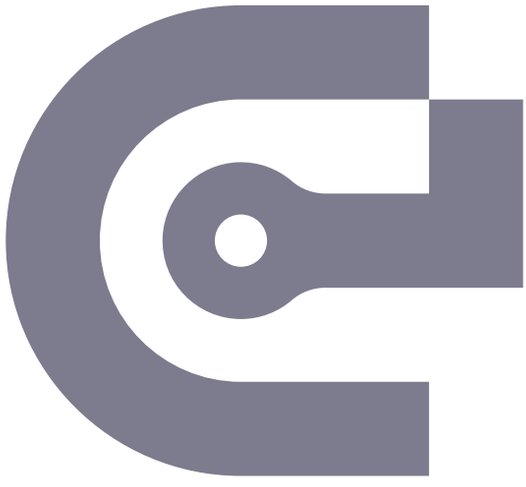


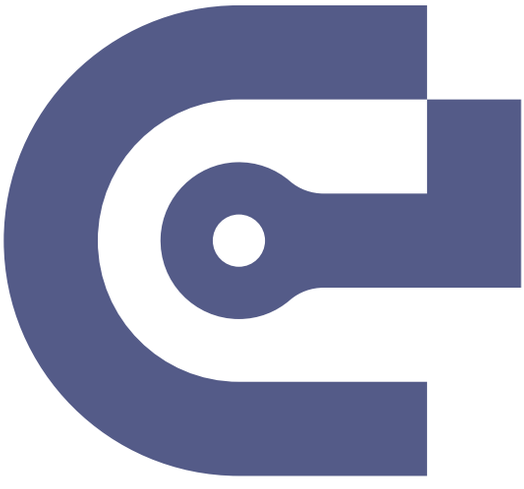
The eHealth Interdisciplinary Curriculum for Higher Education Students

Project Title Cooperation and training on innovation and entrepreneurship in the eHealth community

Project Acronym CONNECT

Grant Agreement Number 2020-1-RO01-KA203-080244

Contents



Module 1: Innovation in Health

Learning objectives of the Innovation in Health module are:

1. Students will be introduced to the concept of innovation in the healthcare system.
2. Students will learn about challenges when it comes to innovation in the healthcare system.
3. Students will learn to ideate, innovate, and deliver results from innovation.
4. Students will learn to use a systematic approach for analyzing and improving their work in health care settings.
5. Students will understand and apply the key steps involved to take an innovation from idea to realization.
6. Students will recognize healthcare innovation initiatives.
7. Students will learn how innovation in healthcare can improve cost, quality, and access.
8. Students will learn what other elements combine to create a feasible business model for an innovative healthcare venture.
9. Students will learn to identify critical economic issues, evaluate determinants of demand for medical care, describe the role of physicians in resource allocation, compare competition in medical care markets, and assess policy instruments.
10. Students will discuss and analyze relevant use cases in the field of innovation.
11. Students will be provided with a forum for a critical discussion of current developments, research topics, and impact within the field of telemedicine.
12. Students will be provided a forum for interdisciplinary collaboration focused on future directions for innovation in healthcare (e.g., communication, research, and development).

Foundational knowledge of the Innovation in health module

Definition of Innovation in Health

The term “innovation” has made its way into healthcare as a concept adopted from other fields, with a similar definition to those used in business, technology, and marketing. The World Health Organization (WHO) explains that ‘health innovation’ improves healthcare efficiency, effectiveness, quality, sustainability, safety, and/or affordability. This definition includes ‘new or improved’ health policies, practices, systems, products and technologies, services, and delivery methods that result in improved healthcare. Improvements in research, patient satisfaction, education, and access to care are additional factors to keep in mind. The ultimate goal of health innovation is to improve our ability to meet public and personal healthcare needs and demands by optimizing the health system’s performance (*WHO Health Innovation Group*, n.d.).

Key components of Innovation

BIODESIGN INNOVATION PROCESS (STANFORD UNIVERSITY)

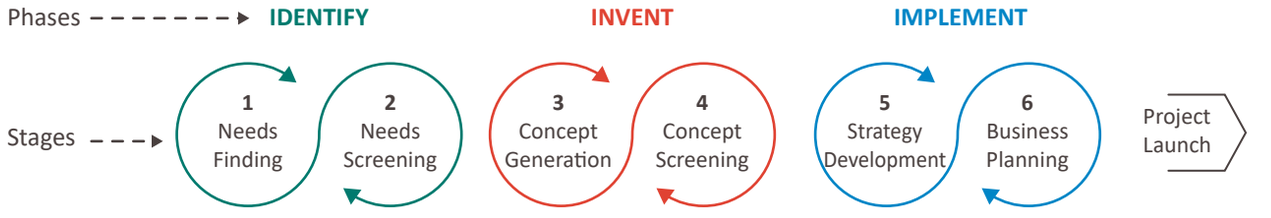


Fig. 1.1. Bio design Innovation Process (Biodesign, n.d.)

Identify

The identify phase is first and foremost about finding important unmet health needs by directly observing the full cycle of care from diagnosis and treatment to recovery and billing. In this way, you have to watch what's done and how it affects the provider, the patient, and the system while asking pointed questions that challenge the status quo.

During this first-hand observation period, it's ideal for collecting hundreds of needs, initially without judging or prioritizing. Then, it's time to filter the list with rigorous objectivity, taking into account everything from the different stakeholders affected by each need to how much potential it has to improve care and save the system money. This is an intense and iterative process, with progressively deeper dives into the needs with the most potential. Ultimately, the trainees arrive at the two or three most favourable conditions, which—if they can be solved—will have a major impact on health and wellness (*Process | Stanford Byers Center for Biodesign | Stanford Medicine*, n.d.).

Invent

Next, Stanford Bio designers begin to invent. They brainstorm hundreds of potential solutions for each of their top needs. Then, they organize their ideas and objectively compare them against key criteria for satisfying the requirements. During this phase, rough prototypes are created in a rapid "think-build-rethink" sequence, so failures emerge early, and iteration can lead to better solutions. They then filter the surviving solutions by researching everything from intellectual property issues and business models to reimbursement and regulatory pathways. In the end, the process produces a lead concept that has battled with several other ideas that were almost as good. It's survival of the fittest and guarantees that the lead concept has a good chance of reaching and improving patient care (*Process | Stanford Byers Center for Biodesign | Stanford Medicine*, n.d.).

Implement

In the implementation phase, the next steps are prototyping and testing the technology, developing the approach to patenting, regulatory approval, and reimbursement, charting the market potential for the innovation, and exploring sources of funding (*Process | Stanford Byers Center for Biodesign | Stanford Medicine*, n.d.).

MIT HACKING MEDICINE MODEL

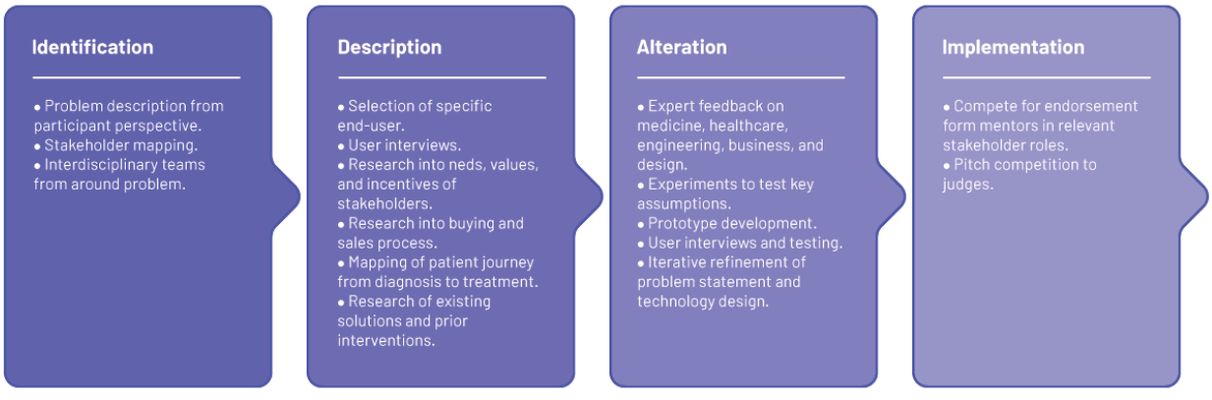


Fig. 1.2. Phases of the MIT hacking Medicine Hackathon Model Using a Systems Approach (MIT, n.d.)

The main phases of this process are listed below:

Identification

Teams are asked to focus on understanding the context and stakeholder perspectives around the problem they are studying without discussing solutions. Teams identify the relevant stakeholders in the healthcare system (e.g., patients, clinicians, hospitals, pharmacies, healthcare insurance organizations) appropriate to a specific clinical need. This allows teams to understand existing barriers to implementing a solution. Teams are encouraged to scrutinize the incentives and preferences of these stakeholders closely and to seek early feedback from these groups (MIT, n.d.).

Description

Following a discussion of the problem space, teams analyze and describe the highest value points of intervention among the identified key stakeholders. In systems thinking methodology, these highest value points are known as the levers that allow for the creation of a virtuous cycle of change (Senge, 2006). Teams should specifically target particular stakeholders to be the likely users and/or payers for the solution they will develop and identify the needs that their particular innovation addresses (MIT, n.d.).

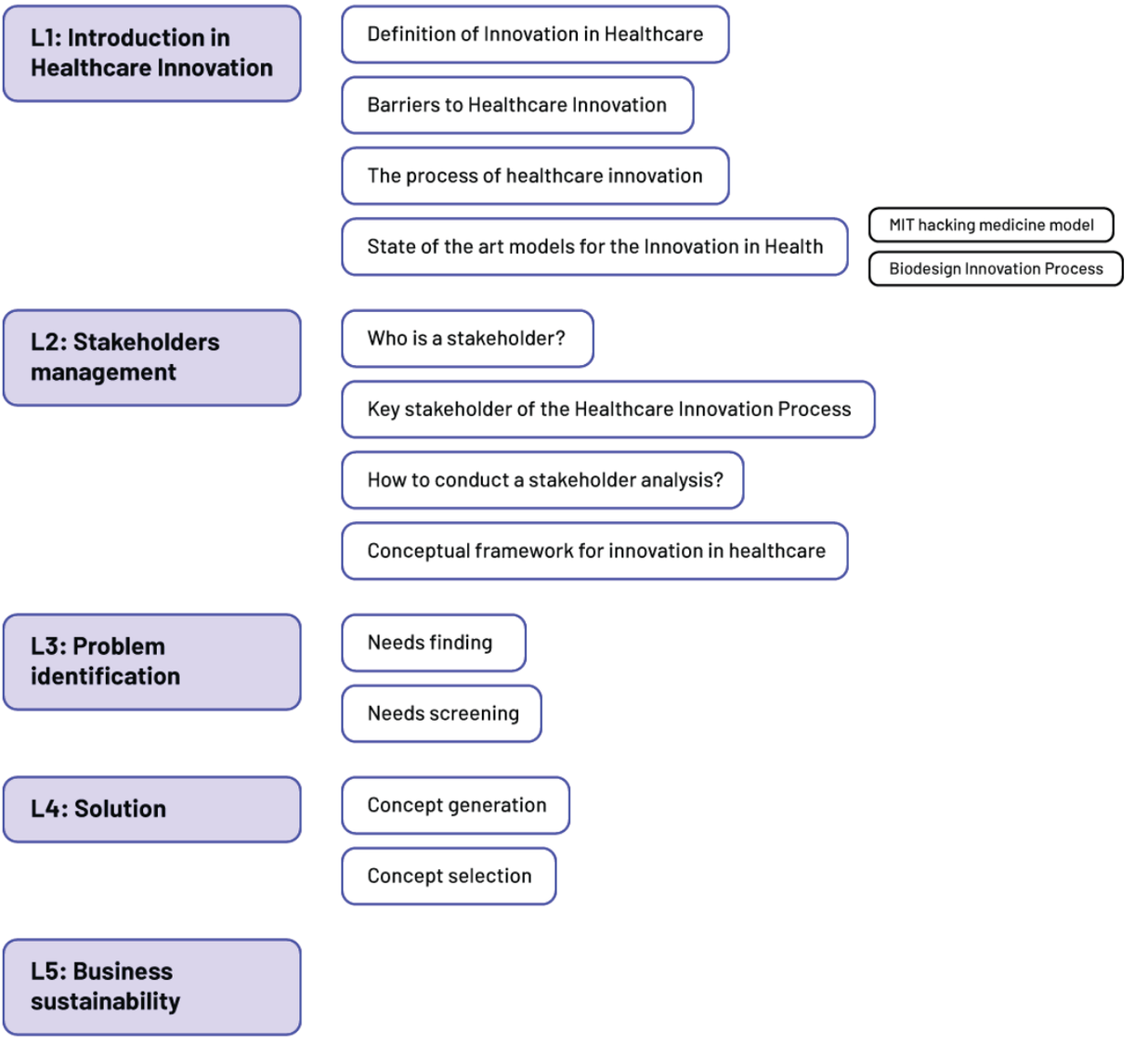
Alteration

Based on the incentives and needs identified in this analysis, teams design initial solutions to their selected clinical challenge. We encourage teams to prototype potential solutions for unmet needs as proposed alterations to the existing standard of care. Expert mentors were recruited from patient advocacy groups, local hospitals, and industry to supplement, evaluate, or assist teams. With rough prototypes, teams can receive feedback directly from users, such as patients or providers, and rapidly iterate upon their proposed solutions. Teams use their refined understanding to develop increasingly focused solutions with greater clarity for their potential impact on relevant stakeholders and workflow (MIT, n.d.).

Implementation

Teams are asked to concisely summarise their clinical challenge, stakeholder analysis, and proposed solution. In addition to directly addressing the technical feasibility of their proposals, teams must demonstrate a plan for implementing, distributing, and scaling their solution. The final team evaluation is based on a comprehensive, systems-level description of the need and the likelihood of successful implementation (MIT, n.d.).

Lesson plans for the Innovation in health module



Lesson plan 1: Introduction to Healthcare Innovation

After completing this lesson, students will be acquainted with the following:

- What is Innovation in Healthcare
- Barriers and challenges in Healthcare Innovation
- The process of Healthcare Innovation
- The most important models in Healthcare Innovation and how they are applied

FOUNDATIONAL KNOWLEDGE

Definition of Innovation in Health

The term “innovation” has made its way into healthcare as a concept adopted from other fields, with a similar definition to those used in business, technology, and marketing. The World Health Organization (WHO) explains that ‘health innovation’ improves healthcare efficiency, effectiveness, quality, sustainability, safety, and/or affordability. This definition includes ‘new or improved’ health policies, practices, systems, products and technologies, services, and delivery methods that result in improved healthcare. Improvements in research, patient satisfaction, education, and access to care are additional factors to keep in mind. The ultimate goal of health innovation is to improve our ability to meet public and personal healthcare needs and demands by optimising the health system’s performance (*WHO Health Innovation Group*, n.d.).

Innovations in healthcare are related to product, process, or structure. The product is what the customer pays for and typically consists of goods or services (for example, clinical procedure innovations). Process innovation entails innovations in the production or delivery method. The customer does not usually pay directly for the process, but a process is required in order to deliver a product or service. A process innovation, therefore, would be a novel change to the act of producing or delivering the product that allows for a significant increase in the value delivered to one or more stakeholders. Structural innovation usually affects the internal and external infrastructure and creates new business models (Omachonu & Einspruch, 2010).

Barriers to Healthcare Innovation

Medical efficacy review

To be successful, a new healthcare innovation must improve upon the current standard of medical care without causing harm to the patient and ideally lower costs simultaneously. But gaining access to medical professionals with the appropriate expertise to determine medical efficacy can pose a major obstacle to even the largest, most established companies, not to mention the individual inventor. The diverse sets of clinical expertise necessary to review projects are rarely found in-house and can be expensive to purchase from outsiders (The guardian, n.d.).

Product distribution

Unlike consumer products, healthcare products are distributed through a more complex supply chain that involves multiple parties, including medical device manufacturers and distributors, the national health service purchasing and supply agency, physicians and nurses who provide the product to the end-user, and the patient, who generally has no input on product or pricing considerations. Determining how best to break into this elaborate network can be daunting, if not truly impossible, for inventors (The guardian, n.d.).

Manufacturer access

Gaining access to quality manufacturers is a major hurdle for many healthcare inventors because of manufacturers’ concerns about “intellectual property contamination” issues. In this scenario, manufacturers avoid learning about an individual inventor’s idea since it may be too similar to an innovation their internal research and development team is already working on; manufacturers do not want to run the risk of having to later prove it to the inventor (or to a judge) that the idea was not stolen (The guardian, n.d.).

Lack of access to national health service (NHS) purchasing data

Even large, well-connected medical manufacturing companies may find it difficult to access purchasing and product needs data and input from NHS. And operating in the absence of this information makes accurately estimating product adoption rates and potential market size virtually impossible (The guardian, n.d.).

Regulatory oversight

While enforcing strict guidelines on healthcare product manufacture and distribution is necessary to prevent incompetent or unscrupulous suppliers from harming patients, the EU regulatory environment slows the innovation process considerably (The guardian, n.d.).

Intellectual property complexity

Intellectual property rights have always been a confusing aspect of the inventing process for most individual inventors. It can be virtually impossible to navigate without professional help (The guardian, n.d.).

Healthcare culture

By nature, and for a good reason, the healthcare industry is incredibly risk-averse. As one doctor said: “The moment we step into medical school, we are trained to identify the most statistically proven method for treating a particular disease, and we are taught to not deviate from that path until a better method has been found proven.” Compounding this issue is that most healthcare workers are increasingly time-pressed today, so learning and adopting new systems, new care methods or new devices often take a backseat to day-to-day patient care (The guardian, n.d.).

High-stress environment

Healthcare workers have high-stress jobs and often work long hours. They are dedicated to delivering great patient care. Still, the nature of the job can make it difficult for innovative thinking to flourish since creativity naturally diminishes when an individual is in steady “fight or flight mode” (The Guardian, n.d.).

Complex value analysis model

In the healthcare sector, it is difficult for a product developer or individual inventor to generate data on how the product affects not only direct treatment but also the downstream healthcare supply chain, which means that determining the true value of an innovation idea is difficult (The Guardian, n.d.).

Misconceptions about what constitutes innovation

Within healthcare, those traditionally tasked with product development (ie engineers and technical experts) are generally not the same people who are living with or treating a particular healthcare challenge (The guardian, n.d.).

The process of healthcare innovation:

Even though much has been written about the process of innovation; however, there is very little information concerning the process of innovation in health care. Although the process of innovation typically is not linear, most innovations go through the process of problem identification and idea generation, idea evaluation, development, first use, commercialization, and diffusion.

To fully understand the process of innovation in healthcare, it is critical to answering the question, what is the catalyst for healthcare innovation? Another way to ask the question is to ask a) if innovation chases needs or b) if needs to chase innovation? In the first case, new or existing technology searches for a problem to solve. In

contrast, in the second case, new or current problems chase after solutions in the form of innovation. Stated differently, it comes down to solutions looking for problems to solve versus issues looking for solutions to adopt. In either case, technology is pivotal in facilitating the process (Omachonu & Einspruch, 2010).

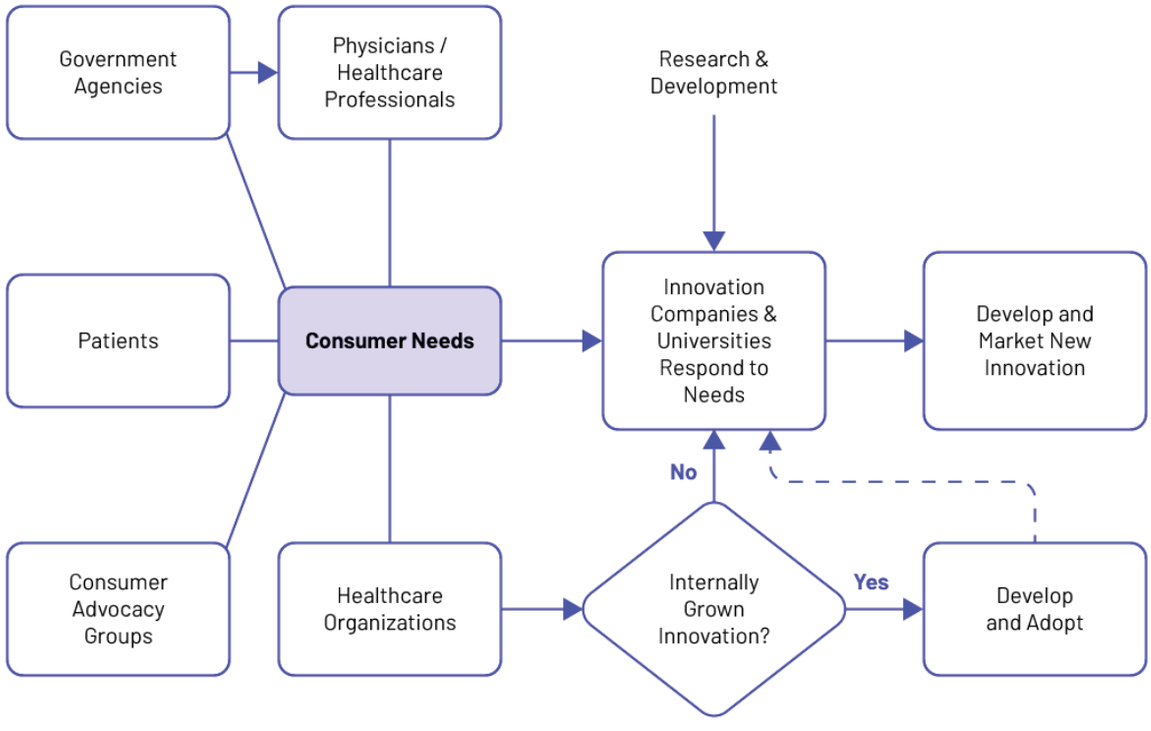


Fig. 1.3. The process of Healthcare Innovation (Omachonu & Einspruch, 2010)

State-of-the-art models and knowledge for Innovation in Health

BIODESIGN INNOVATION PROCESS (STANFORD UNIVERSITY)

Innovation and entrepreneurship have been widely celebrated in recent years, reaching as far as mainstream television with multiple current on-air shows (e.g., Silicon Valley, Shark Tank, etc.). In parallel with this increased cultural awareness, universities across the country have developed entrepreneurship training programs, initially focusing on engineering but more recently expanding to the life sciences. One of the oldest life science programs is Stanford Biodesign, which focuses on training young innovators of biomedical technologies (particularly medical devices). A primary distinction between the Stanford Biodesign process and more traditional approaches to innovation is an upfront focus on identifying and characterizing the clinical need, rather than beginning with a promising technology. The central dogma of the Stanford Biodesign process is that "a well-characterized need is the DNA of a great invention". This needs-based approach to innovation begins in the clinical environment, where practising clinicians are ideally placed to spearhead the process. Although many companies have germinated from the fellowship program, the true goal is to teach a repeatable approach to health technology innovation, which can lead to a "multiplier effect," where graduates can apply this process serially to solve unmet needs clinical needs (Schwartz et al., 2016).

MIT HACKING MEDICINE MODEL

MIT Hacking Medicine is a student, academic, and community-led organization that uses systems-oriented ''healthcare hacking'' to address healthcare innovation challenges. The group has organized more than 80 events worldwide that attract participants from diverse backgrounds. These participants are trained to address clinical needs from multiple stakeholders' perspectives and emphasise the utility and implementation viability of proposed solutions. We describe the MIT Hacking Medicine model as a potential method to integrate collaboration and training in rapid innovation techniques into academic medical centres. Built upon a systems approach to healthcare innovation, the events' time-compressed but expertly guided nature could enable more widely accessible preliminary training in systems-level innovation methodology, as well as create a structured opportunity for interdisciplinary congregation and collaboration (Gubin et al., 2017).

EXAMPLES AND ANALOGIES

Examples of Healthcare Innovation (Case studies)

1. An electronic Personal Health Record solution (ePHR) to enable consumers to record and selectively share healthcare information about themselves and their loved ones in a secure manner. (**Startup example:Phable**) (*Phable | India's Largest Chronic Disease Management Company*, n.d.).
2. An electronic Clinician Health Record solution (eCHR) enables physicians and other healthcare providers to securely access information collated from any number of trusted sources relating to an individual patient in a structured and easily accessible way. (**Startup example: Oncochain**) (*Oncochain - Data comes to life*, n.d.).
3. A healthcare informatics platform to enable all healthcare data to be stored and accessed via the ePHR and eCHR solutions. The platform is based on industry-standard technologies and data models (Omachonu & Einspruch, 2010).
4. The use of robots in rehabilitation therapy for victims of stroke. Robots built by a team at MIT can help deliver therapy with the promise of reducing elbow and shoulder impairments in stroke victims (Omachonu & Einspruch, 2010).
5. High-definition television signals are used in cameras (known as videoscopes) by surgeons to snake through patients' bodies to search for stomach tumours, perform colonoscopies, or assist in removing diseased gallbladders (Omachonu & Einspruch, 2010).
6. The da Vinci Surgical System allows physicians to perform minimally invasive procedures most commonly in treating urological and gynaecological conditions (Omachonu & Einspruch, 2010).
7. The CyberKnife Stereotactic Radiosurgery System is used by physicians to deliver high doses of radiation with great accuracy, which allows incisionless surgery for previously inoperable tumours (Omachonu & Einspruch, 2010).
8. The Elekta Synergy Cone Beam CT system for image-guided radiation therapy provides a 3-D view of the patient. It can detect very small shifts in position that can be corrected before treatment (Omachonu & Einspruch, 2010).
9. Ablation therapy transformed what 20 years ago was a risky, invasive open-heart surgery for the treatment of abnormal heart rhythms into a procedure that takes a matter of hours and has a 95 per cent success rate (Omachonu & Einspruch, 2010).
10. Intel Corp. is taking its next step in building a business in health care by introducing technology to help homebound patients with chronic medical problems such as diabetes, hypertension and heart disease. Intel's offerings include a simplified computer and software that are designed to help elderly people and other patients

monitor and manage their conditions at home. It connects to medical devices such as scales, blood-pressure monitors and glucose readers, recording information that can be shared with health professionals over the Internet (Omachonu & Einspruch, 2010).

APPLICATION AND INTEGRATION

Identify 3 to 5 needs for the healthcare system in a context you are familiar with and come up with innovative ideas

Find online in the news 3-5 problems in healthcare and propose innovative solutions

REFERENCES FOR FURTHER INFORMATION AND AREAS OF INQUIRIES

https://biodesign.stanford.edu/programs/stanford-courses/biodesign-innovation.html

https://www.cell.com/cell-systems/pdf/S2405-4712(17)30084-4.pdf

http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.1088.4711&rep=rep1&type=pdf

Lesson plan 2: Stakeholders management

After completing this lesson, students will be acquainted with the following:

- How are the stakeholders in the healthcare domain
- Framework for innovation in healthcare
- Developing stakeholders strategy

ABILITIES THAT WILL BE DEVELOPED

- Strategic thinking
- Critical thinking
- Planning

FOUNDATIONAL KNOWLEDGE

Who is a stakeholder?

Stakeholders in a process are actors (persons or organizations) with vested interest in the policy being promoted. These stakeholders, or “interested parties,” can usually be grouped into the following categories: international/donors, national political (legislators, governors), public (ministry of health [MOH], social security agency, ministry of finance), labour (unions, medical associations), commercial/private for-profit, nonprofit (nongovernmental organizations [NGOs], foundations), civil society, and users/consumers (Schmeer, 2000).

The comprehensive stakeholder analysis is an important tool in identifying, planning and implementing strategies for managing stakeholder relationships and identifying current and future opportunities and threats (Schmeer, 2000).

Key stakeholders of the Healthcare Innovation Process

The innovation process is complex and multi-dimensional regardless of the industry in which it is being applied. Innovation in the healthcare industry has its unique challenges. Any attempt to understand the healthcare innovation process must begin with an in-depth analysis of its challenges. There are five key stakeholders in the innovation process, and each has its unique and deliberate needs, wants and expectations as follows:

Table 1.1. Key stakeholders of the Heathcare Innovation Process (Omachonu & Einspruch, 2010)

Stake Holders	Needs, Wants & Expectations
Physicians and Other Care Givers	Improved clinical outcomes, improved diagnosis and treatment
Patients	Improved patients' experience, improved physiological well-being, reduced waiting time, reduced delay
Organizations	Enhanced efficiency of internal operations, cost containment, increased productivity and quality and outcomes improvement
Innovator Companies	Profitability, improved outcomes
Regulatory Agencies	Reduced risks and improved patient safety

Several researchers have suggested that changing clinicians' behaviour, current medical practices, and healthcare organizations is difficult. The adoption of healthcare innovations is often regulated by laws, making changes more laborious. In healthcare, specific starting points of an innovation process may lead to death, disability, or permanent discomfort. This, together with the clinicians' tendencies to protect their autonomy and reputation, can promote a culture of blame and secrecy that inhibits organizational learning and the generation of innovations. Furthermore, new practices in patient care are traditionally scrutinized thoroughly in their early development phase so that potentially harmful innovations are not adopted. Any attempt at modelling the process of health care innovation must consider all five key stakeholders.

How to conduct a stakeholder analysis?

- Arrange a group brainstorming session and compile a list of stakeholders who will have an impact on your project or be affected by it.

- After compiling a comprehensive list of potential stakeholders, assess their individual interests in your project by analyzing factors such as the benefits the project provides for them, the modifications they may need to make to accommodate the project, and any activities that could create problems or disagreements for them.

•Evaluate every stakeholder mentioned in the first column by asking the question: how crucial are their interests to the proposed project's achievement? Take into account:

The significance of the key stakeholder's role in ensuring the project's success and the probability that they will fulfill this role
The possibility and consequences of a stakeholder's unfavorable reaction to the project
Assign the letters A for highly important, B for important, and C for not significant to determine the impact of each stakeholder, and document these letters in the "Assessment of Impact" column. (Schmeer, 2000).

- Consider the kinds of things that you could do to get stakeholder support and reduce opposition. Consider how you might approach each of the stakeholders. What type of information will they need? How important is it to involve the stakeholder in the planning process? Other groups or individuals might influence the stakeholder to support your initiative? Record your strategies for obtaining support or reducing obstacles to your project in the last column in the matrix (Schmeer, 2000).

Table 1.2. The tool for stakeholder analysis (Schmeer, 2000)

Stakeholder	Stakeholder Interest(s) in the Project	Assessment of Impact	Potential Strategies for Obtaining Support or Reducing Obstacles

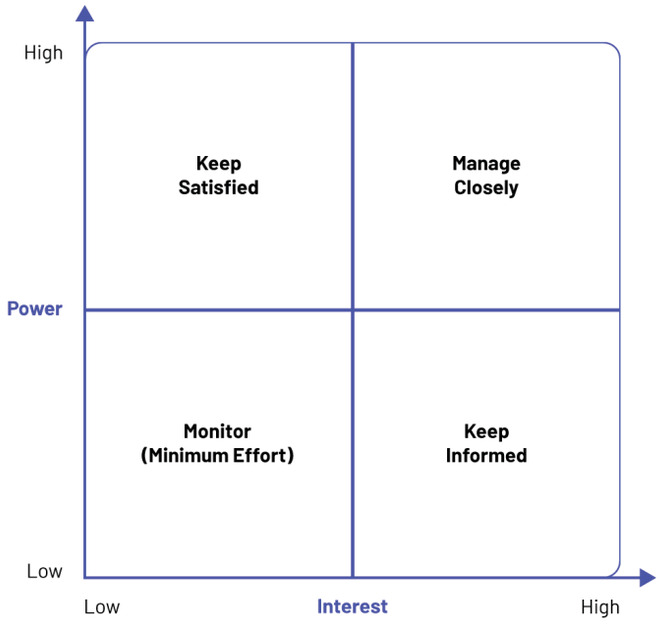


Fig.1.4. Stakeholder mapping (Schmeer, 2000)

Guidance for using the Stakeholder map:

- **High power, interested people:** these are the people you must fully engage and make the greatest efforts to satisfy.
- **High power, less interested people:** put enough work into these people to keep them satisfied, but not so much that they become bored with your message.
- **Low power, interested people:** keep these people adequately informed and talk to them to ensure no major issues arise. These people can often be very helpful with the detail of your project.
- **Low power, less interested people:** again, monitor these people, but do not bore them with excessive communication (Schmeer, 2000).

The needs of stakeholders with low power but high or medium interest should be addressed mainly through continuous, selected information distribution. Gaining the support of these stakeholders through lobbying can be a good tactic because they can be valuable allies in influencing the attitudes of other, more powerful stakeholders.

Stakeholders with high or medium power but low interest often have difficulty planning and developing consistent strategies. These stakeholders might generally be quite passive but unexpectedly exercise their authority in reaction to a particular event or policy. Under-estimation of this group can have disastrous consequences for adopting the new approach. These stakeholders should be kept satisfied through continuous communication and possibly through selected involvement in focal activities.

Stakeholders in the middle of the power/interest matrix with relatively high power and interest should be encouraged for the solid and continuous support of the work and activities undertaken. These stakeholders can be valuable resources and support needed to plan and initiate new ideas.

The most important stakeholders, who are crucial to the success of any strategic development in occupational health care, are the ones with high power and with high interest. These might also be stakeholders whose opinions and views must be discussed and elaborated, as their views can differ and vary (Auvinen, 2017).

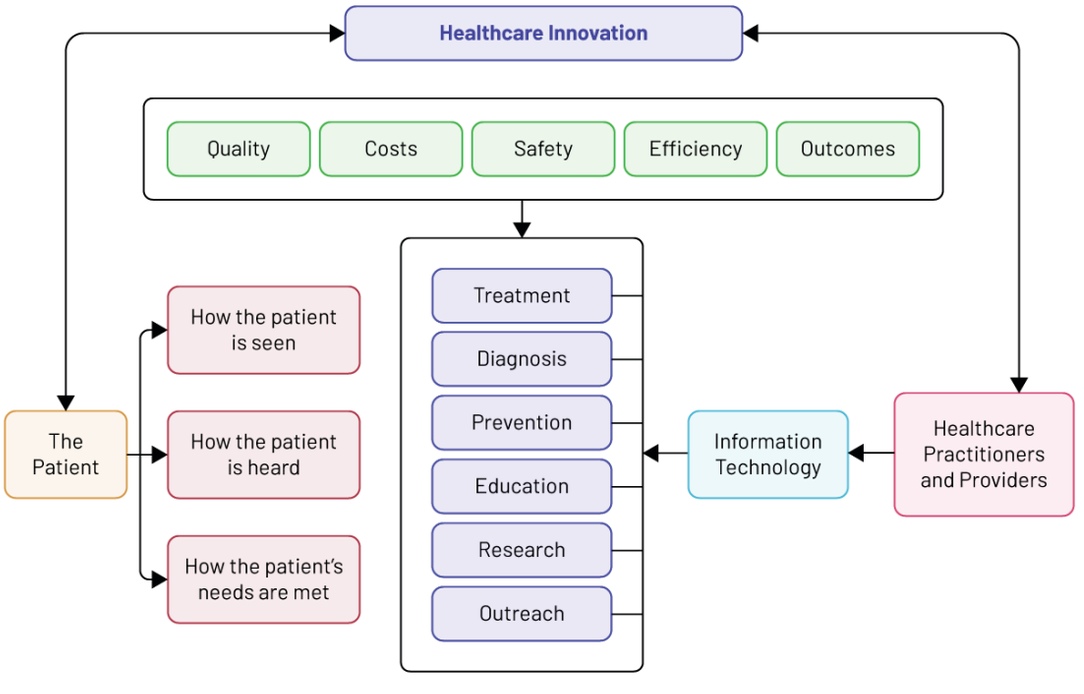


Fig. 1.5. The conceptual framework for innovation in healthcare (Omachonu & Einspruch, 2010)

Healthcare organizations serve six distinct purposes – treatment, diagnosis, prevention, education, research, and outreach. In performing these purposes, healthcare organizations must effectively manage quality, costs, safety, efficiency, and outcomes. At the very core of healthcare, innovations are the needs of patients and the healthcare practitioners and providers who deliver care.

Healthcare organisations often arrive at innovation by relying on new or existing information technology. When successful, healthcare innovation focuses on three areas the most – a) how the patient is seen, b) how the patient is heard, and c) how the patient's needs are met (Omachonu & Einspruch, 2010).

EXAMPLES AND ANALOGIES

https://www.healthcareis.com/blog/how-to-identify-key-stakeholders-for-a-healthcare-it-project
Biodesign: The Process of Innovating Medical Technologies (Book)

APPLICATION AND INTEGRATION

Define the key stakeholders for your proposed concept using the template below.

https://www.mindmeister.com/maps/public_map_shell/1298392026/stakeholders-in-health-care?width=900&height=600&z=auto#

Identify stakeholders of healthcare problems/bottlenecks, pinpoint their specific needs, and propose plans and timelines to satisfy them.

REFERENCES FOR FURTHER INFORMATION AND AREAS OF INQUIRIES

BIODESIGN: THE PROCESS OF INNOVATING MEDICAL TECHNOLOGIES

https://www.healthcareis.com/blog/how-to-identify-key-stakeholders-for-a-healthcare-it-project

https://www.intechopen.com/chapters/53519

https://innovation.mit.edu/assets/MIT-Stakeholder-Framework_Innovation-Ecosystems.pdf

https://www.who.int/workforcealliance/knowledge/toolkit/33.pdf

Lesson plan 3: Problem identification (Identify phase)

After completing this lesson, students will be acquainted with the following:

- How to identify unmet health needs
- How to define a strategic focus
- How to search for relevant problems in the healthcare domain
- How to define a need statement
- How to screen the finding needs

ABILITIES THAT WILL BE DEVELOPED

- Problem-solving
- Critical thinking
- Strategic thinking
- Planning

FOUNDATIONAL KNOWLEDGE

NEEDS FINDING -> NEEDS SCREENING

The **identify phase** is first and foremost about finding important unmet health needs by directly observing the full cycle of care from diagnosis and treatment to recovery and billing. In this way, you have to watch what's done and how it affects the provider, the patient, and the system while asking pointed questions that challenge the status quo.

During this first-hand observation period, it's ideal for collecting hundreds of needs, initially without judging or prioritizing. Then, it's time to filter the list with rigorous objectivity, considering everything from the different stakeholders affected by each need to how much potential it has to improve care and/or save the system money. This is an intense and iterative process, with progressively deeper dives into the needs with the most potential. Ultimately, the trainees arrive at the two or three most favourable conditions, which—if solved—will have a major impact on health and wellness (*Process | Stanford Byers Center for Biodesign | Stanford Medicine*, n.d.).

Needs finding

Step 1: Strategic Focus

One of the first, most important steps in the bio-design innovation process is for innovators to discover and explicitly commit themselves to the strategic focus area that stimulates their enthusiasm.

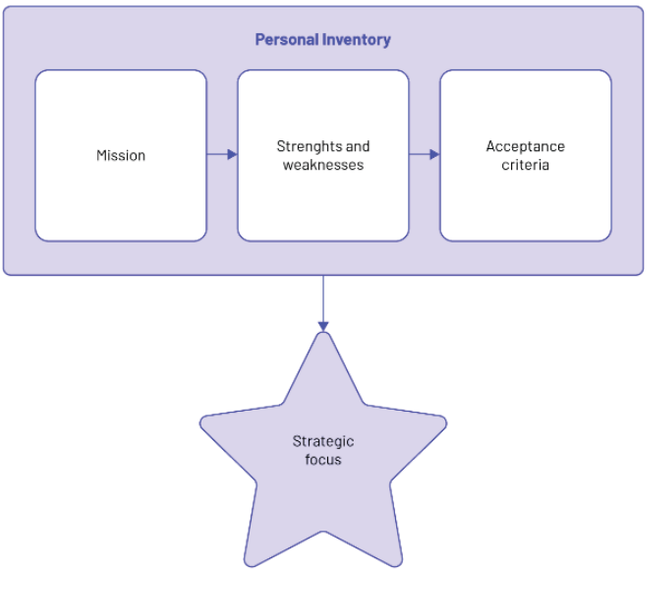


Fig. 1.6. Personal inventory (Zenios et al., 2010)

In order to arrive at a purposeful and valuable decision regarding a strategic focus area, such as a medical practice area, specialty, or specific requirement, innovators need to reflect on their reasons for pursuing this direction, their intended objectives, and how their strengths and weaknesses may impact their pursuits. By conducting a thorough personal assessment, innovators can recognize a suitable and engaging strategic focus. (Zenios et al., 2010)

Determine a mission = It's crucial for innovators to clearly define their mission. A mission refers to a general and guiding ambition that outlines what an individual or a group aims to achieve. (Zenios et al., 2010).

Identify strengths and weaknesses = Apart from establishing a mission, it would be advantageous for individual innovators, academics/researchers, small teams, young companies, and large corporations to analyze their strengths and weaknesses. They should assess their areas of expertise and strategize how to leverage their strengths. Additionally, they should examine the areas where they lack experience, proficiency, or confidence and plan on how to mitigate these weaknesses.(Zenios et al., 2010).

Define acceptance criteria = Acceptance criteria, at their most fundamental level, refer to the conditions or standards that an innovation project must satisfy to appeal to the innovator. (Zenios et al., 2010).

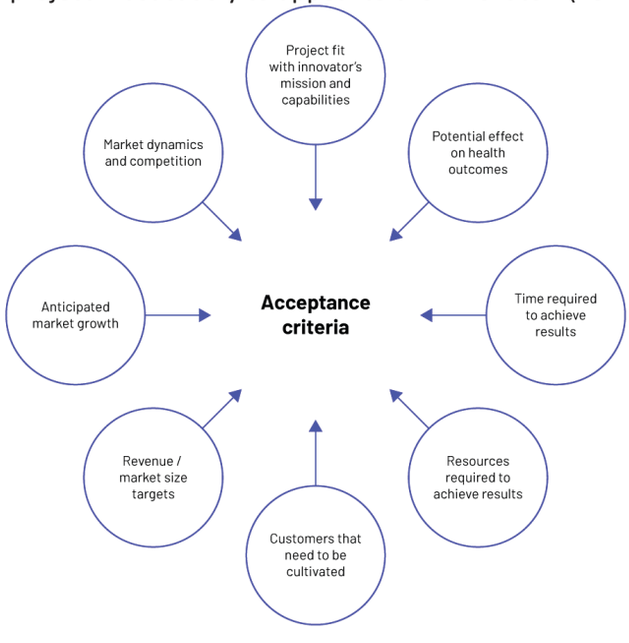


Fig.1.7. The Acceptance criteria (Zenios et al., 2010)

Step 2: Observation and problem identification

Innovators need to recognize and comprehend the clinical problems linked to their selected strategic focus area before devising new solutions. The identification of critical clinical issues necessitates the utilization of observation skills and novel perspectives on processes, procedures, and events. (Zenios et al., 2010).

There is a vast array of medical requirements, but the essential factor is to focus on the needs arising from authentic and significant clinical problems. Problems refer to substantial issues identified in various healthcare settings in the real world. While some problems are evident, others may not have been acknowledged, even by those directly involved. Thus, identifying a clinically relevant project should commence with unbiased and firsthand observation. Clinical observations are not problems themselves but rather a fundamental aspect of the approach for identifying them. (Zenios et al., 2010).

This methodology includes three important steps:

1. observing a real clinical situation
2. identifying the problem that appears in that situation
3. changing the problem into a need (Zenios et al., 2010).

Consider the following example

Observation: A trainee medical resident faced difficulties in intubating a patient (inserting a breathing tube into the trachea) in the emergency room, causing a decline in the patient's oxygen levels.

Problem: In emergency situations, an unskilled practitioner may need a considerable amount of time to insert an endotracheal breathing tube, which could significantly affect the patient's outcome. (Zenios et al., 2010).

Need: To reduce the time required for unskilled medical practitioners to place endotracheal tubes in an emer gency setting (Zenios et al., 2010).

Step 3: Need statement development

Needs represent the changes required to address a defined clinical problem, and they act as the link between issues and solutions. The success of innovative solutions depends on whether they address genuine customer and market needs. Defining a need clearly helps to identify the critical parameters and criteria that should guide the design and development of the solution. Evaluating potential concepts and solutions against these criteria ensures that they effectively address the clinical need.

Crafting effective need statements is an experiential process that many innovators learn "the hard way" by making mistakes and learning from them. Poorly defined need statements can be costly since they usually become apparent when the solution fails to address the problem much later in the innovation process. Although there is no foolproof approach to crafting successful need statements, there are at least two common mistakes that innovators should recognize and avoid: (1) embedding a solution within the need and (2) inappropriate definition of the scope (Zenios et al., 2010).

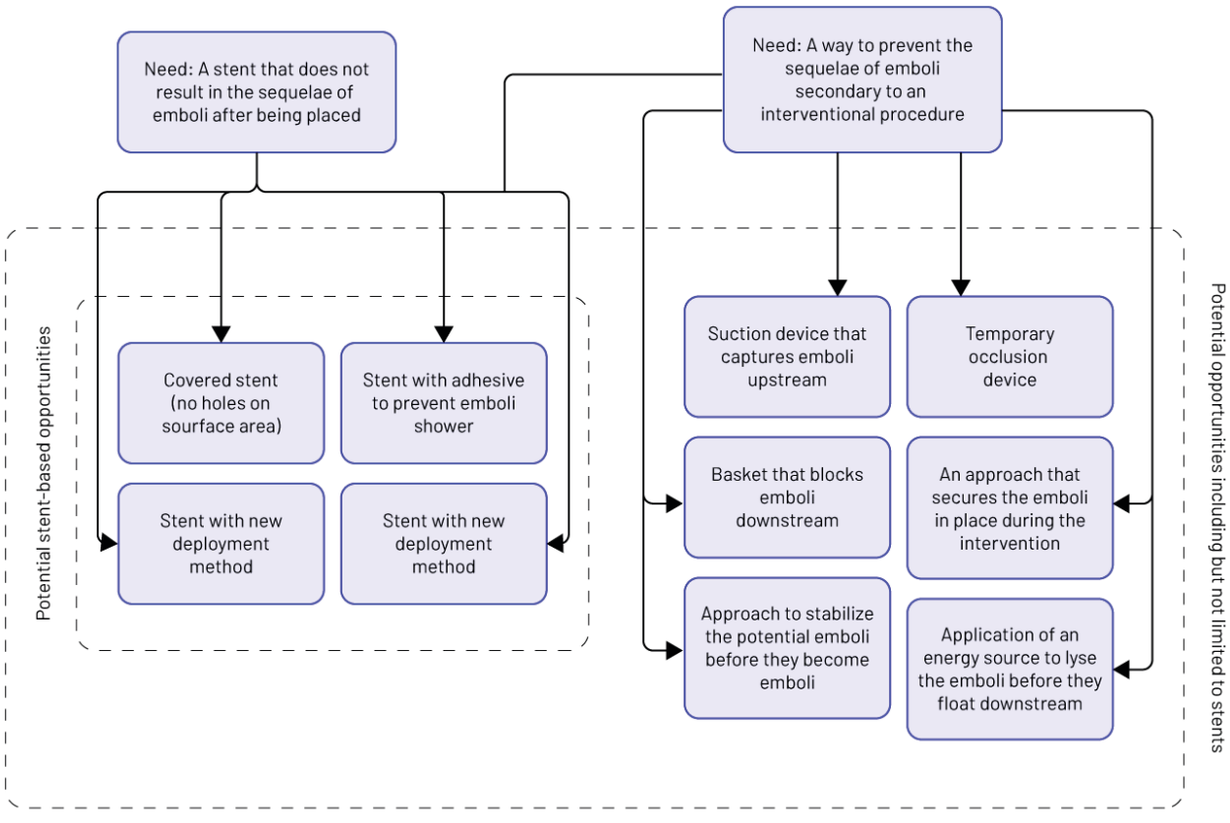


Fig.1.8. Embedding a solution within a need can dramatically limit the number of types of solutions that an innovator eventually explores (Zenios et al., 2010)

Needs screening

Step 4: Disease state fundamentals

Comprehending the fundamental aspects of a disease state involves conducting research on the anatomy and physiology, pathophysiology, symptoms, outcomes, epidemiology, and economic impact of a disease. This knowledge is crucial in identifying a clinical need or verifying a need that has already been established. Moreover, this process equips the innovator with a significant level of understanding about a condition, enabling them to be authoritative when communicating with external stakeholders like physicians and other field experts. (Zenios et al., 2010).

Step 5: Treatment Options

The ultimate objective of treating a disease or disorder is to enhance patient outcomes. Analyzing treatment methods entails extensive research to comprehend the established and emerging therapies, their usage, effectiveness, economics, and mechanism of action. Through a comprehensive investigation of existing treatments and how they are employed, an innovator can identify areas for improvement and gaps in the available therapies. This analysis also facilitates the innovator's understanding of the clinical and patient-related criteria that new treatments must satisfy to be equivalent or superior to existing alternatives. (Yock et al., 2015; Zenios et al., 2010).

Step 6: Stakeholder Analysis

Stakeholder analysis involves a systematic examination by the innovator of all parties involved in financing and delivering care to the patient, and their direct and indirect interactions. The purpose of this analysis is to comprehend the impact of the patient's needs on these entities and determine their requirements or interests in how the need is addressed. Different stakeholders have varied perspectives, some benefiting from addressing the need, while others may suffer negative consequences. It is essential to uncover these viewpoints and potential conflicts to refine the need statement and criteria. Additionally, it helps the innovator anticipate resistance and prioritize the requirements that will influence the eventual solution to ensure its adoption among the most critical and influential stakeholders. (Schmeer, 2000).

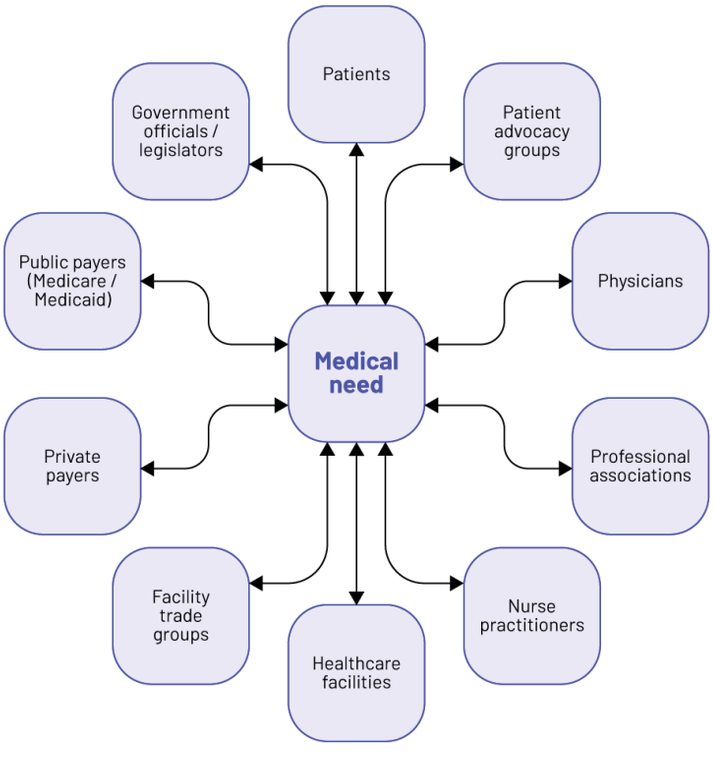


Fig. 1.9. All stakeholders have the capacity to embrace or resist new medical technologies. While some exert more influence than others, all should be considered, particularly in a preliminary stakeholders analysis (Zenios et al., 2010).

Step 7: Market Analysis

The aim of market analysis is to systematically examine these matters. The innovator can estimate the potential market size, measured in terms of revenue, associated with the need to determine the number of resources that can be feasibly allocated to address the issue and assess whether it can sustain a viable business. Through market analysis, the innovator can also comprehend the market's dynamics, such as its growth or decline, competitiveness, and determine whether the market opportunities will increase or decrease over time. (*How Do I Conduct a Healthcare Market Analysis? (with picture)*, n.d.).

Table 1.4. There are six key steps for performing a market analysis (Zenios et al., 2010)

Step	Topic	Questions to investigate
1	Market segmentation	What are the key factors that can be used to divide potential customers into distinct market segments in which the population shares common needs and perceptions (e.g., patient characteristics, treatment options, provider attributes, and payer mix)?
2	Market size	What is the size of the market opportunity in each market segment and its potential for growth and expansion?
3	Market dynamics	What are the competitive dynamics in each market segment that a new entrant would face? Are new companies created and are they successful? What is the nature of their competititve relationship with existing companies? Are companies acquired in this space?
4	Market needs	How well are the needs of customers within each segment addressed by existing solutions? How closely aligned are they with the need the innovator is seeking to address?
5	Willingness to pay	How willing is each market segment to pay for a new solution and, if applicable, what do customers pay for existing solutions?
6	Target market	Which market segment(s) is (are) most likely to embrace a solution?

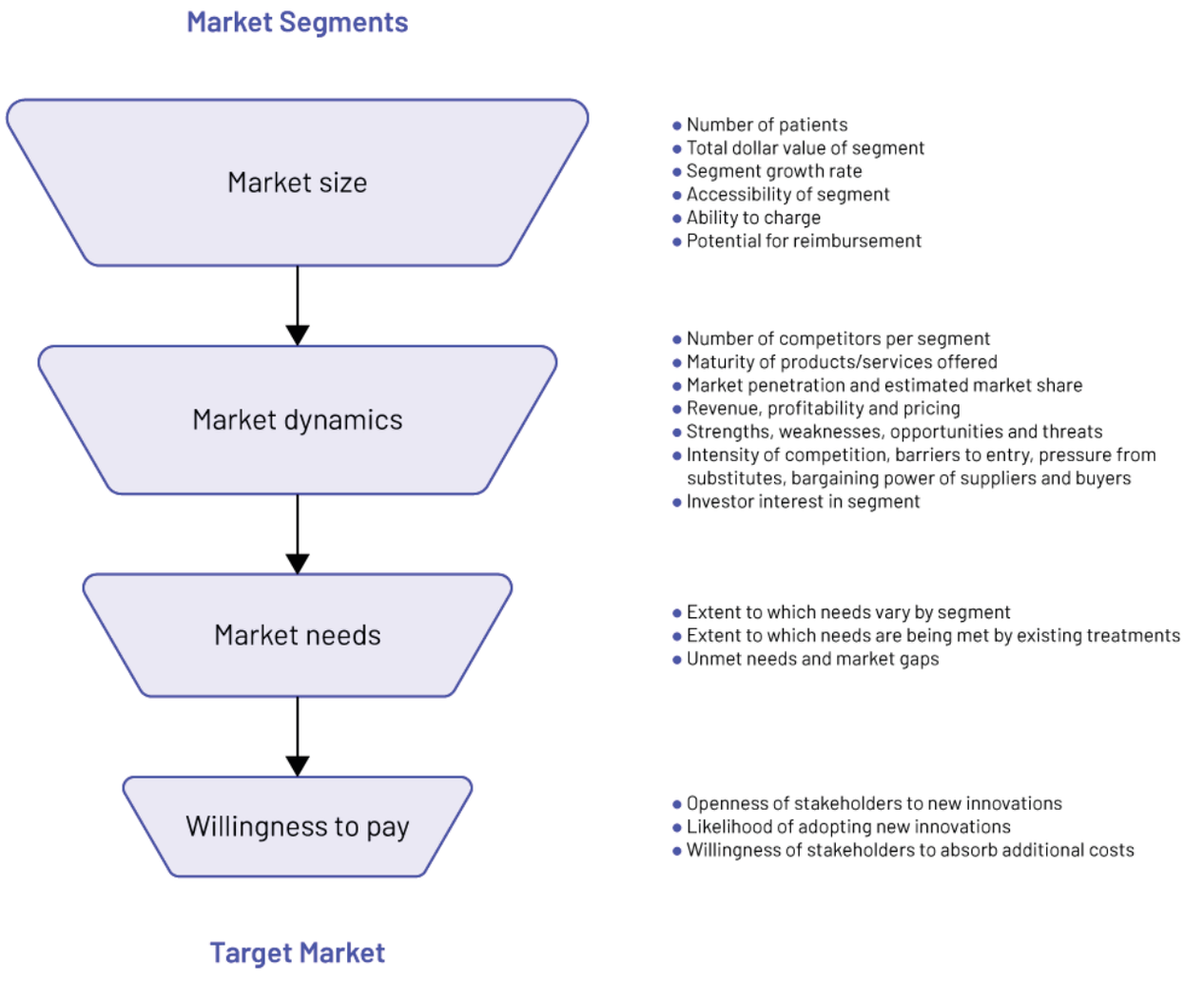


Fig. 1.10. The target market should be the market segment that appears the most promising in terms of size, competitive dynamics, market need and willingness to pay. (Zenios et al., 2010)

Step 8: Needs filtering

Needs filtering involves utilizing the data collected in the Biodesign innovation process to identify a reduced set of needs, sometimes just one need, that requires further research and investigation.(Zenios et al., 2010).

