

Modern Medicine

Part 3

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Contents

1. Introduction	2
2. Evidence-Based Medicine	4
3. Technology and Innovation	
▪ Vaccine	11
▪ Surgical Anaesthesia and Antisepsis	12
▪ Blood Transfusion	14
▪ Antibiotics and Antivirals	15
▪ Imaging Technology	16
▪ Endoscopy	18
▪ Organ Transplantation	21
▪ Laboratory Medicine	22

Contents

▪ Personalised Medicine	27
▪ Regenerative Medicine	38
▪ Predictive Medicine	44
▪ Nanotechnology and Nanomedicine	45
▪ Pharmaceuticals and Medical Devices	58
▪ Information Technology in Modern Medicine	80
▪ Medical Robotics	98
▪ Assisted Reproductive Technology	105
4. Modern Medicine: Environment of Care	
▪ Fragmentation of Care	110
▪ Demographic Changes	115

Contents

▪ Regulatory Environment	117
▪ Ethics and Quality	127
▪ Law and Medical Ethics	128
▪ Political Environment Influencing Healthcare	129
❖ Health Expenditure	110
❖ Recent Public Sector Health Initiative	
○ Ayushman Bharat	134
○ Health and Wellness Centre	139
• Social and Economic Mobility	143
• Defensive Medicine	146
5. Privatisation of Medicine	
▪ Private Healthcare in India	150

Contents

▪ Corporate Hospital	154
▪ Corruption in Healthcare	162
▪ Medical Education	166
▪ Violence in Healthcare	170
6. Conclusion	174
7. Bibliography	175

Medical Device Rule, 2017

- Govt. of India has promulgated medical device rules on 31st January 2017
- This comes into force with effect from 1st January 2018
- The rules shall be applicable in respect to:
 - substances used for *in vitro* diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i);

Medical Device Rule, 2017

- substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified under sub-clause (ii); and
- devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940);
- **Classification of Medical Devices**
 - Medical devices other than *in vitro* diagnostic medical devices shall be classified in the following classes, namely:—
 - 1. Low risk – Class A**

Medical Device Rule, 2017

2. Low moderate risk – Class B
 3. Moderate high risk – Class C
 4. High risk – Class C
- *In vitro* diagnostic medical devices shall be classified in the following classes, namely:—
 1. **Low risk – Class A**
 2. **Low moderate risk – Class B**
 3. **Moderate high risk – Class C**
 4. **High risk – Class D**

Medical Devices

- Global health challenges are becoming more and more complex
- This is because of duality of infectious disease outbreaks and the global burden of non-communicable diseases
- To provide quality, affordable and appropriate healthcare services, resilient health care systems are needed
- The healthcare system must also include trained health work forces, information systems, financing mechanisms, infrastructure, medicines and technologies

Medical Devices

- India is a signatory of Universal Health Coverage (UHC)
 - UHC has been mandated under the Sustainable Developmental Goals
 - For achieving UHC, there is a need to prevent diseases, diagnose early and treat them effectively
 - For implementing such a programme the needs are
 - Trained health work forces, health information systems, financing mechanism and safe, effective, and appropriate medical devices



SUSTAINABLE DEVELOPMENT GOALS

17 GOALS TO TRANSFORM OUR WORLD

1 NO POVERTY 	2 ZERO HUNGER 	3 GOOD HEALTH AND WELL-BEING 	4 QUALITY EDUCATION 	5 GENDER EQUALITY 	6 CLEAN WATER AND SANITATION
7 AFFORDABLE AND CLEAN ENERGY 	8 DECENT WORK AND ECONOMIC GROWTH 	9 INDUSTRY, INNOVATION AND INFRASTRUCTURE 	10 REDUCED INEQUALITIES 	11 SUSTAINABLE CITIES AND COMMUNITIES 	12 RESPONSIBLE CONSUMPTION AND PRODUCTION
13 CLIMATE ACTION 	14 LIFE BELOW WATER 	15 LIFE ON LAND 	16 PEACE, JUSTICE AND STRONG INSTITUTIONS 	17 PARTNERSHIPS FOR THE GOALS 	 SUSTAINABLE DEVELOPMENT GOALS

Medical equipment (niveau 3)

- Are medical devices that require installation, maintenance , calibration, consumables, spare parts.
- Their design, evaluation , procurement, planning, training, maintenance and decommissioning usually done by biomedical engineers.



