in the field of STEM are known to be paid less for their research work compared to men.
- ❑ **Patriarchal culture in STEM:** According to the UN, girls are often made to believe that they are not smart enough for STEM
- ❑ A significant drop in the number of women in science happens at the stages following graduation.
- ❑ The percentage of women faculty at high profile institutes like IITs, IISc is only 10-12%.
- ❑ **Steps taken by govt to address these issues**
  - DST has launched DISHA Programme for Women in Science to address issues such as break in career due to marriage, child birth, looking after old or ailing parents, children's education and so on. DISHA Programme focuses on efforts to facilitate the re-entry of such women to mainstream science.
  - In 2014, DST restructured the women specific programmes under one umbrella called "KIRAN (Knowledge Involvement in Research Advancement through Nurturing). Through KIRAN, DST aims to provide opportunities in research, entrepreneurship, science communication, etc.
  - Vigyan Jyoti is a programme to promote STEM learning among girl students of class 9-12
  - UDAAN launched by MHRD to address the lower enrolment ratio of girl students in science and

engineering colleges.

- GATI Scheme: The Gender Advancement for Transforming Institutions (GATI) will develop a comprehensive Charter and a framework for assessing Gender Equality in STEM.
- Aiming to create women leaders, the DST is developing a framework (under the new STP 2020) to rate and rank science institutes depending on the proportion of women employed

## Conclusion

- ▣ According to the United Nations, India is a paradox when it comes to STEM opportunities for women. Despite producing more women graduates (in STEM), as compared to global average, it employs fewer women researchers. In STEM 40% of graduates are women in India but only 14% of researchers in India are women while the global average is 30%. There is an immediate need to invest in supporting infrastructure, incentivising institutions to promote gender equity, transparency in decision making etc. to bridge the persisting gender imbalance in STEM majors.

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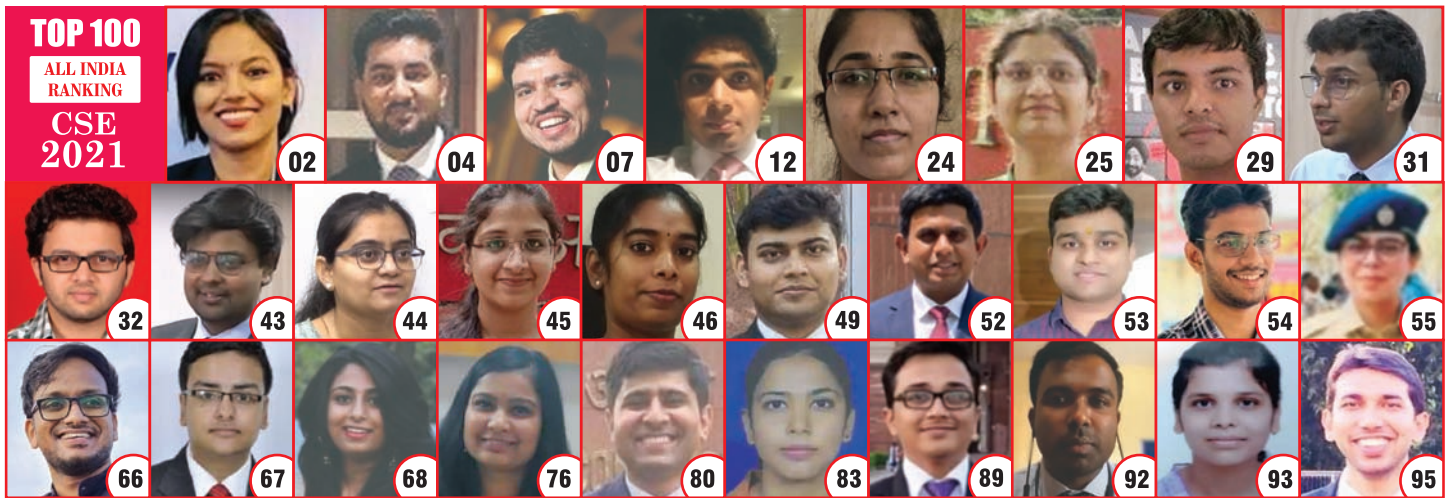
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