The process of needs to be filtered can be performed in many ways but generally involves four essential steps:

1. Select screening criteria or the factors to consider in planning;
2. Assign ratings for each factor for each need;
3. Combine values to produce a score that can be used to prioritize the needs;
4. Filter the need to produce a small set for further investigation (Zenios et al., 2010).

EXAMPLES AND ANALOGIES

https://www.sciencedirect.com/science/article/pii/S2452302X16301139

https://biodesign.stanford.edu/resources/learning/biodesign-case-studies.html

https://www.cell.com/cell-systems/pdf/S2405-4712(17)30084-4.pdf

APPLICATION AND INTEGRATION

Find minimum of 10-20 needs in a clinical department or a healthcare context and imagine and try to filter them using the model presented in the lesson.

REFERENCES FOR FURTHER INFORMATION AND AREAS ON INQUIRIES

https://www.a-star.edu.sg/sb/about-us/biodesign-process
Biodesign: The Process of Innovating Medical Technologies (Book)

Lesson plan 4: Solution (Invent phase)

After completing this lesson, students will be acquainted with the following:

- What is ideation
- How to organize a brainstorming session
- Intellectual property basics
- Regulatory basics
- Reimbursement basics
- Types of business models in healthcare
- Prototyping

ABILITIES THAT WILL BE DEVELOPED

- Problem-solving
- Critical thinking
- Strategic thinking
- Planning

FOUNDATIONAL KNOWLEDGE

Concept generation

Step 9: Ideation and brainstorming

"Ideation" is the process of generating fresh ideas or concepts. It is crucial during the Biodesign innovation process when new solutions are necessary to address clearly defined needs. "Brainstorming" is a type of ideation technique that has evolved within the design field, based on the potential of group creativity. This approach demands that participants temporarily set aside their natural inclination to critique novel ideas and instead embrace a rapid stream of innovative possibilities and connections. (Yock et al., 2015).

Brainstorming serves to drive the Biodesign innovation process towards achieving the ultimate objective of a high-quality idea and a corresponding development strategy to support it. Nonetheless, it is crucial to acknowledge that, similar to needs finding, brainstorming could generate tens or hundreds of ideas that require screening, sorting, and evaluation before a single idea can be selected. (Zenios et al., 2010).

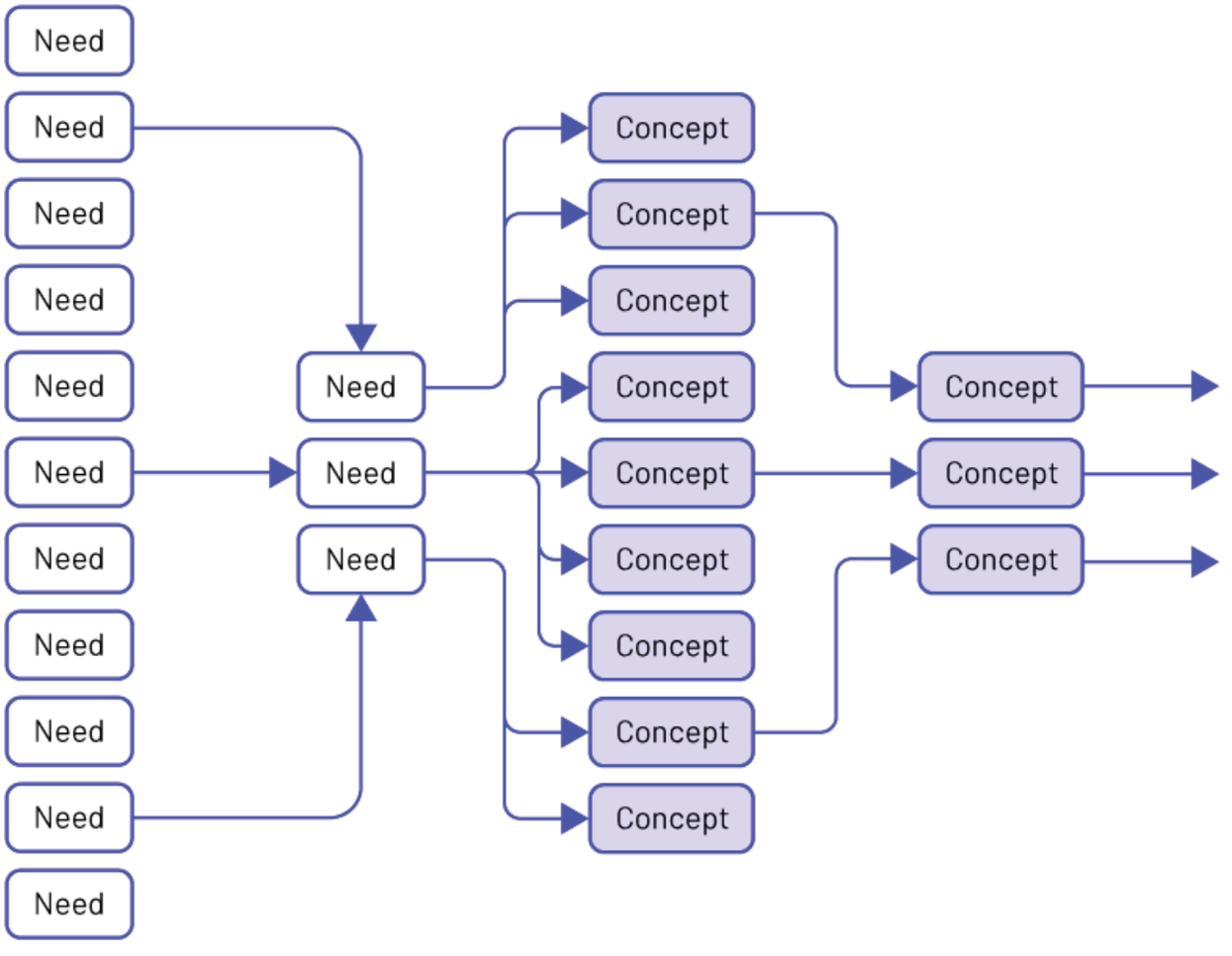


Fig. 1.11. An overview of the ideation process: multiple needs are filtered into the most important few: the brainstorming produces many concepts that are screened down to the leading prospects. (Zenios et al., 2010)

Brainstorming rules:

a. Defer judgment

The objective is to defer critical analysis or remarks until a later stage in the innovation process, well beyond the brainstorming session. The purpose of brainstorming is to stimulate both individual and group creativity. One effective approach to facilitate this is to welcome all new ideas, even those that initially appear impractical or absurd, and promptly transition to the next concept. (*7 Simple Rules of Brain storming – IDEO U*, n.d.).

b. Encourage wild ideas

During brainstorming, it is important for participants not only to set aside their critical filters but also to engage in unconventional thinking to generate ideas that are innovative and "outside the box." (*7 Simple Rules of Brain storming – IDEO U*, n.d.).

c. Build on the ideas of others

Expanding on others' ideas involves using one concept as a basis for proposing another suggestion. (*7 Simple Rules of Brainstorming – IDEO U*, n.d.).

d. Go for quantity

To encourage the free flow of ideas, a group may establish a target goal of generating a substantial number of concepts without concerning themselves with their quality. Typically, a brainstorming session lasts between 60 to 90 minutes. (*7 Simple Rules of Brainstorming – IDEO U*, n.d.).

e. One conversation at a time

The fundamental principle that underlies this guideline is that during the creative process, listening can be just as crucial as speaking. (*7 Simple Rules of Brainstorming – IDEO U*, n.d.).

f. Stay focused on the topic

Maintaining focus within a group requires avoiding distractions, side conversations, immediate analysis, and evaluation of ideas.(*7 Simple Rules of Brainstorming – IDEO U*, n.d.).

g. Be visual

Having tools such as blackboards, whiteboards, large flip pads, sticky notes, or other similar items that facilitate drawing and writing can be beneficial for promoting a free, rapid, and unrestricted flow of ideas. (*7 Simple Rules of Brainstorming – IDEO U*, n.d.).

Step 10: Concept screening

The process of concept screening entails assessing all the proposed ideas in relation to the defined requirements to determine their level of alignment with the need. Additionally, this process involves categorizing the ideas into relevant groups to identify any possible shortcomings or prejudices in the suggested solutions, and to explore opportunities for merging concepts into innovative and complementary solutions and to explore opportunities for merging concepts into innovative and complementary solutions that can more effectively address the need than any individual concept. . (*Ipsos Encyclopedia - Concept Screening | Ipsos*, n.d.).

Table 1.5. The concept screening (Zenios et al., 2010)

Organizing principle	Description	Example
Anatomic location	Group ideas according to the part of the anatomy they pertain to and/or target. Differences between groupings might be small if all solutions are in a highly focused area (e.g. the vertebral discs). Alternatively, groupings might span entire regions/organ systems if the solutions focus on a need pertinent to a significant portion of the body (such as the various places that emboli dislodged from the heart can travel through the vasculature)	For solutions to address the problem of obesity, ideas might naturally cluster around the mouth, esophagus, stomach, pylorus, small intestines (duodenum, jejunum, and ileum), large intestines and the various valves in the GI tract.
Mechanism of action	Group ideas according to how the solutions are intended to work	Increasing energy expenditure, regulating food intake, reducing nutrient absorption, and reducing the motivation to take in energy are all different mechanisms of action for reducing weight.
Engineering or scientific area	Group ideas according to the type of engineering or scientific approach underlying the solution.	Solutions could be supported by the three main types of engineering: ***chemical*** (pharmacological weight control), ***electrical*** (gastric pacing), and ***mechanical*** (laparoscopic banding, bariatric surgery, liposuction)
Technical feasibility	Group ideas according to their likeliood of coming to fruition. This is based on understanding what is feasible using current engineering and scientific methods, which implies some knowledge of the science behind the solution and/or the engineering development timeline required.	Solutions such as reprogramming fat cells might have low feasibility; a drug eluting implant might have moderate feasibility; a space-occupying stomach device could have high feasibility.
Funding required	Group ideas around the amount and/or source of funding required to develop them. While this may be difficult before researching the funding landscape, a "best guess" based on prior information (see Chapters 2.4 Market Analysis and 2.5 Needs Filtering) may suffice.	For obesity, a solution such as filling the stomach with a space-occupying device would likely require less money to develop than a drug eluting implant.
Affected stakeholder	Group ideas around the stakeholder most affected, typically the patient or healthcare provider. While this may result in rather general groupings, it can provide insights into which concepts are more likely to be adopted (see 2.3 Stakeholder Analysis). While payers will be affected by all concepts, a consideration of variations in cost-effectiveness will be useful.	For obesity, solutions focusing on medications might be more attractive to patients than those requiring surgeries. From a payer's perspective, solutions requiring a one-time payment may be more attractive than solutions requiring recurrent payments.

Concept selection

Step 11: Intellectual Property Basics

Intellectual Property – refers to creations of the mind, such as inventions; literary and artistic works; designs; symbols, names, and images. Intellectual Property rights protect creations and inventions, to enable creators and inventors to earn recognition and financial benefit from their work (*Basic aspects of Intellectual Property*, n.d.).

Criteria for obtaining a patent

When evaluating the patentability of an invention, three fundamental factors are considered:

1. Utility - The invention must serve a useful purpose.

2. Novelty - It should be original, meaning it should not have been previously described or patented, nor made available to the public.

3, Non-obviousness - The invention must not be obvious to a person with average knowledge and expertise in the relevant field, based on the existing prior art.

(Zenis et al., 2010)

.**Step 12: Regulatory Basics**

It is crucial to comprehend the regulatory pathway for new technology due to the significant impact that regulatory issues can have on its success. Therefore, even in the initial stages of developing a device, understanding the regulatory process is essential. Typically, innovators engage a specialist to oversee and prepare regulatory submissions. However, regulatory considerations are intricately interwoven into product design and development. Thus, innovators must have a working knowledge of regulatory processes and language to provide effective leadership throughout the bio-design innovation process. (Zenios et al., 2010).

The US Food and Drug Administration (FDA), a scientific, regulatory, and public health organization in the US, has significant authority over a broad range of products, representing about 25% of all consumer spending in the country. Its jurisdiction covers various products, such as human and animal drugs, biological therapeutic agents, radiation-emitting products, cosmetics, animal feed, and most foods, except meat and poultry. Additionally, the FDA regulates medical devices. (*Regulatory Process | FDA*, n.d.).

For Romania – ANMDM

For EU – EMA

Table 1.6.The classification of a device has a direct impact on the number and complexity of the FDA requirements that are imposed. (Zenios et al., 2010)

Class	Examples	Description	FDA requirements
I	Bandages, tongue depressors, bedpans, examination gloves, handheld surgical instruments	**Class I** devices present minimal potential harm to the person they are being used on and are typically simple in design	With class I devices, most are exempt from premarket clearence. There is no need for clinical trials or proof of safety and/or efficacy since adequate predicate experience exists with similar devices. However, they must meet the following "general controls": • Establishment registration with FDA. • Medical device listing. • General FDA labeling requirements. • Compliance with quality system regulation (QSR).
II	X-ray machines, powered wheelchairs, surgical needles, infusion pumps, suture materials	**Class II** devices are often non-invasive, but tend to be more complicated in design than class I devices and, therefore, must demonstrate that they will perform as expected and will not cause injury or harm to their users.	Class II devices must generally be cleared via the 510(k) process, unless exempt by regulation. They must also meet all class I requirements, in addition to the "special controles", which may include: • Special labeling requirements. • Mandatory performance standards. • Post-market surveillance.
III	Replacement heart valves, silicone breast implants, implanted cerebellar stimulators, implantable pacemakers	**Class III** devices are typically implantable, therapeutic, or life-sustaining devices, or devices for which a predicate does not exist.	Class III devices must generally be approved by the PMA regulatory pathway, although a small number are still eligible for 510(k) clearance. They must also meet all class I and II requirements, in addition to stringent regulatory approval requirements (see below), before they can be used in humans.

Table 1.7. The four device categories in the EU typically align with the three classes that the FDA in the United States has established. (Zenios et al., 2010)

EU class	Description	US equivalent
Class I	Devices that present a relatively low risk to the patient and, except for sterile products or measuring devices, can be self-certified by the manufacturer. Tipically, they do not enter the human body.	Class I
Class II a	Devices that present a medium risk to patients and may be subject to quality system assessment. Generally, they are invasive to the human body, but only via natural body orifices. The category may also include therapeutic diagnostics and devices for wound management.	Class II
Class II b	Devices that present a medium risk to patients and may be subject to quality system assessment, as well as third-party product and system certification. They are usually either partially or totally implantable and may modify the biological or chemical composition of body fluids.	Class II
Class III	Devices that present a high risk to patients and require design/clinical trial reviews, product certification, and quality system assessment conducted by a European notified body (see below). In most cases, they affect the functioning of vital organs and/or life-supporting systems.	Class III

Step 13: Reimbursement Basics

Reimbursement analysis aims to assess whether the current healthcare payment system can support a proposed solution to meet a particular need. It evaluates factors such as whether physicians and facilities providing patient care would receive adequate compensation for using the solution. Additionally, it examines whether there is sufficient coverage within the target market to make developing the solution financially feasible. If not, in the current healthcare landscape, the innovator must anticipate slow adoption or consider advocating for a change to the established payment infrastructure to accommodate the new solution. (MEDIClever, n.d.; *Reimbursement basics - PubMed*, n.d.).

Sometimes the go-to-market strategy might not include reimbursement, but this can only apply in very selected cases and pose a serious challenge to the project's sustainability.

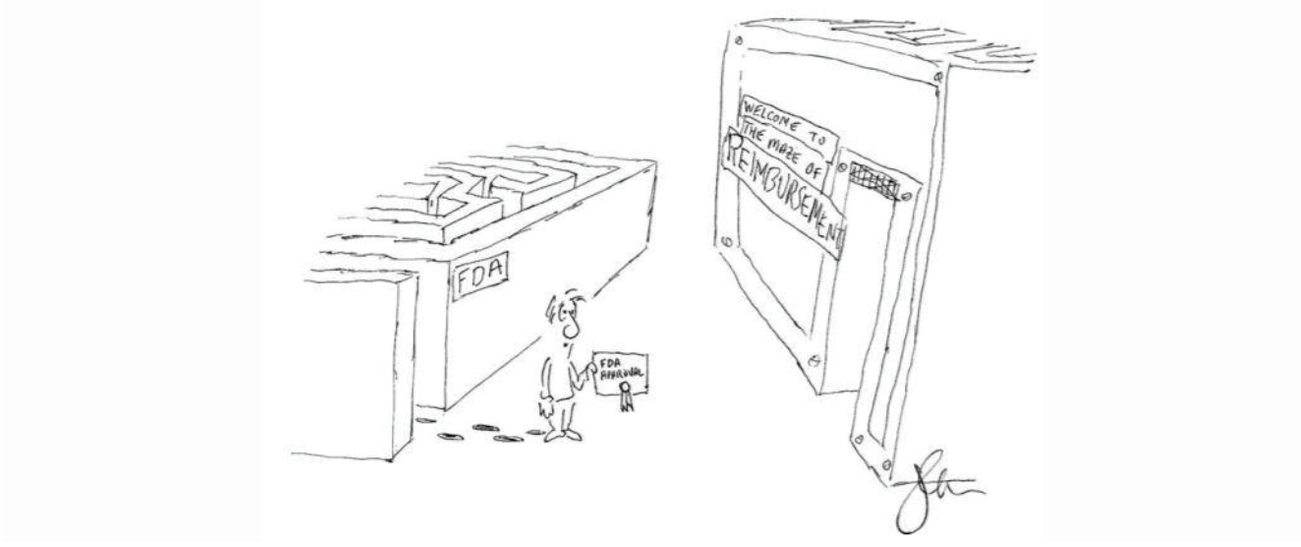


Fig. 1.12. Reimbursement basics (Zenios et al., 2010)

Step 14: Business Models

In the MedTech industry, a business model broadly encompasses how a product or service offering is defined and how it generates revenue while delivering value to customers. There are several common business models in MedTech, including disposables, reusables, implantables, and capital equipment, among others. Each model generates revenue in distinct ways and presents different challenges to the innovator in terms of how the company structures its operations, resources, and processes. The business model also guides how the innovator interacts with customers and other external stakeholders to achieve mutually beneficial outcomes. Therefore, just as an innovator evaluates the intellectual property, regulatory, reimbursement, and technical feasibility of their ideas, they should also assess the appropriate business model before selecting a final concept. (Sharan et al., 2016).

Table 1.8. By comprehending the effects of the business model selection and its impact on various factors, an innovator can identify which business model would be the most suitable and advantageous for success. (Zenios et al., 2010)

Factor	Explanation
Revenue stream	How revenue is generated and its frequency.
Price	How much the business can charge for its products or services.
Margin structure	The profit to the company from sales (and its adequacy to support the inherent characteristics of the chosen business model).
Sales investment	The required mechanism for getting the innovation into customers' hands.
Customer training requirements	The extent to which specialized training is required to utilize the innovation.
Competitive differentiation	The degree to which the innovation is unique.
Intellectual property	The importance of IP protection to the success of the business model.
Other barriers to entry	Factors that could serve as barriers to adoption (e.g., high switching cost, brand or customer loyalty, access to distribution channels, etc.).
Clinical hurdles	The complexity and duration of clinical requirements (e.g., trials) before commercialization can begin.
Reimbursement	The way physicians, surgical centers, and hospitals are paid.
Financial requirements	The level of investment necessary to develop and commercialize the innovation.
Culture/geography	The extent to which customer needs related to the same clinical area differ across geographic boundaries or different cultural environments.

Types of business models:

- **Disposable products:refer to items that are designed for one**-time use and are discarded after use, such as paper examination gowns and stopcocks used with intravenous tubing.
- **Reusable products:** are items designed to be used multiple times during their average lifespan, and their cost is typically lower than that of capital equipment.
- **Implantable products:** are generally classified as mid-range ($1,000 to $5,000) to high-end (>$5,000) items. For instance, a coronary artery stent is an example of a mid-range implantable device.
- **Capital equipment products:** are those that require customers to make a one-time capital expenditure to acquire a technology that they will use repeatedly. Examples of such products include magnetic resonance imaging (MRI) or computer tomography (CT) scanners
- **Service:** refers to the work carried out by an individual or a team with the aim of benefiting another person or group.

- **Fee-per-use:a** fee-per-use business model is suitable for innovations that lie at the crossroads of products and services.

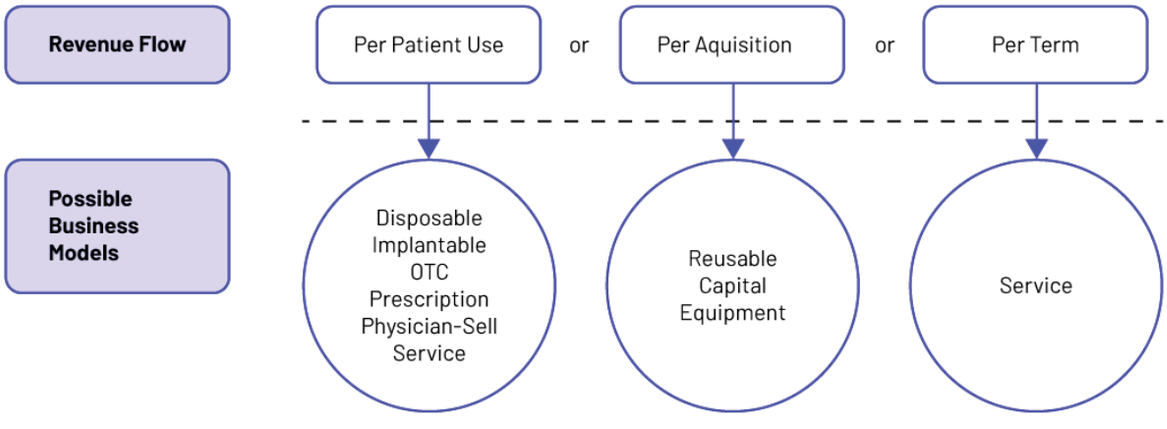
- **Over-the-counter products:** an over-the-counter business model relies on patients' ability to select a treatment option and purchase the product(s) independently. This model is commonly associated with drugs like Motrin® and Benadryl®, but it can also encompass devices such as home blood-pressure cuff devices, glucose monitors, or steam machines for treating sinus congestion

- **Prescription products:** are the quintessential example of prescription-based medical products. Nevertheless, prescriptions can also apply to medical devices, combined with services such as physical therapy, disposables like blood glucose monitoring testing strips or drug cartridges for delivery systems, and hardware, such as nerve stimulator pain control units or certain inhalers.

- **Physician-sell products:** are treatments that are directly sold by physicians (Zenios et al., 2010).

Step 1 - Scale down the possible universe of business models

Determine the unit (or units, if taking a blended approach) which defines the revenue flow to the company.



Step 2 - Set unit pricing

All models typically have an associated price/unit. Some models may also include after-sale revenue for each term in use.

Step 3 - Calculate the potential market size (revenue/time)

Multiply expected units per time by the pricing/unit. For example, there may be 500.000 patient candidates for a particular implant per year (units/time) x the implant pricing (set in Step 2). Another example is 2000 hospitals need this equipment installed over the first 10 years it is available (units/time) x the pricing (set in Step 2). See 2.4 Market Analysis for a more detailed discussion of how to calculate market size.

Step 4 - Determine the cost per unit

Step 5 - Calculate the gross margin = (price/unit - cost/unit) divided by price/unit

The following rule-of-thumb can be used for validation.
Financing types available:

1. If revenue/time is greater than $500 million per year, it is typically backable by a venture capital firm and may lead to an **IPO**.
2. If revenue/time is greater tha $100 million but less than $500 million, it may be backable by a venture capital firm and may not have IPO as an option.
3. If revenue/time is less than $100 million, it is probably not likely to be backed by a venture capital firm, but may be interesting to individual (or angel) investors.

Operating expense coverage (the ability of the business to support high sales costs like a direct sales organization, big advertising budgets, or to repay the cost of extensive clinical trials).

1. If gross margin is greater than 70 percent, the business can support higher operating expense costs.
2. If gross margin is less than 50 percent, the business most likely will not be able to support higher operating expense costs and it may need a partner to support key activities such as clinical trials or marketing.

When additional brainstorming might be needed:

If the business requires an extensive clinical trial to reach the market, and therfore a significant amount of capital, but the revenue/time is less than $100 million per year, then there is a problem. If it is greater than > $500 million, then it is probably acceptable.

If a product requires a direct sales force to sell it, and it is a low-margin product, then there is a problem. If the product cannot be reimbursed at a higher level or the cost cannot be reduced, it may not have a future.

If a product riquires high margins (e.g., due to a direct sales force, customer training, or large research and development or clinical investments) and has little IP and low barriers to entry, then there is a problem.

If one wants to sell a product OTC, or if insurance providers try to push a product OTC, and the product requires technical training, then there may be a problem. If simplifying the current product is not a possibility, then the product may not be feasible.

Fig.1.13. Decision Tree and Rules-of-Thumb for Choosing a Business Model. (Zenios et al., 2010)

Step 15: Prototyping

Prototyping serves the purpose of transforming a promising idea into a preliminary design and ultimately into a functional product. It is an indispensable step for any innovator seeking to understand the functionality of their concept, explore different features, gather initial feedback from target users, and find answers to questions that can only be resolved by bringing the design to life. Prototyping plays a critical role in various stages of the bio-design innovation process. In the early stages, quick and low-cost prototyping helps innovators assess multiple solution ideas against specific design criteria before selecting a final concept. As the innovator progresses, prototype requirements, designs, and models become more advanced, serving to test the functionality and features, often in conjunction with tissue and animal testing. Finally, near-final prototypes that meet design requirements are used to gather data for quality documentation and manufacturing preparation. (Zenios et al., 2010).

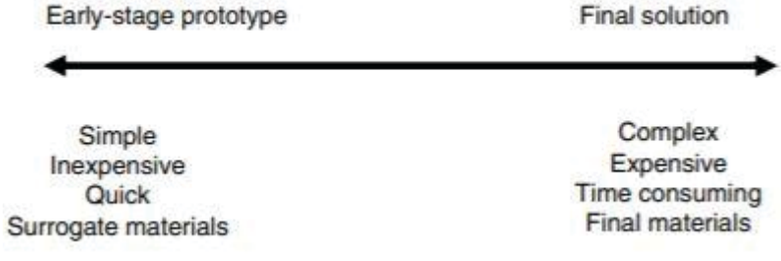


Fig.1.14. Prototypes (Zenios et al., 2010)

Table 1.9. The process of resolving issue (Zenios et al., 2010)

Issue	Process for resolving issue
Will the concept work? Is it technically feasible and will the product function as designed?	Understand the underlying fundamentals of the clinical problem and then build the prototype and test it.
Is the innovation novel and unobvious? Can it be patented?	Having sketches and/or prototypes of the idea will help to define the claims of the invetion.
Will customers adopt and use the product?	Take the prototype to thought leaders and target users in the market. Let them touch and feel it to provide feedback and confirm their interest.
Can it be manufactured?	The development of sketches and/or CAD drawings will help determine manufacturability. It can also be helpful to find precedents and reverse-engineer them. Discuss the prototype with materials and manufacturing vendors to understand their input, ideas, and concerns.
When can it be made available?	Use vendor estimates/quotes (volume, price, time frame) to develop a project plan to outline when it is realistic to expect a finished product. Consider hiring a consultant to assist with the process.

Step 16: Final Concept Selection

The goal of selecting a final concept is to utilize all the information gathered about the various concepts being considered to identify the one that will be developed further. Even though the chosen concept will still be refined, tested, and improved during the development and implementation stages, the innovator will concentrate on pursuing one idea instead of splitting their attention between several potential solutions. While some experienced innovators rely on intuition to make this decision, many find it useful to follow a structured process, such as the Pugh concept selection method. (Zenios et al., 2010).

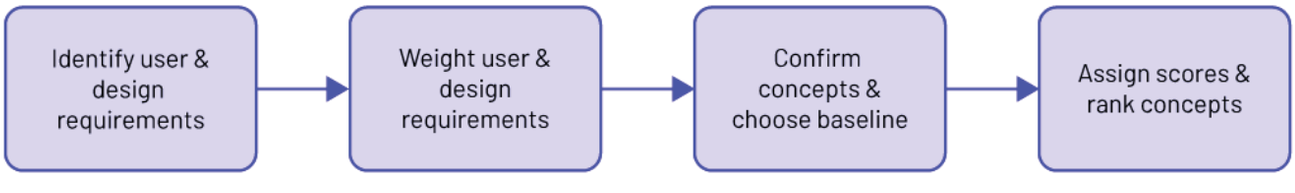


Fig. 1.15. General steps of the Pugh concept selection methods (Zenios et al., 2010)

EXAMPLES AND ANALOGIES

https://www.sciencedirect.com/science/article/pii/S2452302X16301139

https://biodesign.stanford.edu/resources/learning/biodesign-case-studies.html

https://www.cell.com/cell-systems/pdf/S2405-4712(17)30084-4.pdf
Biodesign: The Process of Innovating Medical Technologies (Book)

APPLICATION AND INTEGRATION

Complete the templates below with your innovative project idea

Pick 2-3 different solutions for the same problem and fill each a template

https://www.innovationcanvas.ktn-uk.org/

https://www.rose-hulman.edu/about-us/get-to-know-rose-hulman/office-of-innovation/_assets/documents/blank_innovation_canvas_a3v1.pdf

REFERENCES FOR FURTHER INFORMATION AND AREAS ON INQUIRIES

https://www.a-star.edu.sg/sb/about-us/biodesign-process
Biodesign: The Process of Innovating Medical Technologies (Book)

https://www.rose-hulman.edu/about-us/get-to-know-rose-hulman/office-of-innovation/innovation-canvas.html

https://www.ignitionframework.com/innovators-canvas-3-quickly-effectively-document-validate-innovation-idea/

Lesson plan 5: Business sustainability through reimbursement

After completing this lesson, students will be acquainted with the following:

- Reimbursement strategy
- Reimbursement analysis

ABILITIES THAT WILL BE DEVELOPED

- Strategic thinking
- Planning

FOUNDATIONAL KNOWLEDGE

With a sophisticated reimbursement strategy, innovators can be proactive. They can anticipate the most pressing questions payers will raise about their new devices and prepare a recommended approach to coding, coverage, and payment, a strong body of supporting evidence, and advocacy from powerful physician groups that can dramatically increase their chances of receiving favourable reimbursement decisions.

Table 1.10. An effective reimbursement analysis allows the innovator to answer these basic questions (McKinsey&Company, n.d.)

General reimbursement questions
Who will initially purchase the device?
Who will ultimately be responsible for payment?
Where will it be used, and who will use it?
What are the existing codes used to gain reimbursement of the device?
What type of coverage is associated with those codes?
What is the average payment level?
Are there important coverage and reimbursement issues associated with the device?
What was the process used to secure reimbursement for the proxy device?
Are reimbursement conditions stable or are future changes anticipated, such as restricted or reduced reimbursement?
Are there other warning signs in the reimbursement landscape (e.g., stories in the press, talk of class reviews, TEC assessments or demonstration projects) that may affect reimbursement?
Is the new technology sufficiently similar to existing devices and/or the proxy device to allow the company to capitalize on existing codes, coverage, and reimbursement payment levels?
Will it be necessary to obtain new codes, coverage determinations, and reimbursement levels? Or is it possible to work whitin existing reimbursement codes but expand coverage criteria and payment levels?

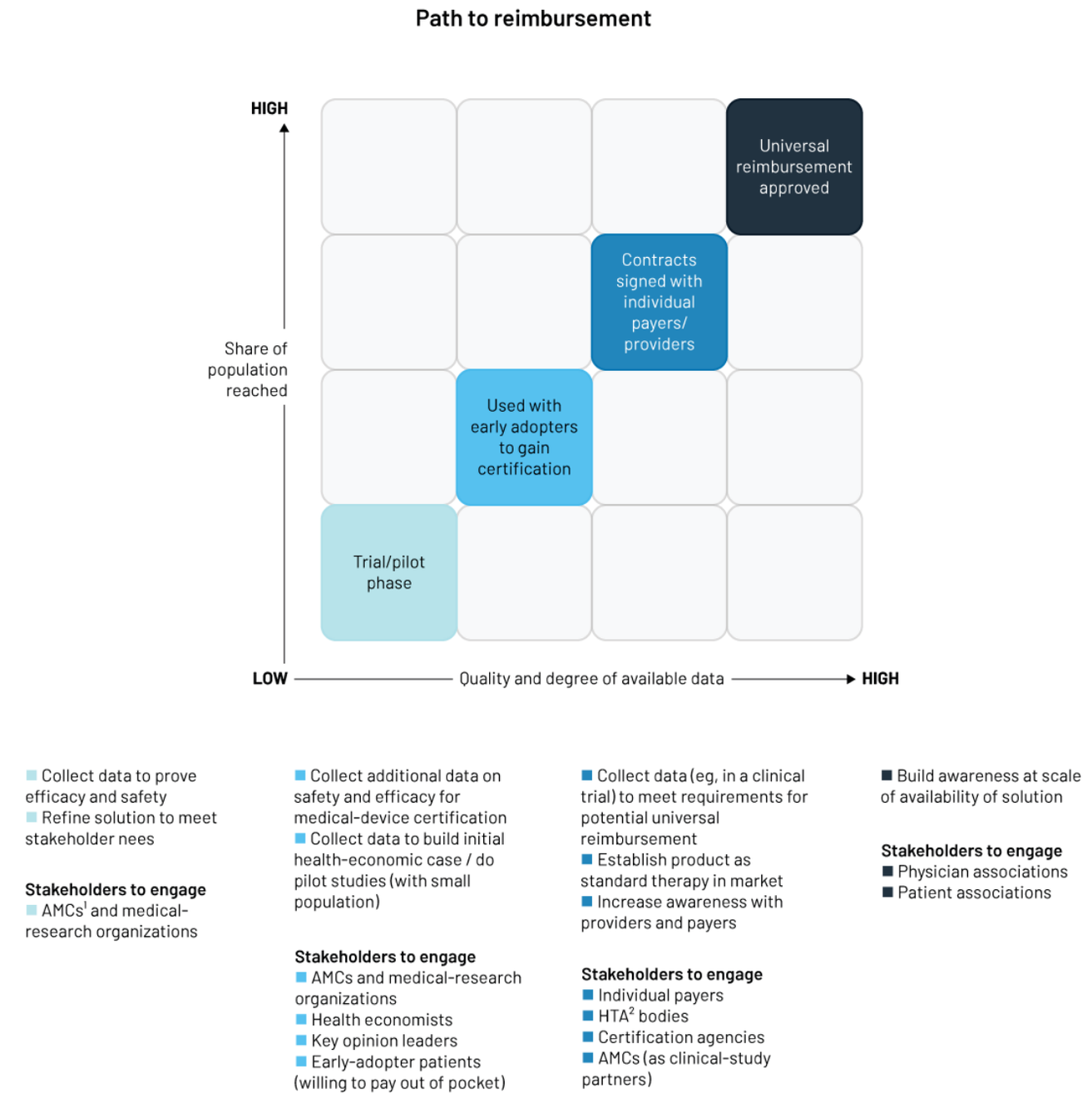


Fig. 1.16. Path to reimbursement (McKinsey&Company, n.d.)

An alternative to reimbursement can be marketing the solution directly to the end-user (healthcare provider or individual person), but this option should be evaluated, and the business plan should be adjusted accordingly.

EXAMPLES AND ANALOGIES

https://www.mckinsey.com/industries/life-sciences/our-insights/the-european-path-to-reimbursement-for-digital-health-solutions

Biodesign: The Process of Innovating Medical Technologies (Book)

https://pharmaboardroom.com/legal-articles/regulatory-pricing-and-reimbursement-romania/

APPLICATION AND INTEGRATION

For the defined concept, answer the questions from the table above.

Do this for 2-3 proposed solutions to see the similarities and the differences.

REFERENCES FOR FURTHER INFORMATION AND AREAS ON INQUIRIES

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Biodesign: The Process of Innovating Medical Technologies

https://mediclever.com/medical-device-reimbursement-europe-eu.php

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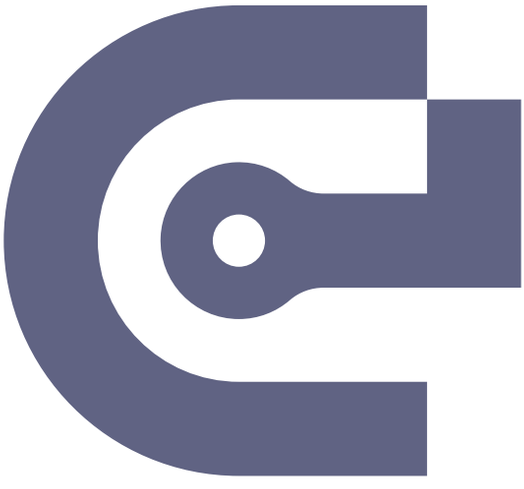

Module 2: Human Resources in Health and e-Professionalism

Learning objectives of the Human Resources in Health and e-Professionalism

Students will examine the strategic role of human resource management in response to changes in the health care industry. In addition, issues such as recruitment, retention, performance management, organisational development, monitoring and evaluation will be examined.

At the end of the module, students will be able to:

1. Explain the concept of Human Resources and e-Professionalism in the health sector.
2. Understand how to prepare, attract, maintain, and enable HRH.
3. Explore the interaction of key elements of the health system and health outcomes.
4. Discern different strategies to ensure equitable distribution of sufficient and qualified staff.
5. Understand HRH needs and explore how to respond to them adequately.
6. Explore how the private sector may mitigate existing issues in the health sector.
7. Understand and value the strategic role of human resources in a health care organisation and in effectively managing organisational transformation.
8. Understand the role, importance, and technologies for monitoring HRH.

Foundational knowledge of the Human Resources in Health and e-Professionalism module

Human Resources in Health (HRH)refers to planning, development, performance, management, retention, information, and research on human resources for the health care sector. The official definition from World Health Organization for human resources in health is “all people engaged in actions whose primary intent is to enhance health”(WHO, 2006). The health workforce is another phrasing used to refer to HRH. Human Resources in health include the clinical and non-clinical staff whose intent is to enhance health and the healthcare system’s performance. This includes physicians, allied health professionals, health services managers, medical records, health information technicians, management and support staff (managers, ambulance drivers and accountants etc) who are not directly involved in delivering medical services but are essential to the performance of health systems. Private-sector workers and owners of pharmacies who may provide access to health services are also considered the health workforce.

e-Professionalism refers to the attitudes and behaviours seen in traditional professionals showcased in digital media. It represents the electronic professional identity of an individual.

Key components of Human Resources in Health and e-Professionalism:

- Recruitment;
- Induction;
- Working Environment;
- Staff Relations;
- Staff Development;
- Professional identity.

Lesson plans for the Human Resources in Health and e-Professionalism module

Lesson plan 1: Human Resources in Health and e-Professionalism: Core Concepts

FOUNDATIONAL KNOWLEDGE

Health workers drive health systems. They are agents of positive change in their communities. Without health professionals, health care services cannot be delivered. A health system, a health care system or a healthcare system, is defined as the "organisation of people, institutions, and resources that deliver health care services to meet the health needs of target populations" (WHO, 2007a). These services are essential for assuring the health of the entire population.

In the past, the health workforce was considered an expensive part of the health system. In many low- and lower-middle-income countries, governments, had been warned not to scale up their investments in civil servants, including public sector health workers, out of a concern that they would be costly to support in the long term (WHO, 2016b).

Building on years of contrary evidence, the Global Health Workforce Strategy (Workforce 2030) recognises HRH investments as having the potential for a triple return on investment (ROI):

- **Improved health outcomes**: Health workers drive health systems to deliver health care services;
- **Global health security:** The reintegration of health staff in post-conflict settings can be linked to strengthened governance; skilled health workers improve health systems' resilience and responsiveness;
- **Economic growth**: A community's productivity is more significant when it is healthy (WHO, 2016b).

Strategic HRH investments are considered a "proven return on investment" and may contribute to the achievement of additional Sustainable Developmental Goals (SDGs), including

#1 no poverty;

#2 zero hunger;

#3 health and well-being;

#4 quality education;

#5 gender equality;

#8 decent work and economic growth;

#10 reduced inequalities;

#11 sustainable cities and communities;

#17 partnerships for the goals (WHO, 2016b).

The sole existence of human resources is not sufficient to achieve the SDGs, as they need to be equitably distributed and accessible by the population, competent, and adequately supported by the health system. Human resources management (HRM) can facilitate the SDGs mentioned above by entailing activities such as:

- Design and analysis of job descriptions;
- Personnel planning;

- Recruitment, selection and personnel orientation;
- Consultancy offered to personnel for the future of personal career;
- Performance evaluation;
- Compensations and advantages specific to their workplace;
- Health and insurance;
- Workplace relationships;
- Discipline, control and evaluation of personnel functions etc.

This list is not exhaustive and only includes most of the important actions of the HRM (United Nations, 2013).

HRM has three important characteristics:

1. **HRM is action-oriented**. It is not focused on filing, description or rules. HRM emphasises and searches for solutions to the employees' problems to help achieve the organisational goals and facilitate individual growth and satisfaction.
2. **HRM is individual-oriented**. As often as possible, HRM treats each employee individually and offers services and programs to satisfy their individual needs.
3. **HRM is future-oriented**. It focuses on the organisation's objectives and assists their future achievement by "offering" competent, highly motivated employees (United Nations, 2013).

The objectives of HRM in the attempt to increase the organisation's effectiveness are the following (United Nations, 2013):

1. To help the organisation achieve its goals;
2. To efficiently use the abilities and skills of their workforce;
3. To offer the organisation well-prepared and motivated employees;
4. To increase the level of satisfaction of the employee at the workplace;
5. To develop and maintain a certain quality of the working environment that can transform the employee status within the organisation into a personal and socially satisfying situation;
6. To communicate personnel policies to all employees;
7. To help maintain professional ethics;
8. To help introduce changes favourable to individuals, groups, organisations and the public.

It is important to make the most of the existing workforce by considering its performance. HRM must consider practices, approaches and interventions that can optimise health workers' performance, quality, and impact based on where currently practising health workers are located.

Some of these practices include (United Nations, 2013):

1. Identify health needs and service coverage;
2. Address HRH productivity and performance;
3. Implement supportive supervision;
4. Extend services through task sharing and/or differentiated care;
5. Harness appropriate technologies.

Identify health needs and service coverage.

Understanding where health needs are greatest, and related services should be available can help determine the most appropriate HRH investments. HRM must determine where gaps between desired and actual health outcomes are the greatest and allocate the necessary HRH. If, for example, a region from a specific country has more disease cases, more resources need to be assigned to the particular country (United Nations, 2013).

Address HRH productivity and performance.

Proper recruitment, selection and productivity criteria are needed to address productivity and performance. These criteria include HR planning, recruitment, selection, and productivity analysis (United Nations, 2013).

HR Planning (RWBT, 2021; United Nations, 2013)*:*

1. Need requirements and job analysis.
    - Determining whether a vacancy exists: when an employee leaves, there may be alternative ways of filling the gap (reorganisation, reassignment of tasks or automation);
    - Analysis of the particular job: observation of the person doing the job, getting job-holders to record their activities, interviewing the job-holder;
2. Job descriptions and person specifications
    - Job description outlines tasks and duties: title, location, main purpose, responsibilities, working conditions, key result areas;
    - Person specifications identify the job-holder's attributes (competencies)required: skills, knowledge, personality attributes, qualifications and experience. These can be divided into "essential"and "desirable (RWBT, 2021);
3. Competency frameworks
    - Refers to the work-related personal attributes, knowledge, experience, skills and values that a person draws on to perform their job well;
    - Such competencies include communication, results in orientation, planning and organising, problem-solving and teamwork;

Recruitment methods (United Nations, 2013)*:*

Internal sources

- Intranet
- Team meetings
- Noticeboards

External sources » Vacancies information (own website)

- Recruitment agencies
- Advertisements (newspaper, specialist website, radio, TV)
- Employee referral schemes
- Links with schools/ universities
- Apprenticeships, internships

Selection methods (United Nations, 2013)

The classic trio:

1. Application form
2. Interview
3. References

Apart from the selection methods exposed above, a paid probation period is recommended to assess the working compatibility of the employee and to assess if the employee meets the employer's required standard (Venter, 2017).

Productivity analysis

Reaching service delivery goals depends on health workers who are supported to be as productive as possible and perform up to standard. There are several toolkits to assess and improve productivity: Health Workforce Productivity Analysis and Improvement Toolkit.This tool is used to increase the overall productivity of the organisation in which was implemented and the satisfaction of the employees. A good example of the tool is the Christian Health Association of Malawi, which used the toolkit to identify solutions to improve staff attitudes, facility infrastructure, and lodging and institutionalise quality assurance methods to meet health needs (Jaskiewicz & Deussom, 2015).

Implement supportive supervision

Supportive supervision is a continuous process to support health workers and promote quality at all health system levels.

Examples:

1. Strengthening relationships within the system, including supervisors, peers, and communities. Supervision effectiveness depends on having supervisors who are non-judgmental, with good communication skills and clinical knowledge (Manzi et al., 2014).
2. Focusing on problem-solving approaches. Supervisors encourage working in a facilitative manner to solve problems, which can improve health workers' job satisfaction, motivation, confidence, and morale. It also helps improve health system efficiency, systems, and processes (Suh et al., 2007).
3. Helping to optimise resource allocation and improve efficiency. A shared understanding of processes can help resolve service delivery bottlenecks to achieve more results (Frimpong et al., 2011).
4. Promoting clinical quality and performance, including high standards, teamwork, and better two-way communication for ongoing performance management (Manzi et al., 2014)

5. Ensuring an enabling environment for good performance. Key performance support factors for providers include:

- Clear performance expectations;
- Feedback on performance;
- Equipment and supplies;
- Skills and knowledge (training);
- Motivation, including recognition for good performance (USAID, 2012).

Extend services through task sharing and/or differentiated care

Task sharing (task shifting) is the systematic delegation of tasks, where appropriate and allowed by health policy, to health workers with shorter training and fewer qualifications (WHO, 2008). Task sharing is a fundamental approach to promoting efficiencies and overcoming health workforce shortages or maldistribution, as less specialised workers are less costly and can be trained in less time. Task sharing implementation requires consideration of health workers' existing scope of practice and the ability to train and support them in their enhanced scope. HRH planners should also consider "the distribution of roles among cadres, regulatory issues, stakeholder involvement, training and supervision, systems for referral, supply chains, and possible changes to payments or other incentives"(WHO, 2012c).

The following are examples of how sharing selected tasks could improve health service access:

- For family planning, sharing tasks such as IUD, implant, and injectable administration among doctors, nurses and midwives expands access to modern contraception (WHO, 2017).
- For maternal and neonatal health, sharing tasks such as delivering basic emergency obstetric and newborn care with midwives expands access to safe and skilled deliveries (Deller et al., 2015).
- For HIV/AIDS, sharing tasks such as initiating and managing antiretrovirals among doctors and specially trained nurses can expand access to life-saving treatment (WHO, 2008).
- Sharing administrative tasks such as reporting or record-keeping with non-clinical staff can free clinical staff to see more patients (WHO, 2008).

More recently, taking into account the COVID-19 crisis, a new framework for task sharing/shifting called the COATS framework (Orkin et al., 2021) can be observed in Figure 2. The framework offers a simple and adaptable solution for task sharing/shifting.

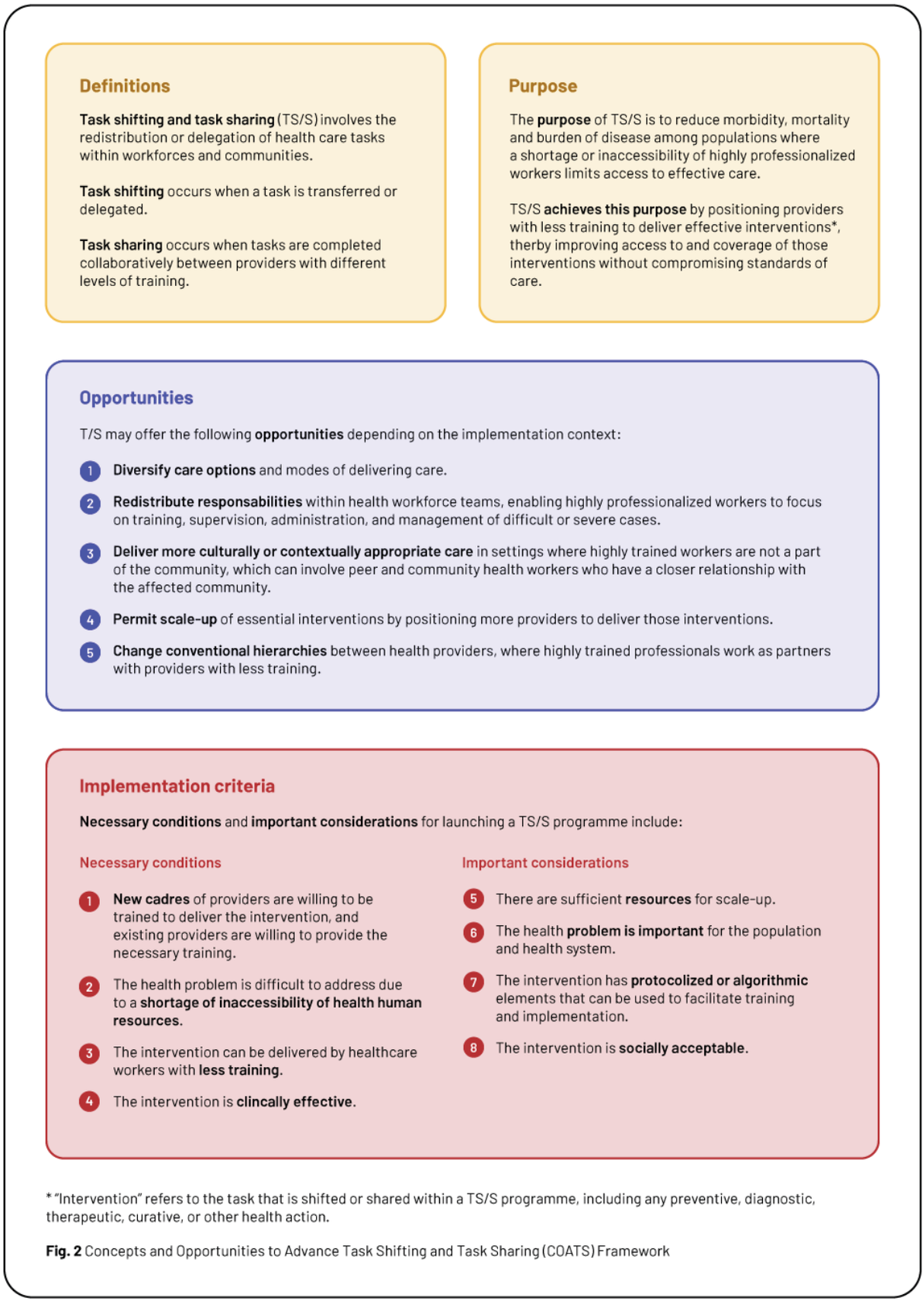

Fig. 2.1. Concepts and Opportunities to Advance Task Shifting and Task Sharing (COATS) Framework (Orkin et al., 2021)

Differentiated service delivery models of care, or differentiated care, are innovative ways health workers can meet client needs by reducing the workload of more highly specialised workers. Differentiated care is considered a client-centred approach that changes the frequency and/or location of client contact and the type of service delivery providers. Differentiated care may include task shifting from more specialised health workers to less specialised staff, or the frequency of consultations with clinical staff may decrease (WHO, 2008).

For example, HIV-positive clients taking antiretroviral treatment (ART) who are known to be stable, adhere to their medication and do not require frequent clinical consultations could be eligible for differentiated care. Differentiated care models for HIV services can be categorised into four types:

- Health care worker-managed groups: Clients receive ART refills in a group setting, managed by either a clinician or lay worker, in or outside the facility.
- Client-managed groups: Clients receive ART refills in a group setting, managed by clients, usually outside the facility.
- Facility-based individual models: Clients receive ART refills without a clinical consultation.
- Out-of-facility individual models: ART refills and clinical consultations are provided outside the facility.

Like task sharing, differentiated care optimises the existing health workforce that emphasises community-based health workers.

Box 3

Putting theory into practice: task shifting in Uganda

In Uganda, task shifting is already the basis for providing antiretroviral therapy. With only one doctor for every 22000 patients and an overall health worker deficit of up to 80%, Uganda is making a virtue of necessity.

Uganda's nurses are now undertaking a range of tasks that were formerly the responsibility of doctors. These include: managing people living with HIV who have opportunistic infections such as herpes zoster, oral thrush and diarrhea; diagnosing tuberculosis sputum positive; prescribing medicine to prevent other infections; determining the clinical stage of people living with HIV; deciding whether people living with HIV have medical eligibility for antiretroviral therapy; and managing people on antiretroviral therapy who have minor side effects such as nausea.

In turn, tasks that were formerly the responsibility of nurses have been shifted to community health workers, who have training but not professional qualifications. These tasks include: HIV testing; counselling and education on antiretroviral therapy; monitoring and supporting adherence to antiretroviral therapy; filling in registers; triage; clinical follow-up; taking weight and vital signs; and explaining how to store antiretroviral drugs.

As part of the approach, Uganda has expanded its human resources for delivering HIV and AIDS services by creating a range of non-professional types of health care workers. These people receive specific training for the tasks they are asked to perform.

The following examples provide a snapshot of what the task-shifting approach really involves.

Field officers are recruited from among social workers who have a university degree and are given brief training. They can take over care from the clinical team about two months after antiretroviral therapy is initiated and are made responsible for home delivery of antiretroviral therapy. Field officers use standardized tools for following up and evaluating people receiving antiretroviral therapy and refer to clinicians when faced with a challenging situation.

Community antiretroviral therapy supporters are community members with no health professional background. They receive training and refresher training. Under the guidance of a community supervisor, they are charged with education on HIV prevention, treatment and adherence to medication. They are also involved in determining the readiness of a client for antiretroviral therapy and contribute to the ongoing support and monitoring of adherence for people receiving antiretroviral therapy and tuberculosis medication.

Antiretroviral therapy aides are trained during a 12-day course focusing on preparing them to offer support to nurses at health centers. In particular, they offer support in triage, adherence support, group education, counselling before and after HIV testing and ongoing support counselling.

Community health workers include people living with HIV with no prior medical background. They follow a 12-week course involving 6 weeks of classroom teaching and 6 weeks of clinical clerkship covering a comprehensive range of theoretical and practical clinical skills.