Medical devices that do not need maintenance:

Single use devices

- Catheters
- IV sets
- Syringes
- Condom
- ...
- Last secondes
- / minutes/ heures
- Incinérable, single use
- \$- \$\$



Implantables

- Prothesis
- Pacemaker
- Stent
- Intramedular
- Many years
- Biocompatible
- Patient monitoring
- \$\$- \$\$\$\$\$



The performance does not depend on the device itself but on the way they are used , this has to be safe and correct,

- Most medical devices require intermediary
- Device - doctor/ nurse/ technician – patient



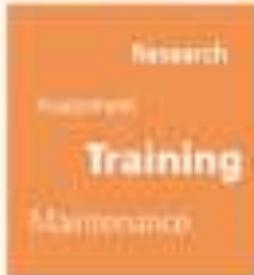
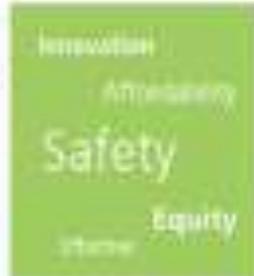
More devices are being used by the persons themselves

Medical and assistive devices, point of care in vitro diagnostics, personal protective equipment, mobile apps w diagnostics.

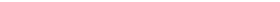
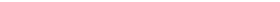


- 10,000 Types of medical devices
- 500,000 different products commercially available

- All medical equipment for patient care
- Diagnostic imaging
- Laboratory and pathology equipment
- Implantable medical devices
- Personal protective equipment
- Prosthesis and orthosis
- Quality assurance
- Radiation protection devices
- Single use devices (IV)
- Solutions and reagents
- Sterilization equipment
- Surgical instruments



Medical devices are technologies indispensable to accomplish the health related SDGs: prevent, diagnose, treat, palliate, assist.

		Target	Example of health technology/ medical device
		3.1 by 2030 reduce the global maternal mortality ratio to less than 70 per 100,000 live births	Blood pressure meters, pregnancy tests, surgical instruments, cord clamps...
		3.2 by 2030 end preventable deaths of newborns and under-five children	Neonatal resuscitation devices, warming devices/ incubators, diagnostics
		3.3 by 2030 end the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases and combat hepatitis, water-borne diseases, and other communicable diseases	In vitro diagnostics to initiate the right treatment.
		3.4 by 2030 reduce by one-third pre-mature mortality from non-communicable diseases (NCDs) through prevention and treatment, and promote mental health and wellbeing	Diagnostics: in vitro, blood glucose meters, pathology; x rays...imaging, Treatment: surgical instruments, implants, radiotherapy, inhalers chemotherapy, cardiac support
		3.7 by 2030 ensure universal access to sexual and reproductive health care services, including for family planning, information and education, and the integration of reproductive health into national strategies and programmes	From condoms to contraceptive devices

Information Technology in Modern Medicine

- Information Technology has invaded all sphere of human life
- Healthcare is no exception
- The specific areas where IT is used in healthcare are:
 - Patients' relevant health information contained in health registry, patient list by clinical condition can help
 - In providing proactive outreach to patients
 - Improve prevention and treatment outcomes by focussing on both patients being seen and patients who need to be seen
 - Create bench marks that monitor patients' health progress and overall health status

Information Technology in Modern Medicine

- Healthcare needs to be supported by systems that are carefully and consciously designed to produce care
 - This care should be safe, effective, patient-centered, timely, efficient and equitable.¹⁶
 - In the area of safety, there is growing evidence that automated order entry systems can reduce errors in drug prescribing and dosing
 - In the area of effectiveness, there is considerable evidence that automated reminder systems improve compliance with clinical practice guidelines

