Implementation of medical devices

Surgery & Anaesthetics BSc Lecture Notes

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Plan

- Why should you be interested in this lecture?
- What is a medical device?
- What is implementation?
- Learning objectives addressed
- Adoption and diffusion of complex innovation
- Psychology of implementation

Why you should be interested

- You will use medical devices every day in your clinical practice
- The global market for medical devices is large and steadily growing
- Failures of medical devices are associated with preventable patient deaths

What is implementation?

- Implementation is the realization of an application, or execution of a plan, idea, model, design, specification, standard, algorithm, or policy

  Putting something into practice

Types of implementation

- Direct changeover
- Hot standby
- Parallel running
- Pilot introduction

What is a medical device?

- A medical device is a product which is used for medical purposes in patients for diagnosis and/or treatment
- Excludes pharmaceuticals (medicinal products), which achieve their principal action by pharmacological, metabolic or immunological means.

EU definition of a medical device

- Directive 2007/47/ec defines a medical device as: *"any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings. Devices are to be used for the purpose of:*
  - Diagnosis, prevention, monitoring, treatment or alleviation of disease.
  - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap.
  - Investigation, replacement or modification of the anatomy or of a physiological process
  - Control of conception
- This includes devices that do not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means."

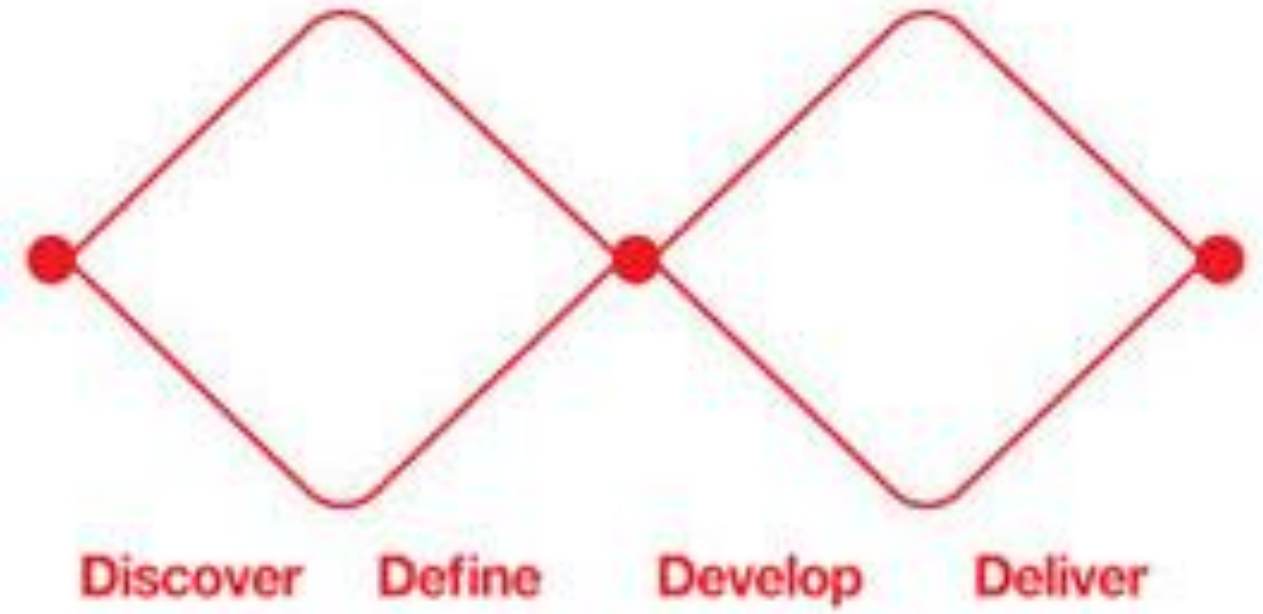
FDA definition of a medical device

- A device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals,
- and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Learning objective 1

- Describe and illustrate the pathway of a new medical device from concept to prototype to product

The Double Diamond



?

- How do I come up with the concept for a medical device?

Concepts/Ideas

- Something new
  - Completely new idea (creativity)
  - New design of existing product (design)
  - New way of using existing product (innovation)

- Start with the problem
  - Is it an important problem?
    - How much harm does it cause? (need)
    - Is money spent on solving the problem? (market)

Discover/characterize the problem

- Cause - why does the problem occur?
- What existing solutions are already in use?
- Has an equivalent problem been solved elsewhere?