Fig. 2.2. Example for differentiated care (WHO, 2007)

Harness appropriate technologies

When used appropriately, advances in technology and telecommunications can transform health systems by supporting health workers at their jobs and helping their supervisors understand performance. Mobile health tools and interventions, known as mHealth, have been documented to improve HRH performance, including in the following ways:

- Data collection and reporting: providing timely information on services the health worker delivered;
- Electronic decision support: providing easily accessible job aids or using clinical algorithms to support health workers to provide care according to defined standards;
- Provider-provider communication: allowing health service providers to exchange knowledge, solve problems, give advice and other support;
- Provider work planning and scheduling – for example, to automate and/or communicate health worker shifts which may be linked to client flows or other service needs;
- Provider training and education: video or blended learning modules, SMS prompts, or interactive voice response (IVR) systems can reduce classroom time and keep health workers at their posts;
- Human resource management: mHealth tools to populate, update, or review HRH information systems (HRHIS);
- Supply chain management: systems to quantify and communicate anticipated drug needs to keep health workers well equipped;
- Financial transactions and incentives: online/mobile banking to streamline payroll processes (Agarwal et al., 2017).

An array of examples of how technology is being used to improve training, monitoring and communication for healthcare workers can be found in the articles from (Long et al., 2018) and (Lapão & Dussault, 2017).

Professionalism and e-professionalism

Professionalism is the competence or skill expected from a professional. Medical professionalism or professionalism in the healthcare sector is defined as “a belief system about how best to organise and deliver health care, which calls on group members to jointly declare what the public and individual patients can expect regarding shared competency standards and ethical values and to implement trustworthy means to ensure that all medical professionals live up to these promises”(Wynia et al., 2014).

However, with the emergence of the internet and social media, a new form of professionalism, called “e-professionalism,” has developed (Cain, 2008). E-Professionalism is “the attitudes and behaviours reflecting traditional professionalism paradigms but manifested through digital media”(Cain & Romanelli, 2009).

E-professionalism includes an online persona; therefore, e-professionalism is an essential and increasingly important element of professional identity formation in medical education. Moreover, e-professionalism encompasses social media behaviours and must develop professional values, actions, and aspirations in medical education (Kaczmarczyk et al., 2013). There are generational differences in the use, perception, and acceptance of social media and digital information sharing. Younger generations born in a time where access to the internet is widely open have been utilising social media for personal purposes before establishing a professional life. Therefore, they may not see social media as a possible problem related to their professional identity. Research shows that a lack of recognition of the role of social media in one's professional identity leads to violations of online professionalism (Greysen et al., 2012). These actions had noticed a surge in the latest pandemic of COVID-19 when

surveys reported medical professionals sharing fake news or misinforming their followers through social media posts (Law et al., 2021).

There are three main classifications of organisations' concerns related to social media in health care (Cain, 2011):

- Reputation: An organisation's reputation depends on the attitudes, behaviour, and work ethic of its members, including students. Patients and other clients may judge an organisation's quality based on conventional and digital interactions with representatives (of any kind) of the organisation.
- Privacy: Privacy concerns arise because social media do not meet the technical criteria for secure communication of patient information.
- Productivity: In health care settings, social media distractions can result in lost productivity and medical errors (Cain, 2011).

Sharing information behaviours on social media can result in violations of medical professionalism. These professionalism violations involve "lapses in integrity or honesty, morality and ethics, self-regulation, responsibility to society, and responsibility to the profession" (Steinert et al., 2005).

The large number of people mixing their personal and professional lives due to social media forced healthcare institutions to formulate and implement policies on social media (Kaczmarczyk et al., 2013). The American Medical Association developed a comprehensive approach to e-professionalism (AMA, n.d.). Many companies publish "personal" guidelines for their employees and procedures for the public's use of their social media sites (Cain & Romanelli, 2009). At the Mayo Clinic, policies stating that "employees should not engage in use during work hours, the work e-mail address should not be provided for social media credentials, and posted opinions or comments should not be attributed in any way to the institutions" are in place (Mayo Clinic, n.d.). Moreover, universities like Vanderbilt University have an extensive Social Media Handbook covering unlawful use, specifically outlining rules related to online harassment and copyright infringement. The handbook describes institutional practices and appropriate student conduct. It also includes a how-to guide for departments and individuals for establishing online networking pages (Vanderbilt University, 2010).

EXAMPLES AND ANALOGIES

- Examples are inserted throughout the text.

APPLICATION AND INTEGRATION

For e-professionalism

Practical activity: Please review all your social media profiles. Do you consider them professional enough based on the example of AMA's e-professionalism policy (AMA, n.d.) and the Social Media Handbook provided by Vanderbilt University (Vanderbilt University, 2010)? What would you change to make your social media appearance more professional?

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Lesson plan 2: Human Resources in Health: current and future needs

FOUNDATIONAL KNOWLEDGE

Human Resources in Health should reduce health inequities by assessing and designing interventions to solve the current and future needs mentioned below (WHO, 2016b, 2018b).

Current needs	Future needs
Improve health workforce distribution	Understand health labour market dynamics
Improve health worker retention	Focus on youth
Develop workforce deployment and retention strategies	Transform health workforce education
Provide decent working conditions	Promote health workforce resilience
Provide continuing professional development	
Promote interprofessional teams to deliver patient-centred care	
Engage communities	

Improve health workforce distribution

While HRH density is one indicator to assess the availability of health workers, another important consideration is the distribution of health workers within a country. More than half the world's population lives in rural areas, but fewer than one-quarter of doctors work there. In many cases, health workers leave jobs in locations perceived as less desirable, accessible, or safe for more desirable ones (WHO, 2018b). This results in high concentrations of health workers in some parts of the world and other areas with low concentrations of health workers. People living in rural, remote, and underserved areas have a harder time accessing health care delivered by skilled workers. Health workforce maldistribution results in geographic inequities in health (WHO, 2012c).

Improve health worker retention

Research has shown that poor working conditions lead to low job satisfaction, which leads, in turn, to high rates of turnover. Keeping a labour-market focus will help policymakers adjust employment incentives as needed in locations where posts are hard to fill and seek ways for the private sector to respond to immediate workforce

needs. World Health Organization developed key strategies for addressing HRH maldistribution by improving health workers' attraction, recruitment, and retention to rural, remote, and underserved areas (WHO, 2010).

They are summarised under four types of interventions:

- Education
- Regulation
- Financial incentives
- Professional and personal support (WHO, 2010).

While they focus on improving rural retention, the recommendations and lessons could apply to any area with health worker shortages.

Table 2. 1. Examples of Interventions (WHO, 2010)

Intervention Type	Examples
Education	● Recruit students from rural backgrounds ● Locate health professional schools outside of major cities ● Conduct clinical rotations in rural areas during studies ● Develop/Revise curricula to reflect rural health issues ● Promote continuous professional development for rural health workers
Regulation	● Enhance rural health workers' scope of practice to empower and satisfy them at their jobs ● Scale up the training of different (less specialized) health workers ● Introduce compulsory service schemes to work in underserved areas ● Sbusidized education for return of service in underserved areas ● Ensure job security
Financial incentives	● Provide appropriate financial incentives, such as hardship allowances, housing grants, or transport to outweigh preceived opportunity costs associated with rural posts
Professional and personal support	● Provide better living conditions, including sanitation, electricity, telecommunications, and schools for children and family ● Ensure a safe and supportive working environment, including avoidance of workplace violence, especially for women; adequate equipment and supplies; supportive supervision and mentoring; and a manageable workload and hours ● Give rural workers outreach support to facilitate cooperation and collaboration ● Provide career development programs and continuing professional development so rural health workers can advance professionally without leaving ● Encourage rural health professional networks to reduce professional isolation, including associations and journals ● Recognize rural health workers publicly to boost morale and motivation

Develop workforce deployment and retention strategies

Building on the WHO's global recommendations (WHO, 2010), health policymakers need to consider which combination of interventions can be most appropriate and attractive to health workers. Job preferences vary depending on health worker type, gender, age, marital status, and location.

Different toolkits are available that can aid the mapping of workforce motivation, deployment and retention strategies based on specific characteristics of the workforce. A couple of these toolkits are presented below.

The Rapid Retention Survey Toolkit provides a step-by-step approach to assess health workers' motivational preferences and design appropriate financial and non-financial incentives for evidence-based job packages to increase job uptake and retention, based on labour market needs and where there are vacancies, high turnover rates, or an under-representation of health workers.

The open-source software iHRIS Retain can help develop job incentive packages over time to consider their feasibility and affordability. In many cases, the cost of losing health workers and recruiting new ones is more costly than providing additional incentives to existing workers.

A case study from Namibia shows how evidence-based job packages using iHRIS Retain were developed to help the Ministry of Health to achieve a 0% vacancy rate over five years (Bailey et al., 2015).

Provide decent working conditions

When health workers feel safe, supported, and well-equipped, they are more likely to be motivated and perform successfully at their jobs. The health system's work environment can be improved by (WHO, 2012b):

- Providing proper equipment, materials, medicines, and supplies so health workers can deliver high-quality care. This results in a stronger health system and more satisfied health workers.
- Addressing occupational safety and health: Reduce the biological, chemical, physical, and psychosocial hazards through Positive Practice Environments. This is shown to keep HRH in the workforce longer.
- Ensuring a workplace free of discrimination and gender-based violence.

Provide continuing professional development

Low job satisfaction and turnover are often driven by a perception of job stagnation and a lack of opportunities for professional development, especially in remote areas. Health workers should continue to learn and update their skills to respond to existing health system needs through continuing professional development, promoting life-long learning, motivating health workers, and improving service delivery quality and coverage (WHO, 2018b).

Continuing professional development can include in-service training, clinical mentoring, and other relevant, practical activities that promote capacity building. Professional development opportunities can improve the quality of care that health workers deliver when there are new standards or models of care (WHO, 2018b).

Low-dose, high-frequency learning is an innovative capacity-building approach showing promising results (Jhpiego, 2016). This approach seeks to promote maximal retention of clinical knowledge, skills, and attitudes through short, targeted in-service simulation-based learning activities, which are spaced over time and reinforced with structured, ongoing practice sessions on the Jobsite. Low-dose, high-frequency learning principles include:

- Competency-focused sessions that are practical, hands-on, take place in the work setting, promote relevant problem-solving, and deliver immediate feedback.
- Simulation and case-based learning ensure brief content delivery, allowing more time for hands-on learning and interactive exercises.
- Appropriately spaced (brief) periods of content delivery, delivered in a single day or over several days so that new skills can be practised and honed.
- Team-focused and facility-based training improves teamwork and encourages staff to address facility-specific challenges.
- Ongoing skills practice and post-training content exposure ensure skills are reinforced and practised. Practice sessions do not need to be more than 15 minutes.

- Facility-based peer staff to conduct practice drills.
- Measure results in clinical outcomes and considers quality improvement approaches to address issues (Jhpiego, 2016)

Promote interprofessional teams to deliver patient-centred care

A single health worker would likely struggle to deliver integrated, comprehensive, patient-centred care for all people. Instead, interprofessional, collaborative healthcare teams (including primary care providers, nurse managers, community-based workers, laboratory, radiology and pharmacy technicians, and specialists) are best skilled to deliver integrated, people-centred care, which the WHO envisions as essential for ensuring health for all. Patient-centred care is aligned with and responsive to client and population health needs.

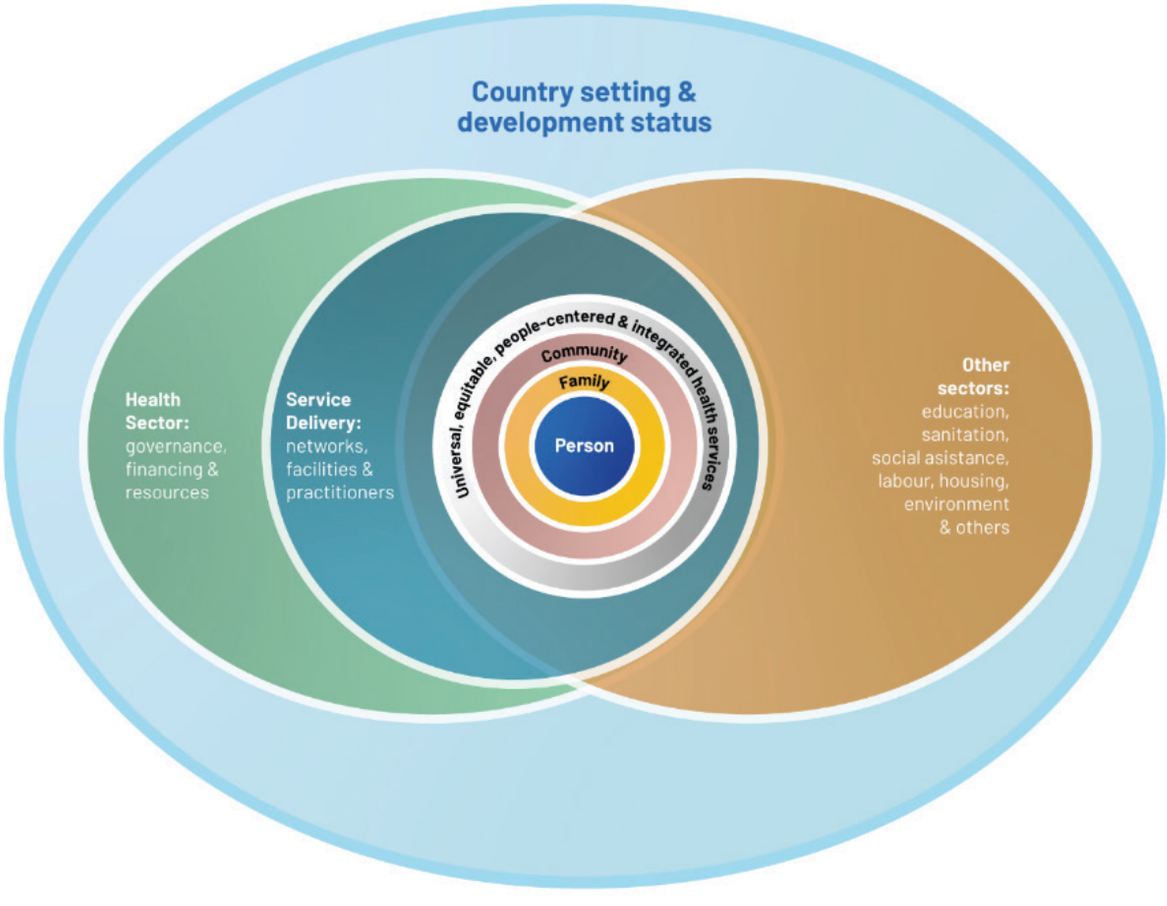

Fig. 2.3. An interprofessional approaches (WHO, 2015)

- Providing collaborative, coordinated, and accessible care;
- Focusing care on physical comfort and emotional well-being;
- Considering preferences, values, traditions, and socioeconomic conditions;
- Encouraging family involvement;
- Providing timely and transparent information for shared decision-making;
- Aligning leadership and management to patient-centred goals.

Patient-centred care may be most effectively achieved in marginalised and underserved communities through a health workforce representing and coming from the community. Health workers can provide more adequate care when they demonstrate linguistic, cultural, and gender competence. This reinforces the WHO education recommendations: recruiting health professional students from rural backgrounds and locating schools in these settings (WHO, 2015).

Engage communities

Community engagement is an approach to strengthening healthcare delivery and establishing or reinforcing trust between patients and healthcare providers. Having trusted health workers on the front lines can dramatically improve health system responsiveness to the threat of disease outbreaks (WHO, 2018b). In communities with strong provider-community relationships, community members and health workers work as a team, improving demand generation, transportation, medication adherence, and health reporting. Communities can also play a critical social support role for providers, including housing, food, and a social network (WHO, 2018b).

Community-based stakeholders in health, peer educators, local health management committees, and health volunteers play critical roles in connecting communities to health care. Community engagement is an important strategy to optimise health worker performance, as it can promote health service utilisation (WHO, 2018b).

Example of Sierra Leone: community engagement by strengthening community-based facility management committees was a key strategy to promote constructive feedback mechanisms, develop local solutions, improve service utilisation and support health workers at their jobs: https://www.advancingpartners.org/sites/default/files/sites/default/files/resources/tagged_mohs_fmc-guidelines_sept2017.pdf

Example of Ghana: community engagement intervention demonstrated health worker motivation to provide quality care and led to reduced frequency of illness: https://www.econstor.eu/handle/10419/177707

Understand health labour market dynamics

Building the future workforce requires an understanding of the production of health workers, the availability of jobs, and the factors that drive health workers and potential health workers to contribute to the health sector. Elements highlighted in the case of medical deserts, where either health workers, medical jobs or access to healthcare do not exist or are not available promptly (V & G, 2018).

In many contexts, the private health sector presents promising opportunities to address health worker shortages or gaps (WHO, 2018b). Through innovative employment strategies—such as short-term contracting, local hires, task sharing, hiring outside the prime age group, or offering unique fringe benefits—the private sector may have greater flexibility than the public sector to respond to specific and changing market needs. For example, in South Africa, the private sector hired workers seasonally to provide circumcision services because of a surge in demand in the winter months (WHO, 2018b).

Part of the health labour market dynamics is the circular migration of the health workforce, which refers to the skilled migration of HRH back and forth between countries (Kroezen, 2016). This has been advocated as a triple win as it brings benefits to the source country –economic gain and skills gain of the returned workers, the destination country -solving part of the need of HRH - and the worker itself, in terms of revenues (International Labour Organization, 2014).

Below are some highlight questions that HRH stakeholders may wish to ask themselves about the underlying HRH factors within the health labour market framework (Sousa et al., 2013):

Education Sector Considerations

- Who and how many health worker graduates are there?
- How are contributions of private-sector education institutions being considered?
- How do policies facilitate or hinder the number and type of health worker graduates?
- What is the quality and relevance of the program and graduates' skills for the job market?
- What is the formal connection between the education sector and the health sector? Is the education sector response to the changing needs of the country and the health sector?

Labour Market Considerations

- What are the primary inputs and outputs from the pool of health care workers?
- What is the relationship between open posts and the financial ability to hire?
- Of the "pool" of qualified health workers looking for jobs, how many can find employment?
- Where are the jobs: in rural or urban settings? At the primary, secondary or tertiary levels? In the public or private sector?
- What are the combinations of financial and non-financial incentives that these jobs offer? Which jobs are the most desirable ones? How do they compare to jobs outside of the country?
- Do financial and non-financial incentives align with HRH distribution needs to the extent they are effective? Are rural and remote posts being filled?
- Once health workers are employed, are there reliable means to track productivity, performance, retention, and distribution? How are the data used, if at all?
- How do health worker jobs ultimately help respond to national population health needs?
- What is the payoff for financial investments in HRH?

Focus on youth

Youth are an immediate and long-term priority for health workforce development. The WHO Global HRH Strategy: Workforce 2030 estimates that 40 million new health jobs will be created by 2030. Indeed, the future health workforce depends on engaging youth and understanding their pivotal role in making health workforce development a long-term priority. Filling these jobs will depend on youth-centred recruitment efforts and understanding of youth decision-making about careers. Engaging youth to pursue meaningful careers in health has the potential to support achieving health for all substantively (WHO, 2016b).

The Positive Youth Development Framework can be useful when designing, implementing, and monitoring health workforce development programs to promote a vision of healthy, productive, and engaged youth.

Transform health workforce education

In response to outdated curricula, skills mismatches, and other HRH production challenges, health professional education must lead the way forward to produce competent, responsive, interprofessional, and connected healthcare teams to achieve high-quality, patient-centred health care for all. In many low- and middle-income countries, health education is run by the Ministry of Education, while health services are governed and provided by the Ministry of Health. There is often a surprising lack of communication between the two ministries. This often leads to over-or under-production of cadres. Fostering close and responsive relationships between the education and health systems is a critical first step, which usually requires buy-in at the highest level of government (WHO, 2016b, 2018b).

Two main outcomes can help support a new generation of health professionals for a new century (Frenk et al., 2010):

1. Transformative learning, achieved by:
    - Building upon global knowledge and best practices for improving health systems while adapting to specific needs or local context
    - Developing leadership abilities with inter-professional and analytical skills to promote team collaboration and reduce hierarchies
2. Interdependent health and education systems, achieved by:
    - Bringing together students, faculty, and health professionals to promote health workforce learning
    - Harmonising procedures for planning, monitoring and evaluation, and ensuring social accountability
    - Linking academic support or continuous learning opportunities to all levels of the health system, especially for primary health workers

Promote resilience

Health system resilience is "the capacity of health actors, institutions, and populations to prepare for and effectively respond to crises, maintain core functions when a crisis hits, and reorganise if conditions require it"(Kruk et al., 2015). Health workers, managers, and policymakers are all key health actors who must cultivate resilience.

Example: An up-to-date mapping of health workers—how many, where they are, and their skills—allows for more rapid response, effective communication, and surveillance. For example, during the Ebola crisis, mHero mobile technologies helped health authorities and frontline workers connect to plan, respond, communicate, and act.

EXAMPLES AND ANALOGIES

- Examples are inserted throughout the text.

APPLICATION AND INTEGRATION

For Human Resources in Health:

You are working with the Ministry of Health to solve the medical personnel crisis in your country. The country is facing a considerable healthcare personnel deficit due to the migration of medical personnel to other countries. The lack of such personnel is visible, especially in remote rural areas where no primary care doctors are available. Develop an idea that uses technology resources to improve the allocation of healthcare personnel in vulnerable areas. How would this solution look?

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Global Health Workforce Alliance: a health worker for everyone, everywhere – video

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https://www.ihris.org/ihris-retain

https://peoplethatdeliver.org/sites/default/files/country-partnership-files/Namibia%20Synthesis%20Report_FINAL_0.pdf

https://hms.jhpiego.org/wp-content/uploads/2016/08/LDHF_briefer.pdf

https://www.who.int/workforcealliance/about/initiatives/ppe/en/

https://interprofessional.global/wp-content/uploads/2019/11/WHO-2015-Global-strategy-on-integrated-people-centred-health-services-2016-2026.pdf

https://www.youthpower.org/positive-youth-development-pyd-framework

https://www.mhero.org/

Lesson plan 3: Human Resources in Health institutional capacity, policy, and leadership

FOUNDATIONAL KNOWLEDGE

Many countries have fragmented HRH leadership and policies. The following approaches can build the capacity of multisectoral stakeholders to strengthen health workforce leadership and governance:

- Build capacity for workforce planning;
- Facilitate national-level HRH stakeholder leadership groups;
- Conduct participatory HRH strategic planning;
- Use HRH research and evidence to inform interventions;
- Engage the private sector (WHO, 2018a).

Build capacity for workforce planning

The ability to assign the right health worker to the right place with the right skills and motivation depends on the ability to state current needs and forecast future needs based on reliable data. Health workforce planning needs to be addressed in the current Health Sector Plan for each country and the country's mid-and longer-term health strategy. The minimum components of a helpful workforce plan are:

- Current and planned health outcomes disaggregated geographically;
- Current and planned service delivery at primary health, secondary and tertiary levels;
- Estimated HRH needed to deliver services by location;
- Current and forecasted inputs to the stock of HRH, including education, re-hiring, and immigration of health workers;
- Current and projected HRH leaving the system, including retirement, death, and voluntary quits to work in other sectors or other countries;
- Projected costs of adding sufficient workers to meet service delivery needs (Health Workforce Advocacy Initiative, 2009; Kinsella & Kiersey, 2016)

A thorough and valuable plan will also forecast future national labour market capacity to recruit, deploy, pay, and retain enough health workers, including the public and private sectors. That is, the plan should provide a "reality check," comparing needs and costs with the country's ability to act, financially and practically (Health Workforce Advocacy Initiative, 2009)

Facilitate national-level HRH stakeholder leadership groups

Policies and interventions to strengthen the health workforce at the national level require multisectoral engagement. When effective, HRH stakeholder leadership groups can (Gormley & Mccaffery, 2011):

- Increase the likelihood of successfully implementing new HRH initiatives;
- Facilitate knowledge sharing across disciplines;
- Leverages resources and expands capabilities to "do more with less";
- Advocate for HRH issues and accelerate momentum to mobilise funding and resources;
- Redefines relationships among HRH stakeholders (Gormley & Mccaffery, 2011).

Conduct participatory HRH strategic planning

National HRH strategic plans provide a roadmap for health workforce strengthening and development in the context of broader national population health and health systems strategies. There may be greater uptake and success in implementing a broad stakeholder group engaged in HRH strategic planning (Health Workforce Advocacy Initiative, 2009).

In addition to improving trust in the health system and the quality of its services, community engagement can result in more relevant and effective HRH strategic planning implementation at the local levels (Health Workforce Advocacy Initiative, 2009).

In Sierra Leone, local facility management committees helped alert district health management teams about staffing problems—such as interpersonal conflicts or insufficient housing—and participated in resolving them: https://www.advancingpartners.org/sites/default/files/sites/default/files/resources/sierraleone_fmc_tagged.pdf

Use HRH research and evidence to inform interventions

National HRH observatories hold and monitor health workforce data to inform national HRH policies, strategies, plans, and implementation. Generally composed of a secretariat of HRH stakeholders—individuals and institutions—the Observatory may also support research (WHO, 2012a).

HRH Observatory leaders may benefit from considering the Research Utilization Framework and its phases (Kim et al., 2018)

Foundational Phase: Engage HRH research producers, knowledge brokers, and end-users to identify evidence gaps to inform research priorities;

Research Phase: Produce HRH evidence (and determine if it should be translated in subsequent phases);

Translational Phase: Develop knowledge into products, disseminate (and decide whether or not to adopt results), promote uptake and practice;

Institutionalisation Phase: Scale up, maintain, sustain, finance, and evaluate proven interventions. (Kim et al., 2018)

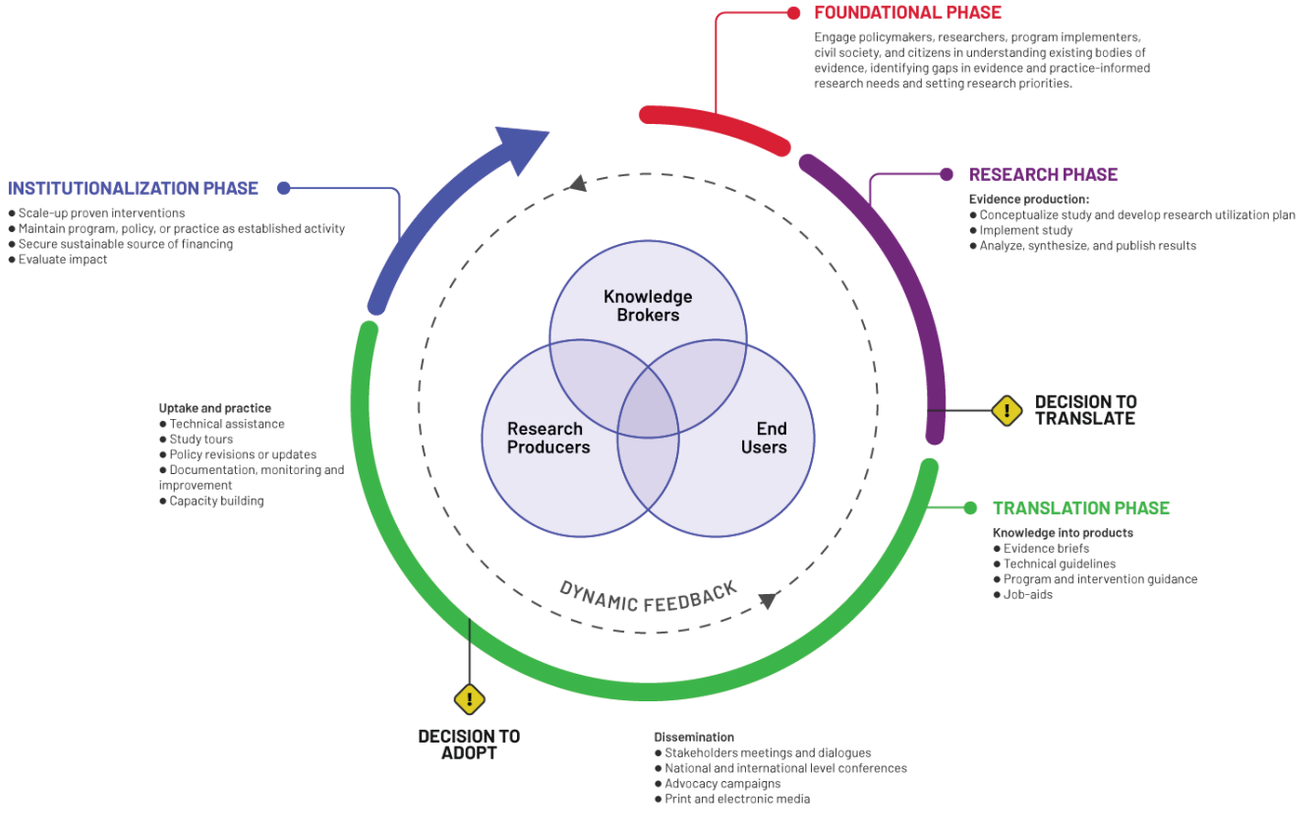

Fig. 2.4. The HRH research and evidence to inform interventions (Kim et al., 2018)

Engage the private sector

Non-profit, for-profit, or faith-based, private-sector institutions are important entities to own and address health workforce strengthening. They are crucial in delivering health care and enhancing service delivery (WHO, 2016b).

For example, in the Democratic Republic of the Congo, Uganda, and Tanzania, about half of all health facilities are managed by faith-based organisations (FBOs): https://www.capacityplus.org/technical-brief-16/index.html

In India, private hospitals provide 80% of outpatient care, and 60% of inpatient care: https://www.commonwealthfund.org/international-health-policy-center/countries/india

HRH stakeholders can benefit from considering the private sector's potential to meet health workforce shortages and include them in national registries and planning processes (WHO, 2016b).

For example, in South Africa, private-sector providers are leveraged to meet population health needs for HIV services: https://www.devex.com/news/opinion-enlisting-the-private-sector-in-the-fight-against-hiv-aids-95515

In addition, when the private sector health workforce is included in regulatory oversight, it can help ensure service quality. It may be essential to support private sector actors—including educational institutions, service providers, and employers—to understand how their engagement can help them reach their financial or non-financial goals to ensure motivation and participation: https://www.tatatrusts.org/article/inside/tata-trusts-ge-healthcare-partnership.

EXAMPLES AND ANALOGIES

- Examples are inserted throughout the text

The HRH visualiser is a useful tool that shows how governance, policy decisions, and the country context affect a health workforce and how a health workforce affects health system outcomes. The tool can support the evidence-to-policy process by presenting research visually appealing and accessible and helping researchers communicate with policymakers and practitioners. The tool is also useful to build consensus on existing and missing evidence on human resources for health, bridging the gap between evidence, policy, and practice. Moreover, the visualiser can be an educational tool for students to understand policy pathways and explore the literature on human resources for health (Sonderegger et al., 2021).

APPLICATION AND INTEGRATION

Lesson Plan 3 and Lesson Plan 4 will have a common practical activity explained in Lesson plan 4.

REFERENCES FOR FURTHER INFORMATION AND AREAS OF INQUIRIES

https://www.capacityplus.org/files/resources/Guidelines_HRH_SLG.pdf

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Lesson plan 4: Human Resources in Health data, monitoring and accountability

FOUNDATIONAL KNOWLEDGE

HRH stakeholders—from policymakers to facility managers—need data to understand how to improve HRH intervention implementation and drive performance. Accurate and timely HRH data are required to connect HRH inputs with health outcomes and calculate the relative success of HRH programs. The following systems and approaches are recommended for health workforce data collection, management, accountability, and use in decision-making:

- Monitor HRH availability and accessibility;
- Implement National Health Workforce Accounts (NHWA);
- Harness appropriate technologies at site and district levels;
- Monitor HRH financial investments (Fort et al., 2017; Riley et al., 2012).

Monitor HRH availability and accessibility

The availability of HRH data in many countries could be improved upon in terms of interoperability, robustness, accuracy, and frequency of updates (Riley et al., 2012). Harmonisation of existing HRH data is critical; with the automation of more in-country governance data and records, rich sources of HRH data may already exist. Private-sector HRH should be included in national harmonised data. Payroll records, education institution records, civil service databases, and professional association rolls are examples of how HRH data may already be available. Systems to capture these data and make them interoperable may be the shortest route to having a complete HRH data picture (Fort et al., 2017; Riley et al., 2012).

The following resources and tools can help access monitor HRH availability and accessibility at various health system levels:

- Global Health Workforce Statistics - Latest national data available, disaggregated by occupation, gender, and age whenever possible. It is also useful to track health workers according to the International Standard Classification of Occupations (ISCO), which provides a comprehensive list of health professionals: https://apps.who.int/gho/data/node.main.HWFGRP?lang=en
- Within a country, the HRH Indicator Compendium and the Handbook on Monitoring and Evaluation of Human Resources for Health provide a comprehensive list of health workforce measures, with accompanying guidelines for developing HRH monitoring and evaluation plans.
- Human resources for health information systems (HRHIS) seek to capture health workforce stock and flows. iHRIS, an open-source software, has helped many country stakeholders develop their HRHIS. The WHO recommends a minimum data set for a health workforce registry: address (physical, electronic), country, date, disciplinary action, education, occupational employment category, employment status, employment title, facility type and ownership, full name, GPS coordinates, identification number, language, license, registration and certification, photograph, postal code, sex at birth, and telephone number.

Implement National Health Workforce Accounts (NHWA)

Consistent with recommendations to "undertake robust research and analysis of health labour markets, using harmonised metrics to strengthen the evidence, accountability, and action" (WHO, 2016c), the National Health Workforce Accounts (NHWA) build on existing HRH information systems (HRHIS), and consider data on population health, as well as data in the education sector and labour market.The NHWA is composed of a set of core indicators organised into modules that can be tracked over time to:

- Generate reliable HRH information for better-informed decision-making;
- Support HRH policy and planning;
- Improve the comparability of the health workforce both nationally and globally;
- Enable research to inform trends and needs for the resilience of the health workforce and health systems.

The indicators in the NHWA help countries around the globe create evidence-informed policymaking and planning by having comparable standardised information in one place.

Harness appropriate data technologies at site and district levels

Just as technology can help improve HRH performance, mobile health (mHealth) technologies can also help improve the frequency, accuracy, interoperability, and robustness of health workforce information at decentralised health system levels (WHO, 2016a). Systematic data-driven approaches can also help district management health teams understand their HRH availability and reinforce health worker accountability, especially for community-based cadres and health workers in rural, remote, and hard-to-reach areas (WHO, 2016a). Moreover, technology can help to improve the digital literacy of medical personnel, which ultimately will lead to better care offered to patients and advances in the medical field (Konttila et al., 2019; Meskó et al., 2017; Pfob et al., 2021; Pol et al., 2020)

A good example of harnessing the appropriate technologies, in Sierra Leone, mobile phones were used to track and hold community health workers accountable for being present on the job without any diminished perception of supervision. mHealth can be a human resources management tool to track community health worker (CHW) activity—such as recording the GIS coordinates of each household visit form completed to ensure that the CHW is following up on the cases she reports (Vallières et al., 2016).

For example, a project conducted in Germany showed that IT and health care specialists showed excellent literacy in their respective disciplines; only a few individuals combined both digital and health care literacy. Multidisciplinary teams and transdisciplinary curricula are crucial to bridging skill gaps between disciplines and driving digital health initiatives (Pfob et al., 2021).

Monitor HRH financial investments

HRH financial investment data could be monitored at the donor, national, decentralised, or community levels through the National Health Workforce Accounts (NHWA) tool.

At the national or decentralised level, the HRH Effort Index survey can be administered among relevant stakeholders to assess and inform strategic health workforce investments. Across seven HRH dimensions (Leadership and Advocacy; Policy and Governance; Finance; Education and Training; Recruitment, Distribution, and Retention; Human Resources Management; and Monitoring, Evaluation, and Information Systems), stakeholders can rank the relative strength of each dimension. Results can provide valuable qualitative information to assist HRH investment prioritisation (Fort et al., 2017).

EXAMPLES AND ANALOGIES

- Examples are inserted throughout the text.

APPLICATION AND INTEGRATION

The growing non-communicable disease burden in Romania, including cardiovascular diseases, hypertension, diabetes, and cancer—requires the health system and workforce to be resilient.

From a health workforce perspective, the following issues challenge Romania's health sector:

- The health workforce is concentrated in the major urban centres (maldistribution).
- There is high attrition from the health sector: from the public to the private health sector, and migration out of the country.
- While HR takes up 45% of the total budget of the MOH, the Ministry lacks data about workloads and staffing needs to argue for required increases.
- HRH managers at the central and regional levels have insufficient training in HR management.
- There is a shortage of primary health care staff compared to specialised facilities.
- There is no evaluation system for continuing education requirements for health professionals.
- Some existent active methods of gathering client feedback on facility/provider performance. Still, they are not systematically being done across the country, and there is no evaluation and evidence of their use.

Please see the questions below:

1. If you were a Romania HRH stakeholder leadership group member, how would you use this information?
2. What recommendations would you make to help Romania's health workforce achieve health for all?
3. What else would you like to know about the situation?
4. What would you propose as possible approaches or solutions?

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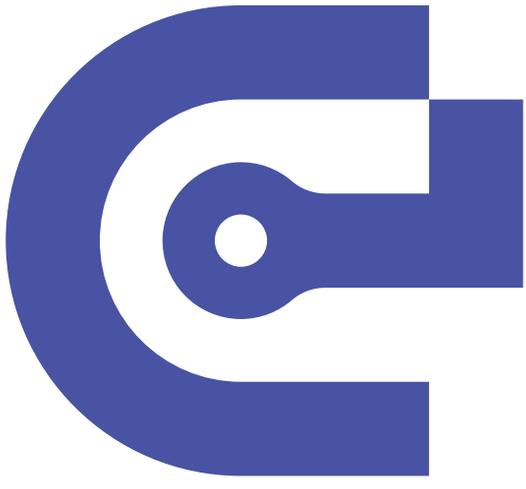

Module 3: eLearning in Health

Learning objectives of the *eLearning in Health module*

This outcome statement is an official list of the goals for students who take your class.

Students must know about relevant areas of competence

1. The concept of eLearning
2. The background “how to learn” and the context to eLearning
3. Active learning and the advantage of this approach
4. Used technology (advantages and obstacles)
5. The use of media and interactivity in the frame of the learning process
6. Planning and implementation of eLearning courses
7. Effective and common assessment methods
8. General and basic provisions

   The multi-part training course consists of face-to-face and online phases.

   The learning aids and handouts for distance learning must correspond to the backward design in terms of content and subject-related didactic considerations.

   The learning objectives must correspond to the applications in practice.
9. For the phases of online or distance learning, the participants are obliged to take part in the introductory lesson, including learning the appropriate tools, at the beginning.

Foundational knowledge of the *eLearning in Health* module

eLearning has become a buzzword and does not have a strict meaning. In this document the term eLearning means a type of learning conducted digitally via electronic media based on technology and specific devices. This does not include any delivering method nor any pedagogical/andragogical preference.S oll aber die Teilnehmerinnen und Teilnehmer dazu ermächtigen Einsichten in Strukturen der Lerninhalte und vor allem in die Strukturen und Abläufe des eLearning konzepts zu gewinnen.

The concept of eLearning and the background of “how to learn” & the context of eLearning

eLearning is an umbrella term used for learning with technology. Specific knowledge in this unit will be:

- eLearning models
- Elearning in various settings like classroom teaching, distance-learning or blended learning
- Preconditions for eLearning in the mentioned settings.
- Knowledge about necessary quality considerations.
- Basics of learning theory, methods to implement sustained learning (https://www.tibl-project.eu/web/en/about-the-project/projects-results/how-does-learning-work/, no date),
- Bloom’s taxonomy as a framework for educational goals.
- Know the principles of “working digital & analogue”,

- Reflexion and repetition.

  (Service-eLearning: educating today's learners for an unscripted future Amber Dailey-Hebert Center for Excellence in Teaching and Learning, Park University, Kansas City, Missouri, USA, and Emily Donnelli Park University, Kansas City, Missouri, USA)

A didactic design for Elearning provides structure and orientation for conveying the learning content. First, it is essential to deal with the definition of digital learning formats (e.g. blended learning, micro learning, web-based training, virtual classrooms, video-based forms of learning, …). The analysis of the special requirements in the respective subject area must be reflected in the conception of the digital learning format. Based on this, the learning materials are developed and used in a trial phase. The conclusion is an evaluation, followed by correction loops to optimize the finished course. The subsequent revision records the findings to optimize the digital learning formats. (https://www.webcampus.de/blog/261/welche-didaktischen-konzepte-unterstuetzen-das-e-learning, no date)

Active learning and the advantage of a learner-centered approach

Active learning principles and active learning methods form the basis for various implementation scenarios. Active learning is the basic approach to sustained learning.

Taking into account that learning cannot be delegated, the learning content is logical and stringent according to a certain specification of work and learning steps, taking into account the method (flipped learning, frontal teaching, project work, multi-dimensional learning, interactive videos, MiniMOOCs, reflective queries, …) and methodology (communication technique, relationship between methodology and didactics).

Used technology (advantages and obstacles)

Knowledge about currently used technology, the problem of multiple devices, problems of interaction with multimedia-based and interactive content, and the ability to develop guidelines for the use of various devices. Knowledge about used networks (local wire-based, WiFi, Internet) and content distribution.

At this point, the following thoughts are essential for the development of digital learning formats:

- "Before developing the e-learning concept, there is an evaluation of the need for knowledge transfer. This area includes questions about the composition of the target group, their prior knowledge and skills, the types of knowledge and learning objectives. What level of expertise should be sought, and for what form is it used (practical or theoretical knowledge, facts, procedures, application examples)? In addition, the organizational framework and the available resources are relevant. Interviews with the members of the target group convey clarity." (https://www.webcampus.de/blog/261/welche-didaktischen-konzepte-unterstuetzen-das-e-learning, no date)
- It makes sense to proceed in two stages when creating concepts for digital learning formats. That means from the rough target to the good targets. "The rough didactic concept defines the forms of learning. This is where the decision is made as to whether a webinar or self-study with digital content makes the most sense. Combinations of videos, face-to-face events and digital tests are also possible and must be coordinated in time. The detailed concept builds on this and deals with the development of the materials for the trainers (guidelines, scripts). Finally, the necessary learning materials are designed. Make sure that the content fits the target group." (Https://www.webcampus.de/blog/261/welche-didaktischen-konzepte-unterstuetzen-das-e-learning, no date).

- This approach reflects a typical top-down structure, as it is used in Backward Design.
- If the target group is not properly addressed or the needs of the learners are not met, even a multimedia design or didactic learning units do not create a knowledge transfer.

The use of media and interactivity in the frame of the learning process

In a starting phase, the technical basics are announced and adapted to the training centre's resources or to the learner. In the initial phase, all learners should get to know the tools and platforms used and be trained in mobile device management. The participants should be motivated and supported by audio-visual or multi-layered working documents and handouts. The ability to react to the tasks set by the learner in the initial phase should be trained, and collaborative work and activities should be used.

Multiple Devices play an important role in the learning process based on multimedia and interactivity. Multiple Devices address the use of different devices for learning. These devices may be desktop PCs, Laptops, Notebooks, Chromebooks, Tablets or even smartphones. The use of Multiple Devices is driven by the desire for mobile learning and the continuous further development of devices. A study about Multiple Devices and their use in Elearning ios is available from the Erasmus+ Project "InterMedia" (https://www.intermedia-project.eu/web/results/downloads/).

Basic knowledge about the use and implementation of multimedia-based content. (Mayer) (Leiner)

Planning, development, implementation, and assessment of eLearning courses

Know the principle of "Backward Design", the direction of method changes and the basic quality enhancement processes. (https://www.tibl-project.eu/web/en/quality-framework/, no date). Know various assessment approaches and use formative and summative assessments following the course development. Know about technical and multimedia-based assessment techniques.

The backward design as a method formulates the goals of the training, the course and / or the training. Teaching methods and forms of assessment are selected based on the goals set.

The backward design of the curriculum typically consists of three phases:

1. Identify the eLearning goals

   Trainers always start with the learner and the learner's needs. The learner is the basis for every aspect of a company's or university training strategy,

   From the learning goals you may define the learner pathways, to the tools they choose to train and how they design their training.

   This first step is necessary to clear from the beginning what will be taught in the course and what should the learners learn.

   Whit this prior knowledge you can create the assessment material to evaluate the defined learning outcomes.

2. Create the assessment material

   Assessments are critical elements of instruction and must be well planned and structured. They determine the accomplishment of lesson objectives. However, in this curriculum, assessments are more than an evaluation of what has been learned. They are part of the learning process ("Learning by assessment") and are also implemented as a learner self-assessment tool.

3. Create the relevant content

   Knowledge of the learning goals and the planned and structured assessment makes planning the content possible. Content –the last link in the chain – will be developed to support the learners to reach the learning goals quickly, efficiently, and in a deep-learning mode (to fulfil the need for sustained learning).

Lesson plans for the eLearning in Health module

Units, or themes, are the main topics that will be covered in this curriculum.(Lorainne Tudor Car, Bhone Myint Kyaw and Rifat Atun The role of eLearning in health management and leadership capacity building in health system: a systematic review)

The pedagogical triangle (Figure 1) is adequately described as a basic principle in the pedagogical literature, for example by Alfred Petzelt and others. He sees pedagogical action as between the teacher, the student, and the material to be taught.(Petzelt Alfred)

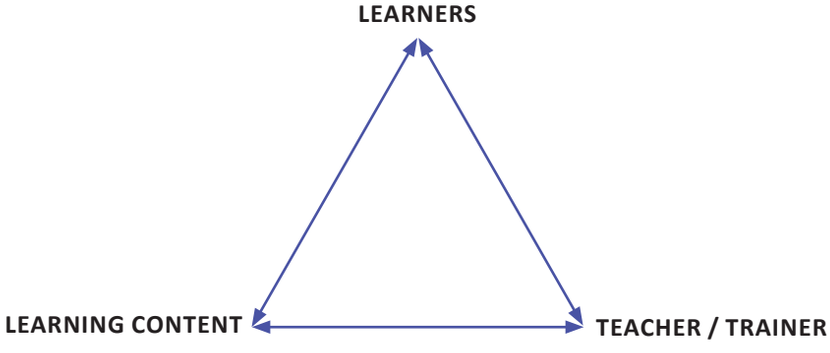

Fig. 3.1. Further developed triangle for the area of e-learingto Mozahl/Makl (Petzelt, 1947)

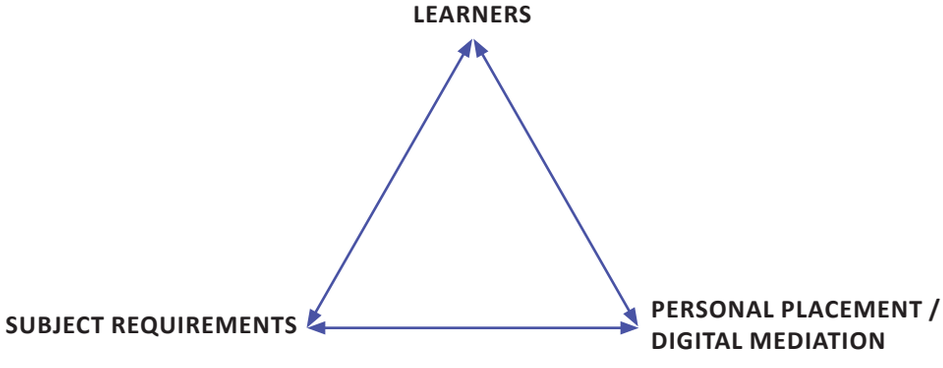

Fig. 3.2. The “Pedagogical Triangle” (Petzelt, 1947)

Based on this basic consideration, the pedagogical triangle (Fig 3.2.) can be further developed in a contemporary context of learning, which is generally characterized by the cornerstones of learner, mediation and subject requirements:

Learners are always to be seen as “pupils” (independent of their age). Content conveyance occurs through personal conveyance, i.e. teachers in face-to-face phases. Digital communication through didactic tools is predominantly used in distance learning settings. Subject requirements are understood as needs-oriented content and objectives.

From the graphical representation (Figure 2), it can be concluded that the corner points should not be viewed in isolation but in a mutually influencing network of relationships.

In medicine and medicine-related professions, specific and special human qualities also apply as a basic requirement for successful professional execution.

Pestalozzi already provided a solid theoretical basis in his holistic approach to learning and training. For him, human action in general and education in particular were seen in the interplay of head, hand and heart. The following graphic (Figure 3) reflects Pestalozzi's cornerstones, focused on education in the health sector (Pestalozzi, 2012).

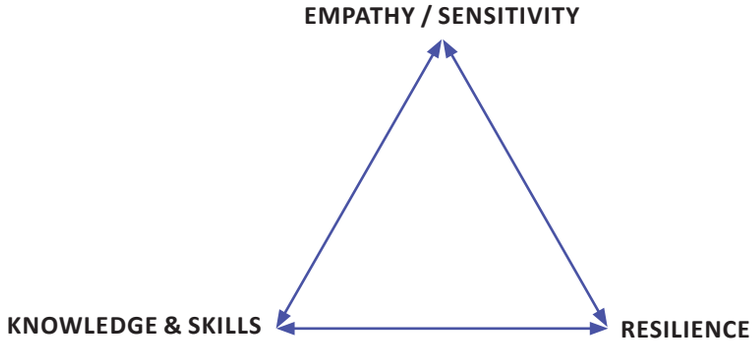

Fig. 3.3. Further development of the "Pedagogic triangle for the field of health professions according to Mazabi/Maki (Petzelt, 1947)

Empathy and sensitivity are intrapersonal characteristics that can hardly be trained, but they are very important for the professional field. Resilience is also in the intrapersonal area and can be strengthened through psychologically oriented interventions, also using digital tasks and discussion incentives. Knowledge and skills can be imparted via digital learning channels. (Huber, 2019)

Lesson plan 1: How to learn

The exercise programs run online and offline with the help of a computer, whereby the learners can work through the content step by step, regardless of time and place, at their own learning pace. Depending on the lesson plan, this leads to an intensification of the learning situation and motivation of the learners.

FOUNDATIONAL KNOWLEDGE

Students must know the basics about the background of physical learning (which does not cover learning theories). The aim is to explain the way of "sustained learning" using a modern interpretation of research results. Sustained Learning means long-lasting knowledge embedded in basic competencies or skills to use this knowledge.

EXAMPLES AND ANALOGIES

The context to analogies is given with examples from sports (training) and nature (path creating).

The tasks, exercises and reviews should be formulated as realistic as possible or taken from the practice of the respective subject area: reflexivity and the ability to discourse are required.

EXAMPLE SHORT TURNS - ALPINE SKIING

An example from the area of winter sports, alpine skiing is carried out here - short turns or short radii (slalom).

The training plan for ski instructors includes several subjects such as language, political education and organizational theory, business studies, sports biology, sports psychology, first aid, training theory and special training theory through to competition psychology, equipment science, skiing and the environment. The example from ski trainer training relates to a sub-area of alpine skiing that has both a practical and theoretical part.

It is assumed that the participants can set up and maintain the basic conditions. Participants are also responsible for maintaining fitness during the training course. The basic technique of alpine skiing is generally required of the participants.

At the beginning of the short turns, the participants are brought into the classroom for a two-day classroom lesson. There is an introduction to the platforms used, online tools (TEAMS, ZOOM, BigBlueButton, …) and learning aids, and the correct use of these tools for distance learning is practised. Special methods and theoretical subjects are also addressed. Academic content from the fields of physics, biomechanics, movement theory, movement analysis and principles of sports motor skills are then presented, taking into account the subject-related methodology and didactics of the selected unique content for short turns. Appropriate illustrative materials, videos and didactic materials (for example, didactic films, level-dependent materials and texts, competence-training blended learning units, …) are used for distance learning. At the end of every distance learning, there is a learning objective check and review, for example, in creating a movement diagram, listing load components and structuring the instructions for a practical learning unit that leads to the short turn.

Finally, there is again a face-to-face phase in the snow, where the theoretical knowledge is put into practice with instructors. With this technique, the skier has to differentiate the upper body from the legs. The upper body remains calm and in the fall line, as it is called in the technical jargon; that is, it always points towards the valley. The legs and hips are bent, which means that the skier stands centrally above the ski, so both soles in the ski boot are evenly loaded. The toes trigger the swing-triggering phase so the legs can swing under the calmly guided upper body. The critical stage of the turn begins in the middle of the curve, where full pressure is built up on the edge, and the ski's edge angle must be observed. In the third phase of the swing, the pull-out phase, the pressure should be shifted to the end of the ski. To control the speed, the ski should always be properly turned up. (Hermann, 2004) (Werner, 2005). At this point, the importance of practical application and exercise before instructors or correction by instructors should be pointed out.

EXAMPLE OF WAY CONSTRUCTION IN NATURAL AREAS

The construction of roads in nature forms the basis for multifunctional forest management. As a course, the subject of road construction can be carried out in several phases. At the beginning of the road construction section, the participants are brought into the classroom for two or more days of face-to-face teaching. The learners learn the guidelines of the course, whereby the requirements for a positive completion of the course are also clarified.

The participants are expected to have good basic conditions for visiting natural areas such as forests, meadows and fields. During the training course, the participants are also responsible for deepening their knowledge and sensitivity for nature conservation and species protection.

There is an introduction to the platforms used, online tools (TEAMS, ZOOM, BigBlueButton, …) and learning aids, and the correct use of these tools for distance learning is practised. Special methods and theoretical subjects important for road construction are also addressed, and the content to be conveyed is optimized for interactive knowledge transfer. This includes information texts with brief reviews at the end of each chapter, interactive vid-

eos or short seminar papers on the sub-areas, such as route planning, including dimensioning and accounting, soil removal, soil application, soil compaction, and damage to earthworks and types of loads. The complexity of the presented content requires additional options, which can be made available through webinars if necessary, for example, on the subject of work steps in the construction process.

Finally, there is a face-to-face phase where the theoretical knowledge is transferred into practice. In addition, the subject area can also be completed with an internship lasting several weeks. (Curriculum of the Higher Education Institute for Gardening and Landscaping, Federal Law Gazette II - Issued on August 16, 2004 - No. 331).

APPLICATION AND INTEGRATION

As an example, the corkscrew experiment is done with learners. In the corkscrew experiment, the trainer shows the learners five different words for "corkscrew" in exotic languages. Learners have 30 seconds to memorize the terms. After this phase, the trainer continues the lesson or lecture. After the study or the instruction, which should last between half an hour and an hour, the trainer gives the participants a few sheets of paper on which they should write down the terms that were noted for the corkscrew.

The result is always similar in all age groups: 5 % to 10 % can remember a word, and all others do not remember any of the exotic terms. (https://www.fade-in.eu/web/el/sustained-learning-the-corkscrew-experiment, NO DATE).

REFERENCES FOR FURTHER INFORMATION AND AREAS OF INQUIRIES

Watching the videos

- How we learn (Youtube: https://www.youtube.com/watch?v=wlaG99awCD8)
- How Adults Learn (Youtube: https://www.youtube.com/watch?v=3LdEwYDDJBg)

Lesson plan 2: Active Learning

Active learning is understood to mean pupils have to perform work themselves to acquire skills and knowledge. Active learning is often equated with problem-based learning, focusing here on the learner's independence. "The pragmatic consequence of the use of ICT in education within these communities is that students become correspondents."(Nieweg, 2005)

"The pragmatic consequence of using ICT in education is that students become correspondents. Students move up to the former position of librarian. The use of ICT flattens the hierarchy between librarians, faculty and student. Students become librarians as they were at the beginning of the era of modern science. Thus, students are learning that all these books, articles and readers they have to stow away are meant to be disassembled into their references and that these books release much of their information through this activity."(Nieweg, 2005)

FOUNDATIONAL KNOWLEDGE

- What does active learning mean?

  The sustained learning principle - deepened
- Active learning method examples: Case Studies, Project-Based Learning
- Active Learning in Distance Learning (Use of the Cornell Method)
- Active learning through interactive videos or fill-in texts for keywords in the learning platform.

EXAMPLES AND ANALOGIES

- Case studies and Project-based learning are typical elements in real life.
- The Cornell System is a well-proven method that might be used in general learning and applied to analyse problems and create solutions.