Information Technology in Modern Medicine

- There are many opportunities to use IT to make care more *patient entered*,
 - For example,
 - By facilitating access to clinical knowledge through under standable and reliable Web sites and online support groups
 - Customized health education and disease management messages ; and
 - The use of clinical decision support systems to tailor information according to an individual patient's characteristics, genetic makeup, and specific conditions

Information Technology in Modern Medicine

- Both patients and clinicians can benefit from improvements in *timeliness*
 - This can be achieved through use of Internet-based communication (i.e., e-visits, telemedicine)
 - Immediate access to automated clinical information, diagnostic tests, and treatment results can also be obtained
- Clinical Decision Support Systems can improve efficiency by reducing redundant laboratory tests

Information Technology in Modern Medicine

- Internet based health communication can enhance equity
 - A broad array of options can be provided for interacting with clinicians
 - To realise this goal, one would need required technology platform
 - And this should be irrespective of race, ethnicity, socioeconomic status, geographic location and other factors
 - The other factors include computer literacy and clinicians willingness to entertain such interaction

Information Technology in Modern Medicine

- The world is becoming more and more health conscious.
- Society, health policy and patients' needs are all changing dramatically.
- The challenges society is currently facing are related to:
 - the increase in the aging population,
 - changes in lifestyle,
 - the need for healthcare cost containment and
 - the need for improvement and
 - monitoring of healthcare quality.

Information Technology in Modern Medicine

- Ambulatory monitoring¹⁶
 - The new possibilities for home care and ambulatory monitoring are provided at 4 levels:
 1. *Microsensors.*
 - Micro technologies offer the possibility of small size, but also of intelligent, active devices, working with low energy, wireless and non-invasive or minimally-invasive;
 2. *Wrist devices*
 - *They* are particularly user friendly and combine sensors, circuits, supply, display and wireless transmission in a single box, very convenient for common physical activities

Information Technology in Modern Medicine

3. *Health smart clothes*

- *These clothes* make contact with 90 % of the skin and offer many possibilities for the location of sensors.
- These sensors have to be thin, flexible and compatible with textiles, or made using textile technologies, such as new fibers with specific (mechanical, electrical and optical) properties;

4. *Health smart homes.*

- The aim of this method is to improve the patient's living conditions and to avoid the cost of long hospitalization.

Information Technology in Modern Medicine

- Some technological innovations that have taken place in the last decade can improve patient outcome
- These innovations include:
 1. **The Electronic health record**
 - In developed countries The HER has made a considerable impact on how medicine is practiced
 - Patient data can be made available irrespective of geographical location of the patient

Information Technology in Modern Medicine

Contd.

2. mHealth

- mHealth is one aspect of telehealth that specifically focuses on using mobile devices such as mobile phones to provide healthcare services
- mHealth is becoming a widely accepted means of supporting patient mobility and medical assistance beyond the conventional boundaries.
- Mhealth data include personal medical history, diagnostic reports, therapy schedule and guidance tutorial through audio video and text presentation on the hand held devices

Information Technology in Modern Medicine

3. Smart Wearable Monitoring and Diagnostic Systems¹⁷

- Many recent advances have been made in ambulatory health monitoring
- To monitor patients health and well being in ambulatory settings, physicians need many physiological data of the patients
- In impending patient's catastrophic events such information is important to provide timely help
- Such capability has been limited

Information Technology in Modern Medicine

Contd.

- Monitoring of multiple physiological, behavioural and other personal parameters has been too complicated to achieve
- To do this it required special equipment that has been unavailable, too expensive, or too cumbersome to be used effectively.
- A new generation of biomedical sensors, have now been made available
 - These sensors are on telecommunications, in computer engineering and user interfaces
 - The first results start to appear in the public domain

Information Technology in Modern Medicine

- Contd.
 - Cardiology is one of the most promising application area
 - Personalised, wearable and ubiquitous systems could significantly improve quality and cost effectiveness of healthcare.
 - Heart disease is the main cause of early disability and premature death in western countries and steadily increases because of the aging of the population
 - The integration of sensors in a “true wearable garment” can offer additional advantages in terms of comfort, usability and body measurements.