Define the objectives

- Difficult to get equipment quickly
- Difficult to stock check

Slow retrieval of equipment could make the difference between life and death

Develop solutions

- Design creativity
- Design briefs/constraints

Concept generation/Development

- Ideas written on paper
- Drawings
- Paper models
- Looks like, works like
- Working prototype

Testing

- Feedback of opinions
  - users
  - purchasers
  - manufacturers
- Simulation trials (research ethics committee)
- Clinical trials (research ethics committee)

Deliver - Manufacture

- Business model
  - Protection of IP (design registration/patents)
  - Market research/Balance sheet (health economics)
- Approvals
  - NICE/MHRA/Other
  - CE mark
  - NHS supply chain
- Implementation (selling/persuading)
- Product surveillance post-release

Learning objective 2

- Compare the research approaches employed in bringing a new technology into routine clinical practice

Research approaches

- Exploratory research – hypothesis generation
  - Literature search
  - Observations (ethnography)
  - Questions (Surveys/Interviews)
- Design – creativity + innovation
- Validation research – hypothesis testing
  - In vitro – simulation (safer)
  - In vivo – clinical studies (more valid)
  - Post-implementation – audit (real)

Types of validation studies

- Case-control
- Cohort
- Randomised controlled trial
  - Individual
  - Crossover
  - Cluster

Research approaches

- Exploratory
- Creative
- Validation

Learning objective 3

- Illustrate the key implications of Good Clinical Practice (GCP) guidelines and justify their existence

Implications of GCP

- Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible

Requirements

- Sponsor must be identified
- Authorization from licensing body (MHRA)
- Approval from Research Ethics Committee

- Deviations from protocol should ideally be agreed in advance and all must be documented

GCP pros

- Tries to make sure that different centers in multicentre trials are doing the same thing
- Protects the patients
- Increases the internal validity of the results

GCP cons

- Increases time/cost/commitment
- Not designed for exploratory research/design
- May discourage research in member countries
- May not improve external validity

Learning objective 4

- Illustrate the role of health economics in establishing, implementing and maintaining new technologies

Healthcare economics - establishing

- What value does the new solution add?
- How much is this worth in money?
  - Efficacy
  - Economic analysis (cost effectiveness/QuALYs)
  - Patient satisfaction

Healthcare economics - implementing

- Putting into practice means *change*
- How much will this cost?
  - hardware/kit
  - time
  - duplication
  - training
  - mistakes?

Healthcare economics - maintaining

- How long will the kit last?
  - How often does it need to be replaced?
  - How often does it need to be serviced/repaired?
  - How future-proof is the technology?

Learning objective 5

- Characterize the assessment of clinical research quality

Assessment of research evidence

- Journal (impact factor)
- Authors (H-index)
- Type of study
- Number of participants
- Validity of measures/comparisons
  - chance
  - bias
  - confounding
- Impact
- Reproducibility

Hierarchy of evidence

- Systematic review of RCTs without heterogeneity
- Large well controlled RCT with narrow 95% CI
- Cohort
- Case-control
- Case series
- Case report
- Expert opinion

Learning objective 6

- Assess and defend the role of medical ethics and it’s impact on research

RECs pros

- Protect patients/research participants
- Independent peer review at the planning stage
  - Can improve methodology
  - Save researchers from doing the wrong study
  - Ensure high-quality plan
  - Required by journals

RECs cons

- Increases work/time/commitment
- May focus on seemingly trivial aspects of the research, such as the exact wording of Patient Information Sheets
- May not be experts in the field, so may not be able to assess the validity, or improve the quality of the study

Learning objective 7

- Discuss the role of patient involvement in establishing new technologies and designing research trials

Patient involvement in technology

- Participants in studies
- Recipients of disseminated findings
- Impact of user preferences
- Feedback of user experience
- Non-patient capacity

Patient study design involvement

- Participant feedback
- Ethics committee
- Expert reference group
- Advisory board
- Non-patient capacity

Learning objective 8

- Discuss the role of NICE and demonstrate its limitations and merits

NICE

- Established 1st April 2005

- Publishes guidance
  - evidence of efficacy
  - cost effectiveness

Roles of NICE

- Eliminate the postcode lottery
- Assess evidence on behalf of healthcare professionals, patients and managers
- Evidence-based commissioning

NICE pros

- Independent academic centre collates and analyses data
- fully independent of government or lobbying influences
- standardized methodology of assessment

NICE cons

- Manufacturer of medical device is involved in appraisal – may lead to bias
- Has been shown to be influenced by public opinion and companies may exploit this
- Cannot assess no evidence before use
- Cannot assess every possible permutation of use in practice
  - rare adverse events (? FMEA)