Example of the Cornell method for the professional group medical-technical laboratory assistant and medical-technical laboratory assistant. For the learning field of designing communication processes, theoretical content such as communication techniques, presentation techniques, conversational skills, conflict management, or IT-supported forms of communication can be quickly grasped by the participants. A three-part grid table with two columns and a field for the summary (see example below!) Creates a basic structure for the records before the lecture or seminar. During the course or the explanatory phase, the contents are noted in the note column in short sentences or groups of words. If possible, after the lesson or the lecture, questions should be formulated based on the right column in the left column. Developing the right questions and writing them down helps to grasp the subject matter. As a result, this technique enables recitation by covering the note column and trying to answer the questions you formulated yourself in the left column. The answers to the questions should be given in your own words and, above all, out loud. In the Summary field, the comments and keywords should be summarized after the lesson. The last learning step can be called repetition and consists of two further learning steps, reflecting and checking. The check should be used for at least ten minutes each week. (http://lsc.cornell.edu/study-skills/cornell-note-taking-system, 17.09.2017) (Lower Saxony Ministry of Culture: Framework guidelines for training medical-technical laboratory assistant / medical-technical laboratory assistant and medical-technical radiology assistant / Medical-technical radiology).

The Cornell Method supports active learning during the Distance Learning phases as well.

Example

Students watch a video. Watching videos is a kind of passive learning. The students get the assignment to create Cornell notes, formulate a certain number of questions (one to three), and create a one or two sentences summary. Engaging with the Cornell notes forces learners to watch the video more intensively and even to repeat several parts of the video to create the notes. This approach is responsible for the deeper-going sustained learning.

Table 3.1. The Cornell mothed Grid (Cornell, 2021)

Lecture:	Topic:	Date:
Summary		

This is the note sheet that goes into class. A heading is entered, the note area is filled during the lecture, and the questions are formulated on the left and the summary below. (https://projekte-leicht-machen.de/blog/soft-skills/zeitmanagement/cornell-notizen, 02.11.2021)

APPLICATION AND INTEGRATION

- The Cornell Method implementation during this module's learning process is practical implementation.
- The development of a micro learning project will be done using Backward design as an approach to project-based learning.

REFERENCES FOR FURTHER INFORMATION AND AREAS OF INQUIRIES

Reading Jennifer Gonzales: Backward Design. Source:https://www.cultofpedagogy.com/backward-design-basics/

Lesson plan 3: Technology

FOUNDATIONAL KNOWLEDGE

Students learn about various devices and possibly occurring problems like missing pointing devices (smartphones), missing processor power (smartphones and tablets) or missing software (Chromebooks).

Learners gain knowledge about the delivery of content and the displayed content on various devices.

Work data or metadata must always be available in a software-independent form. Medical imaging processes are displayed on screens and on printers or made available for download.

EXAMPLES AND ANALOGIES

The multiple device problem is omnipresent in everyday life.

Many software manufacturers and designers of learning platforms explain in advance that their product runs on any computer, laptop, tablet or smartphone. Much of the learning content and information cannot be displayed on all devices despite accessibility and html5. The flow in all systems is still a long time coming.

APPLICATION AND INTEGRATION

- Learners test micro-learning apps on various devices
- Learners learn to evaluate offered material on multiple devices

REFERENCES FOR FURTHER INFORMATION AND AREAS OF INQUIRIES

Reading about multiple devices(https://www.intermedia-project.eu/web/multiple-devices, kein Datum)from the InterMedia project: Multiple Devices, **DOI:**10.13140/RG.2.2.32945.10084, download: https://www.intermedia-project.eu/web/results/downloads/

Lesson plan 4: Media & Interactivity

FOUNDATIONAL KNOWLEDGE

Learners learn the principles of multimedia presentations following the cognitive theory of R. Mayer. (https://www.google.at/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwimzZDbge-v0AhWWS_EDHXUCAukQFnoECBEQAw&url=https%3A%2F%2Fkaneb.nd.edu%2Fassets%2F155013%2Fmayer_cogtheory_multimedialearning.pdf&usg=AOvVaw0okYcAa4u62oRCTeMXVIHh, 02.11.2021).

Students learn to evaluate the efficient use of multimedia to deliver information appropriately and efficiently.

EXAMPLES AND ANALOGIES

- Learners study examples
- Learners develop their own (simple) examples and get them evaluated by other learners (group discussion).

APPLICATION AND INTEGRATION

Providing information efficiently and effectively is a common challenge of everyday life.

Example: Group-based learning

Students get short information (two sentences). Three students are selected to prepare the communication to transfer the information to the other student. The transmission uses three approaches:

The first student draws the information on a whiteboard, and the students have to identify the data and write it down. The second student transfers the information in a nonverbal way without drawing or uses of other means. The third student has to summarize the information in one sentence using maximum words. The other students also note the content they can identify.

Finally, the original information is presented. Students give an analysis of which content they got from three “massage conveyors” and where the problem of misunderstanding can be identified. Finally, each student formulates the information in one sentence.

Learners get assessments to develop multimedia-based information in the medical environment.

Example: Develop a multimedia-based presentation to check a patient’s blood pressure as an instruction for beginners.

REFERENCES FOR FURTHER INFORMATION AND AREAS OF INQUIRIES

Further reading (voluntarily): Richard Mayer’s Cognitive Theory of Multimedia Learning

https://www.mheducation.ca/blog/richard-mayers-cognitive-theory-of-multimedia-learning (28.09.2021)

Lesson plan 5: Development of courses.

FOUNDATIONAL KNOWLEDGE

Students learn to understand the “Backward Design” to develop training and courses.

Students learn the basic issues to develop, create, implement, and evaluate learning material.

Students learn about the “method change approach” in a course

Students get informed about the basic standards of the EADTU (European Association of Distance Teaching Universities)(e-Xcellence Framework) to create eLearning courses.

Students get an overview of possible assessments (mainly formative but summative as well) and possible implementation methods.

EXAMPLES AND ANALOGIES

Course development follows general management processes using a top-down concept. These analogies will be used.

APPLICATION AND INTEGRATION

Case study to create a concept to explain the use of a new technical device in medical treatment.

REFERENCES FOR FURTHER INFORMATION AND AREAS OF INQUIRIES

Further reading about the “Plan-do-check-act cycle”(https://asq.org/quality-resources/pdca-cycle, kein Datum) and the e-xcellence framework(https://e-xcellencelabel.eadtu.eu/e-xcellence-review/manual, kein Datum).

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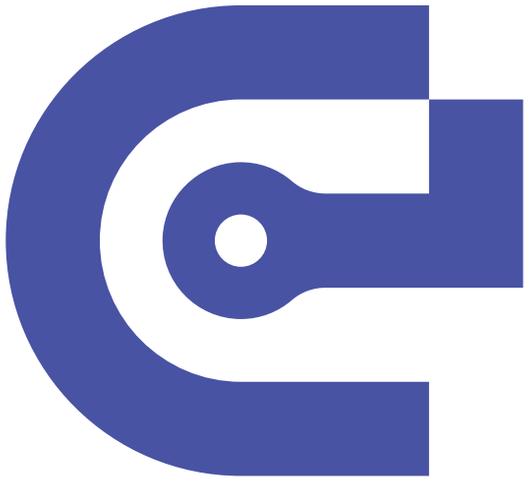

Module 4: Social Media in Health

Learning objectives of the Social Media in Health module

At the end of this module, students will be able to:

1. Understand the advantages and disadvantages of social media in health
2. Differentiate between the concepts of infodemic, misinformation, disinformation, and fake news
3. Identify ways in which social media can be (and is currently) used in global health and development
4. Understand the taxonomy of gamification and how this taxonomy can be used in healthcare
5. Recall the steps involved in developing a social media strategy and link it to programmatic goals and budget

Foundational knowledge of the Social Media in Health module

Social Media Definition

Social media refers to internet-based platforms/tools used for communication, gathering information and/or sharing of information/content. Social media is used to connect and communicate with other users in real-time (Ventola, 2014).

Social Media Platforms

There are a variety of social media platforms. Each platform can offer a range of features that serve a different purpose for different individuals. Social media platforms include:

- Blogs
- Social networks (example: Facebook)
- Video-and-photo sharing sites (example: Instagram)
- Wiki's (example: Wikipedia)

Social media can be used for a variety of purposes (Ventola, 2014):

- Social networking (Facebook, Myspace, Google Plus, Twitter)
- Professional networking (LinkedIn)
- Media sharing (YouTube)
- Content production (blogs, Twitter)
- Knowledge/information aggregation (Wikipedia)
- Virtual reality and gaming environments

In addition to these publicly available platforms, social media platforms are specifically for healthcare providers. These platforms are most often private and not accessible to the lay public or nonmembers (e.g., healthcare providers outside the designated organization).

- Sermo: A physician-only networking platform. It is primarily a large messaging board where physicians create topics for discussion.
- Doximity: A physician-only social networking platform. This platform "offers text and images that are compliant with the Health Insurance Portability and Accountability Act (HIPPA) act, which allows the point of care information crowdsourcing (Ventola,2014).
- Medical Directors Forum: A social networking site for medical directors. This site provides resources, including a comprehensive library and discussion groups

- Student doctor- A social community for undergraduates and participants physicians. This site focuses on clinical career topics.

Social Media in Health:

***Professional Education**:* Social media can provide healthcare professionals with tools to share health information, promote health behaviours, or educate and interact with patients, caregivers, students, and colleagues (Ventola, 2014). Social media is used in health primarily as a tool to improve health outcomes on a national and international level, to professionally network and or to increase awareness of health issues. In addition, healthcare professionals use social media to improve personal knowledge of health-related news and discoveries and provide health information to the community (Ventola, 2014).

***Professional Networking**:* The most popular use of social media in health is for professional networking. In this scenario, healthcare professionals participate in online communities where they can read articles, follow and listen to experts, research new medical developments, and interact and consult with colleagues regarding patient issues. Physicians can share cases and ideas in this community, make referrals, and disseminate their research and market practices for health advocacy (Ventola, 2014).

***Organizational Promotion*:** In addition to networking with other professionals, healthcare providers use social media to promote their organization or services, access continuing education and professional development, or create interest groups. Healthcare professionals can use social media for patient care (Lagu et al., 2016).

Patient Care: The use of social media to directly interact with patients is increasing in popularity. Some healthcare facilities have established platforms where patients can directly contact their doctor to ask questions or request prescription refills.

Patient-Provider Communication: Social media opened the door to better communication between the patient and the provider, offering patients the chance to interact with providers to which they would normally have no access (e.g. providers from other cities or countries) (Junhan & Wang, 2021). Research in this field showed that some challenges exist regarding privacy, confidentiality and skills related to using social media. Still, overall the interactions between patients and providers on social media have benefited them all (Junhan & Wang, 2021).

Patient Education and Public Health Programs: Social media platforms can provide patient education and health monitoring or encourage behavioural changes and drug adherence. This aims to promote better education, "increased compliance and better outcomes " (Ventola, 2014, p. 495)." Further, such platforms could obtain feedback from their patients/clients or link their patients with support groups. The patient can also benefit from social media in health because social media can improve patients' access to health care information. Physicians can use social media to promote patient education by posting health-related videos or participating in specific forums. Forums allow providers to distribute evidence-based information or counter inaccurate material on the Internet (Ventola, 2014).

Similarly, the patient participating in these forums have the opportunity to interact with individuals who may have similar health conditions to them. On these platforms, individuals can exchange health information or tips. Over the years, social media has been widely used to offer health resources and reach and direct campaign audiences and intervention participants, especially populations that otherwise would have no access to health information. Moreover, social media is extremely useful in bridging communication between health professionals, institutions, and the people at large (Junhan & Wang, 2021). Social media is a valuable tool in helping people document and share their progress in different health behaviours and engage in competitions or other challenges related to their health with their peers (Junhan & Wang, 2021).

Facilitate Health-Related Research: Social media has a dual role in facilitating health-related research. First, it provides additional data about patients' disease experiences by analyzing their conversations on social media, which ultimately leads to an enhanced understanding of patients' experiences. Second, social media can potentially recruit participants for health-related research as data shows that social media performs better than traditional methods in terms of recruitment, especially for hard-to-reach populations (e.g. immigrants) (Junhan & Wang, 2021).

Infoveillance: Infoveillance can be defined as "the application of infodemiology with the aim of surveillance". In other words, it refers to surveilling and analyzing the information found over the internet in an unstructured manner to inform public health and policies (Junhan & Wang, 2021). Social media can be used to predict future illness onset for users by analyzing the language and keywords used on social media. Moreover, analyzing emojis and special characters used in social media posts can help predict certain mental health illnesses, asthma, or difficulty breathing syndrome (Edo-Osagie et al., 2019; Thorstad & Wolff, 2019).Infoveillance also has the potential to predict different infectious disease outbreaks, such as in COVID-19, where data shows that social media has the potential to accurately predicts the disease outbreak case count and to use geographical data from social media to inform medical research and practice (Junhan & Wang, 2021).

Seek and Share Health-Related Information: Social media is widely used by the general population for finding and sharing health-related information. Many studies raised concerns related to the quality of the information mentioned above and urged not only efforts to reduce misinformation on social media but also for more sources of reliable health-related details on social media (Junhan & Wang, 2021)

Disseminate Health Information and Combat Misinformation*:* Social media can help health institutions to disseminate health information by rapidly sharing information with the population. Information about healthy living, immunization, disease outbreaks, and prevention can be offered to populations via social media (Junhan & Wang, 2021). Moreover, social media can potentially combat the spread of misinformation by refuting rumours, fact-checking algorithms, and optimization strategies to only display evidence-based health information to users (Junhan & Wang, 2021; Mheidly & Fares, 2020).

Offer and Exchange Social Support for Health-Related Problems: Social media offers an excellent outlet for social support as people with different medical conditions can connect and provide and receive informational support content (Junhan & Wang, 2021). Moreover, people can offer and receive emotional and network support to better manage and cope with their medical condition. Research in the field demonstrated that people with health concerns benefit from participating in online communities by suffering from less discrimination and stigmatization, receiving support promptly, and having a sense of control over the help-seeking process. Overall, it was found that online communities offered better perceived social support and predicted increased subjective well-being of users (Junhan & Wang, 2021).

Concerns when using social media in health:

A primary concern with using social media in health is maintaining confidentiality, privacy, and boundaries concerns. In a breach of confidentiality, a health care professional and their organization may become liable under federal HIPPA and state privacy laws. To comply with HIPPA laws, social media posts must exclude any personal identifying information (of the patient). This is known as "de-identification" and should ensure that no identifiable information is shared. It is suggested that healthcare organizations establish employee guidelines regarding the use of social media and the type of information that can be posted.

Generally, the guidelines should (Ventola, 2014):

- Address leaking of confidential or proprietary information, damage to the organization's reputation, discrimination, harassment, and wrongful termination of service.
- Address expectations regarding employee behaviour outside work perimeters.
- Forbid, limit, and/or monitor employee access to the internet and/or social networking sites while at the job.
- Define employees' responsibilities and actions when witnessing inappropriate use of social media.
- Design policies regarding the use of organizational email addresses and graphics or logos.
- Define disciplinary actions for employees for the inappropriate use of social media.
- Assign and define who can access social media on the organization's premises and for what purpose.
- Ensure that employees acknowledge that they do not represent the organisation when posting material on their social media sites.
- Ensure that employees disclose any possible conflicts of interest.
- Ensure that the employees are familiar with state guidelines regarding patients' privacy.
- Ensure that the employees include a disclaimer when they are not speaking on behalf of the organization.
- Ensure that employees understand the need to adhere to the organization's social media policy.
- Revise or expand current policies regarding informed consent.

For example, in 2012, the American Society of Health-System Pharmacists released guidelines for social media use. These guidelines state that:

- A pharmacist should only provide clinical advice in adherence to professional standards
- Providers should recognize when a patient's needs would be better met with a different form of communication
- Providers should provide timely and accurate information
- Providers should rebut any misleading information
- Providers must protect patient's privacy
- Providers must maintain their reputation during anonymous or personal use of social media

Another risk with social media in health pertains to difficulties in upholding a professional image. Because social media inevitably convey information about an individual's personality, values, and priorities, posting unprofessional images risks healthcare providers and their organization's preserved professionalism. Amateur content can include violations of a patient's privacy, discriminatory pictures or use of discriminatory langue etc. (Ventola, 2014). The guidelines established by a healthcare organization should address what is deemed to be unprofessional content.

Lesson plans for the Social Media in Health module

Lesson plan 1: Social media in healthcare

FOUNDATIONAL KNOWLEDGE

Social media is constantly evolving. Therefore, it is impossible to cover the thousands of global and local platforms. What is trending now can become obsolete a year from today. MySpace was once the largest social networking platform globally, with over 200 million users in 2008. Today, only a fraction of users are still active. While Youtube, Facebook, Twitter, Instagram, Snapchat and Tik Tok are currently the most widely used social media platforms, that statistic can change in the coming years (Brooke &Anderson, 2021).

With the expansion of the internet worldwide, social media quickly became part of most people's life – see and use statistics images from: https://www.broadbandsearch.net/blog/internet-statistics and https://ourworldindata.org/internet

Social media offers significant opportunities for global health organizations to enhance their engagement in community dialogue, contribute to ongoing problem-solving, recognize the work of partner organizations, and help improve mass media coverage of global health issues. Social media can be an addition to traditional media methods (television, print media, billboards, etc.), further expanding the reach and reinforcement of critical health and development messages. Research shows that social media currently reshapes health information management by providing cost-effective ways to improve patient-provider communication and exchanging health-related information and experience with medical professionals (Zhou et al., 2018). More and more people are searching for information online, especially with the new pandemic of COVID-19. Data from Eurostat from 2020 shows that before 2019, 53% of the EU citizens aged 16-74 sought online health information (Eurostat, 2020). In 2020, one in two EU citizens aged 16-74 reported seeking health information online, the total percentage growing to 55%.

Additionally, 20% of EU citizens reported consulting their doctor using the internet and 13% accessed other health services via apps and websites instead of visiting a doctor in person (Eurostat, 2021). The health information sought varies from online discussions about specific diseases (e.g. cancer) to different public health concerns (e.g. food waste, pollution) (Zhao & Zhang, 2017). During the COVID-19 pandemic, a lot of health information was related to the virus, from prevention methods to quarantine and self-isolation practices (Soroya et al., 2021).

These trends lead to more people using the internet and web search engines for obtaining health advice or information online (Arora, McKee, and Stuckler 2019). This phenomenon led to the apparition of new terms, such as "Dr Google" and mobile health apps, being used especially by younger and e-health literate patients (Cocco et al. 2018; Jungmann et al. 2020; Huisman, Joye, and Biltereyst 2019; Ieraci 2018; Thapa et al. 2021). For these patients, using Google positively impacted doctor-patient interaction and was unlikely to reduce adherence to treatment (Cocco et al., 2018). Social media can empower people to make better and informed health decisions and develop personal health information management. Health information management is defined as "activities people perform to acquire, organize, maintain, share, retrieve, and use health information items to complete healthcare tasks and fulfil their needs" (Zhou et al., 2018).

Moreover, social media provides the opportunity to generate vast content from social media users, advancing health science and creating support communities for patients (Zhou et al., 2018). This phenomenon also allowed health professionals to transition from simple consumers of social media to educators for the public (Giustini et

al., 2018; Ieraci, 2018) and for social media to be used in medical education with promising results (Cheston et al., 2013).

Also, by joining online professional networks, clinicians may be encouraged toward new ways of learning, not just access to content. Still, they can also become "skilled in the arts of critical appraisal and willing to interact with knowledge producers to provide thoughtful and meaningful critiques of their work." (Chan et al., 2018).

The major benefits of social media in healthcare settings are as follows:

- increased interactions among healthcare stakeholders
- more available, shared, and tailored information
- increased accessibility and widening access to health information
- peer/social/emotional support
- public health surveillance
- potential to influence health policy (Chan et al., 2018).

Although social media showed promising results in improving healthcare, research in this field is still relatively novel, with many technical, behavioural, and data management issues to be fixed in the future (Zhou et al., 2018). Studies show that many available websites and health apps only increase emotional distress and have inadequate information accuracy, quality, trustworthiness, and readability (Rothrock et al., 2019; Jungmann et al., 2020). Research, especially during the COVID-19 pandemic, also showed that health literacy plays an essential role in managing online health information, and globally most people have poor health literacy skills, thus leading to poor skills in managing online health information (Paakkari and Okan 2020). Social media resources' volume and instant accessibility mean that learners (and their educators) need new skills. These skills refer to filtering the volume of material available, critically appraising social media content, and reconciling the use of social media resources with those considered more "traditional" (Roland and Brazil 2015). To filter the relevant, quality content for clinical learning, people must have a strategy, including technical skills (e.g., web-based aggregators) and familiarity with contemporary (and emerging) platforms.

EXAMPLES AND ANALOGIES

Examples of good practices in using social media:

1. Official social media accounts for WHO, CDC, etc.: https://www.youtube.com/channel/UC07-dOwgza1IguKA86jqxNA, https://www.youtube.com/user/cdcstreaminghealth
2. Contributing to science together – example of a research article stating as authors the participants in the intervention

   Cooper, Seth, Firas Khatib, Adrien Treuille, Janos Barbero, Jeehyung Lee, Michael Beenen, Andrew Leaver-Fay, David Baker, Zoran Popović, and Foldit players. 2010. "Predicting Protein Structures with a Multiplayer Online Game."*Nature 2010 466:7307* 466 (7307): 756–60. https://doi.org/10.1038/nature09304.
3. Social Networks for patients: such as Patients Like Me - https://www.patientslikeme.com/
4. Google Trends: https://trends.google.com/trends/?geo=RO
5. Preparedness information for certain disasters: https://blogs.cdc.gov/publichealthmatters/2011/05/preparedness-101-zombie-apocalypse/ and https://emergency.cdc.gov/ and https://www.challenge.gov/
6. Digital Disease Detection via Health Map -https://healthmap.org/en/
7. Health apps: Certified by the Food and Drug Administration - https://apps.healthskouts.com/

8. How Social Media Impacts Healthcare:https://www.youtube.com/watch?v=xBBgnyD3A5Y
9. Andrew Huberman – Huberman Lab Podcast – Discussing neuroscience: https://www.youtube.com/channel/UC2D2CMWXMOVWx7giW1n3LIg

Examples of bad practices in using social media:

Germani, Federico, and Nikola Biller-Andorno. 2021. "The Anti-Vaccination Infodemic on Social Media: A Behavioral Analysis."*PLOS ONE* 16 (3): e0247642.https://doi.org/10.1371/JOURNAL.PONE.0247642.

APPLICATION AND INTEGRATION

Think about how you might use or have used the internet for health and care. Did you have any benefits from that search? Are there other benefits you would add that weren't mentioned in this lesson? Besides misleading advice, what would you consider negative aspects of social media in healthcare? Please share your thoughts in the discussion.

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Lesson plan 2: Infodemic, disinformation, misinformation, and fake news: how to spot and verify them

We live in a time where any information can be transmitted around the globe in seconds, regardless of its correctness (Maxwell, 2021). Individuals must develop critical thinking to select the correct, updated and error-free information as much as possible. Unverified online information can shake public beliefs about science, health, politics, cultural norms etc. (Maxwell, 2021). With a large amount of information available, much confusion might appear regarding health information. This phenomenon was first coined in 2003 when the words "information" and "epidemic" were combined into the word infodemic (Briand, 2021). The World Health Organization defines an infodemic as the "overabundance of information, both online and offline – including mis/disinformation, that occurs during an epidemic"(Briand, 2021). The infodemic spreads among people similar to a disease epidemic, and it makes it hard for people to find reliable and trustworthy sources of information; during the COVID-19 pandemic, the infodemic was exacerbated by the global scale of the emergency (WHO, 2020). This phenomenon has led to poor observance of public health measures, stigmatization of different groups, health risks and a reduction in the effectiveness of efforts to contain and stop the pandemic (WHO, 2020). Below, we can see some important terms when discussing health information.

Disinformation is intentionally false information, while **misinformation** is unintentionally incorrect information. So when we talk about "mis-"and "dis- ", we talk about the intentionality of spreading such news (Crawford et al., 2016).

How to identify, expose and understand disinformation online?

The 4D model of disinformation campaigns:

- Dismiss: “Don’t listen to them, because [..]” – trying to silence the witness (adding an insult)
- Distort: “If the facts don’t suit your story, make your facts”- inventing data (fake evidence)
- Distract: “If the conversation is getting uncomfortable and unfavourable, change the subject and accuse somebody else of the same thing” – changing the path of the conversation, focus on something else
- Dismay: “Try to scare people off” – if someone says that is going to do something unfavourable to you, explain to them what the disadvantages will be (rhetorical perspective) (Crawford et al., 2016).

Fake news can be seen as a deception intended to influence someone else’s perception of a specific subject. This deception can be done through false or misleading content released on social channels (Crawford et al., 2016). Research showed that fake news related to health could create confusion and influence the uptake of different treatments and vaccination (Domenico et al., 2021). Moreover, research conducted during the COVID-19 pandemic showed that fake news in health could cause various psychological disorders, fear, fatigue, confusion, panic and depression in different nationalities and populations. All reports indicate that people trust the information on social media and that it affects their health decisions (Rocha et al., 2021). The latest COVID-19 pandemic showed that health professionals are willing to combat fake health information and consider it their duty as medical professionals (Bautista et al., 2021). Researchers in the field developed a conceptual model for healthcare professionals to correct health misinformation on social media, as shown in Figure 1 (Bautista et al., 2021).

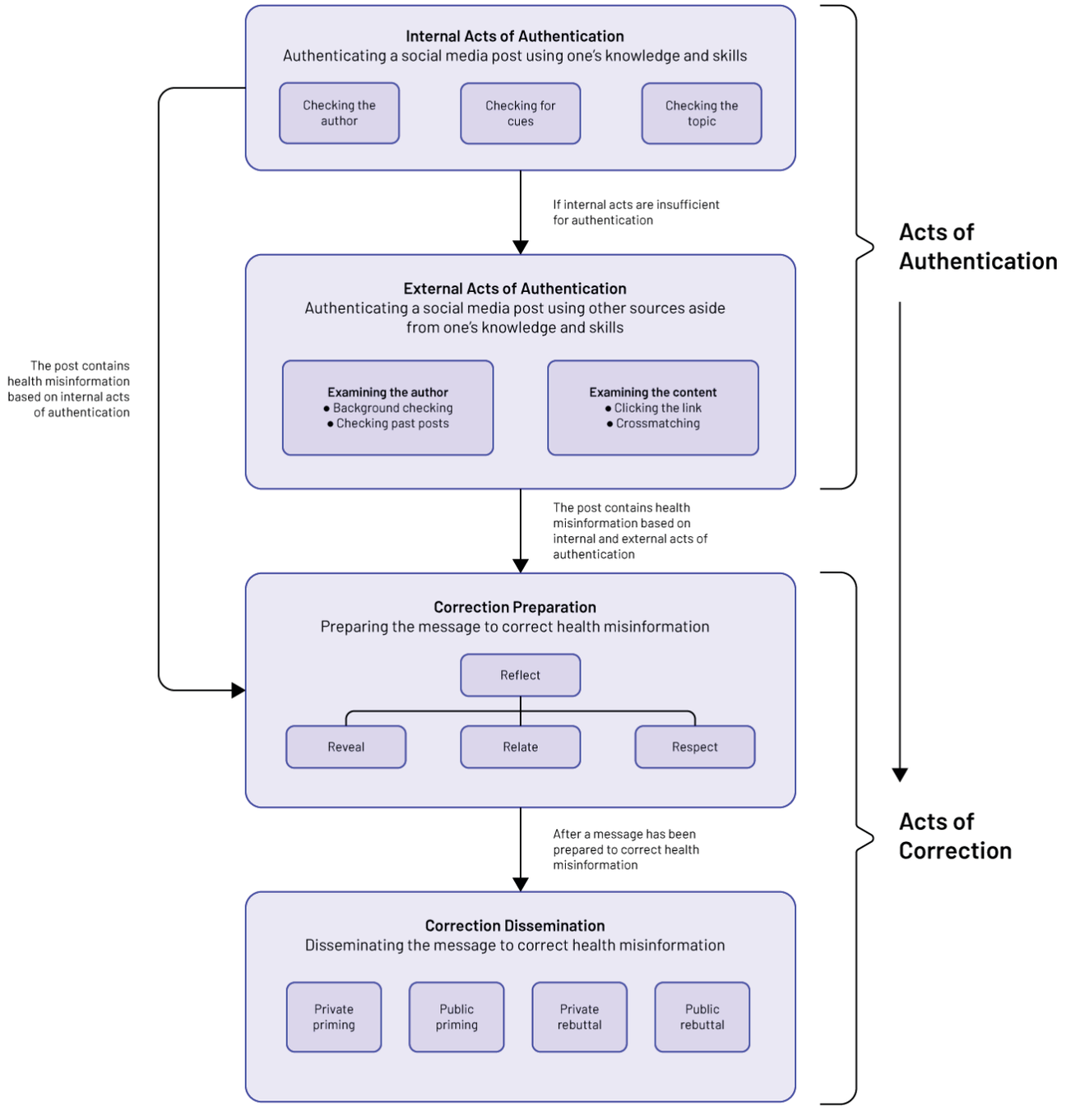

Fig. 4.1. Conceptual model for healthcare professionals to correct health misinformation (Bautista et al., 2021)

COVID19 pandemic and vaccines: a case study

To give you a sense of how fake, the best example is how the COVID-19 pandemic and vaccination generated a lot of discussions on social media platforms. Sarah Brandt, the Vice President of the News Literacy Program at NewsGuard, discussed how over 300 websites with a big audience had spread dangerous lies about the disease since March 2020, when it was brought to attention (Brandt, 2021). Many websites which were spreading alarming news about the deadly effect of vaccines also have official-sounding names like “CDC.News”, “Science.

news" that are more appealing to individuals and eventually generate a big audience (Brandt, 2021). Inserting small amounts of false information into many places works as a strategy to spread a larger disinformation message (Crawford et al., 2016). To understand this association better, think about money laundering. To give you an example, to get rid of suspiciousness, individuals who do such things as money laundering do not deposit a large amount of money in a bank account, so they will not be questioned about it. So, fake news spreads quickly among the population by inserting a small amount of health information in many places on social media (Youtube, Twitter, Facebook, etc.).

Research in the field that used sentiment analysis as a tool for analyzing social media posts from Reddit related to COVID-19 shows that although sentiments expressed in the community are overall positive than negative, vaccine hesitancy was highly prevalent in the discussion. They call for action to strengthen vaccine confidence on social media (Melton et al., 2021).

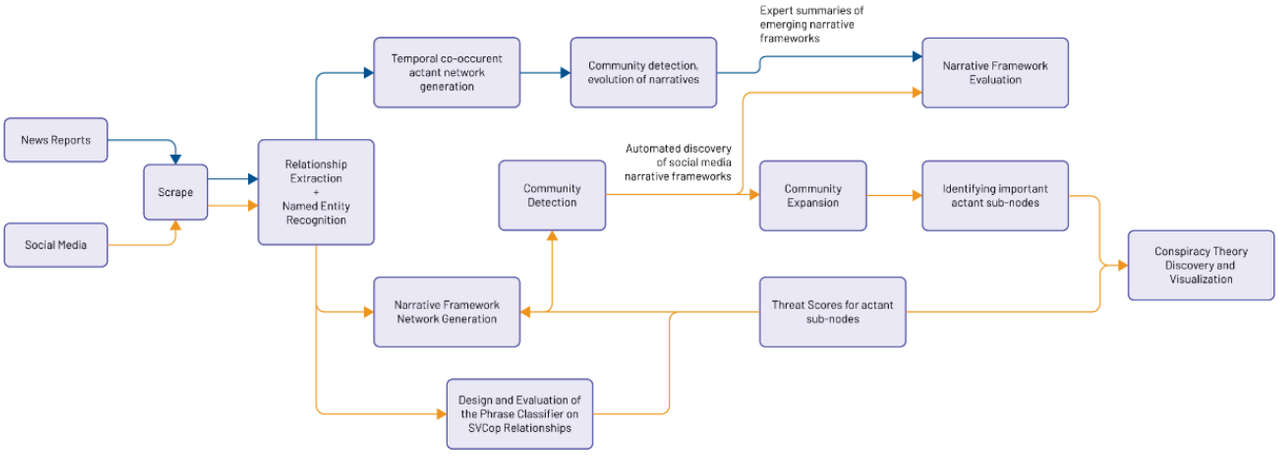

Fig. 4.2. The automated pipeline of processing data
and discovering fake news (Shahsavari et al., 2020)

However, it is hard to destroy all those news and educate populations in a relatively short time since these websites arise overnight. Research in the field focuses on developing tools for early detecting fake news to neutralize them in the shortest possible time. Such devices include machine learning neural networks (Liu & Brook, 2020; Shahsavari et al., 2020)

Moreover, due to the amplitude of the infodemic at global level, WHO established the Network for Epidemics (EPIWIN) to disseminate and amplify evidence-based information about COVID-19, and to track and respond to misinformation, myths and rumours (Briand, 2021). The EPIWIN network developed a competency framework for infodemic management that can assist institutions in strengthening their infodemic management capacity. The framework is conceptualized around the five workstreams for infodemic preparedness and response along the epidemic curve, analogous to an epidemic response, as can be observed in Figure bellow (Briand, 2021).

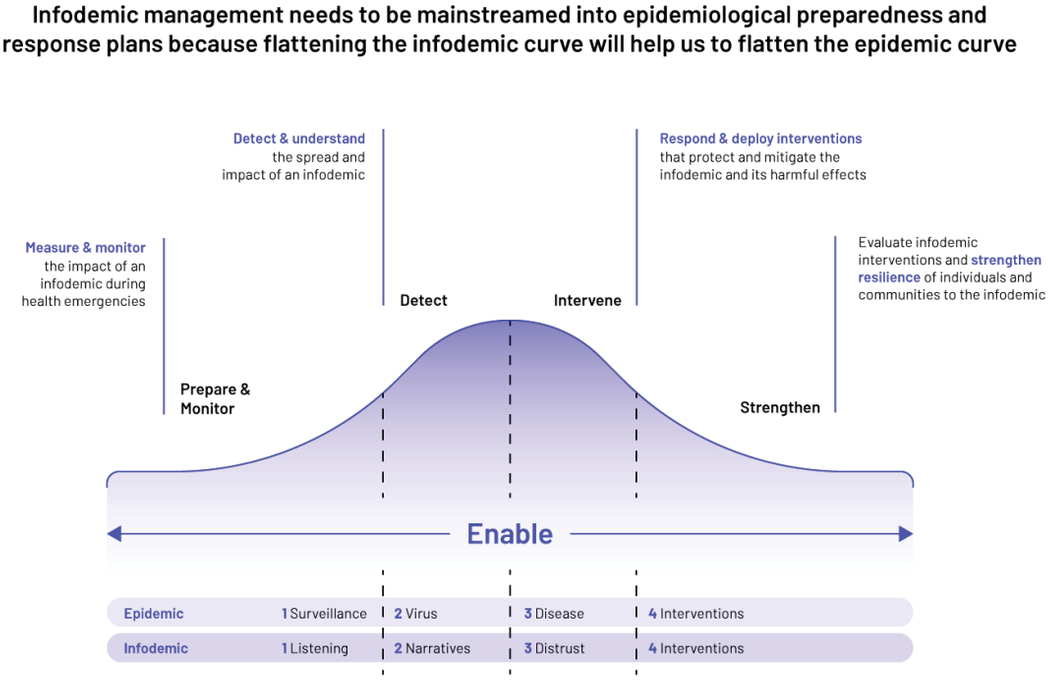

Fig. 4.3. The five workstreams in the epi curve of an infodemic response, analogous to the epidemic response (Briand, 2021)

The five workstreams of the framework are (Briand, 2021):

Workstream 1. Measure and monitor the impact of infodemics during health emergencies.

The application of standardized metrics and tools is needed to track the evolution of infodemics among individuals, communities, societies, and health systems in both digital and physical information environments.

Workstream 2. Detect and understand the spread and impact of infodemics.

A common approach is needed to understand how information and mis/disinformation is spread and how it affects online and offline behaviour in different populations.

Workstream 3. Respond and deploy interventions that mitigate and protect against the infodemic and its harmful effects.

An evidence base is needed to identify effective interventions in different contexts and for different types of acute health events.

Workstream 4. *Evaluate infodemic interventions and strengthen the resilience of individuals and communities to infodemics.*

Standard evaluation frames are needed to improve the development of interventions and programmatic responses to infodemics.

Workstream 5. Enable, and promote the development, adaptation and application of tools for the management of infodemics.

There is a need to enhance the transferability of lessons and evidence-based interventions between contexts, countries and infodemics

The competency framework also comprises four main domains:

1. Infodemic management – competencies in infodemiology;
2. Prepare and monitor - competencies in the use of effective tools to listen to target audiences and how to design and share appropriate health information;
3. Detect and intervene - competencies to design, implement and evaluate interventions to promote resilience to mis/disinformation and to empower individuals and communities to exercise their right to access quality health information;
4. Strengthen - competencies to empower health systems to ensure healthier populations through better IM in emergencies and regular contexts (Briand, 2021).

This competency framework also has a set of related tasks, knowledge and skills needed to perform the activities presented under each main domain. This framework can help stop the present and future infodemics (Briand, 2021).

EXAMPLES AND ANALOGIES

Disinformation, Misinformation and Fake News in Teach-Out: https://online.umich.edu/teach-outs/disinformation-misinformation-and-fake-news-teach-out/lessons/

1. **Some practical manners to discover fake news detection in the following article:**

Saxena, A., Saxena, P., & Reddy, H. (2022). Fake News Detection Techniques for Social Media. *Smart Innovation, Systems and Technologies*, *246*, 325–354. https://doi.org/10.1007/978-981-16-3398-0_15

2. **Case study of fake news related to health:**

Waszak, P. M., Kasprzycka-Waszak, W., &Kubanek, A. (2018). The pilot quantitative study is the spread of fake medical news in social media. Health policy and technology, 7(2), 115-118.

3. **Sentiment Analysis on social media posts related to vaccination:**

Melton, C. A., Olusanya, O. A., Ammar, N., & Shaban-Nejad, A. (2021). Public sentiment analysis and topic modelling regarding COVID-19 vaccines on the Reddit social media platform: A call to action for strengthening vaccine confidence. *Journal of Infection and Public Health*, *14*(10), 1505–1512. https://doi.org/10.1016/J.JIPH.2021.08.010

APPLICATION AND INTEGRATION

Consider how you've shared information lately: have you shared it on a social media post? Emailed a news story to a family member? Had a conversation about a current event? Pick one example, then answer:

- Why did I think this was important to share or talk about?
- Did I review the social media post or a news story before sharing it?
- Did I add any personal perspective?
- Who was my audience? How did I think they'd react to the story?

Please share your answer in the discussion section.

REFERENCES FOR FURTHER INFORMATION AND AREAS OF INQUIRIES

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Saxena, A., Saxena, P., & Reddy, H. (2022). Fake News Detection Techniques for Social Media. *Smart Innovation, Systems and Technologies*, *246*, 325–354. https://doi.org/10.1007/978-981-16-3398-0_15

Briand, S. (2021). *WHO competency framework Building a response workforce to manage infodemics*. https://www.who.int/publications/i/item/9789240035287

Lesson plan 3: Gamification and social media

FOUNDATIONAL KNOWLEDGE

Game-playing is generally characterized by its voluntary nature, goals, and predetermined rules that limit the scope of one's activity. Following this same concept, gamification is an emerging area of research and practice that incorporates game design elements in a non-gaming context to engage better and motivate consumers (Garett and Young 2018).

Most of the research on games and health has focused on their potential for harm. Exposure to violent games has been related to aggressive behaviours, violent desensitisation, and decreased pro-social behaviour. However, more data is suggested to be achieved for better conclusions (Ferguson, Copenhaver, and Markey 2020).

Games also have been associated with (Primack et al., 2012):

- Inactivity and development of obesity
- Game addiction
- Seizures
- Motion sickness
- Musculoskeletal pain related to computer and video game use

However, there is research showing that games are being used to improve health outcomes by:

- increasing physical activity, and therefore reducing obesity (Sween et al. 2014)
- distracting patients from acute/chronic pain (Primack et al. 2012)
- educating on self-management for different diseases such as asthma, cancer and diabetes (Gentry et al. 2019)
- training other medical professions (e.g. surgeons) (Primack et al. 2012; Gentry et al. 2019)

Researchers in the gamification field suggested that gamification needs to be tailored according to the target audience and developed a taxonomy for the best game elements to be used in gamification (Toda et al., 2019).

Table 4.1. Taxonomy of game elements for gamification (Toda et al., 2019)

Concept	Description	Affected Behaviour
Acknowledgement	All kind of feedback that praises the players' specific actions. Some examples and synonyms are badges, medals, trophies.	Engagement
Chance	Randomness and probability characteristics to increase or decrease the odds of certain actions of outcomes. Some examples and synonyms are randomnesses, luck, fortune.	Engagement
Competition	When two or more players compete against each other towards a common goal. Some examples and synonyms are Player vs Player, scoreboards, conflict.	Engagement Motivation
Cooperation	When two or more players collaborate to achieve a common goal. Some examples and synonyms are teamwork, co-op missions.	Motivation
Economy	Transactions within the game, monetising game values and other elements. Some examples and synonyms are markets, transaction, exchange.	Engagement
Imposed Choice	Decisions that the player is obliged to make in order to advance the game. Some examples and synonyms are judgements, foced choices. *(not to be confused with Narrative)*	Engagement Motivation
Level	Hierarchical layers present in a game, which provide a gradual way for the player to obtain new advantages as they advance. Some examples and synonyms are character levels, skill level.	Engagement
Narrative	Order of events where they happen in a game. These are choices influenced by the players' actions. Some examples and synonyms are the strategies the player uses to go through a level (stealth or action), also the good or bad actions that influence the ending, karma system. *(not to be confused with Imposed Choice)*	Motivation
Novelty	New, updated information presented to the player continuously. Some examples and synonyms are changes, surprises, updates	Engagement Motivation
Objectives	Guide the players' actions. Quantifiable or spatial, from short to long term. Some examples and synonyms are missions, quests, milestones.	Engagement Motivation
Point	Unit used to measure users' performance. Some examples and synonyms are scores, number of kills, experience points.	Engagement
Progression	This allows players to locate themselves (and their progress) within a game. Some examples and synonyms are progress bars, maps, steps.	Engagement
Puzzles	Challenges within the game that should make a player think. Some examples and synonyms are actual puzzles, cognitive tasks, mysteries.	Engagement
Rarity	Limited resources and collectables. Some examples and synonyms are limited items, rarity, collection.	Engagement
Renovation	When players are allowed to redo/restart an action. Some examples and synonyms are extra life, boosts, renewal.	Engagement
Reputation	Titles that the player accumulates within the game. Some examples and synonyms are titles, status, classification.	Engagement Motivation
Sensation	Use of players' senses to create new experiences. Some examples and synonyms are visual stimulation, sound stimulation.	Engagement
Social Pressure	Pressure through social interactions with another player (s) (playable and non-playable). Some examples and synonyms are peer pressure, guilds.	Engagement Motivation
Stats	Visible information used by the player, related to their outcomes within the game. Some examples and synonyms are results, health bar, magic bar, HUD, indicators, data from the game presented to the user.	Engagement
Storytelling	It is the way the story of the game is told (as a script). It is told within the game, through text, voice or sensorial resources. Some examples and synonyms are stories told through animated scenes, audio queues or thext queues during the game.	Engagement
Time Pressure	Pressure throgh time within the game. Some examples and synonyms are countdowns, clock, timer	Engagement Motivation

One aspect mentioned about gamification is the need to use more evidence-based, theory-driven empirical evaluations of the gamified solutions (Gentry et al., 2019; Sardi, Idri, and Fernández-Alemán, 2017; Cotton and Cotton and Patel, 2018).

Case study: What elements should be used for gamification in the virtual learning environments

Tenório M.M., Reinaldo F.A.F., Góis L.A., Lopes R.P., dos Santos Junior G. (2018) Elements of Gamification in Virtual Learning Environments. In: Auer M., Guralnick D., Simonics I. (eds) Teaching and Learning in a Digital World. ICL 2017. Advances in Intelligent Systems and Computing, vol 716. Springer, Cham. https://doi.org/10.1007/978-3-319-73204-6_12

EXAMPLES AND ANALOGIES

Examples of gamification in health:

Fitness and nutrition – preventive measures:

1. FitBit - common challenges can be set up through the Fitbit community interfaces and how competition could motivate better gym performances and step counts
2. Fitness Syncer - collects data from trackers and apps we already use to allow friends to compare one another's progress
3. CafeWell – gives guidance and support to people who want to live healthier lives. Its personalized programs focus on your needs to eat better, incorporate exercise into your life, reduce stress, or walk that extra mile.
4. Vivofit jr. - encourages kids to stay on the move.
5. My Fitness Pal – manages nutritional data

Management of diseases:

1. Mango Health - motivate patients to take their medications on time. Users set the times when medications should be taken, and the app reminds them. It also provides medication information and warns about drug interactions and side effects. Users earn points towards gift cards or charitable donations in weekly raffles by taking the medications properly.
2. Bayer's Didget blood glucose meter - which connects to a Nintendo DS gaming platform, is intended for kids between 4 to 14. It helps manage their diabetes by rewarding them for consistent blood glucose testing. As points accumulate, new game levels and options unlock. There are leader boards with kids who collected the most points, web games and an online community.
3. MySugr- gamified solutions for diabetes management in a fun way both for children (mySugr Junior app) and adults.
4. Monster Guard - helping prepare children for emergencies. It teaches kids through "Monster Guard Academy" how to prepare and stay safe during home fires, hurricanes, floods or other disasters, and they get points and medals for completing tasks.
5. Cohero Health – help asthma patients with their medication and treatment
6. Medi&Cate – offer a range of stimulating games for medication adherence

Rehabilitation:

1. SCI Hard gaming app developed by the University of Michigan. Gamified therapies could help make rehabilitation more fun, playfully stretching and divert attention from pain.
2. GestureTek Health - applications specific to health, disability, and rehabilitation. Its VR exercise programs enable patients to have fun while stretching their physical and cognitive capabilities.
3. MindMaze – devices which use virtual reality, brain imaging and gaming technologies to retrain the brain in stroke victims. It also works on solutions for spinal cord injury and amputee patients.

Coping and improving health

1. Re-mission game series - helping children and young adults suffering from various forms of cancer (Kato et al. 2008)
2. Ayogo - employs validated measures of perceived self-efficacy and other psychosocial factors to understand better what people value in their lives – not just their health. This enables timely, personalized, relevant interventions to enhance self-management and improve health outcomes.

Mental health

1. Eqoo – mental health app to grow resilience, improve relationship skills and increase mental well-being.
2. Balance– offers personalized meditation to improve mental health.
3. Headspace – offers meditation and mindfulness techniques to relieve stress.
4. MindShift– uses CBT (cognitive behavioural therapy) to help people living with anxiety.

APPLICATION AND INTEGRATION

Use gamification to design a health app to increase sexual education among teenagers. What are the specific and mandatory elements that the app should contain?

REFERENCES FOR FURTHER INFORMATION AND AREAS OF INQUIRIES

All articles and websites referenced above

Tenório M.M., Reinaldo F.A.F., Góis L.A., Lopes R.P., dos Santos Junior G. (2018) Elements of Gamification in Virtual Learning Environments. In: Auer M., Guralnick D., Simonics I. (eds) Teaching and Learning in a Digital World. ICL 2017. Advances in Intelligent Systems and Computing, vol 716. Springer, Cham. https://doi.org/10.1007/978-3-319-73204-6_12

Toda, A. M., Oliveira, W., Klock, A. C., Palomino, P. T., Pimenta, M., Gasparini, I., Shi, L., Bittencourt, I., Isotani, S., & Cristea, A. I. (2019). A taxonomy of game elements for gamification in educational contexts: Proposal and evaluation. *Proceedings - IEEE 19th International Conference on Advanced Learning Technologies, ICALT 2019*, 84–88. https://doi.org/10.1109/ICALT.2019.00028

DeSmet, Ann, Ross Shegog, Dimitri van Ryckeghem, Geert Crombez, and Ilse de Bourdeaudhuij. 2015. "A Systematic Review and Meta-Analysis of Interventions for Sexual Health Promotion Involving Serious Digital Games." *Https://Home.Liebertpub.Com/G4h* 4 (2): 78–90. https://doi.org/10.1089/G4H.2014.0110.

Lesson plan 4: Developing a Social Media Strategy

FOUNDATIONAL KNOWLEDGE

In global health and development, social media can be used in many ways:

1. Disseminate vital health information and research, such as the World Health Organization Facebook page, which has constant events such as the World Health Organization's live Q&A on Facebook announcing the updated 2015 Medical Eligibility Criteria or the Live Briefing of COVID-19
2. Create a community of practice around a specific topic, such as Global Health (via Meetup), an online social networking site that facilitates offline local "meet-ups")
3. Connect with other professionals on closed or open Facebook groups for medical laboratory scientists
4. Track and monitor disease outbreaks, such as the use of social media during the Ebola crisis and COVID-19 pandemic (Topf& Williams, 2021)
5. Advocate for change, such as the #BringBackOurGirls or #MeToo campaign
6. Promote individual and/or organizational accomplishments and knowledge
7. Expand on fundraising efforts

Individuals and organizations participate in social media for a range of reasons. Some use social media to engage with others who share a concern or passion in hopes of learning how to do it better. As they interact regularly, they ultimately create a community of practice. Others use social media to push information forward about a topic they care about.

Below we provide a list of resources for those interested in participating in global health communities of practice specifically and in developing social media content in general.

Communities of Practice

- +Social Good: This is a global community where people share world-changing ideas and spark action via social media. The group also hosts the annual +Social Good Summit, a two-day conference held during United Nations Week.
- SM4GH Working Group: Social Media for Global Health connects those working in global health development and social media.

Resources for developing good social media content

- Social Media Toolkits: A social media toolkit or packet that allows sharing social media campaigns with others. Social media toolkits provide others with a campaign @ and #, sample Tweets and Facebook updates, visuals/infographics to share, and a schedule of events. For example, End Malaria develops a social media toolkit annually for World Malaria Day
- Bit.ly: Many social media platforms restrict the number of characters per posting. Consider free URL (or website address) shortening services such as a bit.ly to maximize relevant content.
- Photo Editing: Photo-editing programs, such as Photoshop, PicMonkey, and Canva, can help create captivating visual content.
- Infographics: Great visual content comes from infographics (visual images with illustrations, charts, or diagrams to represent information or data). Programs like Piktochart, Canva, Infogr.am, and Visual.ly can help create illustrative infographics.

Social media's popularity consists of its accessibility: it is easy to use and is free in most parts of the world. With the potential for people to connect, express, learn, engage, and act with the simple push of a button, the power of social media is undeniable.

Social media most easily fits into the communications and dissemination activities within projects or organizations. The actual social media posts can be a joint effort, but management and strategy should be centralized within the communications staff. Developing a social media strategy and budget allows social media to be easily integrated into programmatic work plans and proposals.

Creating a Social Media Strategy

One of the first considerations for an organization or project is to develop a social media strategy. This will help determine how involved they will be in social media and the expected outputs. Every organization has different needs and audiences that will impact the development of the strategy.

A well-developed strategy includes the following nine steps:

1. Goals and objectives to match the communication or dissemination strategy
2. Identification of audience
3. Selection of appropriate social media platforms based on goals and audience
4. Definition of metrics and data collection tools to reach goals and objectives
5. Content management guidelines for staff
6. Adoption of a follower policy
7. Social media budget
8. Benchmarking
9. Considerations for maintaining security and privacy

Once the organization or project has a strategic policy, it is recommended to review it each year to see if the needs and audiences have changed over time.

Step 1: Define Goals and Objectives

Consider the following questions:

- Does the organization have a mission and programmatic goals? How can social media help the organization meet that mission or increase brand awareness?
- Does the organization have donors or other stakeholders? How can social media be used to improve or establish relationships with these stakeholders? Will social media be used for fundraising?
- Does the organization advocate for policy or behaviour change? How can social media increase actions or behaviours?
- Does the organization produce publications and resources on a global health and development topic? How can social media be used to reach different stakeholder groups with the relevant information?

Answers to these questions can guide in developing social media goals. These goals should clearly define what is hoped to achieve through social media. Goals are broad principles that guide decision-making. *An example would be: To increase brand awareness of my organization in 2022.*

Objectives are specific and describe how the determined goals will be reached. If the goal is to increase brand awareness, the objective could be*: To increase fans on Facebook by 5% through two awareness campaigns in 2022.* To be able to measure if the goals are achieved, they should be SMART.

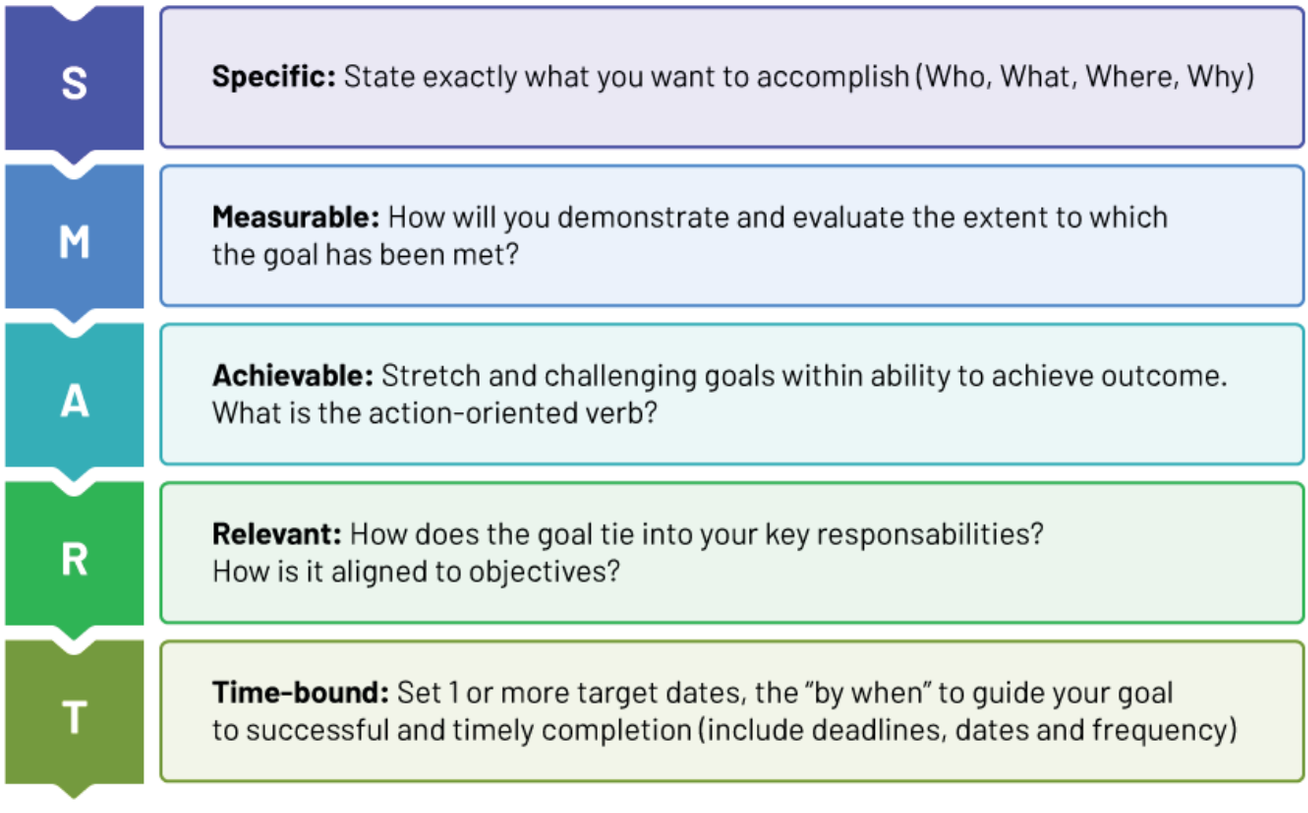

Fig.4.5. SMART objectives (Fuhsharon,n.d.)

S stands for Specific - The objective should say who or what is the focus of the effort and what type of change is intended.