Information Technology in Modern Medicine

- Contd.

- The Lifeshirt™ is composed from a garment, containing respiratory inductive plethysmography ECG, a data recorder and the PC based analysis software.
- It delivers a dynamic cardiopulmonary profile, respiration, ECG, accelerometer and electronic diary.
- Applications are related to respiratory function, sleep diagnostics, early hospital discharge, pre and post operative monitoring and cardiopulmonary function

Information Technology in Modern Medicine

- Contd.
 - However, the market of personal wearable healthcare is only at the early stage.
 - Research and development faces several challenges such as:
 - the activity effects,
 - the posture effects,
 - the sensor placement effects,
 - the baseline drift and
 - the signal integrity.

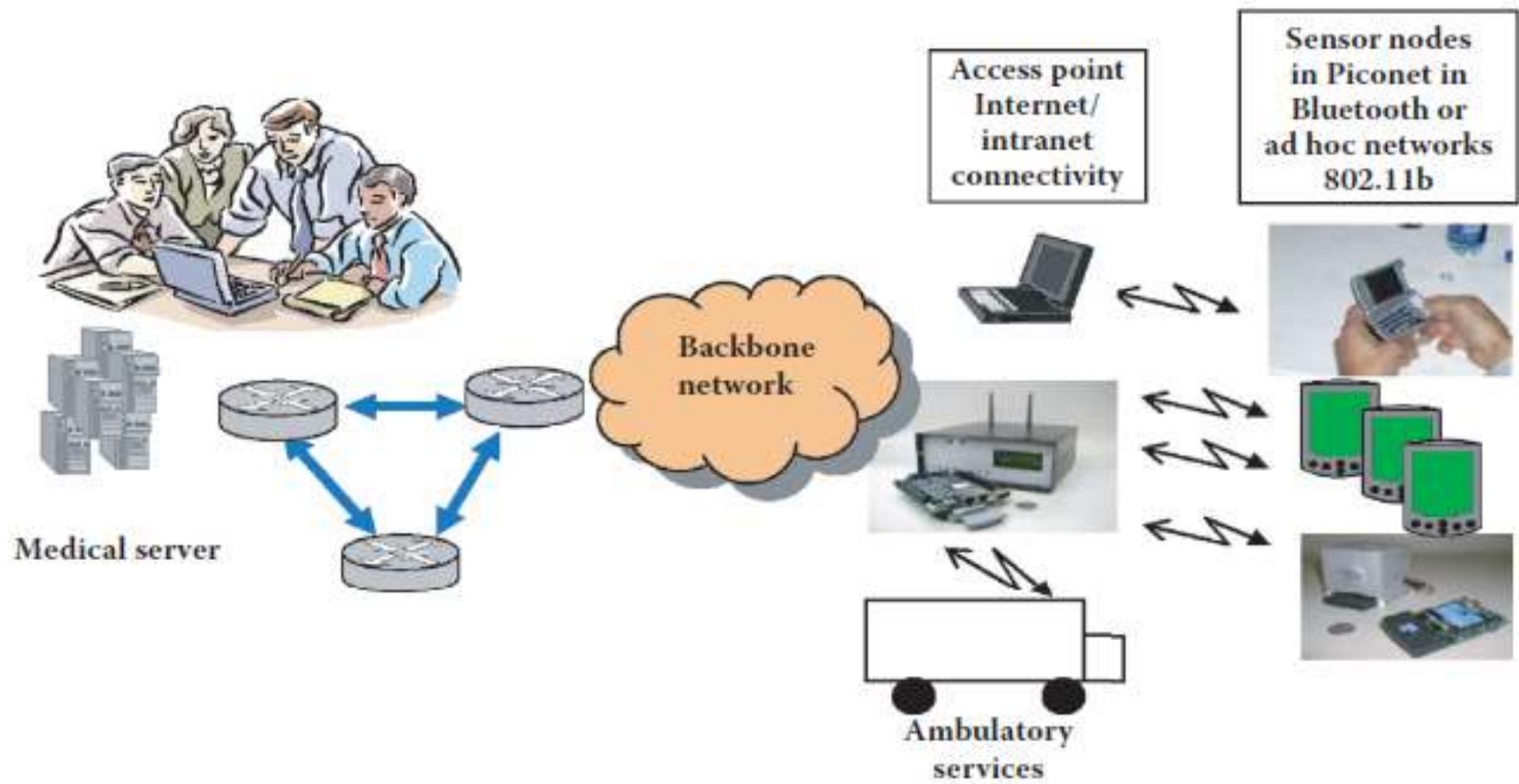


FIGURE 3.7
 Typical **mHealth** network tiers and network services.

Information Technology in Modern Medicine

4. Telemedicine

- The term *telemedicine* is very simply a description of supporting medical services through the use of telecommunications.
- ‘Tele’ is a prefix for distant, originated from ancient Greek.
- So, telemedicine literally translates to providing medical services over distance.’

Information Technology in Modern Medicine

- Another important issue to address is the healthcare services provided to patients,
 - They are the end users who must feel comfortable receiving the treatment given.
- The provision of a technically feasible solution is not the only obstacle to deal with.
