



Medical Technology and Device Development

Foundational Curriculum:

Cluster 7: Patient and Device Integration/Research and Biomedicine

Module 13: Research, Biomedicine, and Device Development

Unit 2: Medical Technology and Device Development

FC-C7M13U2

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Unit Objectives



- Define medical technology, health technology and biotechnology
- Describe the role that anatomy, physiology, disease processes, pharmacology, and health IT play in emerging medical technology and device development
- Describe the medical device development process
- Name the regulatory agencies that oversee medical technologies and device development
- Explain the various roles of Health IT in medical technology and device development
- Describe how health IT can assist in the application of medical technologies and new device development
- Describe the basic concepts and applications of ubiquitous computing
- Define biomedical and clinical engineering
- State the importance of safety, effectiveness and quality in medical technology and device development
- State the importance of analysis, logic, probability theory, statistics, etc., on the development of new health technologies
- Describe some recent innovations in health IT/eHealth

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What is Medical/Health Technology?



- **Medical technology** can be defined as any technology that is used to treat conditions, improve health, and save lives
- The WHO defines **health technology** as the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives.
- This includes the pharmaceuticals, devices, procedures and organizational systems used in health care.
- Medical technology, or "medtech," encompasses a wide range of healthcare products and is used to treat diseases and medical conditions affecting humans. These technologies, which are applications of medical science, are intended to improve the quality of healthcare.





What is Medical/Health Technology?



- Medical or health technology can provide earlier diagnosis, less invasive treatment options and reduction in hospital stays and rehabilitation times. Recent advances in medical technology have also focused on cost reduction.
- According to MedTech Europe, there are more than 500,000 medical technologies currently available. These technologies all share a common purpose: improving and extending the lives of people around the world.
- Medical technology can be familiar, everyday objects such as sticking plasters, syringes or latex gloves. Alternatively, it could also be spectacles, wheelchairs and hearing aids.
- At the high tech end of the scale, medical technology includes total body scanners, implantable devices such as heart valves and pacemakers, and replacement joints for knees and hips





What is Medical/Health Technology?



- Because health technology can involve human body simulations, replacements and enhancements, anatomy, physiology, disease processes and pharmacology all play important roles in the development of new medical devices
- Medical technology may broadly include medical devices, information technology, biotechnology, and healthcare services
- **Biotechnology** is the use of living systems and organisms to develop or make products, or "any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use"
 - Depending on the tools and applications, it often overlaps with the (related) fields of bioengineering, biomedical engineering, bio-manufacturing, molecular engineering, etc.





Medical Device and Technology Development



- Before creating a new medical product, there needs to be an **idea** and **need** for the product. The need can be identified from basic medical fields, e.g. anatomy, physiology or pharmacology.
 - Example of the idea: “The patient’s leg is amputated below the knee, thus the patient is not able to walk”. Possible solutions: 1) Develop an assistive device to balance the patient and enable weight transfer (=crutches) 2) Replace the missing part of the leg with artificial one (=prosthesis)
- Medical devices are usually designed to mimic or replace a physiological function of the body, thus the solution needs to follow the same principles as the original body part
- Health IT allows medical devices to access prior information or to share the input or output of the device to other locations (or devices)



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The Medical Device Development Process



- There are six high level steps to the medical device development process
- There are several sub-steps that vary from location to location, but the general process is the same on a global basis
 1. Device Discovery and Concept
 2. Preclinical Research
 3. Prototype Development
 4. Regulatory Pathway Submission and Review Process
 5. Regulatory Approval Process
 6. Post-Market Device Safety Monitoring





The Medical Device Development Process (cont'd)



Device Discovery and Concept

- Device Discovery and Concept: Typically, the development process begins when researchers see an unmet medical need. Then, they create a concept or an idea for a new device. From there, researchers build a “proof of concept,” a document that outlines the steps needed to determine whether or not the concept is workable.