M stands for Measurable - The objective should include a verifiable amount or proportion of change expected.

A stands for Achievable - The objective should be feasible and easy to put into action

R stands for Realistic - The objective should include a degree of change that can reasonably be achieved under the given conditions.

T stands for Time-bound - The objective should clearly state the period for achieving these behaviour changes.

Step 2: Identify the audience

Consider the following questions:

- Who is the organization trying to reach?
- Where can they be found on social media?

It is important to understand the audience, what platforms they are already using, and how your organization is currently connecting with them. Once the audience is known, information on where to target them on various platforms and how to allocate resources is needed.

There are two main types of audiences:

- Local: May include students and faculty from a local university, journalists, community members, program managers at local NGOs, or private groups such as clients or a community of practice.

- International: May include donors, cooperating agencies such as NGOs, Ministry offices and officials, policy-makers, or a community of practice.

Below are some strategies for identifying the social media audience:

- Develop a list of various stakeholders, individuals, and groups influencing your organization and mission.
- Search for their social media accounts and follow, like, or subscribe.

Once the audience is identified, the social media content should be tailored to different audience segments. It is important to remember that social media campaigns will attract other audiences who may not have considered beforehand.

Step 3: Select the platforms

Social media platforms need to be selected now that the audience has been identified. Channels include Facebook, Twitter, WhatsApp, LinkedIn, Pinterest, Tik Tok, YouTube, and more.

Consider the following questions before selecting the social media platform(s):

- Where does the audience connect: Via text, mobile app, or online social media platforms?
- Which platforms does the audience use?
- How much time needs to be committed to each platform?
- Can you monitor and provide ongoing feedback, support, and participation?

Some helpful resources include the following:

- Conversation Prism 5.0 - is a visual map of social media platforms with categorizations of platform functionalities and purposes.
- Statista – shows real-time statistics of social media platform use.
- Buffer Analyze is a social media analytics tool for online brands that want to make better decisions about their social media strategy and measure their results without feeling overwhelmed.
- Sprout Social is a comprehensive social media management and monitoring tool that provides various enterprise-level options.
- Hootsuite is a great combination of social media management, listening, publishing and analytics tools.
- Zoho Social is a unique and powerful software suite with CRM, collaboration, and other SaaS options that take care of your entire operational workflow.
- Sendible is a social media management tool with considerable monitoring, listening and reporting features.
- Keyhole offers trackers that help you monitor your events, campaigns, influencer activity, brand mentions, and industry-specific social conversations.
- Rival IQ lets you track the number of different companies and compare their performance across social media platforms and SEO.
- Social Report - provides an overview of your activity on multiple social networks and blogs (Read, 2021).

Remember that sometimes not using a specific technology is fine. Do not get caught up in being on every social media platform. Start small on Facebook and/or Twitter or any other relevant platform in your country. As you learn more about your audience, build other social media platforms to meet them.

Step 4: Define the Metrics and Data Collection Tools

Measuring social media activity allows your organization to understand and improve social networks. Key performance indicators (KPIs) are the most important metrics for charting progress toward your SMART goals and objectives.

Many social media platforms and social media management systems (SMMS) provide their analytics. It is essential to keep track of how the activity is measured. A great way to start is to create a spreadsheet to monitor and report.

Collect the data, analyze the data, turn what you have learned from your data into action, and start measuring again. Collect data in regular weekly or monthly increments.

Step 5: Develop Content Management Guidelines

It is important to create simple guidelines for staff members regarding what is appropriate to post, an overview of privacy and legal issues, and general rules about using social media during office hours. These guidelines should address the following:

- Outline the tone of your organization's social media content. It is essential to remain professional, accurate, and respectful but also personable and accessible. Be prepared to accept and respond to comments. Understand that some words may not be positive, and respond to negative comments professionally by providing additional information that may help resolve the issue.
- What is the frequency of social media messages? This will depend on the channel and what content your organization has to use. Keeping a calendar of important campaigns and dates is an easy way to organize your organization's social media efforts.
- One of the great benefits of social media is sharing information almost instantly with a global audience. This timeliness is also one of the expectations of the audience. Set guidelines for when staff must respond to user comments and questions during and outside office hours. There will be exceptions to this timeframe, as some comments may require an immediate response.
- Social media requires that your organization follow and engage other similar global health and development agencies. This engagement allows your organization to participate in global conversations. Set guidelines on who your organization will not follow or endorse, such as politicians, vendors, and advertisements for other companies.
- Most social media channels allow you to select your username and an avatar. Your organization will want the same name and a consistent look and feel across all social media channels, otherwise known as branding.

Step 6: Adopt a Follower Policy

The social media channels must accept feedback and comments. Your organization should be courteous and professional in your messaging and ask that users do the same.

Usually, disagreement is welcomed on social media to foster engagement and discussion. Your organization may maintain a specific position but can also respect different viewpoints if they are presented in a civilized manner. Comments on social media platforms should go through a moderation process and should be posted provided that they do not contain abusive content, use offensive language, are off-topic, or are obviously spam.

It is also important to set guidelines for staff on what you will not address, such as financial matters or other elements of your business.

Step 7: Create a Budget

Although signing up for various social media platforms is free, there are costs involved in maintaining, managing, and measuring your efforts. Therefore, a budget must be created to cover the following:

- Staff time/labour: At least one person should dedicate 33%-100% of his/her time to social media.
- Technology and equipment: Items such as a computer, smartphone, and internet access are essential for social media participation.
- Advertisements or ads: Platforms such as Facebook have made it difficult to reach your audience without spending money on advertisements. Ads can be as cheap as $5 to reach your followers. Platforms such as Twitter, LinkedIn, Instagram, and Pinterest also have ads available.
- Social Media Management System (SMMS) monthly fees.
- Other relevant social media tasks: Other costs to consider could include a graphic designer to develop visuals and infographics for social media platforms or funds needed to create videos for YouTube.

Step 8: Benchmark the organization

A measurement is a comparative tool, so to measure success the organization should be compared to a benchmark or peer organization that is performing well.

Example: Facebook Insights allows you to do this with the “Pages to Watch” function. Facebook Page admins can see how their page compares to others regarding new likes, posts, and engagement. Moreover, the “Insight” function that most social media pages offer (Facebook, Instagram, Tik Tok. Youtube, Twitter – all have them) helps your organization see the metrics of the posts and decide what the benchmark of the organization is.

Step 9: Manage Security and Privacy

It is important to keep a secured master list of social media logins and passwords to make sure passwords are safe and secure. This should only be shared with people who will need this information. If someone is working on social media for your organization leaves, it is a good practice to change all passwords and not to allow them to access the organization’s accounts once they leave.

Some organizations don’t allow staff to use Facebook or other social media platforms during working hours. Work with your IT staff to ensure that the key people working on social media within your organization have permission on their computers and/or smartphones to utilize social media.

What if you or someone in your organization wants to use their personal Facebook account to represent the organization? Keep in mind that there is a fine line between personal and professional in the social media sphere. Set guidelines for staff. For example, suppose a staff member wants to put his/her job title and represent your organization on Facebook or other social media. In that case, this is okay as long as they follow the guidelines set by the organization. For example, you do not want a staff member to tweet points of view that conflict with your organization’s stated goals.

For more information on managing security and privacy, review this Pinterest board of various companies’ social media policies or other social media policy examples from more than 100 companies.

Measuring Social Media Success

A social media management system (SMMS) is an online management tool that integrates various social media platforms into one dashboard. You can schedule messages, monitor metrics, view conversations, and allow multiple staff to work within the SMMS to manage workflow.

When choosing an SMMS, it is important to consider costs. SMMS vary from free to expensive. When selecting an SMMS, consider the following:

1. Size of your organization (small, medium, or large)
2. Optimal integration of all your social media platforms
3. Your organizational budget

SMMS examples include HootSuite, Sprout Social, Buffer, and TweetDeck, and new ones keep popping up daily.

It is easy to get overwhelmed with the amount of data available via SMMS and other analytics sites. How can you start measuring your social media activity? By keeping it simple.

- Determine the frequency of your data collection (weekly or monthly).
- Do not collect more than seven data points per social media platform.
- Start small with manageable measures such as followers and mentions, plus an Excel Spreadsheet for keeping track.
- Ask questions such as, "What went wrong? What went right?"
- Provide recommendations for improvement for future social media efforts.

Beth Kanter describes the Crawl, Walk, Run, Fly Model of social media practice and measurement. Each level is a small but strategic step to becoming a networked and data-informed organization. The crawl, walk, run, fly hierarchy demonstrates that becoming a data-informed organization takes time but, in the end, helps an organization determine what type of measurement it is ready to implement.

EXAMPLES AND ANALOGIES

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APPLICATION AND INTEGRATION

Develop a social media strategy for a healthcare organization following all the steps presented in the lesson.

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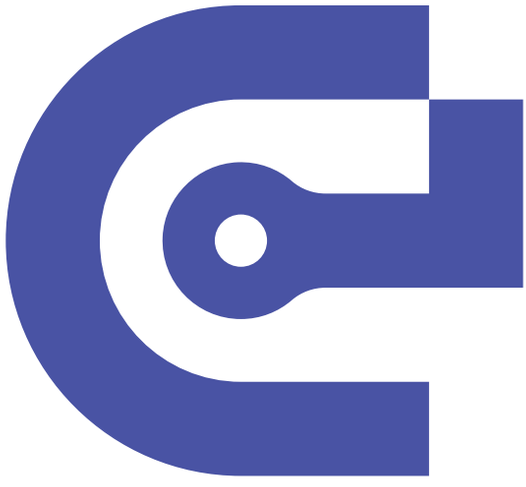


Module 5: mHealth

Learning objectives of the mHealth module:

1. Understand the concept of mHealth and how it can strengthen the health systems.
2. Differentiate between different behaviour change theories, models, and taxonomies.
3. Recall the elements of mHealth software management.
4. Apply the concepts learned in the model to design a potential mHealth app.

Foundational knowledge of the mHealth module

Definition of mHealth

The World Health Organization (WHO) defines mHealth as the use of mobile and wireless technologies to support the achievement of health objectives. Since mHealth is most suitably understood as a tool for strengthening health systems and promoting healthy behaviours, the word "support" in this definition is a key term (World Health Organization, 2011). mHealth is part of the larger field of eHealth. It refers to using mobile phone functions, such as voice, SMS, GPS, Bluetooth and mobile telecommunications systems, to achieve health-related outcomes (World Health Organization, 2011). Data shows that starting in 2014, almost half of the global population was using some form of mobile communication (World Health Organization, 2015), and by 2025 is forecasted to have over 7 billion smartphone users worldwide (Bankmycell, 2021).

Types of mHealth applications

All mHealth products have at least one of the following key components (World Health Organization, 2011)**:**

- Wearable technology
- Mobile phones
- Wireless devices
- Cloud computing and smart sensors
- Medical sensors
- Big data
- Data Collection Software
- Patient monitoring devices
- SMS (Short Message Service) and MMS (Multimedia Messaging Service)
- Mobile phone applications
- Bluetooth
- GPS (Global Positioning Systems) and GPRS (General Packet Radio Service)
- Wireless mobile telecommunications technology (3G; 4G; 5G – latest on the market)

With the rapid advancement of mobile communication, an array of health applications emerged on the market. These mHealth applications can be classified as follows:

1. mHealth apps for health promotion and prevention focus on specific health determinants to help prevent diseases. These apps are specifically relevant for preventing non-communicable diseases since lifestyle factors are responsible for most of them (Davies & Mueller, 2020).

   Example: mHealth app for enhancing physical fitness in healthy adults (Stork et al., 2021)

2. mHealth apps for health management - help patients and providers manage diseases, particularly non-communicable diseases such as diabetes, chronic respiratory conditions, cancer, and specific mental health problems (Davies & Mueller, 2020).

   Example:mHealth app for management of atrial fibrillation (Guo et al., 2017)

3. mHealth apps for remote access to treatment - help patients receive access to treatment by facilitating contact with the healthcare providers and receiving effective treatments from the app itself. These apps are helpful, especially for people living in remote or underserved areas, people with mobility issues, and people with competing responsibilities (Davies & Mueller, 2020).

   Example: mHealth app for management of atrial fibrillation during COVID-19 (Velden et al., 2020)

Purpose of mHealth applications

Much research and usability of mHealth focused only on health applications for personal use (e.g. monitoring calorie intake) (Smahel et al., 2017). Still, significant evidence shows that these applications can be used to improve patients' quality of life and health and improve patient-provider communication (Soriano et al., 2018; Zapata et al., 2015). Results show that mHealth has the potential for information and education related to chronic diseases, such as asthma, diabetes, HIV, and coronary heart disease, for which mHealth apps offered significant improvements in reducing severe symptoms and helping with the management of the disease (Soriano et al., 2018; Youfa et al., 2020). Moreover, mHealth showed promising results in offering people decision support aid related to physical activity outcomes, smoking cessation, and sexual behaviour outcomes (Soriano et al., 2018). Another common feature of mHealth lies in improving communication and interaction between patients and providers, results showing better antenatal care, increased attendance rates to health care appointments, improved adherence to treatment, improvement of diagnostic rates, enhanced data collection and reporting medical information and reducing the costs associated with health (Soriano et al., 2018).

Advantages and disadvantages of mHealth applications

mHealth applications can offer increased benefits in the constant availability of personal health data, affordability, time and resources optimization, and the multitudes of options and functions in an app (Vervier et al., 2019) The scale-up potential of mHealth apps also offers an advantage in creating best practices to improve health promotion (L'Engle et al., 2017). mHealth applications also allow tailoring the health interventions according to the group's specific need, making it easier to reach more people and offer needs-related care due to the widespread availability of mobile devices and anonymity mHealth offers users (Davis et al., 2020). Overall, mHealth apps encourage research and provide advances in the field.

However, the mHealth applications do not come without disadvantages. Lack of data protection, monitoring by third parties, lack of regulations related to mHealth apps, lack of personal contact, reduced engagement, no possibility of asking direct questions, constant data collection by the app, and the dependence on a mobile phone, were all factors identified as disadvantages of mHealth (Vervier et al., 2019). Moreover, the high dropout rates of using health apps (users usually decide within the first 3–7 days if they continue with the app) and technical failures are other disadvantages that slow the adoption of mHealth solutions (Davies & Mueller, 2020). Access to mobile phones in some parts of the world is still only available to men, while women cannot own them due to their high cost or independent status of the woman, creating gender inequalities in mHealth. Studies show that most females share or "borrow" phones and that most phone borrowers are from rural areas (LeFevre et al., 2020). Mobile services availability is still limited in many rural areas, and the cost of phones, mobile services

and Internet connection is still very high compared to monthly income in many areas. Even in areas where services are available, the coverage is not reliable. Many users have to walk to other villages or to the top of a hill to use their phones (LeFevre et al., 2020). In some areas of the globe, less than half of the population is literate, and the rates of digital health literacy and even lower, data showing that people have difficulties using a basic mobile phone or sending a text message (LeFevre et al., 2020; Messner et al., 2019). Moreover, in some parts of the world, the acceptability of mHealth interventions is low due to lack of functionality, dissemination of false information, misdiagnosis, mistreatment and unknown or unwanted side effects (Messner et al., 2019).

Nonetheless, mHealth is a field that has tremendously developed in the past decades and continues to grow. Therefore, more digital health education is needed to fully understand the full potential of mHealth to improve the health and quality of life of groups and communities.

Digital health education and mHealth

According to the WHO, the effectiveness of digital health education and outcomes vary broadly depending on the learning objectives. Different types of digital health education (e.g. online digital education, mobile phones, virtual reality, and gamification), delivery mode (e.g. fully digital or blended), instructional method (e.g. simulations, direct instruction), assessment methods (i.e. use of validated or non-validated instruments), learning pedagogies (e.g. digital problem-based learning or digital team-based learning), study population (e.g. nurses, allied health professionals, doctors), and the topic, discipline and health condition being taught (e.g. smoking cessation, diabetes management, domestic violence, antibiotic management, dermatology, child health, elderly care), all impact the learning outcomes (World Health Organization, 2020).

The digital divide phenomenon may be a significant barrier for students because of the unequal access to digital education among countries (World Health Organization, 2020). Additionally, further research, evaluations, collaborations and investments are required to enhance methods for digital education's effective use (World Health Organization, 2020).

One method for shaping digital education might involve combining knowledge, skills, and professional attitudes in clinical or public health. For example, effective communication between patients and healthcare professionals in the clinical context includes knowledge of ethics, sociology, psychology, interpersonal skills, and attitudes (Fox et al., 2017).

Exercise: Based on the list of previous mHealth limitations available in this chapter, what do you think are some of the key limiting factors for mHealth in your country? Please respond in the discussion section.

Lesson plans for the mHealth module

Lesson plan 1: Introduction to Mobile Healthcare (mHealth)

FOUNDATIONAL KNOWLEDGE

Used terminology in the field

Mobile health (mHealth) solution scans improve access to health information and services for underserved populations, generate cost efficiencies, and improve the capacity of health systems to provide quality health ser-

vices (World Health Organization, 2011). Due to these potential benefits, many countries embrace mHealth approaches to strengthen their health systems and mHealth is often regarded as a game-changing practice for improving health (World Health Organization, 2011). mHealth can transform patient care and provide better access to essential health information (e.g., tracking fitness achievements to allowing real-time remote consultations with physicians) (Lindgardt et al., 2014).

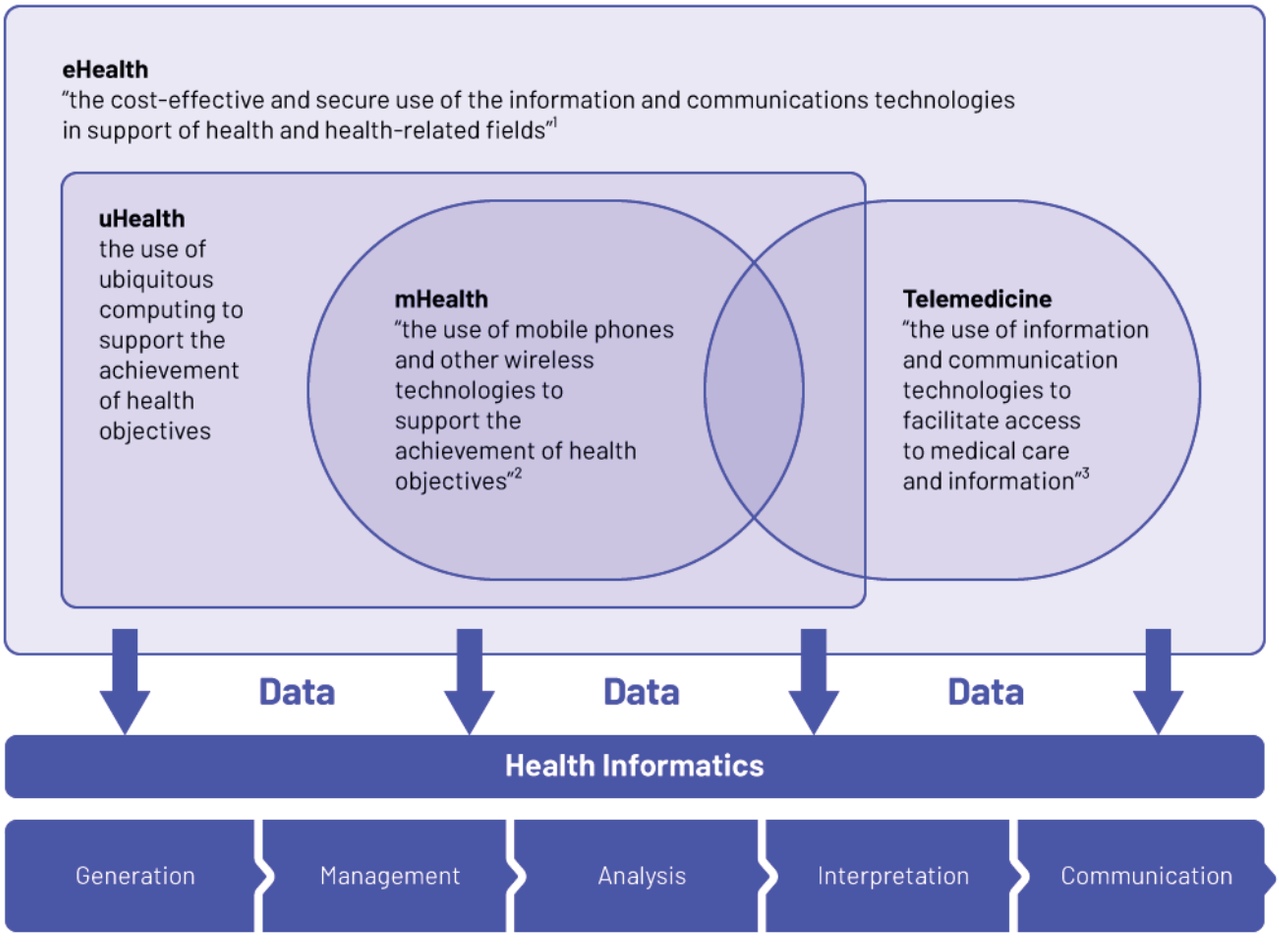
Before further discussing mHealth and health applications, clarification of the most common terminology in this field is required.

The term mHealth is often used interchangeably with eHealth, which is not entirely accurate as mHealth represents a subdomain of eHealth (World Health Organization, 2011). According to the definitions provided by the WHO, eHealth is defined as “the cost-effective and secure use of information and communications technologies in support of health and health-related fields, including health care services, health surveillance, health literature, and health education, knowledge and research”(World Health Organization, 2021). At the same time, WHO’s definition of mHealth is “the use of mobile phones and other wireless technologies to support the achievement of health objectives”(World Health Organization, 2011). Therefore, mHealth is just a sub-component of the larger field of eHealth.

Another term related to mHealth is uHealth, which uses ubiquitous technology for health care and health promotion. Ubiquitous technology refers to devices embedded with processors, such as mobile devices, enabling them to connect to the Internet. Such devices include smartwatches, tablets, smartphones, other activity trackers, and biometric or wearable devices (Davies & Mueller, 2020). Since trackers are involved in medical objects (e.g. in hospital beds to show real-time availability of beds), mHealth is also connected to the telemedicine field, sometimes overlapping. Telemedicine is the “use of information and communication technologies to facilitate access to medical care and information”. It uses video calls, voice calls, text and multimedia messages, and e-mails for medical consultation and communication (World Health Organization, 2010).

Another term that is used synonymously with eHealth is health informatics. Health informatics refers to the “generation, management, analysis, interpretation and communication of health data”(Davies & Mueller, 2020). This can be achieved by using Information Communication Technology (ICT), whicFih facilitates the usage of information and sharing of knowledge by electronic means (Moss et al., 2019)

A visual representation of how these topics are connected in the field of digital health can be found in the figure below.



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[2] World Health Organization. mHealth: New horizons for health through mobile technologies. Geneva, Switzerland, http://www.who.int/goe/publications/goe_mhealth_web.pdf (2011).
[3] World Health Organization. TELEMEDICINE: Opportunities and developments in Member States, https://www.who.int/goe/publications/goe_telemedicine_2010.pdf (2010)

Fig. 5.1. Topics connected in the field of Digital Health (Davies & Mueller, 2020)

mHealth technology

mHealth practice uses mobile phones and other wireless technologies. These include basic phones, feature phones, smartphones, and tablets, as well as remote sensors and wireless-enabled diagnostic devices. Mobile phones and tablets are most commonly used in mHealth in low-resource settings (Moss et al., 2019).

Below are the features commonly available on different types of mobile devices:

Basic Phone- voice calls and voice mail, SMS, USSD (Unstructured Supplementary Service Data - enables instant messaging and other services on basic mobile phones), SMS – or USSD-based services (mobile money, instant messaging) (Global Health eLearning Center, 2013).

Feature Phone – as basic mobile phone, plus: MMS (Multimedia Message Service, or text messages with photos or video embedded), still picture camera, music player, GPS (Global Positioning System) – most phones, 2.5G data access, Java-enabled (can download and/or use data collection forms, treatment algorithms and other applications that were programmed using Java for mobile phones, a software language explicitly designed for mobile phones), removable memory card – some phones, ability to install and use applications – some phones, web browser – some phones (Global Health eLearning Center, 2013).

Smartphone – as a feature phone, plus: video camera, web browser, GPS, internet access (3G, 4G, 5G), mobile operating platform (Android, iOS, Windows Phone OS, and Symbian. Etc.), ability to use and install applications, VoIP (Voice over Internet Protocol - refers to a way to make phone calls over the Internet rather than through the user's cellular company network; Requires an Internet connection), removable memory card, video calls, touch-screen with a virtual or physical keyboard (Global Health eLearning Center, 2013; Hamed et al., 2017).

Smartwatches – devices with a computer system embedded in a wristwatch. Smartwatches are connected to the Internet and offer many functionalities that enable them to collect, process and react to outside stimuli. These devices usually can connect to other devices and share data. Some of the most common functionalities of a smartwatch are: a heart rate monitor, pedometer, reminders for different behaviours, and advice for users (Future Learn, 2021).

Tablet and portable laptop – video and still-picture cameras, web browser, GPS, internet access, ability to download and use applications, VoIP, large screen size and memory, faster processor, video playback, touchscreen with touchscreen virtual keyboard (Global Health eLearning Center, 2013).

Other mHealth technologies include patient monitoring devices, telemedicine devices, data collection software, chatbots, and health applications (Adibi, 2015).

mHealth potential and opportunities

The rapidly increasing availability of wireless Internet and the use of smartphones and data sensors provide a solid foundation for growth (Lindgardt et al., 2014).

There are four primarily converging factors offering growth potential for the mHealth field (Qiang et al., 2012):

- The unprecedented growth of mobile phone users
- The rapid expansion of mobile networks
- The innovation in mobile technology
- The task-shifting/sharing and other health system needs in developing countries

Factor 1: Growth of Mobile Phone Users

There are 5.27 billion unique mobile phone users in the world today, according to the latest data from GSMA Intelligence. The total number of individual mobile users worldwide grew by 117 million in the past 12 months (Data Reportal, 2021).

Factor 2: Expansion of Mobile Networks

Seeking new markets, mobile telecommunications companies are extending their networks further into rural areas, surpassing the reach of other infrastructure such as roads, running water, electricity, and fixed telephone lines. Around 4.80 billion people worldwide will use the Internet in July 2021; that's almost 61% of the world's total population. This number is still growing, latest data showing that 257 million new users came online over

the past twelve months (Data Reportal, 2021). In contrast, before the expansion of mobile networks, many people in developing countries did not have access to a phone of any kind (Global Health eLearning Center, 2013).

Factor 3: Innovation in Mobile Technology

Mobile technology companies constantly innovate and improve mobile phones, wireless devices, and software applications, offering new possibilities for supporting health and health systems through mobile technology applications that can be adapted for different contexts and needs.

Factor 4: Task Shifting and other Health System Needs

mHealth solutions can help simplify task shifting and improve the quality of care by providing health workers with checklists, decision tools and counselling algorithms on mobile phones. mHealth can also help expand community-based services and promote healthy behaviours by providing citizens vital health education and behaviour change messages. Data collection, medical records and logistics solutions using mHealth can introduce efficiencies in health systems (World Health Organization, 2011).

All these factors allow mobile devices to be used more and more for improving health. Development in technology is often used as a potential solution for healthcare crises. The health applications offer one such opportunity. Because of the extensive use of smartphones and the Internet, health applications are viewed as cost-effective and scalable tools for disseminating significant health interventions to the population (Davies & Mueller, 2020).

Healthcare applications can take the burden of the health care systems by helping people to self-manage their health (Davies & Mueller, 2020). Research data shows that health apps effectively improve clinical outcomes, physical functioning and biological parameters for diabetes, chronic lung diseases, and cardiovascular diseases (Whitehead & Seaton, 2016). A report from the UK on digital technologies showed that they could improve health services by freeing healthcare professionals' time and offering them more time for diagnosis and treatment (National Health Service, 2019). Health applications can be useful for health professionals to improve communication, decision making, and health record management (Ventola, 2014).

Common features of mHealth apps

Each health app is a complex intervention with various features and functions tailored to the users' needs to promote health and improve their quality of life. Almost all health apps contain information and education, mostly coupled with decision-making aid for the users in the form of recommendations (Davies & Mueller, 2020). Another feature of health apps is the behaviour change support, which can be materialized in reminders and other nudges. Self-assessment and monitoring are other functionalities that health apps use for keeping track of symptoms over time and helping medical providers decide on the type of treatment. mHealth features also include communication and interaction using varied device functionalities (e.g. messages, video calls, etc.) to facilitate rapid communication (Davies & Mueller, 2020). Finally, one essential feature of health apps is the theory-based interventions, meaning the health app is grounded in an existing and tested theory for behaviour change. All these features increase the usability and success of health apps in improving people's lives (Davies & Mueller, 2020).

EXAMPLES AND ANALOGIES

Examples of mHealth include:

- Community health workers consult maternal and child health information on a mobile phone to recommend a patient (World Health Organization, 2011).

- Citizens use free text-message services to obtain information about family planning methods (World Health Organization, 2011).
- An application tracks the symptoms of COVID-19 in the population (Giansanti, 2021).
- mHealth technologies are used by biopharmaceutical companies to reduce costs (e.g. by conducting clinical trials remotely) and generate new sources of revenue through improved compliance (e.g. providing innovative packaging that reminds patients when to take their medication) (Lindgardt et al., 2014).
- Medical-technology companies can provide technological support for mHealth by developing solutions to patient care, such as mobile devices that transmit data to physicians or digital imaging (Lindgardt et al., 2014).
- Providers can develop innovative ways to manage communication between patients and physicians by expanding remote-consultation services into hard-to-reach areas (Lindgardt et al., 2014).

Here are some examples of mobile health apps available on the market that are being most used:

- Fitbit
- Apple Heart Study
- GoogleFit
- Samsung Health
- AliveCor's KardiaMobile
- BlueStar

Mobile for Reproductive Health (m4RH) is a free text message service that provides information about family planning methods and can be used on a simple mobile phone. Users request the service, or "opt-in," by sending the text "m4RH" to a toll-free, four-digit number or shortcode. The user then receives a menu-based message, and to request information about a particular method, the user texts the two-digit code shown in the menu (such as "21" for IUD). The user receives a text message with information on the method's effectiveness, how long it works or how often it is used, any side effects, and return to fertility after stopping (Olsen et al., 2018).

FrontlineSMS is a free, open-source group-messaging platform that works with a laptop connected to a mobile phone or modem. It allows users to send, receive and handle text message interactions with large groups of people. The software works without Internet access and is easy to set up and operate (Banks et al., 2011).

CommCare is a case management application for community health workers used in community-based maternal and child health projects. The free software runs on low-cost, java-enabled mobile phones and more sophisticated Android smartphones. The application contains registration forms, checklists, danger sign monitoring and client education tools (Duffy et al., 2019).

APPLICATION AND INTEGRATION

Exercise 1: Did you ever use a mHealth app aimed to track/monitor your health? If yes, which one? Did it help you in any way? What would you change (add/remove) on that specific app, and why?

If you have never used a mHealth app, can you think about a useful app that should be available on the market?

Please respond in the discussion section.

Exercise 2: Can you think about health challenges in your country that can be (partially) solved by using mHealth? Please select a health challenge and explain what mHealth solution is most suitable and why.

REFERENCES FOR FURTHER INFORMATION AND AREAS OF INQUIRIES

More in-depth reading and documentation from the articles referenced above

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Lesson plan 2: Behavioral theories/models for mHealth

FOUNDATIONAL KNOWLEDGE

Health behaviour change programs and interventions have a good track record for numerous lifestyle behaviours such as weight loss, dietary changes, smoking cessation, physical activity, treatment adherence and disease management (Salwen-Deremer et al., 2019). However, designing and implementing such health behaviour change programs might be problematic due to the complex nature of human behaviour (Wang et al., 2019). These change programs often require different practices and theories from diverse fields such as public health, economy, psychology, or human-technology interaction (Wang et al., 2019).

Research has shown that these interventions and programs are most effective when they are based on evidence-based strategies, theoretical models, and concepts (Glanz & Bishop, 2010; Webb et al., 2010) and delivered in person. However, good results can be achieved when these are delivered remotely using telephones, mobile phones, smartphones and wearable devices (Cho et al., 2018; Salwen-Deremer et al., 2019). Still data suggests that even with this knowledge, studies consistently show that the inclusion of traditional behavioural change theories is suboptimal in most interventions using mHealth apps (Cho et al., 2018; Salwen-Deremer et al., 2019). Moreover, researchers have indicated that it is difficult to replicate mHealth interventions as they do not offer details about their concepts' structure, content, and evidence base (DeKoekkoek et al., 2015). Therefore, this lack of replicability poses challenges in demonstrating that mHealth apps effectively employ evidence-based behavioural theories, models and strategies for changing behaviour (Salwen-Deremer et al., 2019).

Before continuing, some definitions related to behaviour change are needed:

Behavioural change theories

Are defined as "a set of concepts and/or statements which specify how phenomena relate to each other. A theory provides an organizing description of a system that accounts for what is known and explains and predicts

phenomena" (Davis et al., 2014). The theory is essential in health behaviour change because it provides a mechanism to condense all previous knowledge about different variations in a causal factor to produce an effect. An intervention could represent a causal factor, while the result can be the actual behaviour change (Hekler et al., 2016).

Behavioural change models are concepts that "help us understand specific behaviours, by identifying the underlying factors, which influence them" (Darton, 2008).

The main difference between behaviour change models and theories is that models help us understand behaviour. In contrast, theories of change demonstrate how behaviours can be changed and how they change over time (Darton, 2008). In other words, the theories of change offer the framework for behaviour change, while the models provide the necessary tools to make that specific behavioural change.

Multiple behaviour change theories aim to modify behaviour and help prevent diseases (Salwen-Deremer et al., 2019). Further, we will explore some traditional behaviour change theories and recent behaviour change theories that have evidence-based solid support for their use in mHlealth. We will also observe the interaction between these theories and how that interaction can be harnessed for mHealth apps.

Traditional Theories and Models of Behavior Change

The theories most used in lifestyle interventions with good scientific results are Social Cognitive Theory (SCT), Theory of Planned Behavior (TPB), The Health Belief Model (HBM) and the Trans-Theoretical Model (TTM) (Salwen-Deremer et al., 2019). However, other behaviour change theories exist but are not widely supported according to the latest research, so their results cannot be generalized (Salwen-Deremer et al., 2019).

Social Cognitive Theory (SCT) claims a reciprocal relationship exists between the person, their behaviour and the environment. This theory emphasizes social influence and the importance of external and internal social reinforcement (Bandura, 1996). The SCT has the following components that need to be addressed when designing health change interventions and behaviours:

1. Reciprocal Determinism is the central concept of SCT. It refers to the dynamic and reciprocal interaction of a person (individual with a set of learned experiences), the environment (external social context), and the behaviour (responses to stimuli to achieve goals) (Bandura, 1996).
2. Behavioral Capability refers to a person's ability to perform a behaviour through essential knowledge and skills. To accomplish the desired behaviour, the person must have the knowledge to do it. People learn from both the consequences of their behaviour and the environment in which they live (Bandura, 1996).
3. Observational Learning means that people can witness and observe a behaviour conducted by others and then reproduce those actions, a concept called "modelling" of behaviours. If people see a successful demonstration of behaviour, they can also perform it successfully (Bandura, 1996).
4. Reinforcements refer to the internal or external responses to a person's behaviour that affect the probability of continuing or discontinuing the behaviour. Reinforcements can be initiated by the person or existent in the environment, and reinforcements can be positive or negative (Bandura, 1996).
5. Expectations refer to the anticipated consequences of a person's behaviour. People anticipate the consequences of their actions before engaging in the behaviour, which can influence the successful completion of the behaviour. Expectations derive primarily from previous experiences, focus on the value placed on the outcome and are subjective to the individual (Bandura, 1996).

6. Self-efficacy refers to confidence in performing a behaviour successfully. Self-efficacy is influenced by a person's specific capabilities and other individual and environmental factors that can be perceived as barriers and facilitators (Bandura, 1996).

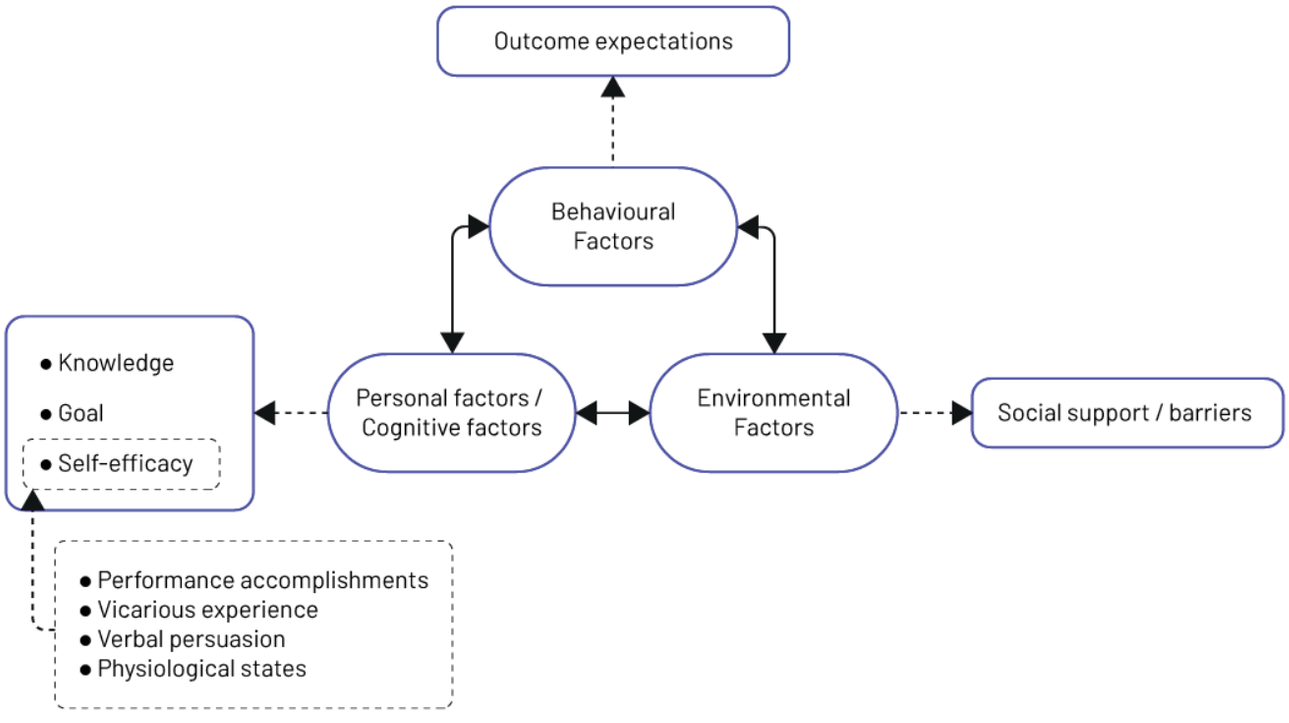


Fig. 5.2. Social Cognitive Theory (Bandura, 1996)

SCT and mHealth

SCT was successfully used for mHealth applications in weight loss interventions (Burke et al., 2012), promoting physical activity (Baretta et al., 2019; Freigoun et al., 2017), chronic disease management (Whittemore et al., 2020), and smoking cessation (Ghorai et al., 2014).

Theory of Planned Behavior (TPB) intends to explain all behaviours over which people can employ self-control, and it is an extension of the Theory of Reasoned Action (TRA) (Ajzen, 1991). The key component of the model is behavioural intent. Behavioural intentions are shaped by the attitude about the likelihood of the behaviour to have the expected outcome and by the subjective evaluation of the risks and benefits of the desired product (Ajzen, 1991). The TPB implies that achieving a specific behaviour depends on motivation (intention) and ability (behavioural control). It makes the difference between three types of beliefs - behavioural, normative, and management. The TPB contains six constructs collectively representing people's actual control over the behaviour.

1. Attitudes refer to a person's degree to have a favourable or unfavourable evaluation of the behaviour of interest. It requires the person to consider the outcomes of performing the behaviour (Ajzen, 1991).
2. Behavioral intention refers to the motivational factors influencing a given behaviour. If the purpose of performing the behaviour is strong, the behaviour will most likely be performed (Ajzen, 1991).
3. Subjective norms refer to the thoughts about whether most people approve or disapprove of the behaviour. It relates to a person's beliefs about whether peers and people of importance think they should engage in the conduct (Ajzen, 1991).
4. Social norms refer to the specific behaviours of a group of people or a larger cultural context. Social norms are considered usually to dictate a group of people (Ajzen, 1991).

5. Perceived power refers to the perceived presence of factors that may facilitate or impede the performance of a behaviour. Perceived power contributes to how a person perceives behavioural control over each aspect (Ajzen, 1991).
6. Perceived behavioural control refers to a person's perception of how easy or difficult is to perform a specific behaviour. Perceived behavioural control may vary across situations and actions, resulting in multiple perceptions of behavioural control depending on the situation (Ajzen, 1991).

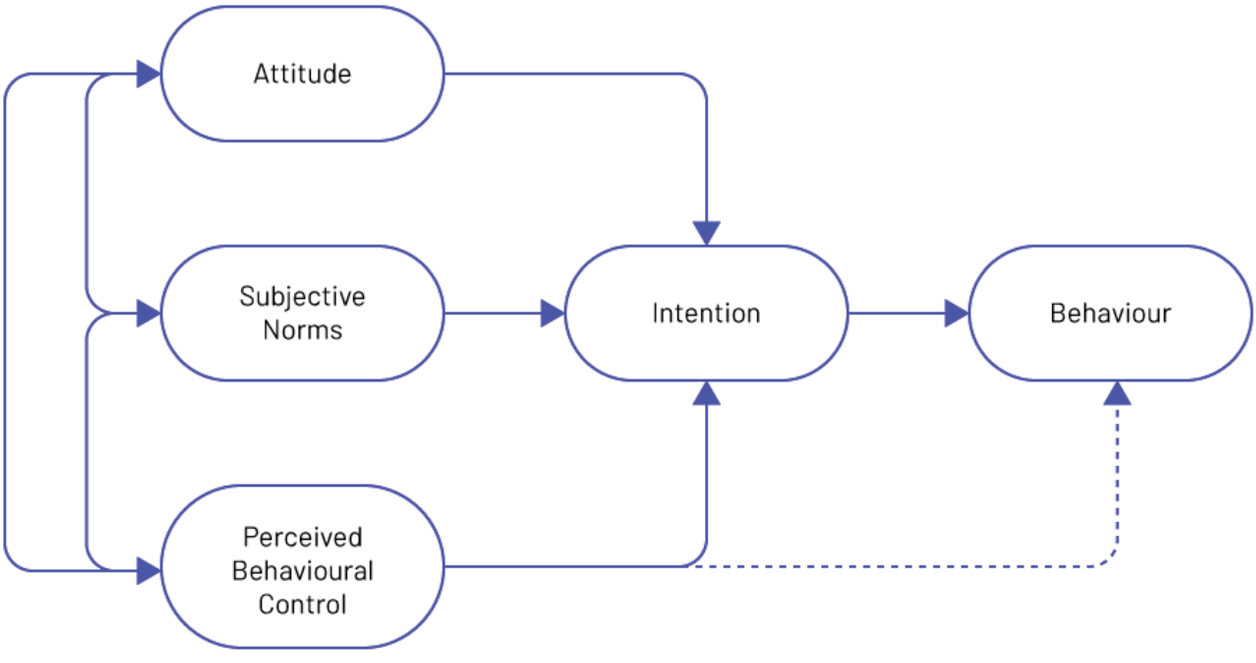


Fig. 5.3. Theory of Planned Behavior (Ajzen, 1991)

TPB and mHealth

TPB was successfully used for mHealth in preventing alcohol abuse (Kazemi et al., 2017), diabetes management (Samer & Al-Shami, 2020), dietary weight loss and physical activity (Salwen-Deremer et al., 2019), and coping with chronic diseases (Guido et al., 2018).

*The Health Belief Model (HBM)*implies that a person's belief in a threat of an illness or disease coupled with a person's confidence in the effectiveness of the recommended health behaviour or action will predict the likelihood the person to adopt the behavior (Ogden, 20112). HBM is composed of six constructs, as follows:

1. Perceived susceptibility refers to a person's subjective perception of the risk of developing an illness or disease. There is wide variability in how people perceive the chances of developing a disease (Ogden, 20112).
2. Perceived severity refers to a person's feelings on how severe an illness will be. When evaluating the severity, a person often considers the health consequences (e.g., disease or death) and social outcomes (e.g. social relationships) (Ogden, 20112).
3. Perceived benefits refer to a person's assessment of the effectiveness of behaviours to reduce the threat of disease. The course of action in preventing (or curing) the condition is based on the perception that activity is beneficial (Ogden, 20112).
4. Perceived barriers refer to a person's thoughts on the obstacles to performing a recommended health action. The person evaluates the usefulness of the actions against the idea that it may be expensive, dangerous, unpleasant, time-consuming, or inconvenient (Ogden, 20112).

5. Cue to action refers to the stimulus needed to trigger the decision to accept a recommended health action. The cues can be internal (disease symptoms.) or external (e.g., advice from others, illness of someone close newspaper article, etc.) (Ogden, 20112).
6. Self-efficacy refers to the person's confidence in their ability to undertake the behaviour (Ogden, 20112).

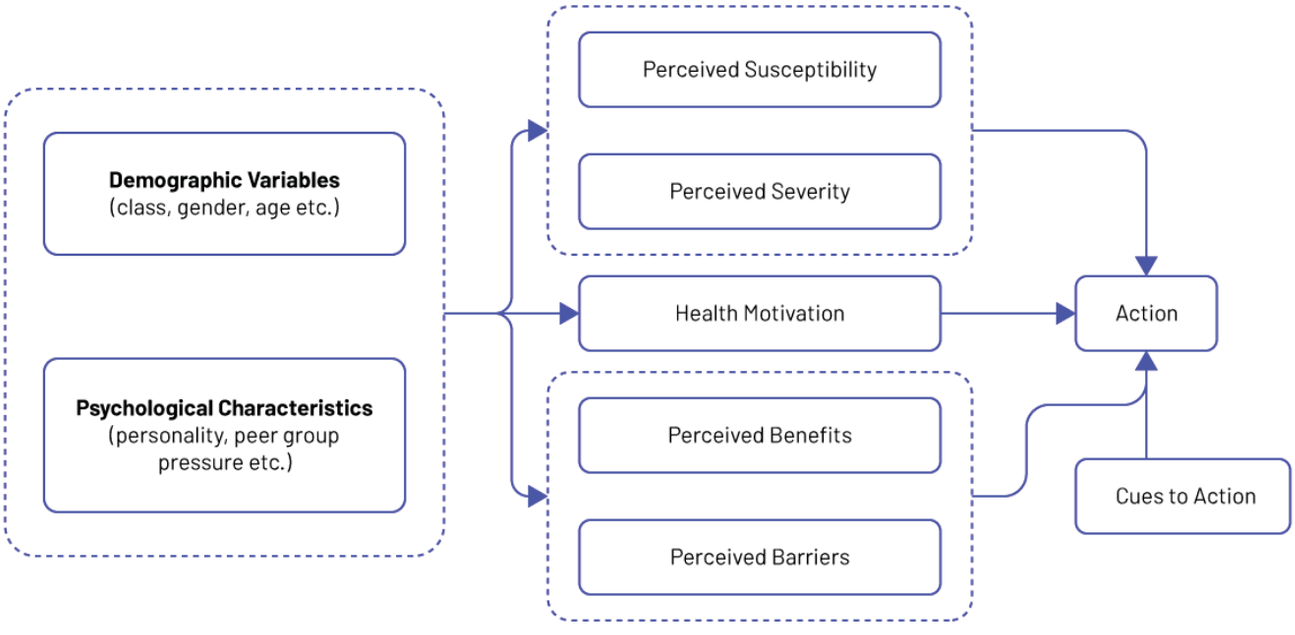


Fig. 5.4. Health Belief Model (Ogden, 20112)

HBM model was found to be successful in mHealth apps targeting HIV testing (Evans et al., 2016), screening for cervical cancer (Khademolhosseini et al., 2017), tobacco control (Ali et al., 2020), and tracking infectious diseases – such as COVID-19 (Michel et al., 2020)

Trans-Theoretical Model (TTM) focuses on the decision-making of the individual and is a model of intentional change, considering that people do not change behaviours quickly (Prochaska, 2013). The TTM states that a person moves through different stages when modifying behaviour. Various intervention strategies are most effective at each stage to move the individual to the next step (Prochaska, 2013). The TTM stages are:

1. Precontemplation. In this stage, people do not desire to take action and are often unaware that their behaviours negatively affect their health (Prochaska, 2013).
2. Contemplation. In this stage, people recognize that their behaviour may influence their health. Even with this recognition, people may still feel ambivalent about changing their behaviour and may not take action towards it (Prochaska, 2013).
3. Preparation (Determination). In this stage, people are determined to take action and start taking steps toward behaviour change (Prochaska, 2013).
4. Action. In this stage, people have just changed their behaviour, which is considered to be within six months of actively pursuing the behaviour (Prochaska, 2013).
5. Maintenance. In this stage, people sustain their behaviour for more than six months and intend to maintain the behaviour change. People in this stage actively work to prevent relapse to earlier stages (Prochaska, 2013).
6. Termination. In this stage, people will not return to their unhealthy behaviours. Since this is rarely reached, this stage is often not considered in health promotion programs (Prochaska, 2013).

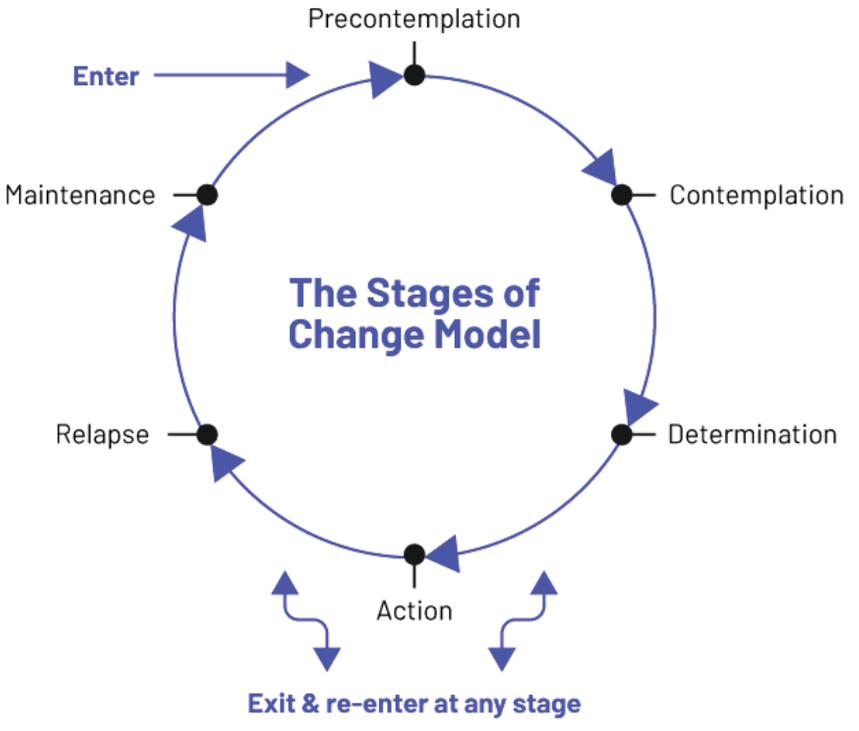


Fig. 5.5. Trans-Theoretical Model (Prochaska, 2013)

TTM has successful results in mHealth application on obesity prevention (Lee et al., 2017), diabetes prevention (Jennings et al., 2019), mental health (Frith & Loprinzi, 2017), eating behaviour (Abdel-Fatah Ibrahim et al., 2017), and smoking cessation (Chahar et al., 2018).

Contemporary Behavior Change Theories

Contemporary theories emerged once with the development of mHealth apps towards more interactive and adaptative functions that required more than just the components of traditional behaviour theories presented above (Salwen-Deremer et al., 2019). Fogg Behavior Model, Internet Intervention Model (RIIM), and Persuasive Systems Design (PSD) model are some promising behaviour change models that showed good results with mHealth apps (Salwen-Deremer et al., 2019).

Fogg Behavior Model is based on three dimensions that converge to prompt behaviour change: motivation, abilities and prompts (Fogg, 2021).

1. Motivation refers to structures that facilitate behaviour change, such as sensation (pleasure vs pain), anticipation (hope vs fear), and belonging (social acceptance vs rejection) (Fogg, 2021).
2. Abilities refer to the person's skills and resources and the difficulty of the behaviour. It is dependent upon time, money, physical effort, brain cycles (how mentally taxing a behaviour is), social deviance (how socially acceptable behaviour is), and non-routine (routine behaviours are easier to perform) (Fogg, 2021).
3. Prompts refer to the constructs people need to make the behaviour. They should be applied at the right time so the person has motivation and ability when the prompt occurs (Fogg, 2021).

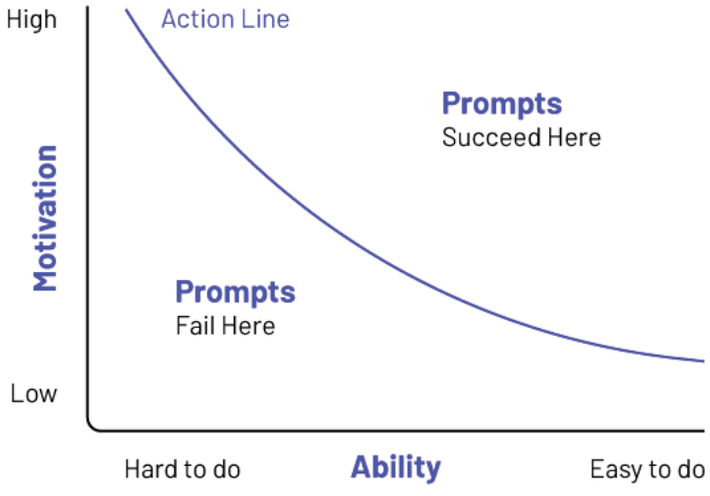


Fig. 5.6. The Fogg Behavior Model. (Behavior Model, 2018)

Fogg Behavior Model was successfully used for mHealth interventions on dietary change and physical activity (Rabbi et al., 2015), preventing obesity (Militello et al., 2016), cervical screen cancer (Lee et al., 2014), and preventing the spread of COVID-19 (Alrige et al., 2021).

*Internet Intervention Model (RIIM)*suggests that internet-based interventions are effective if they follow the nine nonlinear steps of the model, namely:

1. User characteristics refer to the patient, consumer, or research participant who brings their own diverse set of variables or features that cannot be manipulated (e.g., age, gender, cognitive traits) and serve as predictor variables in developing an intervention (Ritterband et al., 2009).
2. Environment refers to multiple factors such as family, friends, employer, and the community, which can either offer support or put barriers to adopting the behaviour; therefore, it needs to be accounted for when developing an intervention (Ritterband et al., 2009).
3. Website refers to the program or application through which treatment is delivered and has eight main areas that need to be considered when developing the intervention: *appearance*, *behavioural prescriptions*, *burdens*, *content*, *delivery*, *message*, and *participation* (Ritterband et al., 2009).
4. Website use refers to the actual utilization of the intervention. The other steps of the model highly influence it; therefore, special attention must be given to them when developing the intervention (Ritterband et al., 2009).
5. Support refers to how the people feel they receive help to make the change. Support usually impacts adherence, ranging from emails and texts to other prompts (Ritterband et al., 2009).
6. Mechanisms of change are the catalysts of transformation and may take the form of knowledge, information, motivation, attitude, beliefs, skill-building, self-efficacy, cognitive restructuring and self-monitoring (Ritterband et al., 2009).
7. Behavior change is the ultimate variable of change, and it is critical to identify behaviours essential to change to reduce associated symptoms and achieve a positive outcome (Ritterband et al., 2009).
8. Symptom improvement is the goal of most interventions, and it refers to improving the well-being of the target group (Ritterband et al., 2009).