- Other important issues including patients' acceptance and accessibility must also be addressed

Medical Robotics

- Medical Robotics¹⁸

- Medical robotics is an interdisciplinary field with methods from computer science, mathematics, mechanical engineering and medicine
- Robotics itself was then a branch of artificial intelligence.
- However, a number of technical and mathematical problems had to be solved to bring robots to routine clinical use.
- These problems were far outside the scope of artificial intelligence, and this supported the emergence of the new field.

Medical Robotics

- Robots are now used in many clinical sub-domains,
 - For example:
 - Neurosurgery, orthopedic surgery, dental surgery, eye surgery, ear-nose and throat surgery, abdominal surgery/laparoscopy, and radiosurgery.
 - This gives rise to a large number of new methods.
 - However, medical robotics is not only limited to surgery.

Medical Robotics

- In recent years, four main types of medical robots have emerged:

1. Robots for Navigation

- The surgical instrument is moved by a robot arm.
- This allows precise positioning, based on pre-operative imaging.
- The motion of anatomic structures (e.g. caused by respiration and pulsation) can be tracked.

Medical Robotics

2. Robots for Motion Replication.

- The robot replicates the surgeon's hand motion, via a passive robotic interface.
- Thus we can downscale the motion, reduce tremor and improve minimally invasive methods.