Learning objective 9

- Defend the regulatory body’s involvement in the establishment of a new medical device

Harmonisation within the EU

- Based on the "New Approach", rules relating to the safety and performance of medical devices were harmonised in the EU in the 1990s. The "New Approach", defined in a European Council Resolution of May 1985, represents an innovative way of technical harmonisation. It aims to remove technical barriers to trade and dispel the consequent uncertainty for economic operators allowing for the free movement of goods inside the EU.
- The core legal framework consists of 3 directives:
  - Directive 90/385/EEC regarding active implantable medical devices;
  - Directive 93/42/EEC regarding medical devices;
  - Directive 98/79/EC regarding in vitro diagnostic medical devices.

- The government of each EU Member State is required to appoint a Competent Authority responsible for medical devices. The Competent Authority (CA) is a body with authority to act on behalf of the government of the Member State to ensure that the requirements of the Medical Device Directives are transposed into National Law and are applied. The Competent Authority reports to the Minister of Health in the Member State.
- The Competent Authority in one Member State does not have jurisdiction in any other Member State, but they do exchange information and try to reach common positions.
- In UK the Medicines and Healthcare products Regulatory Agency (MHRA) acts as a CA
- In the EU, all medical devices must be identified with the CE mark.

CE mark

- The CE marking certifies that a product has met EU consumer safety, health or environmental requirements. Originally "CE" stood for ("Communauté Européenne") "European Community". According to the European Commission today the CE logo has become a symbol for free marketability of industrial goods within the EEA without any literal meaning. By affixing the CE marking to a product, the manufacturer – on his sole responsibility – declares that it meets EU safety and health and environmental requirements.

- Existing in its present form since 1993, the CE marking is a key indicator of a product's compliance with EU legislation and enables the free movement of products within the European market. By affixing the CE marking on a product, a manufacturer is declaring, on his sole responsibility, conformity with all of the legal requirements to achieve CE marking and therefore ensuring validity for that product to be sold throughout the European Economic Area. This also applies to products made in third countries which are sold in the EEA.
- CE marking does not indicate that a product was made in the EEA,[2] but merely states that the product is assessed before being placed on the market and thus satisfies the legislative requirements (e.g. a harmonised level of safety) to be sold there. It means that the manufacturer has verified that the product complies with all relevant "essential requirements" (e.g. safety, health, environmental protection requirements) of the applicable directive(s) – or, if stipulated in the directive(s), had it examined by a notified conformity assessment body.

Self declaration

- 1. Identify applicable directives
- 2. Identify applicable conformity assessment module
  - Module 'A' (Internal Production control): Applicable for products falling under EMC and Low Voltage Directives. Manufacturer's product is tested by a third party. After compliance with the tests, his production process ensures continued conformance. He maintains "Technical Documentation" as a proof of compliance. There is no mandatory involvement of European Lab (i.e. Notified Body).
  - Modules 'B' to 'H': Mandatory involvement of European Lab is required which issues "Type Examination Certificate", certifies documentation (called "Technical Construction File" (TCF) and carries out inspections.
- 3. Identify applicable standard
- 4. Test one sample of the product. Either yourself or from test lab
- 5. Compile technical documentation
- 6. Sign the EC declaration of conformity
- 7. Affix CE Mark to the product

MHRA classes of medical devices

- Class 1
- Class 2a
- Class 2b
- Class 3

Class I: general controls only

- Class I devices are subject to the least regulatory control. Class I devices are subject to "General Controls" as are Class II and Class III devices. General controls include provisions that relate to adulteration; misbranding; device registration and listing; premarket notification; banned devices; notification, including repair, replacement, or refund; records and reports; restricted devices; and good manufacturing practices.
- Class I devices are not intended for use in supporting or sustaining life or to be of substantial importance in preventing impairment to human health, and they may not present a potential unreasonable risk of illness or injury.
- Most Class I devices are exempt from the premarket notification and/or good manufacturing practices regulation.
- Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments.

Class 2: general + special controls

- Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances. In addition to complying with general controls, Class II devices are also subject to special controls. A few Class II devices are exempt from the premarket notification. Special controls may include special labeling requirements, mandatory performance standards and postmarket surveillance.
- Devices in Class II are held to a higher level of assurance than Class I devices, and are designed to perform as indicated without causing injury or harm to patient or user.
- Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes.