9. Treatment maintenance includes some form of relapse prevention in the intervention to help users maintain treatment gains (Ritterband et al., 2009).

The main idea that the model states is that "the user, influenced by environmental factors, affects website use and adherence, which is influenced by support and website characteristics. Website use leads to behaviour change and symptom improvement through various mechanisms of change. The improvements are sustained via treatment maintenance" (Ritterband et al., 2009).

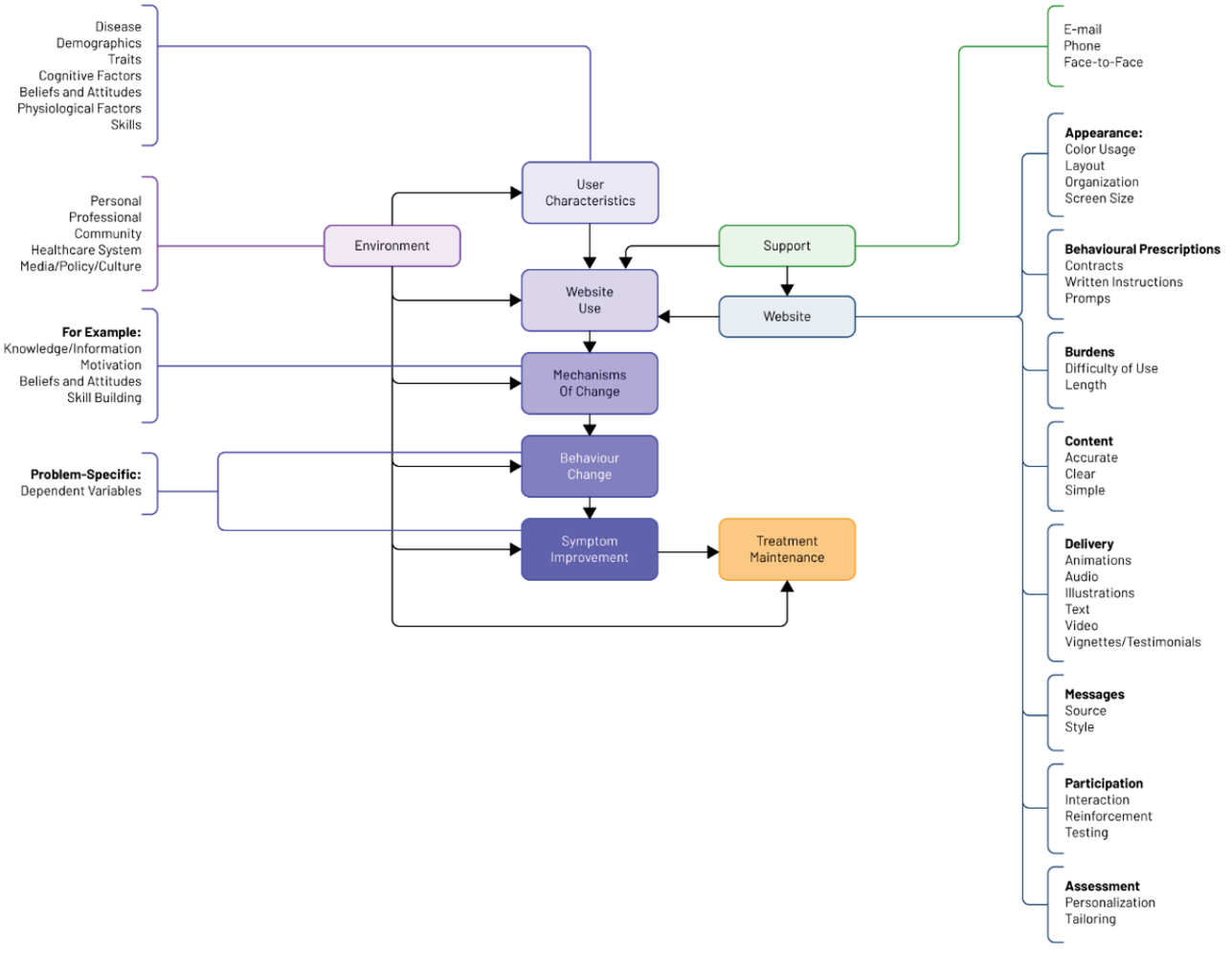


Fig. 5.7. Internet Intervention Model (Ritterband et al., 2009)

The Persuasive Systems Design (PSD) model helps design and evaluate persuasive systems and describes what content and software functions may be found in the final product of an intervention (Oinas-Kukkonen & Harjumaa, 2009). The model suggests that when designing or evaluating persuasive systems, aspects from the following figure should be considered (Oinas-Kukkonen & Harjumaa, 2009).

Table 5.1. Postulates behind Persuasive Systems (Oinas-Kukkonen & Harjumaa, 2009)

1. Information technology is never neutral.
2. People like their views about the world to be organized and consistent.
3. Direct and indirect routes are key persuasion strategies.
4. Persuasion is often incremental.
5. Persuasion through persuasive systems should always be open.
6. Persuasive systems should aim at unobtrusiveness.
7. Persuasive systems should aim at being both useful and easy to use.

Postulates behind PSD model The PSD identifies three main areas of change: (1) forming a behaviour or a cognition; (2) altering behaviour or a cognition; and (3) maintaining a behaviour or cognition (Oinas-Kukkonen & Harjumaa, 2009). The PSD model contains four key design features, each with a subset of components that can be used when designing behaviour change interventions:

1. Primary task support includes reducing complex behaviours into simpler ones, tunnelling experience, tailoring and personalization, self-monitoring, simulation, and rehearsal of the behaviour (Oinas-Kukkonen & Harjumaa, 2009).
2. Dialogue support includes positive reinforcement (praise, rewards), reminders and suggestions, the similarity of actions, visual attractiveness (liking), and social role (Oinas-Kukkonen & Harjumaa, 2009).
3. Credibility includes trustworthiness, expertise, credibility, real-world resemblance, authority, verifiability, and third-party endorsements of the action (Oinas-Kukkonen & Harjumaa, 2009).
4. Social support includes social learning, social comparison, normative influence, social facilitation, cooperation, competition, and recognition (Oinas-Kukkonen & Harjumaa, 2009.

PSD model has been used for mHealth applications targeting the management of chronic diseases, such as cancer (Vlahu et al., 2021), anxiety (Radomski et al., 2019), stress management (Alhasani et al., 2020), and physical health (Halttu & Oinas-Kukkonen, 2017).

Interactions across Theories

The above models provide different explanations and concepts to achieve behaviour change, but researchers demonstrated that they overlap substantially, and there are interactions in how these theories predict behaviour (Salwen-Deremer et al., 2019). These findings indicate that behavioural health theories vary significantly among interventions and that they should be incorporated in intervention design based on desired behaviour change (Salwen-Deremer et al., 2019). Interdisciplinary teams need to work together in mHealth to advance knowledge. Behavioural scientists, psychologists, clinicians, software engineers, designers, and other professionals must share a common understanding of behaviour change theories. This shared knowledge will enable them to

build mHealth technologies that are engaging and acceptable while also impacting and contributing to sustained behaviour change and better health outcomes (Salwen-Deremer et al., 2019).

EXAMPLES AND ANALOGIES

All the mHealth interventions mentioned above will be cited here.

APPLICATION AND INTEGRATION

Lessons 2, 3, 4, and 5 will have a common "Application and integration activity" to design an app to increase vaccination rates in the first year of life. The app should be prepared for parents, while the beneficiaries will be children because they receive their vaccines on time.

REFERENCES FOR FURTHER INFORMATION AND AREAS ON INQUIRIES

Other examples of Behavioral change theories:

1. https://sphweb.bumc.bu.edu/otlt/mph-modules/sb/behavioralchangetheories/index.html
2. https://sphweb.bumc.bu.edu/otlt/mph-modules/sb/behavioralchangetheories/BehavioralChangeTheories_print.html

Lesson plan 3: Current mHealth practice: Behavioral Intervention Technology (BIT) Model and TUDER framework

FOUNDATIONAL KNOWLEDGE

In lesson 2, we reviewed some traditional and contemporary behavioural change theories and models and explored how they can be used for mHealth interventions. While these models have proved to be very useful in describing what cognitive and behavioural changes are required for people and their environment, they offer little information on designing mHealth interventions and evaluating their effectiveness (Riley et al., 2011). As digital health interventions (DHI) have increased rapidly, new taxonomies and frameworks are needed (Mohr et al., 2014; Wang et al., 2019). Therefore lesson 3 explores the Behavioral Intervention Technology (BIT) model and a holistic framework (TUDER) which combines behavioural theories, behaviour change technique taxonomy, and persuasive system design principles to design and evaluate mHealth interventions.

Behavioural Intervention Technology (BIT) model

The behavioural intervention technology model consists of a framework for developing implementable interventions, and it is anchored in the contemporary behavioural change models presented in lesson 2 (Mohr et al., 2014). BIT offers the necessary steps to translate behaviour change theories and models into actions that must be taken when designing and implementing a digital behaviour change intervention. The BIT model proposes the "why", "what", "how", and "when" for developing DHIs, which can be observed in the figure below.

Table 5.2. BIT model (Mohr et al., 2014)

		BIT component	Examples
Theoretical			
	Why	Aims	**Clinical aims:** Weight reduction: Decrease caloric intake Increase physical activity Promote sleep hygiene Decrease depression: Increase positive activities Decrease avoidance behaviors **Usage aims:** Use Intervention tools
	How (Conceptual)	Behaviour change strategies	Education Goal setting Monitoring Feedback Motivation enhancement
Instantiation			
	What	Elements	Information delivery Notifications Logs Passive data collection Messaging Reports
	How (Technical)	Characteristics	Medium Complexity Aesthetics
	When	Workflow	User defined Frequency Conditions: Time-based rules Task completion rules Event-based rules Tunneling

1. *Why.* This component of the BIT model discusses the intervention aims, which can refer to both clinical purposes (e.g. reducing weight) and usage aims (e.g. maintaining the engagement with specific components of the intervention – like daily use of the mHealth app). These outcomes often overlap; therefore, a usage aim is often reflected in the clinical purpose and vice versa (Mohr et al., 2014).
2. *What.* This component of the BIT model refers to the actual behavioural intervention technologies the intervention offers to prompt behaviour change. These can form a data field for logging in the desired behaviour (e.g. food consumption, sleep hours, etc.) to act as a behaviour change strategy of monitoring (Mohr et al., 2014). Other behavioural intervention strategies are notifications, app reports for users, logs, and visualizations; these elements are delivered separately or embedded together (Mohr et al., 2014).
3. *How*. This BIT model component offers conceptual and technical strategies for behavioural interventions that help attain the intervention aims (Mohr et al., 2014). The conceptual strategies are based on theories and models of behaviour change (presented in lesson 2) and are crucial for behaviour change to occur and be maintained. The BIT model offers a list of conceptual strategies developed upon an extensive taxonomy of behaviour change strategies (Michie et al., 2013) to attain behavioural change (Mohr et al., 2014). The technical approach is used to offer the user a good experience with the app in terms of engagement, ability to complete tasks, and app comprehension. These strategies can vary in complexity, media employed, aesthetics, and personalization depending on the interventions' needs and the users' characteristics (Mohr et al., 2014).
4. *When*. This component refers to the workflow of the intervention and defines under what conditions the intervention is delivered. Some common examples of workflow elements are: (1) tunnelling – the use of data to decide which interventions meet the needs and preferences of users in a specific period; (2) frequency – how frequent the intervention is offered; (3) conditions – the use of data to determine when should intervention be delivered (it can be time-based, task-completion, and event-based); (4) user-defined – offers access to all elements of the intervention from the beginning, allowing the user to set the sequence and timing of the app (Mohr et al., 2014). Usually, workflows integrate a number of these elements to achieve behaviour change, depending on the needs of the interventions and the characteristics of the users (Mohr et al., 2014).

The BTI model can be useful for mHealth app developers to decide on the app design and clarify their intentions, aims, and intervention conceptual and technical elements (Mohr et al., 2014).

TUDER framework

TUDER is a holistic framework that aims to “integrate the advantages of behavioural theories, Behavior Change Techniques (BCT) taxonomy, and persuasive technology design principles to researchers design, evaluate, and report their studies in a formative and comprehensive way” (Wang et al., 2019). The TUDER framework goes further from the BIT model and offers a unified taxonomy considering the contemporary models presented in lesson 2 and the BIT model shown above. The framework can be useful for developing and evaluating the intervention (Wang et al., 2019).

The TUDER acronym comes from the framework’s four steps: Targeting, Understanding, Designing, Evaluating and Refining.

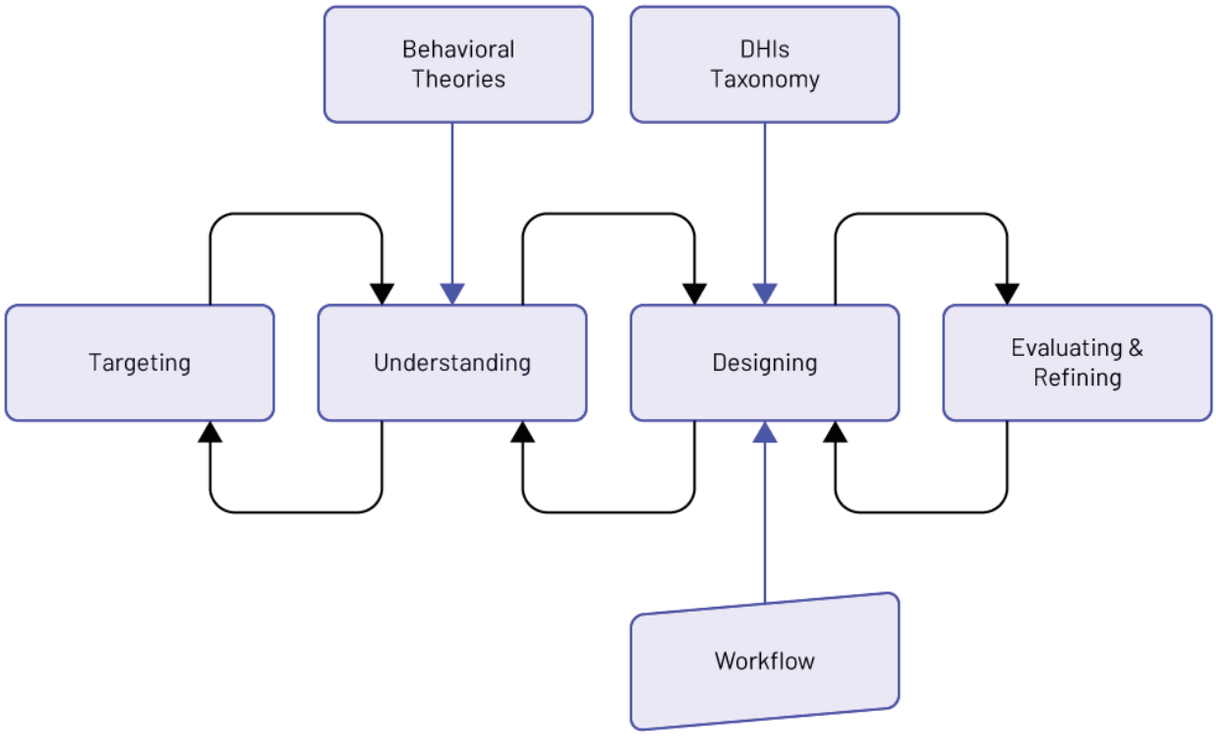


Fig. 5.8. TUDER holistic framework (Wang et al., 2019).

1. *Targeting the users, health problems and behaviour.* This component highlights the importance of tying the user group, the health problem, and the desired behaviour to achieve the intervention's aim. An example from the authors of the frameworks is "an intervention to promote the use of standing desks (the behaviour) to reduce the prolonged sedentary behaviour (the behaviour) of office workers (the user group) to prevent chronic diseases, such as type 2 diabetes (the health problem)" (Wang et al., 2019).
2. *Understanding.* This framework component considers the behavioural theories (or models/constructs) that need to be used to change the behaviour tacked by the intervention (Wang et al., 2019).
3. *Designing the intervention, characteristics, and workflow*. This component refers to the intervention strategies and DHI characteristics that must be considered when designing an intervention. The framework offers 98 intervention strategies and six features to develop mHealth apps. Moreover, the framework also includes the importance of workflows, a concept borrowed from the BIT model (Wang et al., 2019).
4. *Evaluating and Refining the Intervention Design.* A novel approach to the TUDER framework is the importance of constant evaluation of the intervention design. The framework suggests that usability evolution (regarding human-computer interaction and uptake) and effectiveness evaluation (regarding behaviour change and impact) should be considered when designing an intervention. The framework provides suggestions for refining the intervention, such as think-aloud, cognitive walkthrough, pilot-testing, and heuristic evaluations (Wang et al., 2019).

A checklist was also developed for standardized use and reporting of the framework (Wang et al., 2019).

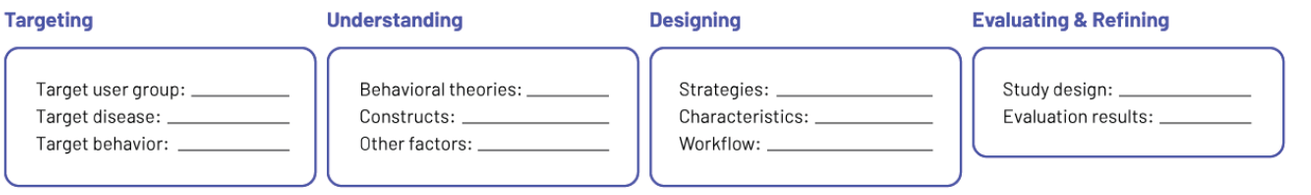


Fig. 5.9. TUDER framework checklist (Wang et al., 2019).

EXAMPLES AND ANALOGIES

BIT model

1. A practical example of BIT mode is the MyFitnessPall application, explained in the following article:

   Mohr, D. C., Schueller, S. M., Montague, E., Burns, M. N., & Rashidi, P. (2014). The behavioural intervention technology model: an integrated conceptual and technological framework for eHealth and mHealth interventions. Journal of medical Internet research, 16(6), e3077.

2. Another practical example of the BIT model is for a mHealth app targeting sedentary behaviours explained in the following article:

   Direito, A., Walsh, D., Hinbarji, M., Albatal, R., Tooley, M., Whittaker, R., & Maddison, R. (2018). Using the intervention mapping and behavioural intervention technology frameworks: development of a mHealth intervention for physical activity and sedentary behaviour change. Health Education & Behavior, 45(3), 331-348.

3. BIT model used for developing a mHealth app for self-management of addictive behaviours, in the following article:

   Beck, A. K., Kelly, P. J., Deane, F. P., Baker, A. L., Hides, L., Manning, V., … & Martini, M. (2021). Developing a mHealth Routine Outcome Monitoring and Feedback App ("SMART Track") to Support Self-Management of Addictive Behaviours. Frontiers in Psychiatry, 12, 820.

TUDER framework

1. Part of this framework has been used to guide the development of a personalized leisure-time physical activity application which is described in the following paper:

   Sporrel, K., De Boer, R. D., Wang, S., Nibbeling, N., Simons, M., Deutekom, M., … & Kröse, B. (2020). The Design and Development of a Personalized Leisure Time Physical Activity Application Based on Behavior Change Theories, End-User Perceptions, and Principles From Empirical Data Mining. Frontiers in Public Health, 8.

2. The underpinnings of the TUDER framework have been used to develop a mHealth care pathways for patients with lifestyle-related chronic diseases:

   Cardol, C. K., Tommel, J., van Middendorp, H., Ciere, Y., Sont, J. K., Evers, A. W., & van Dijk, S. (2021). Detecting and treating psychosocial and lifestyle-related difficulties in chronic disease: Development and treatment protocol of the e-goal e-health care pathway. International journal of environmental research and public health, 18(6), 3292.

REFERENCES FOR FURTHER INFORMATION AND AREAS OF INQUIRIES

1. Myneni, S., Amith, M., Geng, Y., & Tao, C. (2015). Towards an ontology-driven framework to enable development of personalized mHealth solutions for Cancer survivors' engagement in healthy living. Studies in health technology and informatics, 216, 113.
2. Mohr, D. C., Tomasino, K. N., Lattie, E. G., Palac, H. L., Kwasny, M. J., Weingardt, K., & Schueller, S. M. (2017). IntelliCare: an eclectic, skills-based app suite for treating depression and anxiety. Journal of medical Internet research, 19(1), e10.

Lesson plan 4: mHealth software project management and development

FOUNDATIONAL KNOWLEDGE

Disclaimer: Part of the examples presented in this Lesson is taken from a real-life mHealth app called Smoke Free Together. The development and testing of the app were funded through the grant "A Smartphone Intervention for Pregnancy Smoking Cessation with Peer Support (R21-HD103039-01)" from the National Institutes of Health (USA) and competitively awarded to a consortium of four universities (Michigan State University, Wake Forest School of Medicine, Michigan University, and Babes-Bolyai University). The Smoke-Free Together smoking mobile cessation app was designed to be used by pregnant women and one nominated peer supporter of their choice. The summary of the funded research project can be accessed here (NIH RePORTER, 2021).

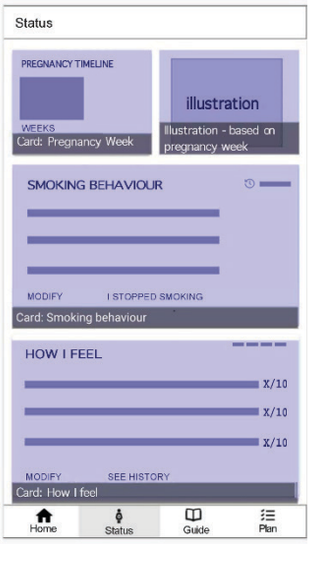
Elements of a mHealth product

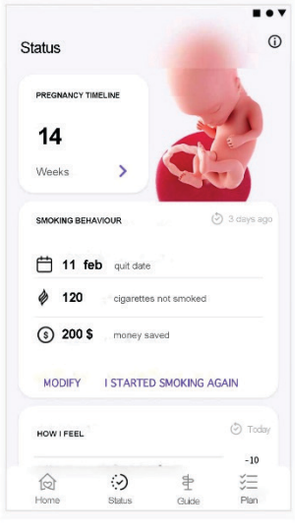
The following are considered the main elements of a mHealth product:

- *T*he *platform* is a software or suite of applications that provide the mobile device functionalities needed for the mHealth intervention.
- The *content* may include health education for clients, health worker decision tools and counselling aids, data collection forms, or a combination of applications.
- The *user interface* is how the content is presented to the end-user—through menus, text, video, audio messages, and drawings.

Roles in a mHealth software project

This Lesson focuses on providing a mix of theoretical principles and hands-on examples that are useful when managing the development of a mHealth application. The first aspect that needs to be considered represents the structure of the team working on such a project. At a minimum, the team needs to consist of at least one individual who meets each of the roles described in the table below. The roles of the team members are defined in a simplified manner, the aim being to offer an overview of the distinction between the responsibilities of each team member.

Role	Description
Project sponsor	This is the individual, organization, institution, or company that provides the resources for developing the mHealth app. For example, the Ministry of Health can decide to sponsor a mobile app for parents to boost vaccination rates and coverage.
Project manager	The role of this team member is to make sure that the work that needs to be done fits the available budget and to track the progress of the project against pre-set milestones, deliverables, and deadlines. In some cases, this person will also recruit other staff members.
Product owner	This team member has several different responsibilities: communicating with and across stakeholders to define and maintain the product's vision during the development phase, managing and prioritising the tasks in the product backlog, and evaluating the product's progress at each iteration.
Developers	The developers' job is to use the software's technical requirements and produce code in line with the requirements. In most software development projects, three types of developers have been involved: a full-stack developer, a front-end developer, and a back-end developer.
Tester	The tester will not use the app from an end-user's perspective but from an analogical approach. The tester's job is to stress test the app and find its pain points and errors. His report feeds back into the work of the developers, who adjust the code.
User experience (UX) designer	The role of the UX designer is to ensure the product/software meets the needs and requirements of the users. To do this, the UX designer will use user personas and flow diagrams (both later described in the Lesson) to develop an app that would be relevant to users' experiences. More specifically, the UX designer will focus on the users' motivations, views, and values to find the best solutions for the users to interact with the app. All these details are embedded in wireframes of the software that depict, in a step-by-step manner, how the user is meant to interact with the product.  A simple wireframe from the Smoke-Free Together app is presented below.

User interface (UI) designer	The job of the UI designer is to apply a visual layer over the wireframes developed by the UX designer. This person will focus on interface animation, visual elements (including the best colours to use in the app, the design), screen layout, and content. To better understand the work of the UI expert, below you can find how the work of the UI designer has enhanced the wireframe previously developed by the UX expert: 
End users	The users are not part of the formal software development team, but the project's success depends on their involvement in concept design and testing, usability testing, and user acceptance testing.

The process of mHealth software development

Now that the roles of the software/mHealth project development team are clarified, we will focus on the app development process.

Initial Planning and Concept Development

During the planning phase, thoroughly assess and describe the problem or health system constraint, the end-users, and the programmatic and policy context of the problem to have a firm foundation for selecting or formulating a potential mHealth solution (Matthew-Maich et al., 2016). When starting a new project, the scope of the project, the time frame, the budget, and the resources need to be considered (Davies & Mueller, 2020).

At the beginning of the design process, the capabilities and functions the platform must have to support the intervention must be defined and established. Mobile devices can collect large amounts of data electronically, especially monitoring data, so ethical considerations such as data protection and usability need to be discussed (Davies & Mueller, 2020; Yanxia et al., 2020).

- These requirements determine whether open-source tools and platforms can be used. Building on existing open-source platforms can save time and expense.
- If needed, determine how the solution will link to or be compatible with the existing health information system.
- Build into the platform the capacity to collect monitoring and evaluation data, if possible.

- Assess and include any relevant regulatory frameworks and legislation to assure data protection for users.

Define the Problem and Ensure that mHealth is an Appropriate Solution

The first step is ensuring that the problem and context drive the solution's identification rather than the desire to use a new mobile technology tool.

- Thoroughly assess and define the problem or health system constraint and end-users or target audiences.
- Define desired outcomes and determine whether and where mobile technology could help (Matthew-Maich et al., 2016).

Coordinate with Programs and Health System

mHealth is a tool for strengthening health systems and achieving health objectives. Still, it might also be ineffective if it is not designed and implemented correctly or if it is incompatible with health information systems (Matthew-Maich et al., 2016). For effective coordination and integration of interventions, thoroughly assess the end-users, the context, and the existent design methodologies capabilities (Davies & Mueller, 2020).

Assess the Context

Before selecting the software engineering methodology, a series of aspects need to be assessed:

- How end-users make use of mobile phones (or tablets) and the context in which they will utilize the mHealth solution (through formative research)
- The mHealth evidence base to identify potential mHealth solutions
- Current programs and policies related to the problem, including eHealth and mHealth programs or policies
- Mobile phone infrastructure (operators, coverage, services and fees), and potential technology partners
- Behavioral theories and frameworks related to the problem (Matthew-Maich et al., 2016)

Select the Software Engineering Methodology

The next step consists of deciding on a software engineering methodology to be employed in developing the mHealth software. One of the most popular umbrella concept software engineering methodologies today is the "Agile" approach (Davies & Mueller, 2020). Agile is an iterative approach that consists of gathering requirements, planning the prioritization of needs, planning the delivery of requirements, development, testing, and deployment of small working versions of the product (minimal viable product - MVP) (Davies & Mueller, 2020).

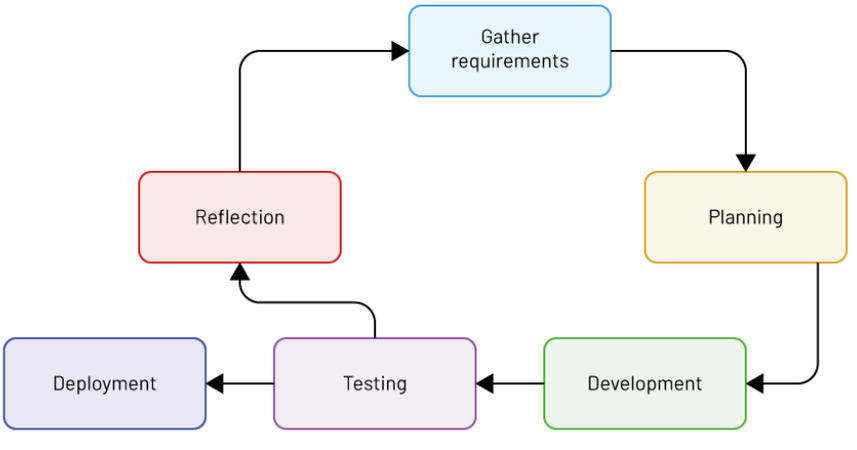


Fig. 5.10. Agile software engineering methodology (Davies & Mueller, 2020)

The Agile software engineering methodology functions on 12 principles presented below:

1. Our highest priority is to satisfy the customer through early and continous delivery of valuable software
2. Welcome changing requirements, even late in development. Agile processes harness change for the customer's competitive advantage
3. Deliver working software frequently, from a couple of weeks to a couple of months, with a preference to the shorter timescale
4. Business people and developers must work together daily throughout the project
5. Build projects around motivated individuals. Give them the environment and support they need, and trust them to get the job done
6. The most efficient and effective method of conveying the information to and within a development team is face-to-face conversation
7. Working software is the primary measure of progress
8. Agile processes promote sustainable development. The sponsors, developers, and users should be able to maintain a constant pace indefinitely
9. Continuous attention to technical excellence and good design enhances agility
10. Simplicity - the art of maximizing the amount of work not done is essential
11. The best architectures, requirements, and designs emerge from self-organizing teams
12. At regular intervals, the team reflects on how to become more effective, then tunes and adjusts its behaviour accordingly

Fig. 5.11. Agile principles (Beck et al., 2001)

The Agile approach's two most common frameworks are Scrum and Kanban. These are detailed below.

Scrum framework is a lightweight Agile framework that "helps people, teams and organizations generate value through adaptive solutions for complex problems" (Schwaber & Sutherland, 2020).

The Scrum master framework contains a Scrum master to develop an environment where:

1. A Product Owner orders the work for a complex problem into a Product Backlog.
2. The Scrum Team turns a selection of the work into an Increment of value during a Sprint.
3. The Scrum Team and its stakeholders inspect the results and adjust for the next Sprint.
4. *Repeat"* (Schwaber & Sutherland, 2020).

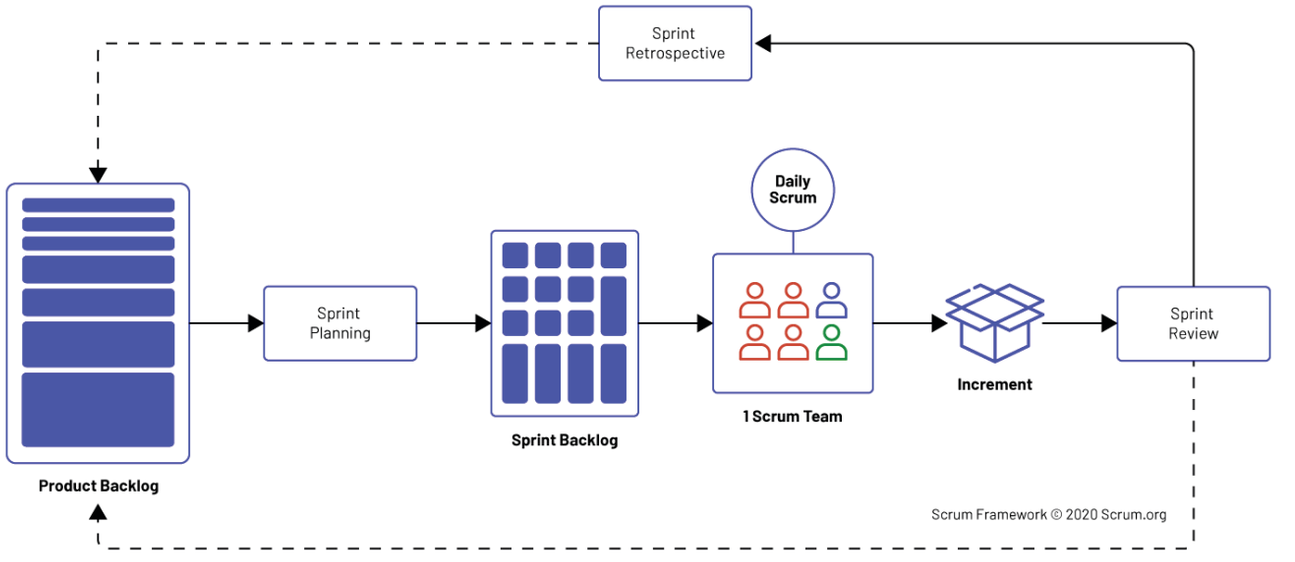


Fig. 5.12. Scrum Framework (Schwaber & Sutherland, 2020)

Kanban is another methodology from the Agile framework that "is typically a large physical board that displays the current state of work visually to offer a transparent snapshot for the entire state of the project" (Davies & Mueller, 2020). The physical board is usually split into columns with different cards that contain the working units. These units are moved between the columns to indicate the current state (e.g., from pending to progress). Kanban boards can also be developed digitally, and different software use this concept (e.g., Asana, Monday, ClickUp).

	To do	In progress		Done
		Next	Doing	
	+ add task Place a complaint regarding books delivery last week Barcelona - book a hotel for July 13th to 20th Plan Barcelona holiday activities Prepare for book club discussion Organize Danny's party	+ add task Order new soccer shoes for Mickey Set a dentist appointment for M. and I	+ add task Invite Tom and Carol for lunch / make a menu (incl. vegan otpions for C.)	+ 1 archived task + add task Print out Sam's best pictures Place online grocery order
	+ add task Send invitations to the Comitee Prepare a presentation for TBD meeting Prepare a speech for UBF Write the speech for the XDP Gala	+ add task Set team notation plan for May Follow up with Daria Garcia about key points of our meeting	+ add task	+ 1 archived task + add task Contact Mary Frisco Arrange a conference call with members of the Comitee Contact Free World Now

Fig. 5.13. Basic Kanban board (Shore Labs, 2021)

Requirements gathering and presentation

After the initial planning, data for the system/mHealth app requirements need to be gathered. Depending on the type of the project, this data can come from either, the project team or the end-users themselves. The idea behind this step is to have a user-centred design that will allow designers to understand user requirements for all product cycles and, in the end, develop a product that offers value to the customers (Davies & Mueller, 2020). Data for system requirements can be gathered using quantitative (surveys) and qualitative tools (focus groups, interviews). This data can already be available from the sponsor or collected specifically for developing the mHealth software. The aim is to assess users' values, needs and wants regarding the mHealth solution to be set. For example, to build the Smoke-Free Together app, the project team made use of qualitative data from 30+ semi-structured interviews and survey data collected in three different research projects spanned over six years and targeting smoker pregnant women (the same target population as the Smoke-Free Together app). The initial purpose of the data was not to serve as a basis for the development of the Smoke-Free Together app. Still, the data collection instruments (questionnaires and interview guides) contained questions that helped highlight the major barriers in smoking cessation, the type of support the women needed to quit, or what expectations would they have from a potential smoking cessation app.

The data collected can be integrated and presented in many ways, including by building user stories and user personas.

User stories

A method for gathering data for specification requirements is to offer examples, which can take the form of user stories. User stories are beneficial in deciding and prioritizing the value of the feature included in the app.A template from Davies & Mueller of how user stories work is presented below:

As a <**type of user**> I want to <**some feature/goal**> so that <**value**>. (Davies & Mueller, 2020)

Usually, the stories that can be split into smaller stories are called *epics*, and data for the epics can be generated through different story points that account for every user's need (Davies & Mueller, 2020). The user stories are useful because they describe the type of user for each action, the tasks and aims for each user, and what value each feature brings (Davies & Mueller, 2020).

Another example of a user story from the Smoke-Free Together app is included below.

Epic	Status Monitoring for Pregnant Smoker
User Stories	As a user, I am **able to**: ● View my pregnancy week ● Read information specific to my week **so that** I am informed about what to expect regarding my pregnancy. As a SMOKING user, I am **able to**: ● View my smoking behaviour (quantity smoked, money spent) ● Modify my smoking behaviour (quantity smoked, cost per smoking product) ● Mark if I have quit smoking (including date and time of last cigarette smoked) **so that** I can monitor my smoking status and receive tailored information to support me quit. As a QUIT user, I am **able to**: ● View my current smoking behaviour and my savings (quit date, quantity not smoked/avoided since quit date, money saved since quit date) ● Modify my smoking behaviour prior to quitting (quit date & time, type of product smoked, quantity smoked, cost per smoking product) ● Mark if I have relapsed smoking (inclouding date of relapse) **so that** I can monitor my quit process, keep motivated and receive tailored information o support me quit. As a SMOKING user, I am **able to**: ● View my importance, confidence, and readiness to quit smoking ● Update/modify my importance, confidence and readiness to quit smoking ● View a history of how I feel (including a tailored message based on my progress) **so that** I can monitor how I feel and receive tailored information to support me quit. As a QUIT user, I am **able to**: ● View my confidence in staying quit, stress level, cravings level and depression level ● Update/modify my confidence in staying quit, stress level, cravings level and depression level

Fig. 5.14. Smoke-Free Together app (Davies & Mueller, 2020)

Personas

Another method for presenting data is using personas or stories about the user for different typologies of system users. These personas or stories might contain background information about the user, as shown in the example below.

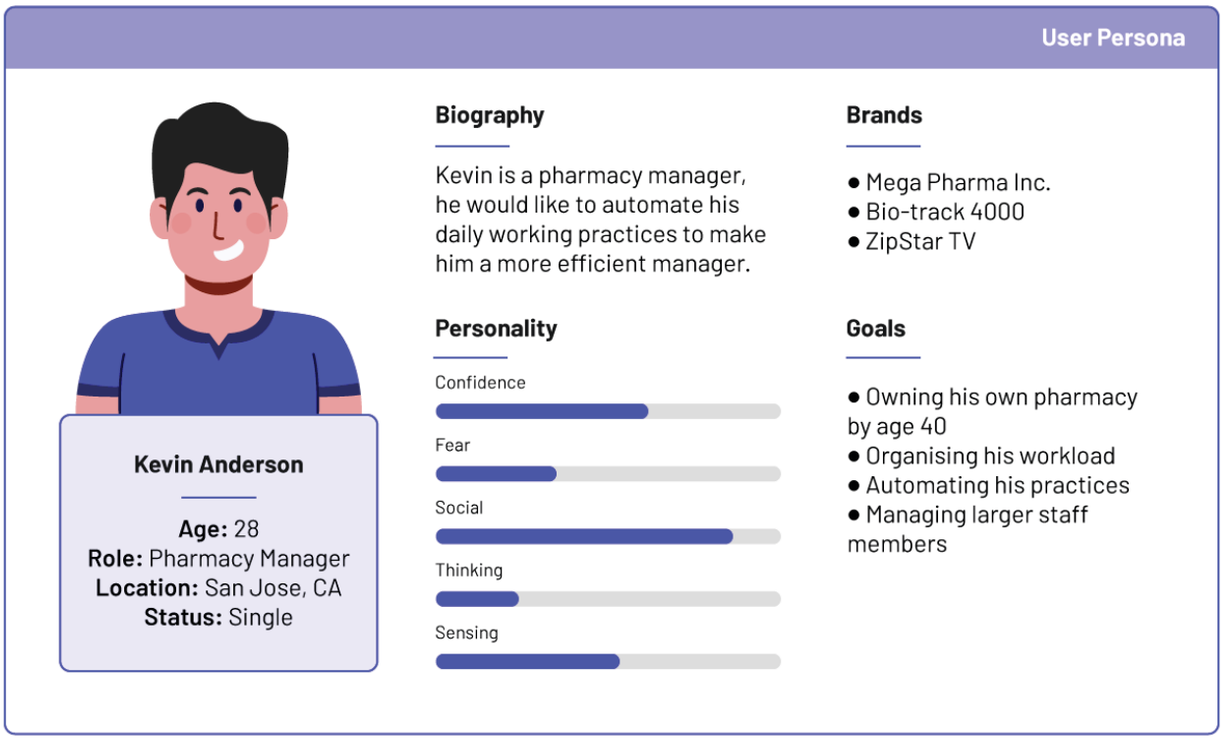


Fig. 5.15. Personas (Davies & Mueller, 2020)

The figure below depicts one of the four personas developed for the Smoke-Free Together smoking mobile cessation app designed to be used by pregnant women and one nominated peer supporter of their choice.

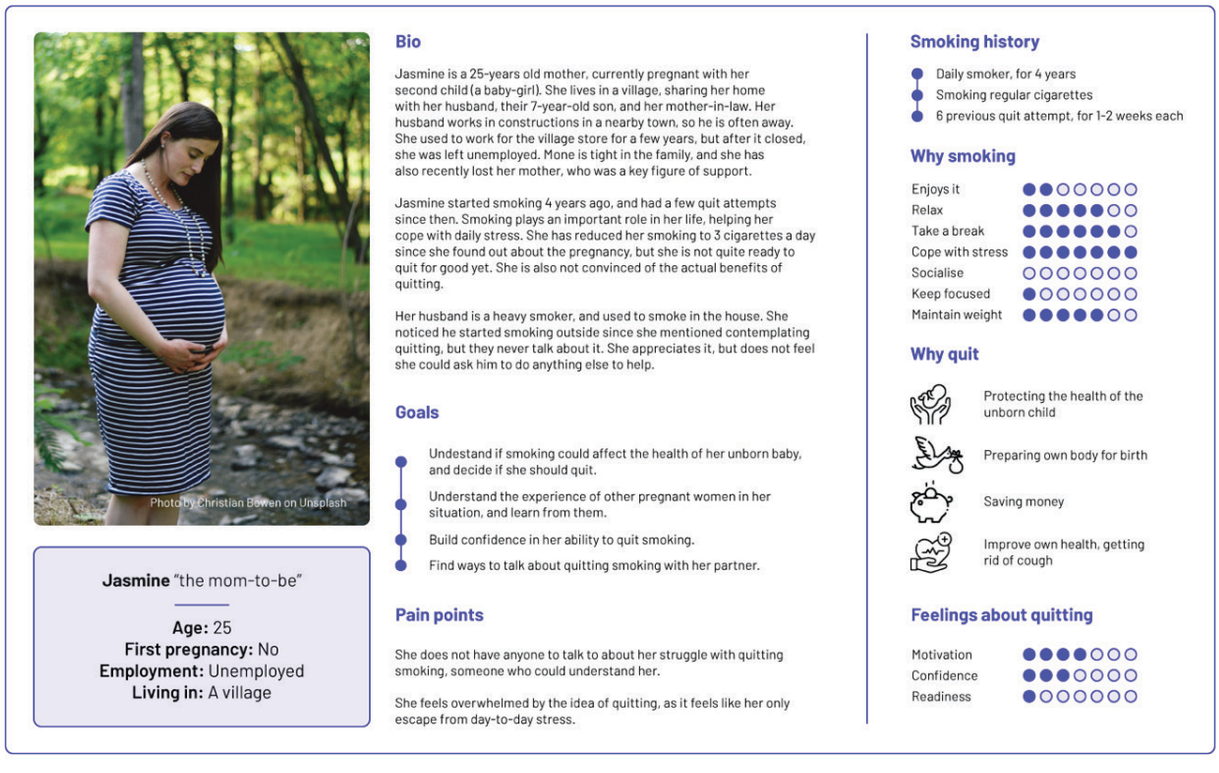


Fig. 5.16. Personas (Davies & Mueller, 2020)

Data modelling diagrams

Data modelling diagrams are used to have a better overview of the structure and flow of the application. These diagrams help communicate the proposed system designed to the developers and stakeholders (Davies & Mueller, 2020). Data flow diagrams are one type of data modelling diagram. These can be general, developed to provide a high-level view of the system or very detailed, showing how different system levels are structured. For example, the image below depicts a high-level view of the architecture of the Smoke-Free Together app.

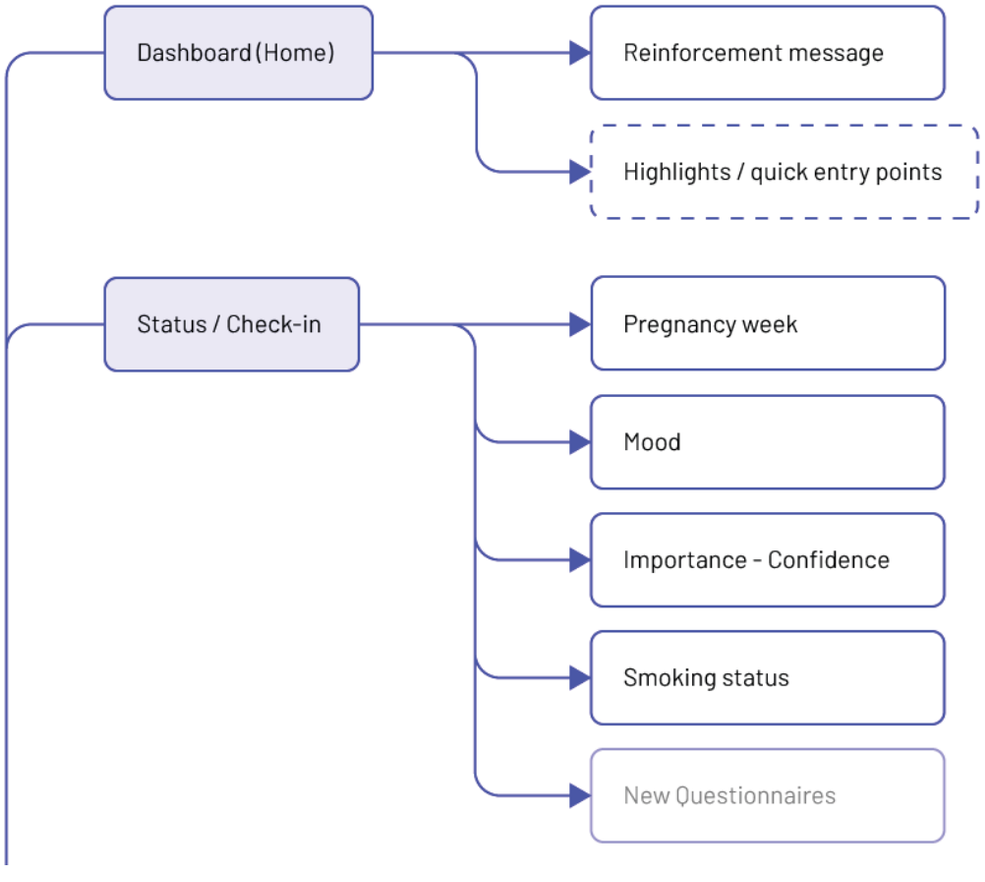


Fig. 5.17. The architecture of the Smoke-Free Together app (Davies & Mueller, 2020)

The phases of mHealth software development

It is important to mention that the development of mHealth software is not a linear process and the phases described below overlap across the app development timeline.

Develop app wireframes

The UX expert works with the product owner to develop the wireframes of the app based on the data gathered from the sponsor and the end-users. The wireframes are usually screens from inside the app that contains the architecture and the main elements and functionalities of the app and detail how the users are expected to interact with the app. Based on these wireframes, the technical requirements of the app are developed. Some examples of app wireframes are included below.

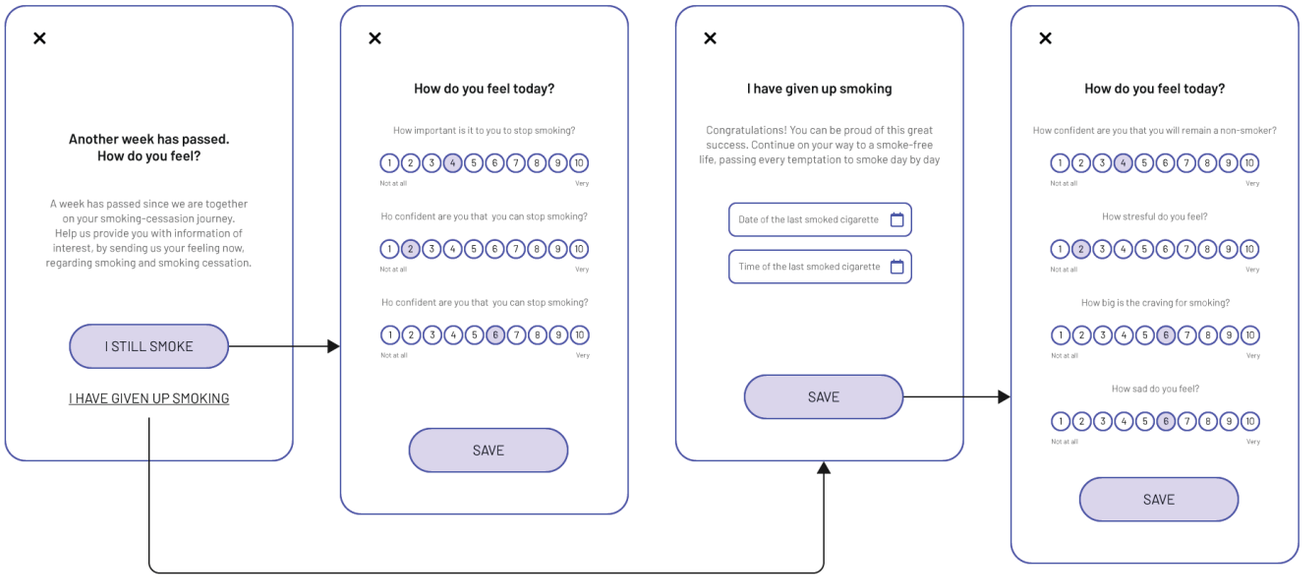


Fig 5.18. Examples of weekly notifications – smokers (Davies & Mueller, 2020)

Designing the user interface

Use a systematic approach to design and test content and the user interface by employing User Experience (UX) testing in all stages of the product life-cycle (Davies & Mueller, 2020). If the app's uptake will be a success if the product is designed in a way that is easy to use, enjoyable, and contains useful information (Davies & Mueller, 2020). Consider rapid prototyping to develop an appropriate user interface to test the product's coverage, software, and usability. (Punchoojit & Hongwarittorrn, 2017; Yanxia et al., 2020). Some examples of UI prototypes are included below:

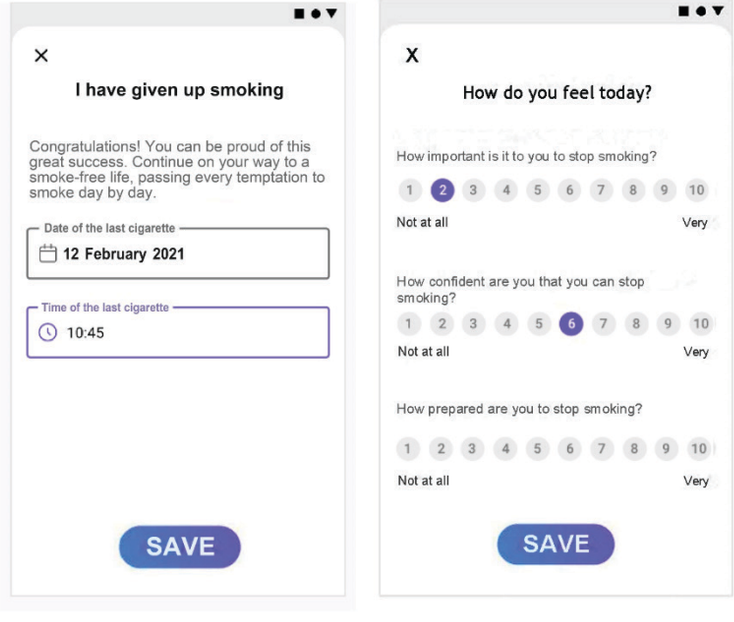


Fig. 5.19. Exemples of the Smoke-Free Together app (Davies & Mueller, 2020)

Coding

Within the software development methodology selected by the project manager (i.e., Agile), the developers use a framework (either Scrum or Kanban) to transfer the app's requirements into code.

Testing the mHealth software

Test message concepts, content, and user interface using a User-Centered Design (UCD). UCD refers to "a design process whereby the users of an intended system or product are involved throughout the development processes, and the design process is centred around the needs and requirements of the end-user" (Davies & Mueller, 2020). UCD can be performed using interviews, focus groups, user stories, personas, scenarios, stories, surveys, stakeholder analysis, and other tools that might fit usability testing needs (Davies & Mueller, 2020).

In general, three testing types are conducted. There is internal testing conducted by the person(s) who has the tester role in the team to find errors in how the software is functioning.

The second type of testing is usability testing. Usability testing can be either moderated or unmoderated, and it can involve either expert in the behaviour targeted by the app or end-users of the app. In moderated usability testing, users are invited to interact with the mobile app on their mobile device, as they would in usual circumstances, by following a list of pre-defined tasks (for example, the user can be asked to find a piece of information available in the app or to change a setting in the app) and while thinking aloud. Throughout this process, the screen and the face of the users are recorded simultaneously. In unmoderated usability testing, users utilize the app independently for several days or weeks and their activity in the app is recorded with various screen recording software already embedded in the mHealth app. One such software is Smartlook, developed to analyze users' behaviours and generate qualitative and quantitative insights that help teams improve their products.

Project management tools

A good management tool is required for good project management and a team working on developing the system. Different tools are used to manage and organize tasks and store the code (these project software management tools are called version control). A selection adapted from Davies & Muellers is being offered below.

Table 5.3. Table adapted from (Davies & Mueller, 2020)

Tool name	Description	Link
Slack	Cloud-based instant messaging with channels. Connects to other apps and allows file sharing	https://slack.com/intl/en-gb/
Trello	For web-based Kanban-style project boards	https://trello.com/
GitHub	Version control tools and hosting	https://github.com/
Asana	Management platform includes lists, task board, progress tracking and calendar	https://asana.com/
TeamGantt	Online Gantt chart software	https://www.teamgantt.com/
SmartSheet	For collaborative work management. Assigns and monitors task progress, manages calendars and allows sharing of documents	https://www.smartsheet.com/
OpenProject	For project planning and scheduling, and support for Kanban and Scrum	https://www.openproject.org/

Additional important aspects to consider

App maintenance

A common misconception is that an app is finished after it was developed and released. However, the life of an app is an ongoing process, and maintenance needs to be considered. Each time the software receives a new update, it affects the application and intervention; therefore, constant maintenance is required. This aspect needs to be covered in the budget of the project for both money and human effort (Davies & Mueller, 2020).

The performance of the app in real-life

Once the mHealth app is finalized, in collaboration with stakeholders and partners, training and promotion plans must be developed, and the preparations for monitoring and evaluation must be finalized. Baseline data should be collected if required for an outcome evaluation (Yanxia et al., 2020). Essential monitoring and evaluation (M&E) tasks consist of collecting end-user feedback, summarizing system data for stakeholders, and evaluating intervention impact (Yanxia et al., 2020).

Gather Evidence that Stakeholders Need

Stakeholders often require different types of information (e.g., demonstration of acceptability, cost and cost-effectiveness, impact on health outcomes etc.). Transparent collaboration with the stakeholders from the beginning will ensure that appropriate types of evidence are obtained for M&E purposes (Yanxia et al., 2020).

Analyze and Report on System Data

Leverage the data generated by the mHealth solution (such as from system usage logs) to regularly analyze and summarize data for stakeholders (Yanxia et al., 2020).

Evaluate Project Impact

Evaluate project impact on end-users and/or the health system. Include health outcomes, gains in quality and efficiency, and cost-effectiveness (Yanxia et al., 2020).

Consider the Potential for Scale Up

The potential for scale-up of the mHealth application needs to be considered from the perspective of the end-users, the perspective of the health system, and the perspective of available resources.