3. Robots for Imaging.

- An imaging device is mounted to a robotic arm, to acquire 2D or 3D images

Medical Robotics

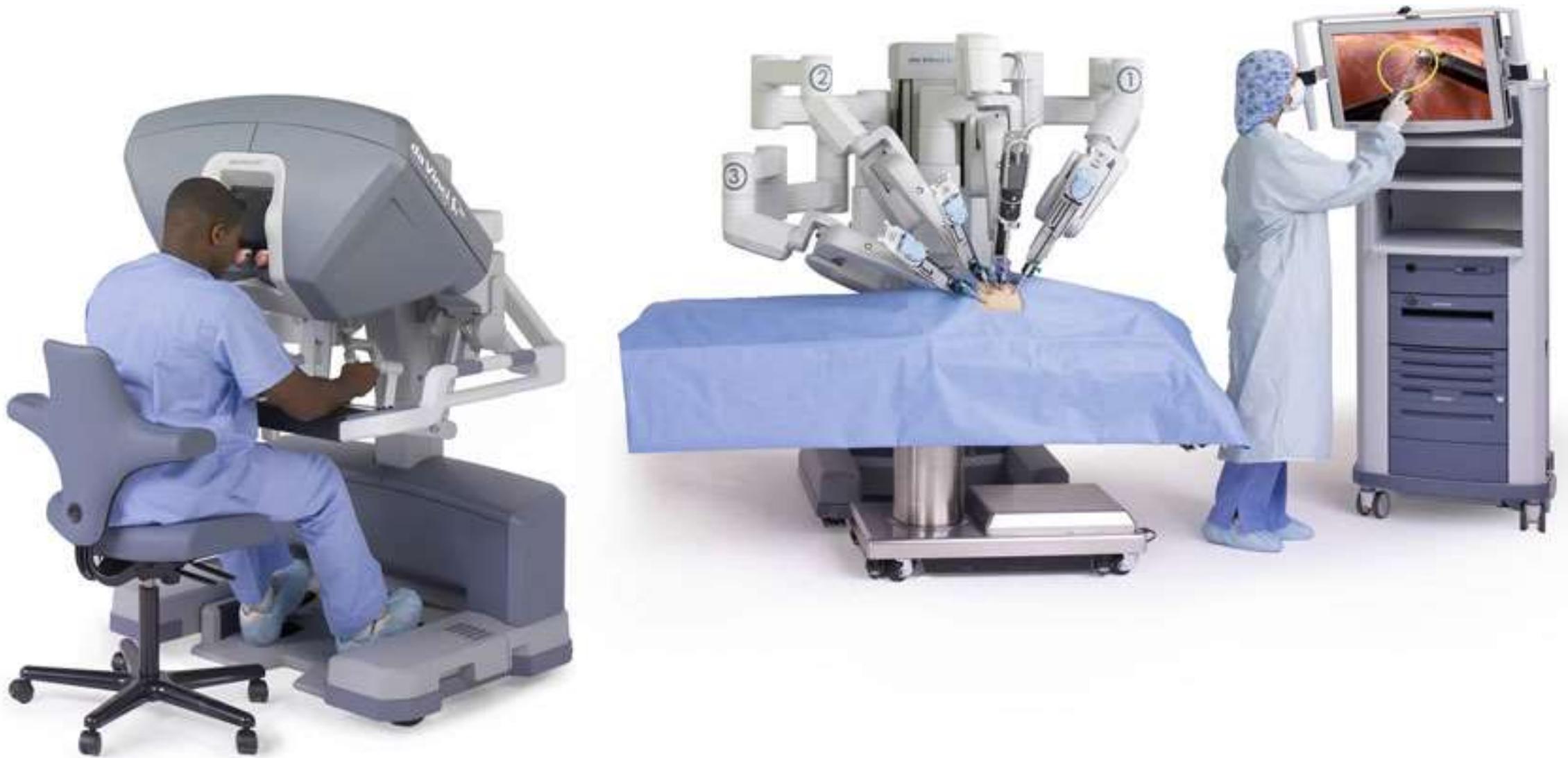
4. Rehabilitation and Prosthetics.

- Mechatronic devices can support the recovery process of stroke patients.
- Robotic exoskeletons controlled by brain-computer interfaces can replace or support damaged anatomical structures.

Medical Robotics

- Definition of Robot

- “A reprogrammable, multifunctional manipulator designed to move materials, parts, tools, or specialized devices through various programmed motions for the performance of a variety of tasks.”
- This definition of robot was given by Robot Institute of America in 1972



The da Vinci[®] Surgical System with its main components (courtesy of Intuitive Surgical, Inc.)

Assisted Reproductive Technology

- Assisted Reproductive Technology (ART)
 - Parenthood is a desired social role amongst married couple
 - Because it involves an inability to achieve a desired social role, infertility is often associated with psychological distress.
 - Researcher found support for the conclusion that infertility is a fundamentally different experience for women than for men¹⁷
 - Though infertility most often is medicalised but its psychosocial impact cannot be ignored
 - Usually the female is blamed and stigmatised for failure to bear a child

Assisted Reproductive Technology

- Assisted reproductive technology brought succour to many infertile couple
- The past four decades have witnessed a transformation in reproductive medicine from science fiction to one of the most advanced medical discipline
- The door was opened by Robert Edwards
 - More than 4 million babies have been born worldwide
- Definition of ART
 - “Assisted Reproductive Technology” with its grammatical variations and cognate expressions, means all techniques that attempt to obtain a pregnancy by handling the sperm or the oocyte outside the human body and transferring the gamete or the embryo into the reproductive tract of a woman¹⁸

End of Part 3