Preclinical Research

- Preclinical Research: The aim of a **preclinical study or preclinical research** is to collect data in support of the safety of the new device. Preclinical research is required before clinical trials in humans can be started.

Prototype Development

- Prototype Development: Researchers build a device prototype, or an early version of a medical device. At this stage, the device prototype is not for human use. Researchers test the prototypes in controlled laboratory settings.



The Medical Device Development Process (cont'd)



Regulatory Pathway Submission/Review

- Regulatory Pathway Submission and Review Process: There is much variation in this process depending upon location, but basically, applicants must provide scientific evidence that:
 - 1) the possible benefits to health from the intended use of their submitted device outweigh the possible risks and
 - 2) the device will significantly help a large portion of the target population.If medical device developers have enough information on a device's safety and effectiveness, they file an application to market the device to the public.
 - The device is reviewed by the regulatory agency, and if the review is satisfactory, the process continues



Regulatory Approval Process

- Regulatory Approval Process: If the regulatory agency finds that the device conforms to regulations, and satisfies the requirements in the pathway submission and review process as outlined above, the device is approved. The device may receive preliminary or final approval, and is categorized.



The Medical Device Development Process (cont'd)



Post-Market Safety Monitoring

- Post-Market Device Safety Monitoring: Although premarket clinical trials provide important information on a device's safety and effectiveness, it is possible that new safety concerns will emerge once the device is on the market. As a result, regulatory agencies continue to monitor device performance after a device has been approved.



Regulatory Agencies Overseeing Medical Technologies and Development



European Union

- European Union regulates the medical devices that can be placed on the European market

Food and Drug Administration

- Food and Drug Administration regulates the medical devices that can be placed on the market in United States



Basic Concepts and Applications of Ubiquitous Computing

- **Ubiquitous computing, or “ubicomp”** is a concept of computer science where computing appears anytime and anywhere in everyday objects without interrupting the user
- The underlying technologies to support ubiquitous computing include Internet, advanced middleware, operating system, mobile code, sensors, microprocessors, new inputs and outputs, user interfaces, networks, mobile protocols, location and positioning, and new materials and devices
- Ubiomp is also described as pervasive computing, ambient intelligence, or "everyware".
 - Each term emphasizes slightly different aspects. When primarily concerning the objects involved, it is also known as physical computing, the Internet of Things, haptic computing, and "things that think".





Basic Concepts and Applications of Ubiquitous Computing (cont'd)

- Rather than propose a single definition for ubiquitous computing and for these related terms, a taxonomy of properties for ubiquitous computing has been proposed, from which different kinds or flavors of ubiquitous systems and applications can be described.
- Ubiquitous computing touches on a wide range of research topics, including distributed computing, mobile computing, location computing, mobile networking, context-aware computing, sensor networks, human-computer interaction, and artificial intelligence.
- Ubiquitous computing is applied to medical device/technology development: smart systems apply human-computer interactions, and they save, analyze and send information to other devices and care providers
- Ubiquitous systems include devices that are not bound to one location, e.g. mobile devices for telemedicine, wearable items and implanted items but also stationary ICT components if they are embedded into everyday objects, such as furniture or buildings





Health IT in Medical Technology and Device Development



- Medical technology and devices include software and data analyzing systems
 - Decision making speed can be improved by health IT solutions and available data can be utilized in improving health
 - Health IT companies can provide business ideas for smart data usage
- Virtualized, modernized infrastructure can enable a primary focus on patients by making other technological innovations available to health care professionals
- Connected medical devices enhance the functional delivery of care, while digital clinical workspaces transform the practical delivery of care.
- Electronic health records keep everyone connected, and they are critical for interfacing into medical technology and device development





How Health IT can Assist in the Application of Medical Technologies and New Device Development



- Medical technology and device development includes a variety of built-in regulations and standards to prove the safety and efficiency of a new product
- As we saw in the new device development process, standards requiring manufacturers to prove safety and efficacy are essential for new medical technology/device approval
- Health IT can provide tools to evaluate whether safety and efficiency properties are acceptable, such as monitoring programs, clinical trials software, quality and data collection applications, safety dashboards, and more
- These tools frequently interface with an acute care or ambulatory EHR to make them even more robust