The perspective of the end-users

To create a scalable system, the mHealth software must be easy to use, acceptable and compatible with users' values and social norms. In addition, it needs to be useful to the end-users or an improvement compared to what the end-users did or used before, such as by making their jobs easier, improving the quality of their work, saving time, or meeting clients' needs. A mHealth solution is more likely to be adopted if it is beneficial to end-users, easy to use and minimizes costs. Additionally, if these aspects are met, some of the benefits can be provided in many ways, such as saving costs, saving time, improving quality, meeting clients' needs, or making it easier for health workers to do their jobs (Yanxia et al., 2020).

The perspective of the health system

The first condition that needs to be met when considering to scale up an mHealth application is the local support and buy-in for its implementation (Nouri et al., 2018; Yanxia et al., 2020). An application is more likely to be scaled up and sustained if it is linked electronically into the health ecosystem. If feasible, ensure that data collected by the solution is linked to facility-level data systems (Yanxia et al., 2020).

The perspective of the available resources

The mHealth application needs to be cost-effective to deploy and run. To the extent possible, help ensure sufficient human and technical resources for scale-up are in place. This may include advocating for supportive policies or more mobile network coverage. Essential scale-up resources include:

- Adequate mobile network coverage. You may need to adapt the solution for the existing mobile network infrastructure.
- Ongoing technical support maintains the system and responds to problems as they arise. If the local technology partner does not have sufficient skills for implementing and maintaining the mHealth solution, it will eventually stop working. Consider mentoring them if needed to improve their skills.
- Reliable electricity for databases and monitoring dashboards in the system. How will phones or tablets be recharged?
- Secure database storage capacity, regular data back-up, and network monitoring.
- A privacy and confidentiality policy. Such a policy is needed when collecting and storing patient data (Yanxia et al., 2020).

Explore Sustainability Models or Make a Business Case for the application

Explore sustainability models or make a business case for the application.

- Identify ways the application can help mobile operators improve their services and expand market share; use these benefits to negotiate lower rates.
- Seek financial support from the public and private sources and/or end-users.
- Explore integrating mobile finance functions for sustainability.
- Explore diverse business models with partners and stakeholders (Yanxia et al., 2020).

EXAMPLES AND ANALOGIES

Using the Scrum framework to develop a self-help pregnancy Android app – taken from (Davies & Mueller, 2020)

The scrum approach was used to develop an Android app to help women achieve a healthy weight during pregnancy.

Roles

The team consisted of 5 people who assumed multiple roles. The authors define the following roles:

- Product Owner: This individual acted as a liaison between the customers, the project sponsors, and the development team and was tasked with communicating the requirements of the project
- Scrum Master: This individual communicated the development goals to the team and liaised between the product owners and the team. The scrum master also organised each sprint by assigning items from the product backlogs into the sprint backlogs and assessed the team's progress at the end of each week.
- Application development team: This group was tasked with coding and testing the application.
- User interface design team: This group was in charge of designing the look and feel of each application screen.

Product backlog

The team created a product backlog detailing the required components and functionalities of the application together with the customer. This included:

- UI component: all screens and UI elements
- Notifications/reminders component: reminders for the user to input data into the app, such as weight and activity
- Weight monitoring component: a feature allowing the user to input and monitor their weight over time
- Dietary information component: a feature allowing the users to input and monitor their food intake, as well as receive feedback regarding the quality of their diet
- Activity monitoring component: a component allowing users to input and monitor their activity levels
- Google Health component: a component which interfaces with Google Health to enable the user to log weight, diet and activity information
- Feedback component: a component which provides feedback to the user based on the information they inputted
- Information library: a component containing information about food (e.g. portion sizes) and help screens
- User manual: a component guiding using the application

Meetings and progress tracking

The following mechanisms were implemented to facilitate planning and progress tracking:

- Weekly meetings
- Frequent communication between individual team members via telephone to track progress • Sprint planning meetings at the start of each sprint
- Weekly meetings with the customers to assess the product backlog

Work plan and sprints

The project spanned 21 weeks, split into three sets of seven-week terms:

1. The first term involved background research and literature reviews on weight gain during pregnancy as well as requirements gathered from the customers
2. The second term focused on software development and involved conducting focus groups to facilitate the development of front-end components. It was split into three two-week sprints: Sprint 1 focused on the user interface and the notifications/reminder component; Sprint 2 and 3 focused on the weight tracking, nutrition tracking, and activity tracking components
3. The final term involved completing the coding of the application and polishing the user interface. This term was also split into three sprints: Sprint 1 focused on the feedback component, the Google Health component, and the information library; Sprint 2 focused on the feedback component and the information library, and Sprint 3 focused on bug fixes, polishing the user interface, and developing the user manual

The team adapted the scrum approach to suit the aims and timelines of their project. Deviations from scrum included:

- No scrum burn-down chart to assess the completed work per day was created due to limited time available to the scrum master (who was also part of the development team) and because the product backlog did not change much throughout the project
- Weekly meetings were held instead of daily standup meetings (for the same reasons outlined above)
- No sprint retrospective meetings were held due to time constraints

Using a Kanban approach in the development of a mobile app to promote a vegetarian diet - (Davies & Mueller, 2020)

A Kanban chart was used to manage the coding stage of developing a mobile app to promote adopting a vegetarian diet. The Kanban chart was created using Kanbanpad (a free online tool) and detailed the app's functional requirements and tasks needed to accomplish these.

The project was managed by combining the Kanban chart with a Gantt chart. The Gantt chart provided an overview of the overall project and the higher-level tasks (e.g. "complete literature review" or "usability testing") as well as their timelines. The Kanban chart, on the other hand, detailed smaller, more specific tasks (e.g. "Find studies on mobile nutrition tracking" or "Find participants for usability test").

Example of a mHealth app – data collection examples

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Lesson plan 5: Strengthening health systems using mHealth solutions

FOUNDATIONAL KNOWLEDGE

Based on the work of the World Health Organization's mHealth Technical Evidence Review Group (mTERG), six types of applications serve as building blocks for mHealth solutions:

- Social and behaviour change communication
- Workforce development
- Service delivery
- Financial transactions
- Supply management
- Information systems (Mehl & Labrique, 2014)

Social and behaviour change communication

Social and behaviour change communication (SBCC) applications provide health information directly to the general public and help to connect people with essential services. They also include client support for treatment adherence, such as text-message appointment reminders and support for medication adherence (Mehl & Labrique, 2014).

Workforce Development and Support

Workforce development and support applications consist of: provider training and education, supervision, work planning and scheduling and human resource management (Mehl & Labrique, 2014).

Service Delivery

Service delivery applications help support health workers' performance related to diagnosis, treatment algorithms, disease management, preventive services, and provide checklists. They include telemedicine (remote provider-client consultation) and provider-to-provider communication. An example is the mobile phone networks of health providers in Ghana, Liberia and Tanzania (set up by the non-profit organization Switchboard) that enable group members to make voice calls to each other for free or for a very low cost, facilitating consultation and knowledge sharing (Mehl & Labrique, 2014).

Financial Transactions and Incentives

Financial transactions and incentives applications help improve access to health services, reduce cash-based operating costs, and accelerate payments to providers by including savings accounts and insurance and performance-based incentives (Mehl & Labrique, 2014).

Supply Management

Supply management applications help track and manage supplies of medicines and other essential commodities, help prevent stock-outs and facilitate equipment maintenance (Mehl & Labrique, 2014)

Information Systems

Information systems applications include a prevalent range of activities, including data collection and reporting of patient health and service provision, registries and vital events tracking, electronic health records (EHR), and surveillance and household surveys (Global Health eLearning Center, 2013). They are meant to increase survey or patient data reporting speed and accuracy by freeing health workers and managers from cumbersome paper-based systems. Data collected on mobile devices can be fed into central servers, enabling monitoring and analysis of health systems, service delivery and disease statistics at district, state and national levels (Mehl & Labrique, 2014).

In 2016, World Health Organization's mHealth Technical Evidence Review Group (mTERG) developed the mHealth Evidence Reporting and Assessment (mERA) checklist to address gaps in the comprehensiveness and quality of reporting on the effectiveness of digital health programs.The mERA checklist aims to assist authors in writing on digital health research, guide reviewers and policymakers in synthesizing evidence, and guide journal editors in assessing the completeness of reporting on digital health studies. An increase in transparent and rigorous reporting can help identify research gaps and understand the effects of digital health interventions as a field of inquiry (Agarwal et al., 2017).

EXAMPLES AND ANALOGIES

Social and behavior change communication

CycleTel - a text-message service piloted in India that delivers the Standard Days Method (SDM) of family planning to a user's mobile phone (Ashcroft et al., 2017).

How CycleTel works:

1. A woman texts "JOIN" to a designated number to request the service.
2. The system asks her questions to determine her eligibility to use SDM.
3. If eligible, the woman texts the date of her last period.
4. She then receives personalized SMS alerts on the days she will likely become pregnant if she has unprotected sex (her "unsafe" days).
5. When problems or questions arise, users can call the CycleTel helpline (Ashcroft et al., 2017).

WelTel - In a randomized clinical trial called the WelTel Kenya trial, clinic nurses in three Kenyan clinics sent weekly SMS messages to adult clients who had recently begun antiretroviral therapy (ART) (van der Kop et al., 2018).

How it worked:

1. The messages asked patients how they were doing, and patients were required to respond within two days.
2. The clinic nurses called patients who did not respond or responded that they had a problem.
3. Patients who received the text messages had significantly higher self-reported ART adherence and improved rates of viral suppression compared to the group receiving standard care (van der Kop et al., 2018)

Workforce Development and Support

In a mHealth study conducted in Kenya, health workers in rural health facilities received daily text messages that reinforced information the health workers' had received during training. The purpose of the reminders was to improve and maintain health workers' adherence to national guidelines for managing outpatient pediatric malaria.

Each week the health workers received ten different messages—two messages a day, Monday through Friday. Messages reflected key recommendations from the guidelines and training manuals. Each included an entertaining or motivating quote to make it appealing (Kaunda-Khangamwa et al., 2018).

Financial transactions and incentives

Using SMS To Reimburse Reproductive Health Service Providers:

As of March 2013, Marie Stopes Madagascar had distributed more than 29,000 subsidized vouchers in 12 rural regions of Madagascar to make it easier for very low-income clients to obtain family planning services. A voucher costs just 200 Ariary (US $0.10). A client can give the voucher to one of 143 franchised providers in exchange for family planning services normally costing 4,000-10,000 Ariary. Marie Stopes Madagascar uses an SMS-based money transfer system to reimburse these providers for their services (E. Burke et al., 2017).

How it works:

1. Providers send the unique code on a client's voucher by SMS to a phone number linked to Marie Stopes Madagascar's online database to receive their payment.
2. The database automatically verifies that the phone number used to send the SMS was that of a participating service provider and acknowledges that it received a valid code.
3. The system then notifies the Marie Stopes voucher manager and finance director, who checks and authorizes the codes for payment.
4. Marie Stopes Madagascar transfers the payment to the provider using a mobile money service. The provider is notified of the payment via SMS (E. Burke et al., 2017).

Supply management:

For example, the ILS Gateway is a mobile phone-based system that supports Tanzania's Integrated Logistics System. It helps improve the availability of commodities by making facility-level logistics data more available to decision-makers. In the ILSGateway, active in more than 2,300 health facilities across Tanzania, staff members use their mobile phones to report stock levels of 20 essential family planning commodities (Sant Fruchtman et al., 2021).

Information systems

In 2011 the Nepal Demographic and Health Survey (DHS) was completed using tablet personal computers (tablet PCs) rather than paper-based questionnaires. It was the first time mobile technology was used to conduct the DHS in Nepal. Interviewers recorded questionnaire responses directly into the tablets and submitted the data to their supervisors via Bluetooth at the end of each day. Supervisors transferred data to the main office via a mobile network (Paudel et al., 2013).

mCARE, a Bangladesh maternal and child health solution, links community health workers and their clients (pregnant women and newborns). The goal of mCARE is to improve pregnancy registration and support the survival of preterm infants (Jo et al., 2019). The mCARE health information system uses several applications that support or provide:

- Pregnancy surveillance and registration
- Scheduling and delivery of antenatal and postnatal care
- Automated reminders for antenatal and postnatal visits
- Home-based newborn care checklists
- Labour and birth notification
- Referral and emergency mobilization (Jo et al., 2019)

mCARE blends information systems (surveillance and registration), workforce development (scheduling), SBCC (automated reminders), and service delivery (checklists, notifications, referral) applications (Jo et al., 2019).

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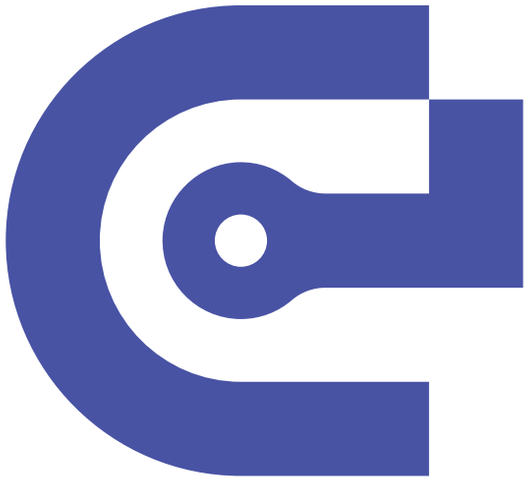

Module 6: Telemedicine

Learning objectives of the Telemedicine module

1. Students will be introduced to the concept of telemedicine and healthcare challenges concerning telemedicine.
2. Students will learn about current technological challenges and opportunities in telemedicine.
3. Students will learn to communicate effectively (including nonverbal) with patients in a virtual space. (Patient communication guides)
4. Students will discuss the development of telemedicine apps and startups as a solution to healthcare challenges. (GDPR & HIPAA COMPLIANT)
5. Students will discuss and analyze relevant use cases in the field of telemedicine.
6. Students with a technical background will be exposed to several major health issues, and the privacy, security, and confidentiality concerns present in healthcare today.
7. Students with a healthcare background will become familiar with the technical aspects of privacy and information security concerns regarding the storing and sharing of private health information. (MALPRAXIS)
8. Students will explore issues associated with telemedicine use, including forces driving to the adoption of telemedicine, liability and insurance, reimbursement and career opportunities.
9. Students will be provided with a forum for a critical discussion of current developments, research topics, and impact within the field of telemedicine.
10. Students will be provided a forum for interdisciplinary collaboration focused on future directions for telemedicine (e.g., communication, research, development).
11. Practical activities
12. Data protection & regulation

Foundational knowledge of the Telemedicine module

Definition of Telemedicine

Telemedicine is a subset of telehealth, which refers to the use of communication networks to deliver healthcare services at a distance. Communication and networking technologies, such as satellite communications, the internet, and Global System for Mobile Communications (GSM), also vary. The COVID-19 pandemics led to a need for socially distanced health care that telemedicine visits increased 683% at the height of the pandemic. Telemedicine will permeate pervasively into healthcare delivery over time (CHIRON, n.d.).

World Health Organization (WHO) defines telemedicine as “the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for the diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities”. What we recognize as telemedicine today started in the 1950s when a few hospital systems and university medical centres began to try to find ways to share information and images via telephone. In one of the first successes, two health centres in Pennsylvania could transmit radiologic images over the phone (WHO, n.d.).

Regarding patients, the main benefits of telemedicine are less time away from work, no travel expenses, less interference with a child or eldercare responsibilities, privacy, and no exposure to other potentially contagious patients. On the other hand, in the case of providers, their benefits are an increase in revenue, office efficiency, better patient follow-through and improved health outcomes, fewer missed appointments and cancellations, and private payer reimbursement.

There are a few limitations to how telemedicine can be applied. Some examples of how it is being used today are follow-up visits, remote chronic disease management, remote post-hospitalization care, preventive care support, school-based telehealth, and assisted living centre support (WHO, n.d.).

According to an economic forecast organization, the size of the telemedicine market was around $45 billion in 2019, and it is projected to reach $175 billion by 2026. The reasons for this growth are the increasing healthcare cost, geriatric population, government funding and grants for telemedicine, medical tourism, the prevalence of chronic and lifestyle-associated diseases, the medical requirement in remote areas, and the need for remote patient monitoring services in developing countries. In the European Union, five projects related to telemedicine are carried out. The scope of these projects is teleradiology, teledermatology, teleneurology, telemonitoring for diabetes and chronic heart failure, but there is no topic on education (Insights, n.d.).

Key components of *Telemedicine*

Teleconsultation

Teleconsultation is defined as synchronous or asynchronous consultation using information and communication technology to omit geographical and functional distance (Deldar et al., 2016).

Examples:

1. Both sides are health providers [e.g., who may need a second expert opinion]
2. Physician–physician consultation
3. Physician–primary care provider (PCP) communication, like nurses
4. One side is the health provider, and another side is the patients [e.g., for telemonitoring or tele-visiting]
5. Physician-patient relationship
6. PCP–patient relationship
7. Tripartite communication among physician – PCP – patient

Telementoring

Telementoring is mentoring carried out at a distance (usually online), when face-to-face mentoring is impossible (*Telementor Guide*, n.d.).

Telemonitoring

Telemonitoring is the remote monitoring of patients, including “the use of audio, video, and other telecommunications and electronic information processing technologies to monitor the patient status at a distance” (Meystre, 2005).

Examples:

1. Cardiovascular: Heart rate, Fetal Heart rate, Blood pressure, ECG, Pacemaker parameters
2. Hematologic: Coagulation (INR)
3. Respiratory: Pulse oximetry, Spirometry, Respiratory rate, CO2 production, O2 consumption
4. Neurologic: EEG, EMG, Intracranial pressure
5. Metabolic: Body weight, Basal metabolic rate, Blood glucose, Blood lactate, Blood ethanol, Diet, Physical activity, Temperature

Teleassistance

Teleassistance represents the act of a doctor assisting other health professionals at a distance in the performance of some medical action (IGI Global, n.d.).

Telemedicine applications can be classified into two basic types, according to the timing of the information transmitted and the interaction between the individuals involved—health professional-to-health professional or health professional-to-patient. Store-and-forward or asynchronous telemedicine involves exchanging pre-recorded data between two or more individuals at different times. For example, the patient or referring health professional sends an e-mail description of a medical case to an expert who later sends back an opinion regarding diagnosis and optimal management. In contrast, real-time, or synchronous, telemedicine requires the involved individuals to be simultaneously present for the immediate exchange of information, as in the case of videoconferencing. In both synchronous and asynchronous telemedicine, relevant information may be transmitted in a variety of media, such as text, audio, video, or still images. These two basic approaches to telemedicine are applied to a wide array of services in diverse settings, including teledermatology, telepathology, and teleradiology. Most telemedicine services, most of which focus on diagnosis and clinical management, are routinely offered in industrialized regions, including but not limited to the United Kingdom of Great Britain and Northern Ireland, Scandinavia, North America, and Australia. In addition, biometric measuring devices such as equipment monitoring heart rate, blood pressure and blood glucose levels are increasingly used to monitor and manage patients with acute and chronic illnesses remotely. Some predict that telemedicine will profoundly transform the delivery of health services in the industrialized world by migrating health care delivery away from hospitals and clinics into homes (WHO, n.d.).

Lesson plans for the Telemedicine module

Lesson 1: Introduction to Telemedicine: Opportunities and Barriers

FOUNDATIONAL KNOWLEDGE

What is Telemedicine?

“The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for the diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities” - World Health Organization (WHO, n.d.).

Key components of Telemedicine

Teleconsultation

Telementoring

Telemonitoring

Teleassistance

Current telemedicine use

Telemedicine, or the electronic transmission of medical information via digital communications, has become an essential tool. It has led to a significant increase in remote telemedicine and telehealth interventions, with many physicians in some regions using these technologies to manage patients remotely. The expanded use of telemedicine in medical care and teleradiology occurred in tandem with the increased need for social distancing. Telemedicine tools are more commonly used for remote treatment, particularly in the United States, where 63% of health care practitioners have used it. Among physicians currently using telemedicine for consultation, nearly half (48%) are using it for the first time. When the outbreak ends, one-fifth of physicians using telemedicine tools expect to use them significantly more than before the pandemic. The COVID-19 pandemic has highlighted the innovative degree to which eHealth can empower health systems to avoid cross-infection of COVID-19 patients and ensure continuity of essential health services (Abdel-Wahab et al., 2020).

Telemedicine within different specialities:

- **Teleradiology** (ultrasounds, MRIs and x-rays)(eVisit, n.d.-b)
- **Telepathology** (static image-based systems, virtual slide systems, real-time systems) (TechTarget, n.d.)
- **Teleophthalmology** (Synchronous teleophthalmology, Asynchronous teleophthalmology) (Wikipedia, n.d.)
- **Teledermatology** (skin mapping, diagnosis, and archiving system) (DermNet, n.d.)
- **Telecardiology** (coronary heart disease, both chronic and acute, as well as arrhythmias, congestive cardiac failure, and sudden cardiac arrest) (News Medical, n.d.)
- Teleobstetrics /prenatal telemedicine service
- Telecare in geriatrics
- Teleoncology
- Teleneurology
- Telediabetes
- Telepsychiatry and telemental health
- Telesurgery
- Teleotorhinolaryngology
- Teledentistry
- Teleemergency service
- Tele-ICU (Intensive care unit)
- Teledialysis
- Telerehabilitation

Advantages of telemedicine

- increases access to specialized and timely urgent care,
- increases the capacity and efficiency of specialists,
- reduces wait times for appointments and follow-up visits,
- reduces emergency department visits and the time patients spend in hospitals,
- reduces the discomfort and anxiety associated with patients travelling to receive services,
- reduces the costs and carbon emissions associated with patient travel,
- connects care teams to provide greater continuity of care,
- connects remote family members with long-stay patients,
- connects healthcare professionals for knowledge sharing,
- integrates with conventional care delivery models,
- keeps patients in their homes and communities longer.
- redaction of healthcare costs in public and private sectors
- easy access to specialists for rural area patients
- prevention and medical education *(Telemedicine Benefits: 17 Advantages for Patients and Doctors*, n.d.)

Barriers to the development of telemedicine

- **Unfamiliarity with the technology**

  Telemedicine is a hybrid system involving the medical and ICT domain for complete understanding of the telemedicine solutions and their delivery. There is a serious lack of such technical persons who can run the day-to-day business of telemedicine. To run any telemedicine system properly, trained technical workforce is required (*Barriers to Development of Telemedicine in Developing Countries*, n.d.; "E-Health and telemedicine: Concepts, methodologies, tools, and applications," 2015).

- **Lack of informed consent before teleconsultation**

  Healthcare providers need to have a clear understanding of what their legal and ethical responsibilities are. Similarly, patients must receive the protection of adequate standards of care and know that the person to whom they are entrusting their health has the proper qualifications. The lack of clear-cut legal guidelines, rules, and regulations hinders telemedicine from improving healthcare access and quality through information and communication technology (*Barriers to Development of Telemedicine in Developing Countries*, n.d.).

- **The initial upfront cost for equipment and connectivity**

  Although telemedicine can be leveraged to increase access to care and reduce cost, that is mainly true from the user's point of view. The story is different if we look from the side of providers or healthcare organizations. Establishing a telemedicine unit needs lots of financial investment. It becomes more difficult for developing countries to allocate a huge budget for investment in telemedicine (*Barriers to Development of Telemedicine in Developing Countries*, n.d.).

- **Reimbursement and insurance barriers**

  Reimbursement of telemedicine services has been reported as one of the important barriers in developed countries. When a patient avails healthcare services through a telemedicine system, an insurance claim may not cover the cost of care as it is not delivered through the traditional healthcare system. Such discrimination

seldom occurs in developing countries, where health insurance is still a rare commodity *(Barriers to Development of Telemedicine in Developing Countries*, n.d.).

- **Licensure issues**

  Highly sophisticated, safe, secure, and speedy teleconsultations have reduced the distance barrier in healthcare-seeking and have improved healthcare access. To avoid malpractice in telemedicine, healthcare professionals should be specifically trained for telemedicine as they do for traditional medicine. Poor availability of experts and trained professions raises legal implications and warrants licensing of telemedicine providers *(Barriers to Development of Telemedicine in Developing Countries*, n.d.).

- **Patient acceptance/satisfaction**

  There is a lack of confidence in patients about the outcome of telemedicine. It is difficult for them to believe that machines can provide healthcare demands without visiting physicians. This cultural perception and attitude toward newer technology also threaten the development of telemedicine. Even many physicians think that patient consultation and treatment are incomplete without touching the patient and prefer face-to-face consultation over remote consultation through the ICT platform. Some medical practitioners do not want to opt for telemedicine practice due to the fear of medical indemnity *(Barriers to Development of Telemedicine in Developing Countries*, n.d.; "E-Health and telemedicine: Concepts, methodologies, tools, and applications," 2015).

- **Lack of legal regulation in telemedicine**

  Telemedicine practices have eliminated many physical and emotional barriers to healthcare seeking but have raised many legal and ethical issues, which are normally not encountered during traditional healthcare delivery. Legal considerations are a major obstacle to telemedicine uptake *(Barriers to Development of Telemedicine in Developing Countries*, n.d.; "E-Health and telemedicine: Concepts, methodologies, tools, and applications," 2015).

Table 6.1. Issues linked to Telemedicine use (Gorgia, n.d.)

8	Technical	Noninteroperability of monitoring devices / sensors	As above	Standards and open systems	No
9	Technical	User acceptability of new telehealth technology (games, avatars, and immersion). Intrusive — asking too many passwords	The best of systems fail because of human factors. An unused technology or system is literally useless.	Participatory design; interventions targeting youth, training; proper reimbursements	No
10	Clinical	Services established outside ordinary protocols; weak links to EHRs	Occurs whenever change management principles are ignored	Include the service into the traditional healthcare system and EHRs (if available)	No
11	Personnel	Loss of interpersonal relationships due to wrong words and misinterpretation	Miscommunication and misinformation are common, for example, autotyping leading to wrong words	Rechecks; a general slowdown; Guidelines	Yes
12	Personnel	Loss of respect for timelines	Calls for help on a 24/7 basis — sometimes the care seeker is in a different time zone	Strict appointment system; guidelines	Yes
13	General	No clear method of reimbursement. Care access through unconventional means competing with regular channels.	Insurance companies do not reimburse the travel and time cost. In India, telehealth has had higher success rate as healthcare expenses are out of pocket	Creation of telehealth-related care and reimbursement protocols; engagement of insurance companies	Yes

Adapted from Gogia SB, Maeder A, Mars M, Hartvigsen G, Basu A, Abbott P. Unintended consequences of tele health, and their possible solutions. Contribution of the IMIA Working Group on telehealth. Yearb Med Inform. 2016;(1):41-46. doi:10.15265/1Y-2016-012.

EXAMPLES AND ANALOGIES

Examples of startups that are using Telemedicine:

- **Telios**

  Telios brings your business immediate and direct access to experienced doctors and other healthcare professionals. Employees save time by avoiding the issues prevalent with accessing traditional medical care, such as synchronizing appointments with their schedules, wasting time in traffic and waiting room delays.

- **Atlas**

  Atlas.app is Romania's largest therapy, parenting and personal development platform. They have over 200 specialists in one safe place, and the customers can meet them online at Atlas or directly at their office.

- **Docbook**

  Docbook is Romania's only online medical appointment booking service app integrated with clinics software. It addresses the problem of patients needing immediate medical appointments by allowing free-of-charge doctors to search & booking within seconds.

- **MEDICAI**

  MedicAi is a collaborative online imaging platform that enables better sharing and communication between patients, doctors & clinics.

Table 6.2. Departments which can benefit from Telemedicine (Gorgia, n.d.)

Service	Important components	Role
Wound care	Unless very serious, wounds should be managed at the subprimary level. Requires transfer of images mostly. Sometimes telementoring and VC	Very high
Radiology	Images and video. Preexisting digitization and PACS make it easy. DICOM a specific standard	Very high
Dermatology	Images. Most problems are chronic, so decrease in frequency of visits is important.	Very high
Cardiology	Tele-ECG, telestethoscope, and emergency support for MI	High
Ophthalmology	Images, which used to be taken through a slit lamp, an ophthalmoscope, and a fundoscope, can now be replaced by smart mobiles with special attachments.	High
Psychiatry	Video conference and face-to-face contact for counseling	High
Pathology	Images and opinion. Special microscopes allow remote manipulation of the slide	Moderately high
Intensive care	Monitoring devices and emergency support	Moderately high
Emergency care	Allows care to begin as soon as a 911 call is made	Moderately high
Rehabilitation	Immobility of patients is a constant concern	Moderately low
Pediatrics	Emergency support and telemonitoring home-based care. A comfortable environment and access to parents is helpful for the child development	Moderately low
Orthopedics	X-ray films. Home monitoring of splints and dressings. Emergency support	Low
Neurology	Tele-ICUs with robotic assistants and home care	Low
Plastic surgery	For preop assessment, planning, and also follow-up care (See example in Box 4)	Low

APPLICATION AND INTEGRATION

A practical exercise in which, for several different patient journeys, students need to identify the segment of care that can be performed through telemedicine and the specific benefits for each stakeholder.

A practical exercise in which one of the available resources in the hospital could be performed through telemedicine and how the different stakeholders' needs would be impacted.

A practical exercise to define the main factors/stakeholders directly involved in the telemedicine process. (With the help of the resources below)

Health system transformation requires the involvement of all stakeholders. Partnerships usually facilitate change, and the telemedicine sector is no different. Community leaders, health professionals, academic institutions and educators, health administrators, and policymakers represent the best alliance to make changes necessary to reflect and react to societal needs.

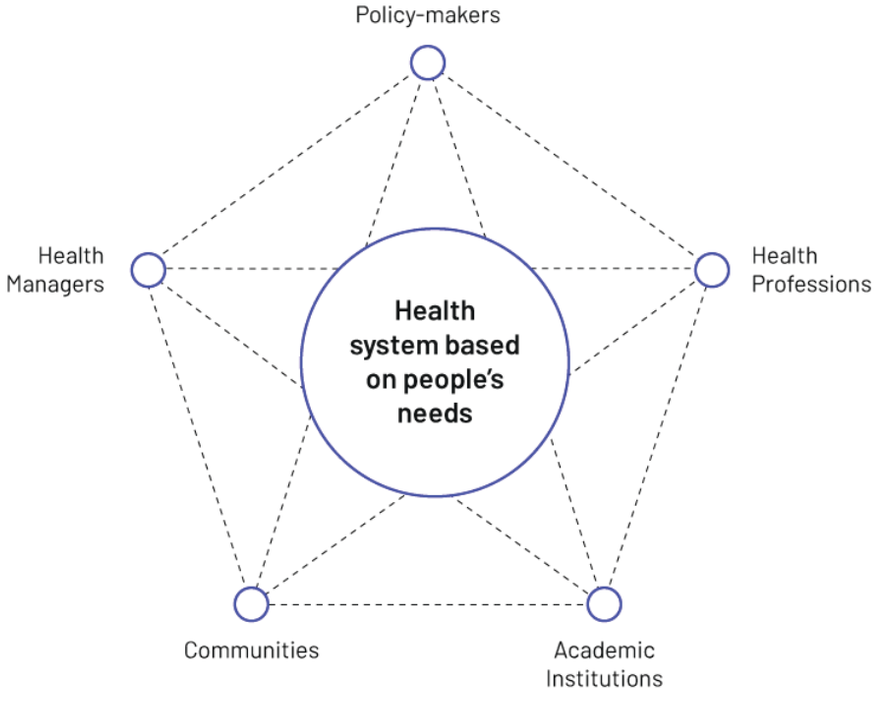

Figure 6.1. Health system based on peopleţs needs (WHO, n.d.)

L1: REFERENCES FOR FURTHER INFORMATION AND AREAS OF INQUIRIES

https://www.who.int/goe/publications/goe_telemedicine_2010.pdf

https://www.intechopen.com/chapters/64650

Fundamentals of Telemedicine and Telehealth
https://www.youtube.com/watch?v=FAW1JjnCpdQ

Lesson 2 and 3: Teleconsultation (Telediagnosis and Telemonitoring)

FOUNDATIONAL KNOWLEDGE

What is Teleconsultation?

Teleconsultation is defined as synchronous or asynchronous consultation using information and communication technology to omit geographical and functional distance. Its goals are for diagnostics or treatment between two or more geographically separated health providers (for example, physicians or nurses) or between health providers and patients. “Remote consultation” is the superior term for teleconsultation in MeSH (Medical Subject Headings) and is defined as “Consultation by remote telecommunications, generally for diagnosis or treatment of a patient at a site remote from the patient or primary physician” (Deldar et al., 2016).

The advantages of Teleconsultation

- The teleconsultation system does not replace medicine but allows easy access to care and provides good added value thanks to videoconferencing and electronic documents.
- It is essential in the current infectious disease emergency situation because it limits travel and contact and, therefore, the risk of contamination.
- It protects patients, healthcare professionals and citizens (CNS, n.d.).

Types of Teleconsultations

Telediagnosis

What is Telediagnosis?

Telediagnosis refers to remote diagnosis (“tele” means remote, prefixed to diagnosis). These platforms are designed to transmit physical examination records and medical reports remotely or concurrently to a specialist at a different or the same geographical location. The examining specialist doctor may be in the same geographical region at the same time of the examination, or the specialist may be remotely located: the transmission platform is designed to work identically. Telediagnosis platforms ensure that records of images and videos preserve the diagnostic quality even after being subjected to compression procedures for transmission. The Digital Imaging and Communications in Medicine (DICOM) standard is a recommended requirement to allow heavy file traffic without impairing efficiency in use. A limitation might be low connection speed for data transmission or restrictions with bandwidth. Therefore, balancing image quality, efficiency in use, and available bandwidth pose significant challenges to telediagnosis platforms (Basu, 2019).

Implications of Telediagnosis for Diagnostic Quality and Safety?

Table 6.3. Implication of Telediagnosis for Diagnostic Quality and Safety (Smith et al., 2020)

Diagnostic Process	Prospects	Pitfalls and Challenges
Supportive Infrastructure	● The tools (phones, video chats, others) are familiar to many and generally available. ● The general approach is similar enough to in-person care. ● Widely used videoconferencing tools may provide opportunities to engage disadvantaged patients.	● Disadvantaged patients may lack internet access or video-chat tools. ● Infrastructure is immature compared with in-person care. ● Standardized language and protocols have yet to emerge. ● Providers may need specific training to perform telediagnosis well. ● Some platforms are not HIPAA compliant (Note: During the COVID-19 pandemic, the Office for Civil Rights was waived civil monetary penalties for noncompliance, however, it remains a legal requirement to use HIPAA-compliant software [U.S. Department of Health and Human Services; Office for Civil Rights, 2020 #7516]).[25]
Access to the Health System	● E-visits can provide enhanced access to healthcare professionals. ● Multiple platforms are potentially usable. ● Video visits may offer enhanced "presence" vs. telephone (e.g., more eye contact, deeper listening). ● Tips on how to strengthen "presence" are emerging.	● Creating relationships and presence via phone and video may be challenging. Telehealth experts suggest that it can be difficult to replace the value of "touch" when establishing trust in the therapeutic relationship. ● Some platforms are not HIPAA compliant.
Patient History	● History should be comparable to the office-based history. ● It may be better than an office-based history to the extent that other family members can be involved and the clinician can get a sense of the home environment.	● Getting the patient history may be problematic with non-English speakers although this issue may be mitigated through improved access to translation services and family members. ● Telehealth programs may not be set up to allow patients to pre-enter health information before the visit.
Physical Examination	● With full knowledge of the limitations, virtually al aspects of the in-person visit can be conducted effectively. ● At-home devices can augument the ability to collect physical findings (ECG, others).	● Clinicians cannot visualize the tympanic membrane or the retina or listen to heart or lung sounds. ● Incidental findings that might have been detected in an office-based visit may be missed.
Clinical Reasoning	● For challenging diagnostic scenarios, telediagnosis could enable timely convening of multiple clinicians (peers, consultants from other specialities, or other health professionals) to be involved in the clinical reasoning process.	● The impact of telediagnosis on the clinical reasoning process is hard to predict and will require focused study.

Diagnostic Process	Prospects	Pitfalls and Challenges
Diagnostic Testing	● At-home testing tools could enhance testing for some conditions (diabetes, asthma, chronic obstructive pulmonary disease, others)	● Most laboratory tests and imaging require a separate visit. ● If lab testing or imaging requires a separate in-person visit, it may discourage their completion and followup.
Referral, Consultation, Interfaces	● Virtual conferences with patient, family, and different members of clinical team may be facilitated by technology. ● Consults are easily ordered. ● In-person evaluation can be arranged for those who need it.	● Virtual visits may not allow a patient's full engagement or the engagement of the full diagnostic team. For example, the patient may be less likely to stop by and chat with the dietitian or social worker and fewer opportunities arise for exposure to patient education materials or health screening.
Communication of Diagnosis	● Communication may be enhanced if family members participate and facilitate communication and understanding.	● Communication is probably reduced if the diagnostic team (for example, the nurse, pharmacist, therapist) is not engaging to the same extent as they would in person.
Monitoring of Health Outcomes	● Monitoring simplifies followup possibilities for patients and providers. ● Followup reminders can be set.	● Most telehealth programs as yet do not have systems in place to monitor quality and safety.
Diagnostic Safety	● Safety may be enhanced by improved access, a better sense of the patient's home environment, and participation of family members.	● Safety may be reduced by missed physical findings, lack of presence, and decreased participation of onsite team members (nurses, pharmacists, others).
Family Involvement	● Video visits provide an opportunity to engage patients and families. ● Video visits provide a glimpse into the patient's living environment.	● It can be difficult to discuss issues of violence or abuse if the patient cannot complete the visit in a private location.

Telemonitoring

What is Telemonitoring?

Telemonitoring refers to the transmission of symptom scores and physiological data, including heart rate, blood pressure, oxygen saturation, and weight, directly to care providers via automated electronic means or by web-based or phone-based data entry. Over time these interventions have evolved from automated phone response systems to the web, to interactive television-based systems, to mobile phone or PDA-based systems, to complex systems, which wirelessly transmit recorded physiological data.

As an illustrative example of a telemonitoring platform, think of an application that assists a patient in controlling weight. The telemonitoring platform monitors the patient's physical activity and the individual's records of meals and calories consumed in a day and transmits the data for analysis by professionals. The professionals can then act based on received data to help the patient reduce weight. Here the telemonitoring platform is used with the active participation of the patient. In other situations, users may have their data collected through connected devices, for example, blood glucose for diabetics or blood pressure measurements for a hypertensive patient. Such monitoring may lead to prevention or post-discharge planning and treatment in a heart attack or stroke

patients. In yet another scenario, telemonitoring platforms can be integrated into home care equipment to enable continuous monitoring and generate emergency alerts or for elderly patients, who can be continuously monitored with sensors that transmit an alert when the patient falls at home (Gogia, n.d.).

The advantages of Telemonitoring:

- Telemonitoring allows patients to remain in their homes. Better follow-up of patients reduces the complications of chronic diseases such as diabetes, hypertension, or chronic heart failure.
- Telemonitoring may reduce patient travel, time off from work, and overall costs.
- Several systems have proved to be cost-effective, such as home monitoring of high-risk pregnancies, infants, pediatric pacemaker patients, and patients suffering from chronic diseases.
- The cost of simple telemonitoring was evaluated to be approximately $70 per month. A standard emergency room charge is $260.
- Telemonitoring provides accurate and reliable data, stabilising and often improving chronic diseases and avoiding unnecessary treatments because of the “white-coat” effect.
- Real-time telemonitoring of patients transported in ambulances reduces the time for treatment and allows the emergency crew to be better prepared (Meystre, 2005)

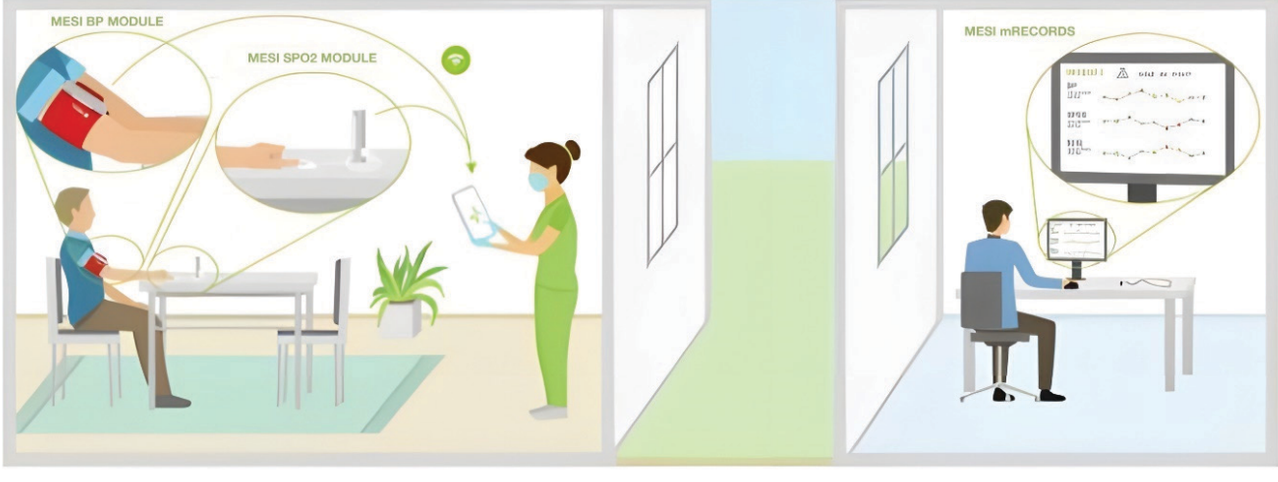

Fig 6.2. The physician, based in a remote location, has access to quality measurements on which he can base his diagnosis and determine the best medical care (MESI, n.d.).

BIDMC@Home

BIDMC@Home provides personalized home monitoring in many different conditions. HealthKit allows the app to collect data from various sensors and 3rd party apps to gain a holistic picture of health and help prevent hospital readmissions. With HealthKit-enabled wireless devices such as scales and blood pressure cuffs, patients with congestive heart failure can use BIDMC@Home to monitor vital signs and symptoms. Daily fluid, sodium intake and important predictors of fluid retention can also be imported via HealthKit. Connected thermometers allow patients with autoimmune diseases such as lupus and rheumatoid arthritis to predict infections better and monitor inflammation. Outpatient chemotherapy is associated with varied symptoms and side effects. The app allows these patients to monitor their health during treatment better. BIDMC@Home simplifies complicated post-operative instructions given to patients after orthopaedic surgery by utilizing the dynamic care card and allowing them to track their recovery. Major bowel surgery can place patients at risk for severe dehydration. Connected

scales and electronic patient-reported outcomes will help prevent complications in these patients in-between visits to the doctor's office. The plan and thought process in the health care providers' notes are essential to staying healthy. These are often hidden in the silos of individual electronic health record systems. BIDMC@Home harnesses the capabilities of the Health app in iOS 10 to serve as a secure, patient-controlled, shareable medical records database (Cerrato & Halamka, 2019).

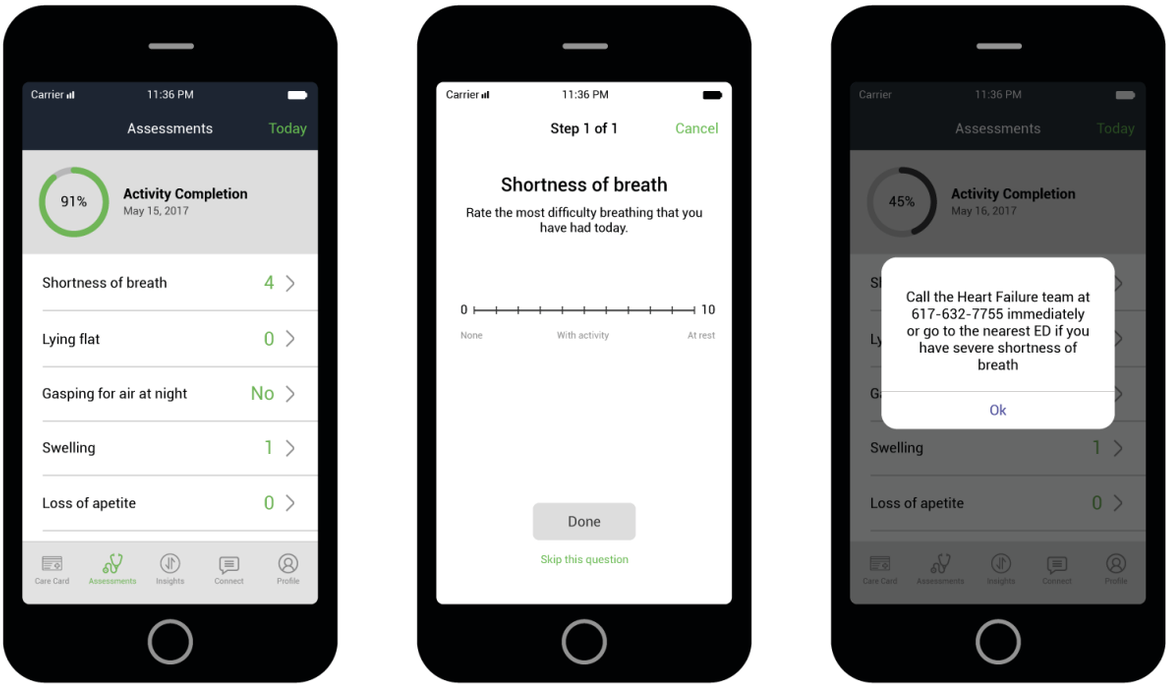

Fig. 6.3. The Health App (Cerrato & Halamka, 2019).

APPLICATION AND INTEGRATION

Imagine a scenario in which Telemedicine is introduced in a medical speciality/ field. Using your smartphones or computers, try to roleplay with your colleagues in which each of you plays a specific character (doctor, nurse, patient, relative, etc.). Try to be as imaginative as you can; imagine the environment, the case, the attitude, the emotions, etc

REFERENCES FOR FURTHER INFORMATION AND AREAS ON INQUIRIES

https://www.sciencedirect.com/science/article/pii/B9780128149232000027

https://www.ahrq.gov/sites/default/files/wysiwyg/patient-safety/reports/issue-briefs/Telediagnosis-brief2.pdf

Lessons 4 & 5: Tele Imaging and Telepathology

FOUNDATIONAL KNOWLEDGE

Tele Imaging involves transmitting a patient's X-rays, CT scans, and MRIs from one site to another, usually to a radiologist based at a different location. Before the internet, teleradiology mostly involved consulting individual radiologists over the phone for emergent cases. With the advent of the internet, everything changed. Sending CT

scans or MRIs digitally and securely became simple. Now, with the visual data and patient health record in front of them, the radiologist can provide an analysis, record it, and send it back to the patient's physician(*[Medical tele-imaging: a good chance for the future] - PubMed*, n.d.).

Types of Imaging Modalities

There are several methods of medical imaging in modern medicine. Each has different potential advantages and disadvantages, including exposure to radiation with some types of imaging.

The commonly used imaging techniques are:

1. **X-rays**

- X-rays are the oldest and most frequently used form of medical imaging.
- The images are taken by passing x-rays through a part of the body under investigation and recording the amount of x-radiation not received in the body.
- It is a non-invasive medical test that helps physicians diagnose and treat medical conditions.
- From a diagnostic and imaging point of view, the resolution of the x-ray as 4K x 4K is required to capture the necessary details (OrthoInfo, n.d.).

2. **Computed Tomography (CT)**

- Computed tomography is another imaging system which also makes use of x-rays.
- CT images are generated by making the patient lie on a table, which passes through a doughnut-shaped scanning machine. The x-rays that pass through the patient are digitized and detectors detect pulsed signals on the opposite side of the x-ray source.
- The CT scanner computed an image of the tissue density and represented as a slice of the patient's body.
- In modern CT scanners, three-dimensional (3D) images can be computed from multiple scans. A CT scan may consist of 10 to 12 individual cross-sectional images.
- These can be laser printed onto high-quality transparency film. Each image is a 512x512 data matrix containing 256 shades of grey (OrthoInfo, n.d.).

3. **Magnetic Resonance Imaging (MRI)**

- MRI is a non-invasive imaging technology based on excitation and detecting the change in the direction of the rotational axis of protons found in the water that makes up living tissues.
- The patient is surrounded by extremely powerful electromagnets that align the atomic nuclei in the body.
- When a radiofrequency current in the pulsed form is externally applied to the patient, the protons are disturbed and spin out of equilibrium. When the radiofrequency field is turned off, the nuclei return to their initial orientation; emitting radiation picked up by a receiver coil. The analysis of this radiation forms the basis for identifying the concentration of certain atoms within the body and helps generate an image based on this concentration.
- MRI image resolution conforms to 128x128 or 256x128 matrix size (OrthoInfo, n.d.).

4. **Ultrasound Imaging Systems**

- Ultrasound imaging systems involve passing a high-frequency sound wave (2-4 MHz) into the patient's body.
- In an ultrasound examination, a transducer (probe) is placed directly on the skin of the patient's body or a body opening. A thin layer of gel is applied to the skin so that the ultrasound waves are transmitted from

the transducer through the gel into the body. The ultrasound waves get reflected off from various internal body structures of the patient.

- The received ultrasound waves are then amplified, processed, and a two-dimensional image of the scanned area is constructed.
- Unlike x-ray imaging, ultrasound imaging does not involve exposure to ionisation radiation. The advantage of ultrasound lies in detecting soft tissue, such as tumours and lesions.
- Ultrasound today is the preferred non-invasive diagnostic imaging modality practised in most medical specialities, including cardiology, internal medicine, obstetrics and gynaecology (OrthoInfo, n.d.).

5. Nuclear Medicine Imaging Systems

- Nuclear medicine uses certain properties of isotopes and the energy particles emitted from radioactive material to diagnose or treat various pathological conditions.
- Based on the principle of injecting the patient with a radioactive substance and detecting the gamma rays emitted (OrthoInfo, n.d.).

Types of Tele Imagistics Systems

In practice, there are three types of tele Imagistics systems:

1. **On-call:** Typical “on-call” tele imaging systems are most frequently used for after-hour, “on-call” applications.
2. **Off-site:** “Off-site” systems are set up mostly by radiology specialists and hospitals to establish a central database to expand the interpretation network.
3. In-hospital systems are meant to transfer images within the same facility over a LAN.

Telepathology refers to practising pathology from a distance. Telecommunications technology is used to facilitate the transmission of pathology image-rich data between two distant locations for diagnosis, research, and education purposes. To perform telepathology, a pathologist must choose the video images to be analyzed and then render a diagnosis. Television microscopy, which preceded telepathology, didn’t require a pathologist to have a virtual or physical hands-on involvement in choosing the microscopic fields of view to analyze and diagnose (Farahani & Pantanowitz, 2015).

Telepathology has been used successfully for many applications, including histopathology tissue diagnoses being rendered from a distance. In developed countries, digital pathology imaging, which includes virtual microscopy, is preferred. However, in some developing countries, analogy telepathology imaging still is used in patient services(eVisit, n.d.-a).

Telepathology System Types

1. Virtual slide systems

The virtual slide pathology system digitizes slides. It completely removes glass slides from the practice of pathology.

With virtual slide pathology, scanners copy glass slides and turn them into digital slides for remote pathologists to use. These images are high-resolution, which means that they are highly detailed.

When scanning these slides, there are no alterations to the image. The specimen on the slide appears precisely the same as if someone were viewing it under a microscope with a glass slide.

Virtual slides may help pathologists be even more accurate because of the hugely detailed images. These are much more useful than past kinds of pathology procedures.

Virtual slides are also better at preserving slides. With regular glass slides, specimens can age and become discoloured. This is a severe problem if the pathologist doesn't view the slide before any alterations occur.

With virtual slides, pathologists can look at the original images at any time. Because of this, these professionals can go back and look at any sample they want or need to. They can also use these older samples for research and education if the care is particularly interesting (Direct, n.d.).

2. **Real-time systems**

Real-time pathology systems are arguably the best kind of pathology system for pathologists to use. With real-time pathology systems, the remote pathologist can use a remote to move a microscope that is viewing the specimen in real-time.

Once the slide is placed under the electronic microscope, the pathologist can use their technological systems to move the microscope around and view the specimen to diagnose any potential problems.

Real-time pathology systems give remote pathologists access to fresh slides they can view as if they are in the medical facility where the sample was taken. The robotic microscope allows the pathologist to adjust the positioning, magnification, illumination, and focus.

The pathologist views the microscope's point of view from a screen at a remote location. From this, they can view the specimen with a high-resolution image.

One of the most significant benefits of the real-time pathology system is that the pathologist can manipulate the image in any way they want. The photos aren't pre-shot and sent to the pathologist. Instead, they can use the image's quality and scope to be how they want it to be (Direct, n.d.).

3. **Image-based systems**

Image-based pathology systems are the cheapest of all three of these kinds. This is also the easiest form of pathology to use.

Image-based pathology simply uses pictures of those specimens on the slide. In this way, the system is most in-line with in-person pathology work.

Pathologists that are working with image-based pathology systems look at the images that are sent to them. Typically, these images aren't on a large, detailed scale like those from virtual pathology systems.

These images are usually a collection of small, up-close pictures of whatever samples the pathologist is looking to study. With virtual pathology systems, there is one high-resolution image that the pathologist can zoom in on and move around with. Image-based systems give smaller, slightly lower-quality images for the pathologist to study.

However, image-based pathology systems are still beneficial for pathologists and the medical staff that they're working with. They just aren't quite as advanced as virtual pathology systems.

Image-based pathology systems also work by taking pictures of glass slides. Usually, there is no slide digitisation except for the images themselves.

Because these images are taken when the specimen is fresh, it also prevents discolouration of the images. They standstill and cannot age over time as the standard slide would (Direct, n.d.).

EXAMPLES AND ANALOGIES

Micro Telepathology Solutions

SPOTMeeting: Interactive Real-Time Telepathology

SPOTMeeting™ is an easy-to-use, fully interactive software environment for sharing high-definition images and collaborating with remote specialists in real-time. Audio, cursor, annotations, files and software controls are shared, and presenters can be swapped, making communication simple. SPOTMeeting is ideal for remote pathology consultations *(SPOTMeeting Collaborative Imaging System - SPOT Imaging*, n.d.).

SPOTBroadcast: Real-Time Telepathology Broadcasting

SPOTBroadcast captures video in high definition and provides cost-effective, one-way streaming of images over the internet without a computer or software *(Pathology Imaging Systems | SPOT Imaging*, n.d.).

Micro Telepathology Solutions

PathStation 2: Macro Imaging System with Real-Time Interactive Telepathology

The PathStation 2 macro digital imaging system makes it easy to capture, annotate, measure, and save high-quality images of gross specimens in the frozen section room and share them with specialists in other locations. Its fully enclosed HD camera and touch screen monitor take up a minimal workspace. It can be mounted in a grossing hood, configured as a freestanding unit with lighting, or on a wall in the laboratory per your needs *(Pathology Imaging Systems | SPOT Imaging*, n.d.).

APPLICATION AND INTEGRATION

https://www.youtube.com/watch?v=LPUkb8i06CU

Tele Imagistics can be considered a mature field; however, opportunities could appear due to increased technology in the patient-s hand (home echo machine after the home thermometer e.g.)

Telepathology could provide faster access and additional relevant information to services that usually take significant time and provide limited information.

Students should study current procedures and guidelines in this field and think about how these could be improved by implementing telepathology (teams of 3,4 members). They should imagine a scenario in which an existing guideline is changed by using telepathology, and they should discuss it with another team.

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Lessons 6 and 7: Tele-Expertise and Teleassistance

FOUNDATIONAL KNOWLEDGE

What is Tele-Expertise?

A doctor seeks the opinion of one or more colleagues, at a distance, based on medical data related to a patient's care (Morquin et al., 2018).

Tele-expertise system is designed to improve the availability of information needed for an understanding of the clinical situation and consequently for medical decisions, and to improve the traceability of the information provided by the doctors to prescribers facilitating the monitoring and the re-assessment of patients (Morquin et al., 2018).

Given the current and future pandemic context, it might be preferable to have the patient information be evaluated instead of sending the patient to different specialities. The inter-speciality collaborations are improving patient outcomes, as seen in now highly recommended and used "tumour boards" (Morquin et al., 2018).

What is Tele-Assistance?