Class 3: general controls and premarket approval

- A Class III device is one for which insufficient information exists to assure safety and effectiveness solely through the general or special controls sufficient for Class I or Class II devices. Such a device needs premarket approval, a scientific review to ensure the device's safety and effectiveness, in addition to the general controls of Class I.
- Class III devices are usually those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.
- Examples of Class III devices which currently require a premarket notification include implantable pacemaker pulse generators and endosseous implants.

Role of the MHRA

- Monitor and ensure compliance with statutory obligations relating to medical devices
  - Regulate clinical trials of medical devices
  - Ensure medical device manufacturers comply with regulatory requirements before putting devices on the market
  - Operate post-marketing surveillance for reporting, investigating and monitoring of adverse incidents with medical devices
  - Promote safe use of medical devices

Adoption and diffusion of complex innovation

- Factors
  - Innovation
  - Adopter
  - Communication
  - Context

Reference

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Diffusion of complex health innovations—implementation of primary health care reforms in Bosnia and Herzegovina

Rifat A Atun,[1]* Ioannis Kyratsis,[1] Gordan Jelic,[2] Drazenka Rados-Malicbegovic[3] and Ipek Gurol-Urganci[1]

Attributes of the innovation

- Subjective increase in value
- Compatibility
- Complexity
- Trial-ability
- Observe-ability (of benefits)

Attributes of the adopter

- Healthcare Professionals
- Patients
- Managers

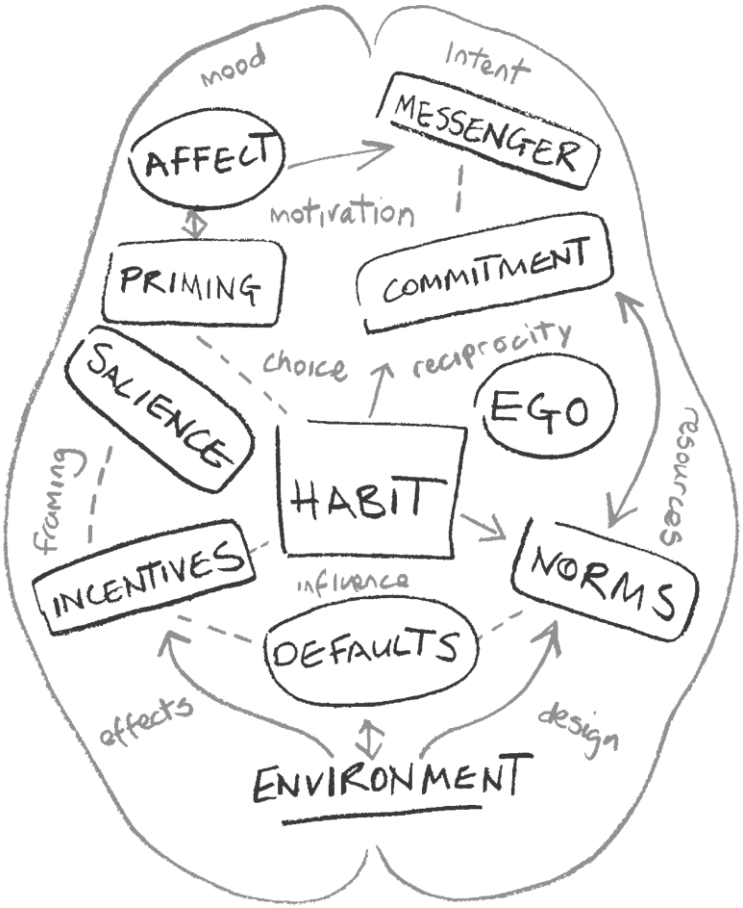
Attributes of communication

- Change agent – outsider
- Opinion leader – insider
- Champion – insider

Attributes of the context

- National priorities
- Recent media headlines/public opinion
- Economic climate

Psychology of implementation



MINDSPACE

Messenger	we are heavily influenced by who communicates information
Incentives	our responses to incentives are shaped by predictable mental shortcuts such as strongly avoiding losses
Norms	we are strongly influenced by what others do
Defaults	we ‘go with the flow’ of pre-set options
Salience	our attention is drawn to what is novel and seems relevant to us
Priming	our acts are often influenced by sub-conscious cues
Affect	our emotional associations can powerfully shape our actions
Commitments	we seek to be consistent with our public promises, and reciprocate acts
Ego	we act in ways that make us feel better about ourselves

Summary

- Double diamond: design pathway
- Research: exploratory and validation
- Requirements of regulators
- Adoption and diffusion of complex innovation
- Psychology of implementation

Sources of information

- NPSA website
  - Design for patient safety report
- MHRA website
- Department of Health
  - MINDSPACE report

DOME

Designing Out Medical Error

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