Biomedical and clinical engineering



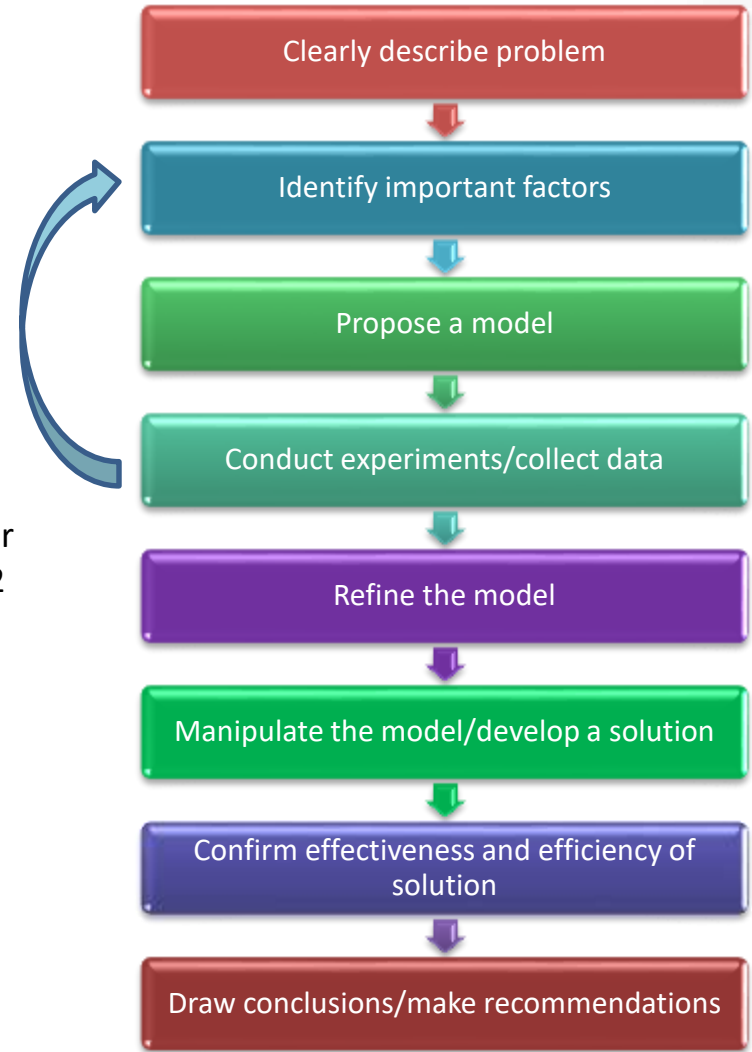
- **Biomedical engineering** is a field of engineering that aims to combine engineering principles and design concepts to medicine and biology to create methods and solutions for the purposes of medicine and health care.
- **Clinical engineering** is a specialty within biomedical engineering. Clinical engineering focuses on applying and implementing medical technology in hospitals or other clinical settings.





The Engineering Process

- The engineering process, including medical device, biomedical and clinical engineering, can be broken down into eight steps:
 1. Develop a clear and concise description of the problem.
 2. Identify the important factors that affect the problem or that may play a role in its solution.
 3. Propose a model for the problem, using scientific or engineering knowledge of the phenomenon being studied, stating any limitations or assumptions of the model.
 4. Conduct appropriate experiments and collect data to test or validate the tentative model or conclusions made in steps 2 and 3. This step may need to be repeated after going back through steps 2 and 3 until the model is finalized.
 5. Refine the model on the basis of the observed data.
 6. Manipulate the model to assist in developing a solution to the problem.
 7. Conduct an appropriate experiment to confirm that the proposed solution to the problem is both effective and efficient.
 8. Draw conclusions or make recommendations based on the problem solution.





Analysis, statistics & probability theory, and the development of new health technologies



- The field of statistics deals with the collection, presentation, analysis, and use of data to make decisions, solve problems, and design products and processes
- Since many aspects of health technology development involve working with data, some knowledge of statistics is important to any medical technology developer or biomedical engineer
- Probability models help quantify the risks involved in statistical inference, that is, the risks involved in decisions made every day in engineering and medical technology and device development
- Specifically, analysis, logic, statistical techniques and probability theory can be powerful aids in designing new products and systems, improving existing designs, and designing, developing, and improving production processes



Safety, Effectiveness and Quality in Medical Technology and Device Development



- Safety: Safety needs to be ensured in all aspects of technology, privacy and information security is as important as electrical or mechanical safety. Also radiation safety and other exposures need to be considered.
- Effectiveness: Technology and devices produce effective benefits to the patient or doctor, new technology needs to be better than the existing one to be implemented.
- Quality: Quality of the products ensures better products, lower costs and risks and healthier patients.





Some Recent Innovations in Health IT/eHealth



2017

- Augmented Reality Healthcare Education
- Star Trek like “Tricorders”
- “Leadless” Pacemakers
- Organs on a microchip
- 3D printed drugs

2018

- Artificial Intelligence (AI) in Healthcare
- Blockchain in Healthcare
- Non-Invasive Diabetes Monitoring
- Hybrid Closed-Loop Insulin Delivery System
- 5G Mobile Technology



Unit Review Checklist

- Defined medical technology, health technology and biotechnology
- Described the role that anatomy, physiology, disease processes, pharmacology, and health IT play in emerging medical technology and device development (CCB12)
- Described the medical device development process
- Named the regulatory agencies that oversee medical technologies and device development
- Explained the various roles of Health IT in medical technology and device development (CCB16)
- Described how health IT can assist in the application of medical technologies and new device development (CCB11)
- Described the basic concepts and applications of ubiquitous computing (GGN07)
- Defined biomedical and clinical engineering
- Stated the importance of analysis, logic, probability theory, statistics, etc., on the development of new health technologies (CCB17)
- Stated the importance of safety, effectiveness and quality in medical technology and device development
- Described some recent innovations in health IT/eHealth (CCB01)



Unit Review Exercise/Activity



1. Describe the difference between biomedical engineering and clinical engineering.
2. Activity: Search for novel innovations in health IT / eHealth
3. Why is probability important to medical device development?



Unit Exam



1. Collecting data in support of the safety of the new device describes which medical device development process:
 - a) Preclinical research
 - b) Prototype development
 - c) Regulatory pathway review
 - d) Regulatory approval process

2. A document that outlines the steps needed to determine whether or not a device concept is workable is called a:
 - a) Prototype
 - b) Preclinical trial
 - c) Proof of concept
 - d) Regulatory approval



Unit Exam (cont'd)



3. Pervasive computing, ambient intelligence, and "everyware" all describe which concept?
 - a) Regulatory compliance
 - b) Ubiquitous computing
 - c) Biomedical engineering
 - d) New device prototyping

4. Which of the following statements is true about ubicomp?
 - a) Ubiquitous computing always involves furniture or buildings
 - b) Ubiquitous computing often involves out of the ordinary objects that frequently interrupt the user
 - c) Ubiquitous systems never include artificial intelligence (AI)
 - d) Ubiquitous systems include devices that are not bound to one location



Unit Exam (cont'd)



5. Which step of the engineering process may need to be repeated until the model is validated and finalized?
 - a) Clearly describe problem
 - b) Identify important factors
 - c) Manipulate the model
 - d) Draw conclusions

6. How does probability theory help in medical technology development?
 - a) it adds a 1/6 greater chance of to the equation in medical technology development
 - b) it takes the risks out of ubiquitous computing
 - c) it helps quantify the risks involved in statistical inference
 - d) it allows developers to seek risky approvals of controversial medical devices