A doctor assists other health professionals at a distance in performing some medical act.

Given the scarcity of certain specialities and the increased specialization of doctors, teleassistance might provide significant value to patient care in specific cases. Also, in some situations the patient might benefit from guidance from a healthcare professional beyond teleconsultation (IGI Global, n.d.).

EXAMPLES AND ANALOGIES

The design of the tele-expertise system in a French university hospital

In 2012, the University Hospital of Montpellier (France) shifted its method of clinical documentation (e.g., patient charts and flowsheets, medication order) from a paper-based system to an EPR (an electronic patient record). The hospital centre is in the south of France and features approximately 2,000 beds in seventy-four different departments. Overall, the hospital staff consisting of 6,000 caregivers, 1,400 doctors (physicians, anaesthetists, and surgeons), and 500 residents provides treatment to more than 235,000 inpatients and 540,000 outpatients annually. The new EPR system, which is an information technology (IT)-based enterprise-wide healthcare solution, was designed to support all aspects of patient care, covering medical and paramedical notes and reports, physician order entry and treatment plans, laboratory management system, operating room management system, billing, and follow-up procedures. This "off-the-shelf" EPR was implemented in 9 months with a task force of one physician, one pharmacist, three manager nurses, and 100 full-time technicians recruited for the customization during one year. The EPR allows for the customization and configuration of patients' records by setting new forms, queries, and personalized views.

Aware of these opportunities, an IDS (infectious diseases specialist) decided to formalize the counselling activity and customize the EPR for his team. He aims to facilitate the IDS' daily practice of providing counsel to clinicians from every department and to increase the traceability of the activity of the IDD (infectious disease department). For this, in collaboration with the other IDS, a form was designed and deployed for the initial assessment, re-assessment and the decisions made during the team consultation meeting of all the IDS, the pharmacist, the microbiologist, and the infection control team. The global process is described in Figure 1. When a clinician

needs more specific information than provided by standard recommendations embedded into the EPR, they may contact the IDS on a unique telephone number 24 hours a day, seven days a week. A Web-based telephone call routing system is used to switch the telephone line to the IDS on call, which may change daily according to the availability schedule. The requesting clinician briefly explains the medical situation and the degree of emergency, and the IDS may ask for additional clarifications on the request. The call is then followed by remote access by the IDS to the full patient's record (including laboratory results, radiology, medical and nurses' notes), with a specific template view (inflammation biomarkers graphs, table of microbiological results, past antimicrobial use). The information recorded includes the IDS' previous advice, allowing follow-up care. These advices focus mainly on diagnosing infectious diseases or the therapeutic use of the appropriate antimicrobial strategy. Still, they may also be related to infection control issues, unexplained fever, accidental exposure to biological fluid, or rabies. The IDS may choose to respond make an answer alone and may justify their response by providing hypertext links to scientific articles. For complex cases, the clinician may decide that the response requires a decision made by the team consultation meeting of all IDS, the pharmacist, the microbiologist, and the infection control team. The IDS's response is recorded in a specific IDS form in the EPR and available for all clinicians in real-time. To enable clinicians to make medical decisions, IDS do not make any prescriptions. They only provide and record argued counsels. Originally, the specific IDS form was designed to record the medical reasoning and the diagnosis or therapeutic proposal, the identification details of the IDS and the patient with a timestamp. Later, the users' remarks and all input errors were considered. Consequently, all unused or ambiguous fields were removed. The information framing is based on: (a) ergonomics choices, such as tabs that designate the steps of the counselling, combo boxes, and checkbox under form for the use of the typical instructions associated with dosages and monitoring of each suggested drug; (b) standardized requirements and mandatory elements, as remote or bedside assessment, allergies related to anti-infective drug, and monitoring decisions; (c) indexing of each situation by combining the clinical category of infection, the pathogens classes (bacteria, viruses, etc.), and the disease context (i.e., immunosuppression, cancer, pregnancy, etc.). The most important elements, as the analysis of the clinical situation, its history and therapeutic proposal, are described in the narrative text. The size has been defined to fit the work practices of each IDS. An input help has been added. Requests have been computerized to allow monitoring of use. Furthermore, media fields have been inserted to associate an image in scientific papers form (e.g., biological result curves or patient photos) concerning the clinical situation. Additionally, binary radio buttons were set up linked with the automated mailing at defined time intervals (e.g., the IDS may ask for a specific pharmaceutical monitoring). The form evolved iteratively during the first year of use of the system. After, the rate of change of the form has slowed considerably with updates on the new instructions associated with treatment proposals and new ways to alert collaborators (Infection Control [IC] staff, microbiologists, pharmacists) for specific queries and to provide automatic instructions associated with the proposed antibiotic treatment. Especially, in the summer of 2015 a new feature was designed: every time the IDS completed the checkbox "alert the IC team," a secured mail with essential clinical data is sent to the IC department. This applies to all major healthcare-associated infections and community-acquired infections with an epidemic potential (e.g., measles or tuberculosis). Regular automatic queries provide real-time anonymous data from IDS activity, such as the number of telephone calls, the regimental number, the prescriber's department, the infection class, the time passed since the first evaluation, and the antimicrobial suggestion. In this context, a prospective observational study was conducted to assess the diffusion of the tele-expertise system and the perceived utility for the medical managers of most demanding departments (Morquin et al., 2018).

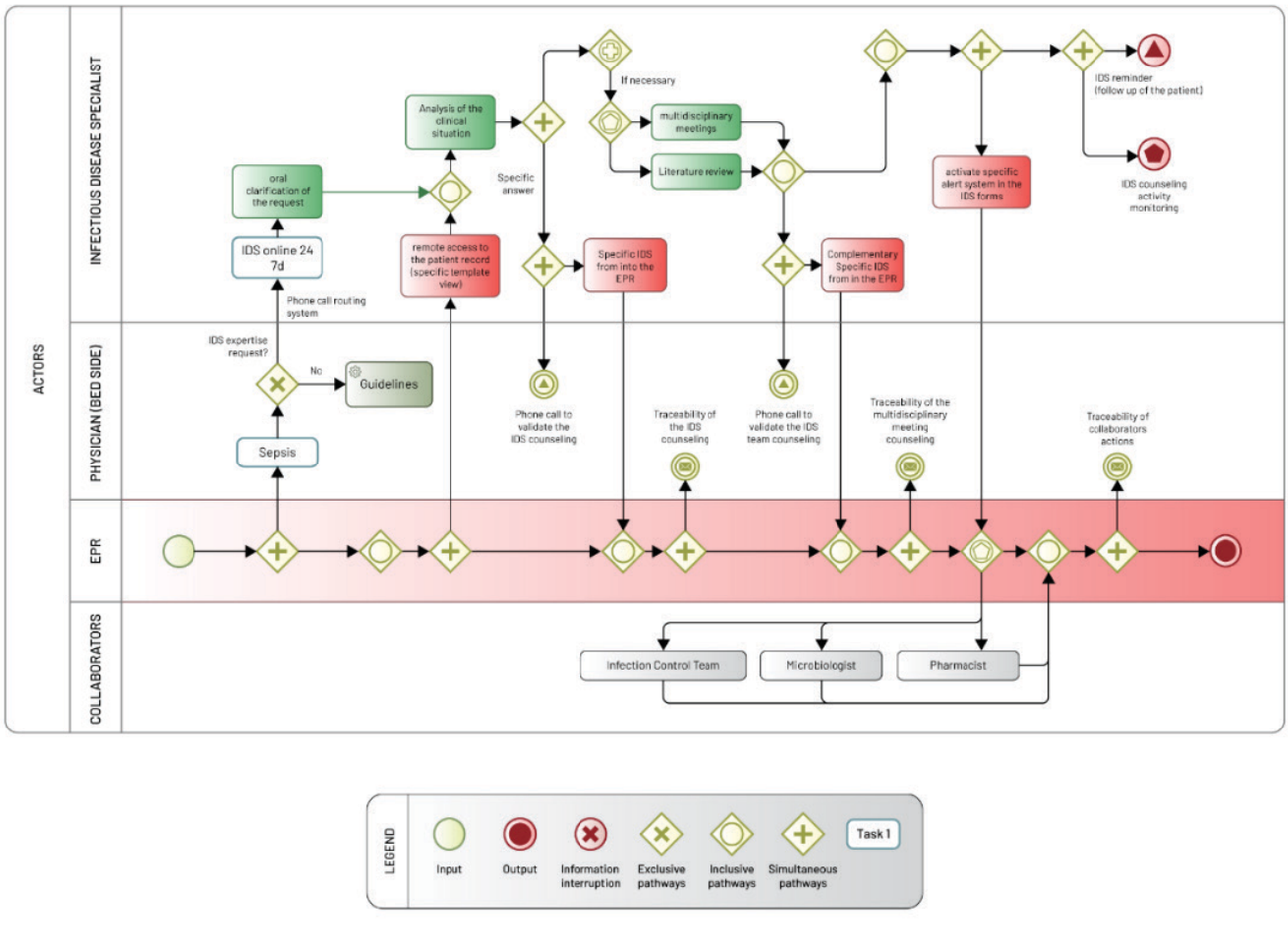

Fig. 6.4. Tele-expertise process (Morquin et al., 2018)

APPLICATION AND INTEGRATION

There is any tele-expertise process in your country? If not, imagine a tele-expertise process in a hospital department.

Analyzing the patient journey of a chronic patient identifies situations where tele expertise might be of value and identify the current limitations.

Tele assistance might increase the value/efficacy of specific therapeutic solutions (especially the ones requiring patient involvement). Can you identify and explain the pros and cons?

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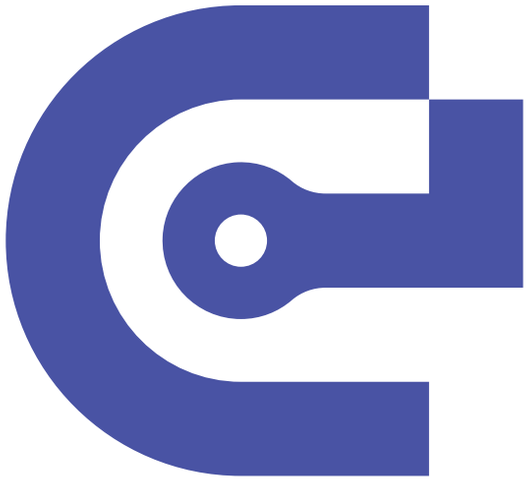

Module 7: Health Analytics and Big Data in Health

Learning objectives of the Health Analytics and Big Data in Health module

This course has the general objective to instruct students on the fundamental concepts of health analytics and big data, enabling students with full comprehension and critical attitude on the complex process of the current data science field of work - that is the base for decision-making in health. Students are expected to understand the process of collecting, managing and analyzing health data, as well as approaches for transposing the results of this analysis to the decision and management of health services and its application to social problems.

At the end of this course, the student must:

1. Know the basic concepts and principles of health analytics and Biga Data (use of secondary data and some of its sources, data collection and management, intelligent data analysis, and incorporating these concepts into health decisions)
2. Know basic concepts of health information systems (technical terms used in Health Information Systems; Information Systems architecture and processes and main sources of databases)
3. Understand and describe the main theoretical constraints on Big Data and Artificial Intelligence systems
4. Know the theoretical foundations and challenges of Data Governance and Policies.

Foundational knowledge of the Health Analytics and Big Data in Health module

Data plays a key role in modern industry and any organization. As healthcare systems continue to adopt innovative technologies for different purposes (e.g. epidemiological surveillance, monitoring, treatment or diagnostic), the volume of available data also continues to grow due to the increased availability of information and the capacity to store it. (Shortliffe & Cimino, 2014) The collected amount of such large and complex data, which is - by definition - difficult to analyze and manage with traditional software or hardware, characterizes Big Data in healthcare. Nevertheless, the available information is often insufficient and limited, especially when relying on secondary data or since the available tools do not always allow the fine collection, analysis and interpretation of data to generate quality information to apply the best interventions or decisions. The volume of data collected does not necessarily mean that it can be aggregated into useful, valid or reliable information. Transforming data into valuable information is still a challenge in health ecosystems. (Cruz-Correia et al., 2009; Gao & Yu, 2020)

Decision-making can be complex and always involves some degree of uncertainty. Integrating individual clinical knowledge with the best available evidence from systematic investigation enhances the possibility of converting data into value and increases objectivity and confidence in deciding on action. Through a stepwise process, decision-making understands how to use and apply information to create knowledge and wisdom, increasing effectiveness during the decision process. Thus, it becomes evident that health care systems and providers have become increasingly focused on the need to use evidence to inform and make clinical and operational decisions. (Sackett, Rosenberg, Gray, Haynes, & Richardson, 1996)

The growing need for evidence-based decision-making in the clinical and governance process has revealed the need to strengthen principles and practices that ensure data quality throughout its lifecycle – highlighting some data governance challenges. Data governance aims to ensure data lifecycle management and implementation of data quality management strategies. Integrating a set of processes that aim to implement and maintain an organizational culture of data quality which must produce, maintain, execute, and communicate data quality manage-

ment practices, may guarantee the specifics of quality requirements and ensure continuous data improvement. (Mehta & Pandit, 2018; Shabani, 2021) (Magnuson J.A., 2020) (Cruz-Correia et al., 2009)

The Concept of Big Data

A collection of data sets is so large and complex that it becomes difficult to process using hand database management tools or traditional data processing applications. (Halevi, 2014) The advent of big data brings new challenges in translating datasets of various quality, quantity, and velocity (3 V´s of Big Data) into actionable information and, ultimately to, knowledge. Big data are of significant interest to the public health domain due to the size, diversity, and complexity of varied data sources that could prevent disease and promote health and wellbeing.

Big Data includes real-world data such as electronic health records, registry data, claims data, data from wearable devices, and social media platforms, among others. Moreover, integration and analysis of the data of different nature, such as social and scientific, can lead to new knowledge and intelligence, exploring new hypotheses, and identifying hidden patterns – which would be difficult (or even impossible) otherwise.

Data can often be collected in real-time (e.g. monitoring patients through wearable devices), which requires specific technology. Conversely, large amounts of data have already been collected for different purposes through the years. Hence, secondary data refers to data already collected for some other purpose. (Schlomer & Copp, 2014) This highlights some constraints in analyzing and interpreting this amount of data - as it was not controlled for the intended purpose.

Guaranteeing data quality through its life cycle requires a robust information system infrastructure. In contrast, a robust information system infrastructure requires the ability not only to provide and make available quality data but also to receive data, so they need to support bi-directional communication (of alerts, population health statistics and case or care management) - to inform clinicians and decision-makers in real-time. Information architecture (AI) refers to the logical configuration of various elements, including hardware, software, information flow and technical standards needed to support users' information needs. Robust AI can increase the effectiveness and scope of its performance by integrating internal and external information systems. A fundamental component of information architecture is interoperability. Interoperability is "the ability of a system to exchange electronic health information and use information from other systems without additional effort by the user". Problems with data interoperability (i.e., send, receive, find, and eventually be able to of use) restricts data exchange with other interested parties. (Janssen & van der Voort, 2020; Magnuson J.A., 2020)

Big Data Analytics

Big data analytics covers the integration of heterogeneous data, data quality control, analysis, modelling, interpretation, and validation. (Halevi, 2014) The application of big data analytics provides comprehensive knowledge from the available huge amount of data. Big data analytics seeks to leverage improvements in computer science to address these needs.

Analytical approaches can be divided into three categories: descriptive, predictive, and prescriptive. (Magnuson J.A., 2020) Overall, Big Data Analytics can be understood as an umbrella term for data analysis applications in the context of Big Data, namely using algorithms to analyze data: regression analysis, simulation, and supervised and unsupervised machine learning methods, among others. (Halevi, 2014; Watson, 2019)

Such applications of big data analytics can improve the patient-based service to detect earlier spreading of diseases, generate new insights into disease mechanisms, monitor the quality of the medical and healthcare insti-

tutions, provide better treatment methods, or increase the cos-effectiveness of health interventions. (Watson, 2019) Such applications are, however, not free from limitations or disadvantages. (Pastorino et al., 2019)

Artificial Intelligence

On 8 April 2019, the High-Level Expert Group on AI at the European Commission presented Ethics Guidelines for Trustworthy Artificial Intelligence. (Commission, 2019) In this report, Artificial intelligence systems (AI) were defined as " software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can either use symbolic rules or learn a numeric model, and they can also adapt their behaviour by analyzing how the environment is affected by their previous actions. As a scientific discipline, AI includes several approaches and techniques, such as machine learning (of which deep learning and reinforcement learning are specific examples), machine reasoning (which includes planning, scheduling, knowledge representation and reasoning, search, and optimization), and robotics (which includes control, perception, sensors and actuators, as well as the integration of all other techniques into cyber-physical systems)."

Challenges

The previous definition raises awareness of some constraints that should be considered. Any analytical process is only as good as the quality of data available for analysis. As such, it is important to ensure that datasets used for analysis are cleaned and parsed to present a concise, valid, and clear picture of the datasets being used. Moreover, trusted and reliable analytics and artificial intelligence —key ingredients for transparent, evidence-based policymaking— require findable, accessible, interoperable, secure and high-quality data. In fact, regarding collecting large amounts of data and applying such systems, some challenging issues should be considered. (Maissenhaelter, Woolmore, & Schlag, 2018) Therefore, later in July 2020, parallel to the following necessity raised by the COVID-19 pandemic, it was released a strategy for data governance and data policies at the European Commission (Commission, 2020) focused on processes that endure (1) Data Governance and management; (2) Protection and information security; (3) Data Quality; (4) Interoperability and standards.

Table 7.1. Proposal for the module

	Theoric	Practice	Hours
FUNDAMENTALS	Concepts definition Big Data & secondary data Data sources and types of data Information systems in Health		1
BIG DATA ANALYTICS	Introduction to Descriptive, Predictive and Prescriptive analysis Computational methods for large databases (analytical and modeling techniques) Artificial intelligence in healthcare: Fundamentals Artificial intelligence in healthcare: Issues		1
DATA-DRIVEN DECISION MAKING	Principles and definition of Data Governance Challenges of Data Governance: 1. Data Quality 2. Protection and Information Security 3. Data Interoperability and Standards 4. Data Governance and Management		1
CASE STUDIES		Case 1 Case 2	1 1
		Total	5

Lesson plans for the Health Analytics and Big Data in Health module

Lesson plan 1: Fundamentals

FOUNDATIONAL KNOWLEDGE

Concepts definition

Evidence-based making decision-making (Hunink et al., 2014; Shortliffe & Cimino, 2014)

Data are central to all health care as it is crucial to the decision process**.** All health care activities involve gathering, analyzing, or using data. Data provide the basis for categorizing the problems and identifying subgroups, patterns or outliers within a population of patients. Evidence-based Decision Making includes healthcare policy decision-making, public health and population-based decision-making (in the form of guidelines using formal evidence criteria and processes). It is a process for making decisions grounded in the best available research evidence and informed by experiential and relevant contextual evidence from the field (see example 1).

What is Big Data? (Halevi, 2014)

Big data means there is more of it; it comes more quickly and comes in more forms. It is a collection of datasets that is so large and complex that it becomes difficult to process using on-hand database management tools or traditional data processing applications.

The V's of Big Data

Three concepts drive the definitions and assessment of big data, often referred to as the three V's, volume (quantity of data), variety (types of datasets), and velocity (how often the data are being captured/reported).

Big Data Analytics

Big Data Analytics can be understood as an umbrella term for data analysis applications in the context of Big Data, namely using different algorithms to analyze data. Big data analytics covers the integration of heterogeneous data, data quality control, analysis, modelling, interpretation, and validation.

Big Data Technologies (Davenport & Harris, 2007)

Requires new technologies/techniques to collect, store, analyze and visualize it. Some examples are provided below:

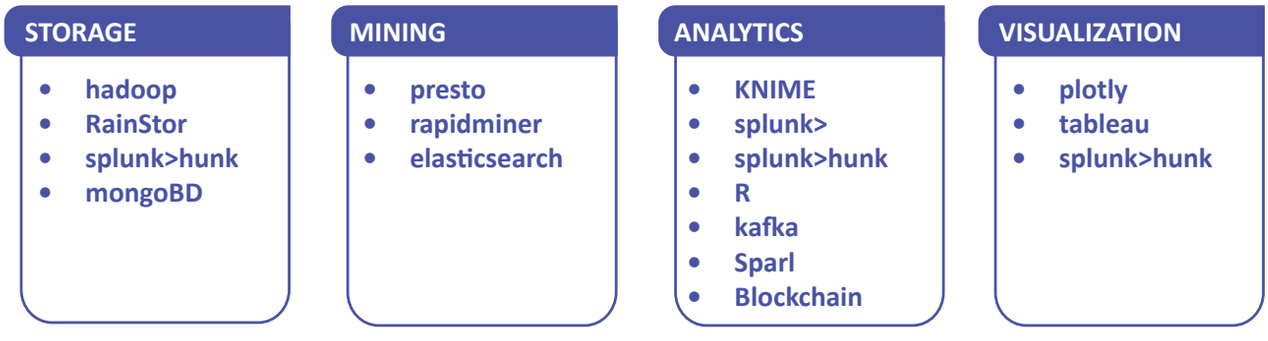

Fig. 7.1. List of technologies applied in Big Data (Edureka, n.d.)

Big Data Analytics Lifecycle

Due to the characteristics (3 V´s) previously described of Big Data, Big Data analysis differs from traditional data analysis - requiring organizing the activities and tasks involved with acquiring, processing, analyzing and repurposing data. A specific proposal for the data analytics lifecycle contains and manages the tasks and activities associated with analysing Big Data. The Big Data analytics lifecycle can be divided into the following nine stages, as shown in figure 2 below:

STAGE 1	• Business Case Evaluation
STAGE 2	• Data Identification
STAGE 3	• Data Acquisition & Filtering
STAGE 4	• Data Extraction
STAGE 5	• Data Validation & Cleansing
STAGE 6	• Data Aggregation & Representation
STAGE 7	• Data Analysis
STAGE 8	• Data Visualization
STAGE 9	• Utilization of Analysis Results

Fig. 7.2. Stages for the Big Data lifecycle (Informit, n.d.)

There is a vast diversity of applications of big data analytics. In fact, throughout the process of gathering and analyzing data and supporting decision-making with the best available evidence, they can:

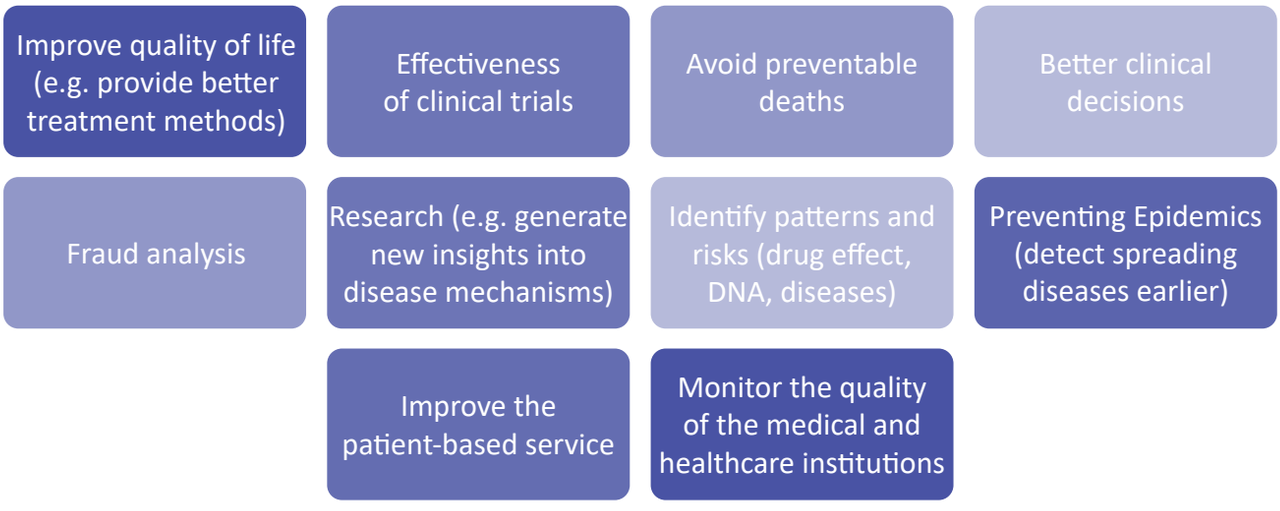

Fig. 7.3. Big Data Applications (Jiang et al., 2017; Moghadam & Colomo-Palacios, 2018; Ristevski & Chen, 2018)

Big Data and secondary data (Benchimol et al., 2015; Cheng & Phillips, 2014)

Secondary data is defined as data used for different purposes than the ones they were originally collected for. Secondary data sources have been gaining attention as they provide an unparalleled retrospective opportunity to capture information across the health system (see example 4).

There are several main sources of secondary data, including administrative databases, electronic health records, scientific literature, scientific reports, surveys and internet-based data.

Secondary data's most visible advantages are carrying out studies with less cost (most obvious), in less time and with a larger sample size, which are also useful to raise new research hypotheses. Other advantages include assessing long periods and large geographical areas (e.g. entire regions or nations). The analysis of large volumes of secondary data can overcome some limitations of "traditional" observational studies based on primary data. However, concerns remain about these databases related to their possible heterogeneity and lack of control during the collection process - with likely omission and lack of data quality. Inherent to the nature of the secondary analysis, since any available data has been previously collected for other purposes, it can lead to missing information on some third important variable or specific population segment. Moreover, researchers analyzing the data are not usually the same individuals as those involved in the data collection process, so they may not be aware of some specifics that can lead to misinterpretation of the findings. Succinct documentation of important information about the validity of the data can partly mitigate this problem.

Data, data sources and types of data

We consider a clinical datum to be any single patient observation—e.g., a temperature reading, a red blood cell count, a history of rubella, or a blood pressure reading. If a clinical datum is a single observation about a patient, clinical data are multiple observations (see example 3).

There is a broad range of data types/formats in the practice of medicine and the allied health sciences. They range from narrative, and textual data to numerical measurements, genetic information, recorded signals, drawings, and even photographs or other images.

A database is a collection of individual observations (i.e., data) without summarizing analysis. An Electronic medical record (EHR) system is thus primarily viewed as a database— the place where patient data are stored. When properly collected and analyzed with other data, these elements in the EHR provide information about the patient.

EHR has been described as a general term describing computer-based patient record systems. However, it is sometimes extended to include other functions like order entry for medications and tests, amongst other common functions which can start to actively support clinical care by providing a wide variety of information services. There are various types of EHR, namely:

- Electronic Medical Record (EMR) - includes all information (clinical and administrative) of one patient and focuses on relevant information for specific medical problem episodes;
- Electronic Patient Record (EPR) - is an organised collection of all records about an individual patient stored in the computer systems and databases of all the providers who have provided care to that patient within an enterprise;
- Virtual Patient Records (VPRs) - is a record that is not stored on any individual computer but assembled dynamically, in real-time, from various systems when needed;
- Electronic Health Record (EHR) - is a longitudinal record of patients' health. It combines information about patients' contacts with primary care and subsets of information associated with the outcomes of regular care, whether held in EMRs, EPRs or other information systems.
- Personal Health Record (PHR) - is a record that allows patient empowerment through personal management and sharing personal health information.

Other examples of health data sources are provided in example 5.

Data from different sources are used for multiple purposes at different levels of the health care system. We can stratify data at an individual level, health facility-level data, population-level data and public health surveillance. For example, the patient's profile, health care needs and treatment serve as the basis for clinical decision-making for individual clinical care, while aggregated facility-level records from administrative sources enable health care managers to determine resource needs.

A data lake is a system or repository of data stored in its natural form (usually files). A data lake is typically a single repository of all business data, including raw copies of data from the source system and transformed data used for reporting, visualization, analytics, and machine learning tasks. Data Lakes increase agility and provide more opportunities for data exploration, proof of concept activities, and self-service business intelligence within predefined privacy and security settings.

Remember:

DATA refers to raw numbers or other measures (objective facts about events), while **INFORMATION** refers to what emerges when data are processed, analyzed, interpreted, and presented. In other words, Information is Data transformed (contextualized, categorized, corrected, calculated, condensed) into a message. The key to any successful big data initiative is getting information from the vast deluge of data, separating the noise from the signal.

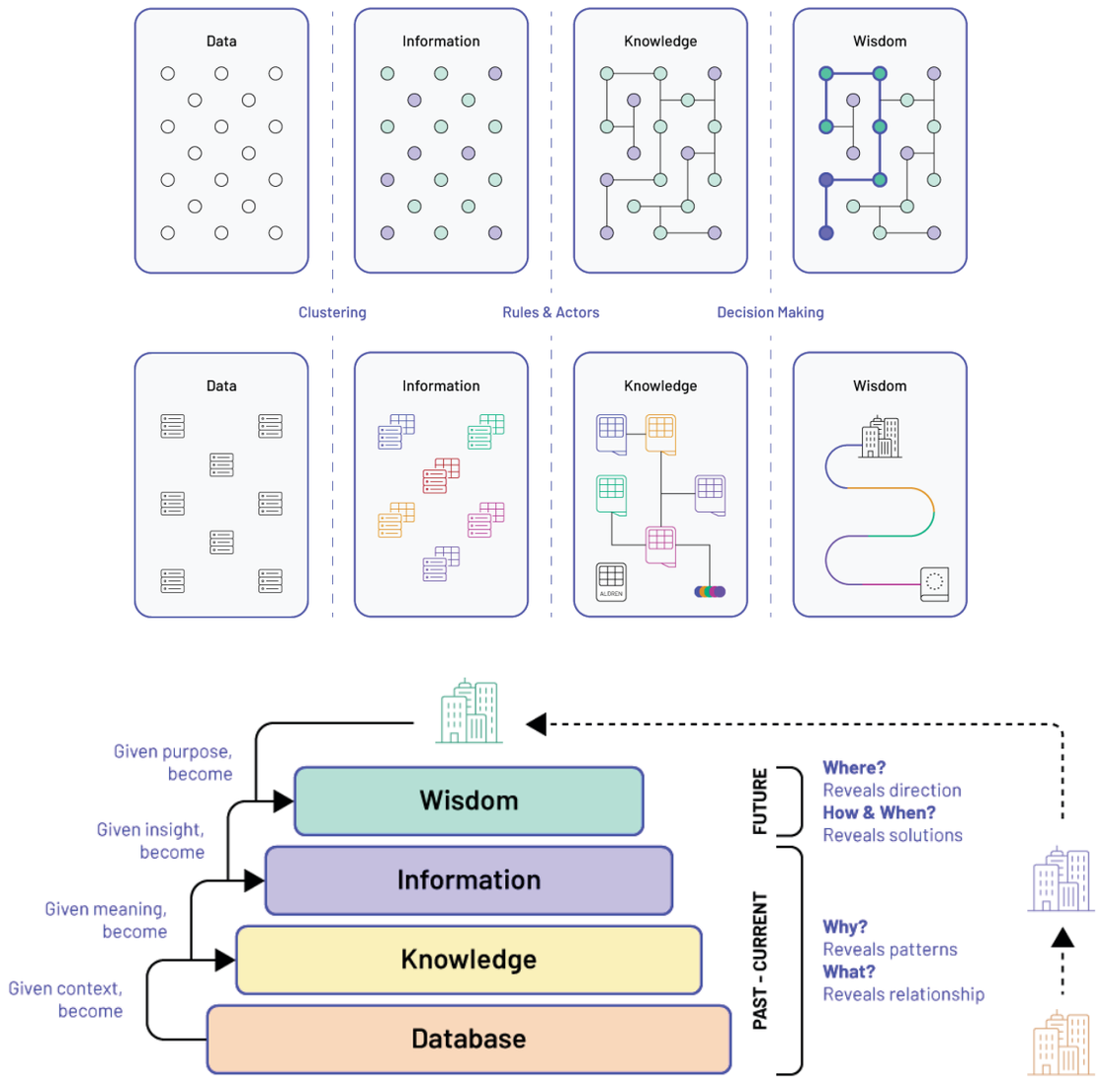

Fig. 7.4. Model for each level of information during data processing: from data do decision. Available source: (Sesana, Rivallain, & Salvalai, 2020)

Information systems in Health

According to WHO, "the health information system collects data from the health sector and other relevant sectors, analyses the data and ensures their overall quality, relevance and timeliness, and converts data into information for health-related decision-making."

The health information system provides the underpinnings for decision-making and has four key functions:

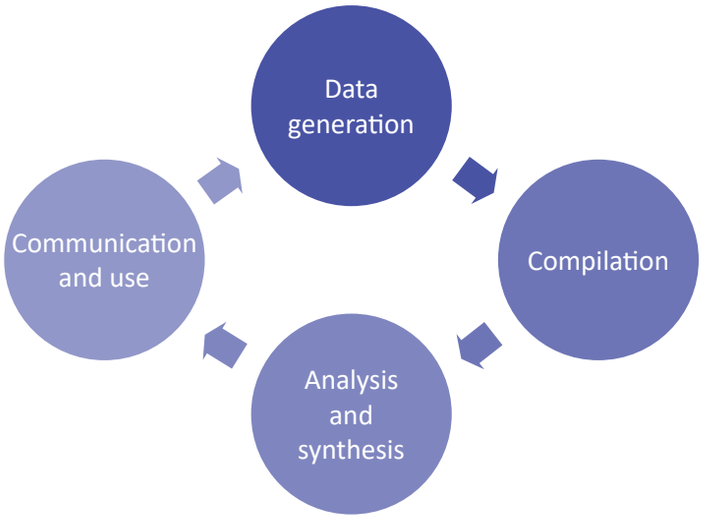

Fig. 7.5. The four key functions of health information system (WHO, 2008)

A robust information system infrastructure requires the ability not only to provide and make available quality data, but also to receive data, so they need to support bi-directional communication (of alerts, population health statistics and case or care management) - to inform clinicians and decision-makers in real-time. Information architecture (AI) refers to the logical configuration of various elements, including hardware, software, information flow and technical standards needed to support the information needs of users. Robust AI can increase the effectiveness and scope of its performance by integrating internal and external information systems. A fundamental component of information architecture is interoperability. Interoperability is defined as "the ability of a system to exchange electronic health information and use information from other systems without additional effort by the user". Problems with data interoperability (i.e., send, receive, find, and eventually be able to of use) restrict data exchange with other interested parties (see example 5).

For an EHR to be effective, the data must be portable, which requires the means to accurately and securely transfer a patient's health data from one healthcare provider or facility to another in a timely and efficient manner. Hence, the main focus of EHR technologies is standardization and connectivity. In fact, integration within and outside the healthcare facility constitutes a successful EHR deployment. Seamless connectivity between multiple, distributed systems in the healthcare continuum is the cornerstone of delivering a complete and accurate picture of the patient, their condition, treatment received, and subsequent outcomes. These connectivity challenges have been approached through the computerization of the world's healthcare operations, resulting in increasingly interoperable environments.

In conclusion, despite the introduction of EHR, which aim at recording and making accessible a patient's journey, it is only recent advances in information technology that have created the infrastructure that allows these data to be used - by enabling data to be securely aggregated, stored, processed, and transmitted.

EXAMPLES AND ANALOGIES

Example 1 – Understand the flow from real-world to decisions

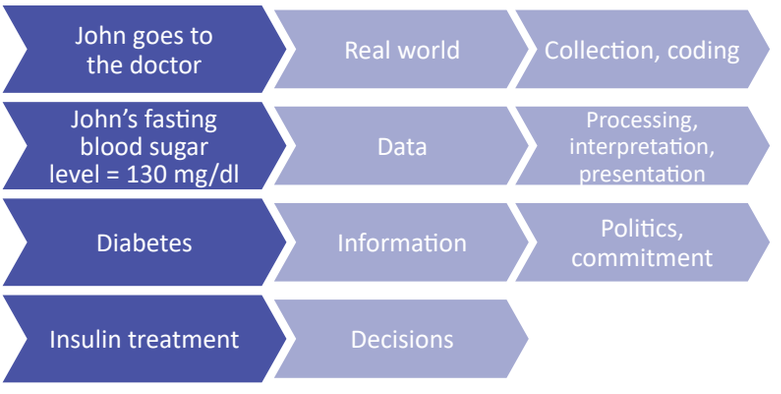

Fig. 7.6. Applying the datum concept(sursa?)

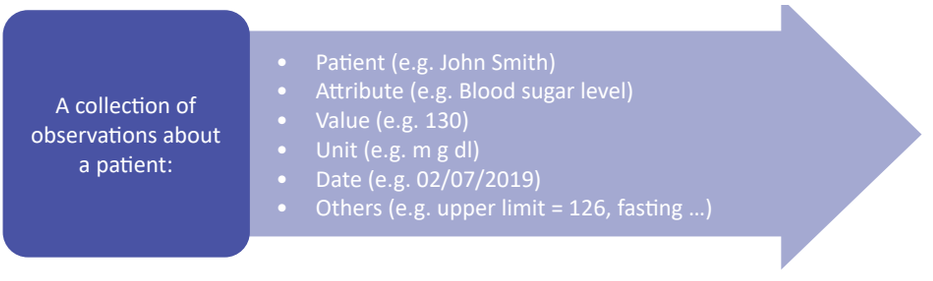

Fig. 7.7. Observation about a patient (sursa?)

Example 3 – Few types of data sources

- Electronic health record (EHR)
  - Patient's health records
  - Clinical provider controlled (not owned)
- Claims data
  - Administration
  - Billing
- Personal health record (PHR)
  - Wearables
  - Social
  - Patient-controlled

Example 4 - Primary vs Secondary use of Clinical Data

1. Clinical data is primarily used for clinical care
2. "Secondary" opportunities:
   a. Healthcare quality measurement
   b. Outcome comparison
   c. Clinical research
   d. Public health
   e. Learning health system

Example 5 – EHR integration among multiple systems in the healthcare continuum

Figure 7.8. EHR system interactions among multiple systems. Available at (Magnuson J.A., 2020)

APPLICATION AND INTEGRATION

Case Study 1 – Big Data Applications (Bhardwaj, Wodajo, Spano, Neal, & Coustasse, 2018; Wang & Hu, 2018)

As previously explained, the ability to make timely and truly evidence-based informed decisions to provide more effective and personalized treatment while reducing costs has been empowered by the introduction of big data analytics in healthcare. In fact, obtaining and analysing big data can aid the identification of high-risk individuals, inform more effective treatments, and select cost reduction areas across the health care system. The application of big data analytics is vast within health care. It goes beyond managing chronic diseases and resources to managing acute public health situations (e.g., as foreseen with COVID-19). Many of these applications are listed in the following article. (Bhardwaj et al., 2018)

Nevertheless, acquiring such novel information is not free of limitations. It requires the integration of multiple kinds of datasets and information from many sources (questionnaire interviews, standard clinical tests, and

modern sources such as electronic medical records, mobile apps, and wearable devices). As a case study from a clinical perspective, the following paper provides an overview while highlighting some of these limitations on how combined multiple data sources integration and applied big-data analytics may potentially inform personalized nutrition interventions, prevention and management of type 2 diabetes. (Wang & Hu, 2018)

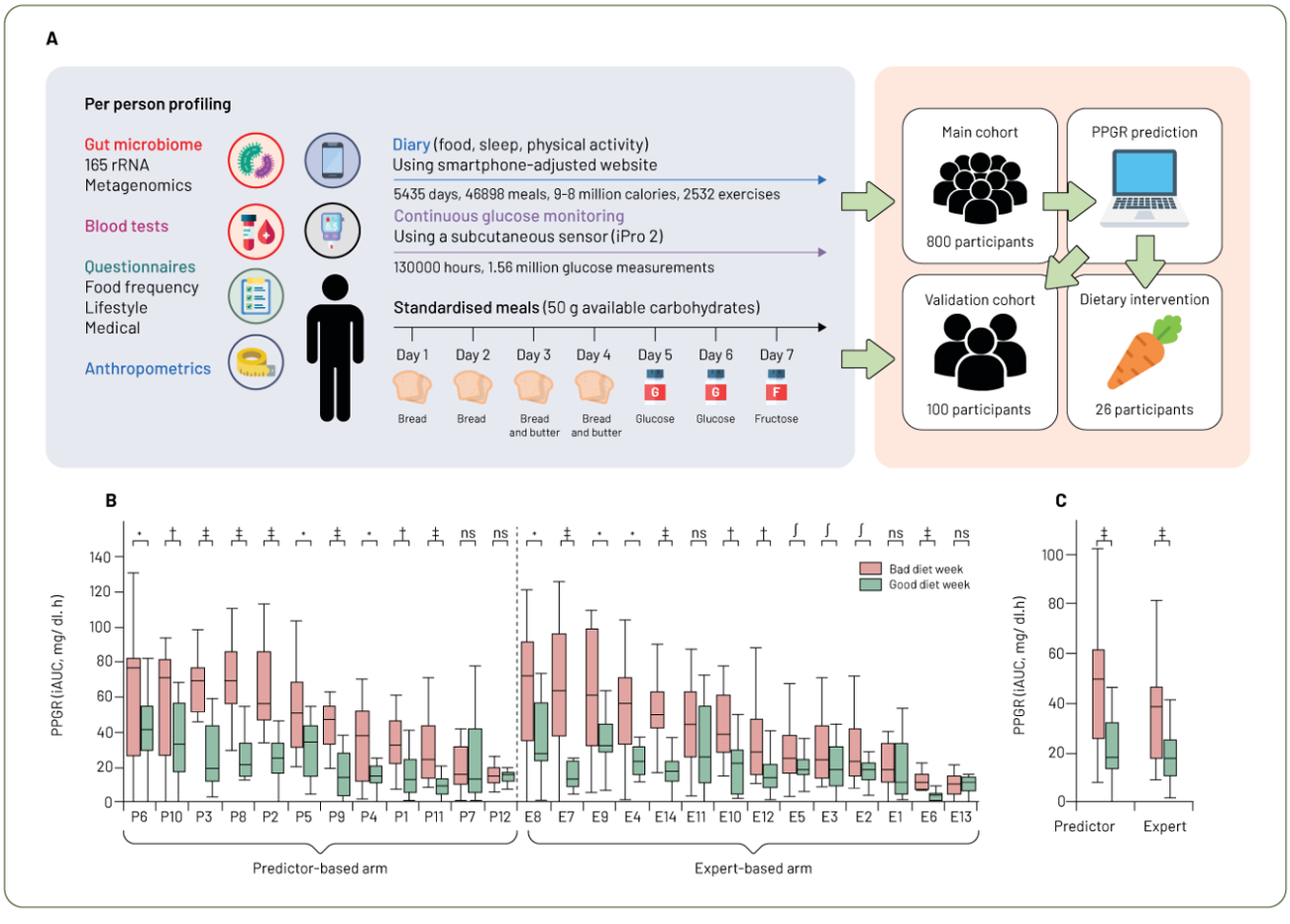

Figure 7.9. Design for the case study 1: multiple sources of information (Wang & Hu, 2018)

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Lesson plan 2: Big Data Analytics

FOUNDATIONAL KNOWLEDGE

Introduction to Descriptive, Predictive and Prescriptive analysis

Science and technology are developing at an unprecedented rate. The convergence of new treatments, diagnostics, wearables, sensors, and connectivity generates enormous amounts of data. As the amount of data available increased dramatically, the motivation for different analytical approaches increased. More data available does not always mean more knowledge to be used in decisions, as we need automatic methods to exploit such data.

Analytical approaches can be defined into three categories, namely descriptive, predictive, and prescriptive:

- Descriptive analytics refers to the summarization of datasets, making them interpretable to researchers.
- Predictive analytics approaches estimate the likelihood of future events or outcomes - or are used to address gaps or missing information.
- Prescriptive analytics goes beyond descriptive and predictive analytics by attempting to quantify the impact of future decisions before these decisions are made.

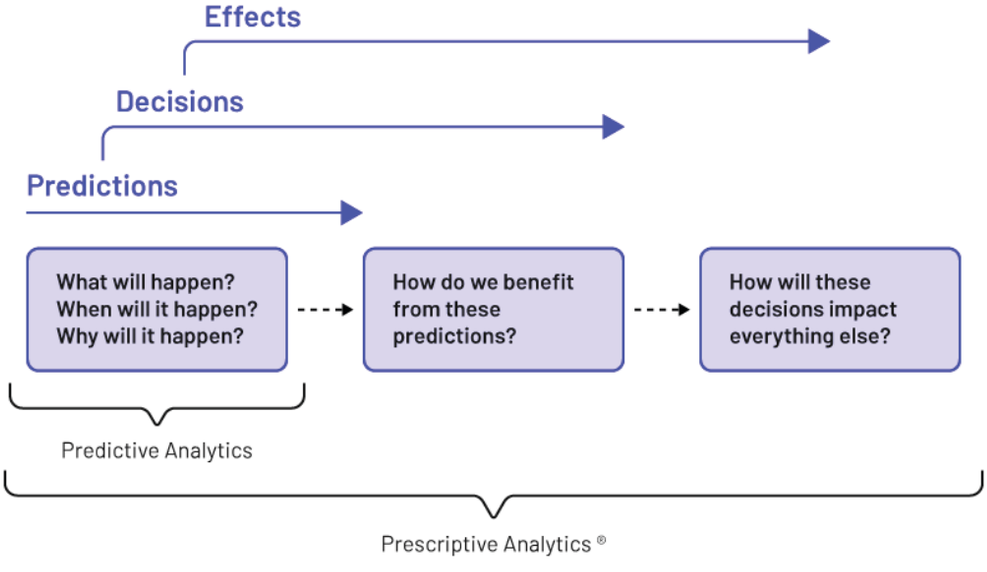


Figure 7.10. Analytical approaches to process data (Wikipedia, n.d.)

Computational methods for large databases (analytical and modelling techniques) (Magnuson J.A., 2020)

Computational power and approaches based on bioinformatics tools and algorithms, machine learning (ML) or artificial intelligence (AI), are gaining access to the health care systems. Likewise, our possibilities for evidence generation are growing.

MLtechniques can be categorized into supervised and unsupervised learning approaches.

Machine Learning Main Techniques:

- Supervised Techniques
  - Classification
  - Regression

- Unsupervised Techniques
  - Clustering
  - Association Rules

Supervised and Unsupervised Learning Algorithms

The availability of the outcome of interest is the big difference between both approaches. While in supervised learning algorithms, the result is given to the algorithm – which can use it as the gold standard to convert the input features into the outcome – in unsupervised learning approaches are methods where an algorithm must learn to model the underlying distribution of data elements given input features, but no outcome variable. Supervised methods can be costly and resource-intense as they may require human expert input for defining and preparing a gold standard (i.e. the output label). In contrast, unsupervised methods rely purely on the quantity and quality of data for the training process - do not require the manual cost and effort needed to develop a gold standard which can lead to weaker performance.

Classification (which can predict a discrete or categorical output variable) and Regression (predicts numerical continuous output variable) models are the major categories for supervised approaches. Some classification models are(1) Simple logistic – which uses a logistic function which is used to predict the outcome variable; (2) Support vector machines - identifies an optimal hyperplane (a subspace whose dimension is -1 of its ambient space) capable of separating data into each outcome; (3) Decision trees – generally predicts the value of an outcome by learning decision rules inferred from the training dataset. Among examples of Regression, Algorithms are simple logistic regression and random forest regression.

Overall, the process is supervised ML encompasses the following steps:

1. During training, the model is given both the features and the labels and learns how to map the former to the latter.
2. A trained model is evaluated on a testing set, where we only give it the features, and it makes predictions.
3. Then, the predictions are compared with the known labels for the testing set to calculate accuracy.

K-means clustering and Hierarchical clustering are the most widely known unsupervised learning algorithms. The first approach seeks to group each observation into a subset of clusters where each observation belongs to the cluster with the nearest mean value. In contrast, the second uses an approach which seeks to build out a hierarchy of clusters, which can be agglomerative (each instance starts as a separate cluster, with pairs of clusters merging as instances traverse up the hierarchy)or divisive (all observations start with one cluster and splits are performed as instances traverse down the hierarchy). Please see example 6.

Artificial intelligence in healthcare: Fundamentals

While designing and selecting the best model approach, there are a few methods or approaches: train and test, cross-validation and train, validation and test. In the first method, a dataset is randomly split into two sets. A larger training dataset was used to train the decision model, and a smaller test dataset was used to test the newly introduced model. In the Cross-validation approach, the dataset is split into k and many randomly selected subsets (using a pre-defined size *k*). In each stage, one subset plays the role of the validation set, whereas the other remaining parts (K-1) are the training set. Each stage involves removing part of the data, then holding it out, fitting the model to the remaining part, and then applying the fitted model to the data that we've held out. Performance results for each iteration are averaged to produce less variable performance results. The last approach randomly splits the dataset into the train, validation, and test sets—the training dataset issued to train the decision model. The validation dataset is then used to test the decision model iteratively and update

its parameters for optimal performance. Once model parameters have been configured for optimal results, the model is then evaluated using the test dataset (see figure 9).

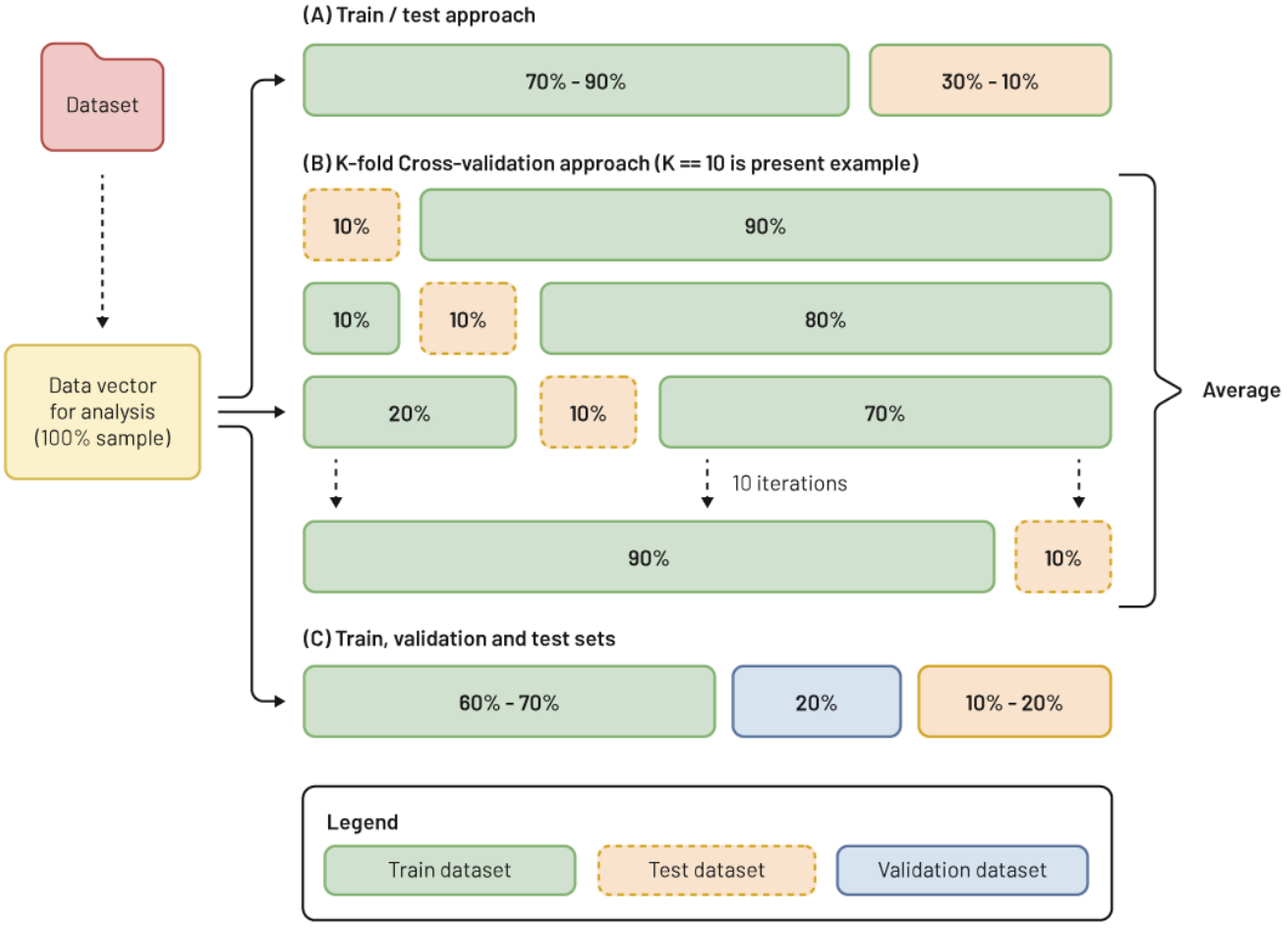


Figure 7.11. - Methods to design and develop an algorithm of machine learning (Magnuson J.A., 2020)

Likewise, it is essential to evaluate the performance characteristics of a decision model. For this, some used performance metrics are sensitivity (i.e. The proportion of actual positives that are correctly identified); specificity (i.e. the ratio of true negatives that are correctly identified); precision (i.e. the proportion of identifications that are correct); F1-score (i.e. Accuracy measure representing an average used for numbers that represent rate or ratio between precision and sensitivity; and Area under the Receiver Operator Characteristic curve (AUC ROC) which demonstrates through a graphical plot the diagnostic performance of a classification model across various threshold configurations (this score can range between0-1).

A model learns relationships between the inputs (features) and outputs (labels) from a training dataset. Models can take many shapes, such as logistic regression – described in the previous section.

However, ML algorithms are not free of constraints. While building these models, researchers should be aware of and concerned about some challenges. Overfitting, broadly speaking and in contrast to underfitting, means the training fits exactly against its training data resulting in an inability to generalize to unseen datasets. This happens when noise (irrelevant or incorrect data elements) is included in the dataset. On the other hand, underfitting means the model has not captured the underlying logic of the data; thus, it cannot perform across both the current andnew datasets properly. Finally, class imbalance occurs when classes are not present in proportion across the dataset, i.e., the occurrence of one of the classes is very high compared to the other classes current

(there is a bias or skewness towards the majority class present in the target). Two sampling methods are usually used to address this problem: oversampling (supplementing with observations of minority instances) and under-sampling(removing instances of the majority class).

Artificial intelligence in healthcare: Issues

In a recent report on Ethics Guidelines for Trustworthy Artificial Intelligence (AI), AI systems were defined as " software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can either use symbolic rules or learn a numeric model, and they can also adapt their behaviour by analyzing how the environment is affected by their previous actions. As a scientific discipline, AI includes several approaches and techniques, such as machine learning (of which deep learning and reinforcement learning are specific examples), machine reasoning (which includes planning, scheduling, knowledge representation and reasoning, search, and optimization), and robotics (which includes control, perception, sensors and actuators, as well as the integration of all other techniques into cyber-physical systems)." Likewise, according to the same guidelines a "trustworthy AI has three components, which should be met throughout the system's entire life cycle; it should be:

1. lawful, complying with all applicable laws and regulations;
2. ethical, ensuring adherence to ethical principles and values, and
3. robust, both from a technical and social perspective since, even with good intentions, AI systems can cause unintentional harm."

There are still many open ethical, scientific and technological challenges to building the capabilities that would be needed to achieve a trustworthy AI, especially if, for example, we consider a general AI system which is intended to be a system that can perform most activities that humans can do, such as common-sense reasoning, self-awareness, and the ability of the machine to define its own purpose. Nevertheless, currently deployed AI systems are examples of narrow AI (systems that can perform only one or few specific tasks).

Moreover, ensuring a trustworthy AI requires efforts during its life cycle as such systems can inherit many issued. Constrains may refer to data bias and/or model explicability. In fact, since AI systems rely on data to perform well, if the training data is imbalanced or biased, the model will not have the capacity to generalize. Explicability refers to explaining the system's decisions, i.e., transparency in understanding how they make decisions.

To sum up, overall, achieving a Trustworthy AI must be translated into concrete requirements (i) Respect for human autonomy, (ii) Prevention of harm, (iii) Fairness and (iv) Explicability. These requirements apply to different stakeholders intervening in AI systems' life cycle - developers, deployers and end-users, as well as the broader society and are listed below in figure 10.

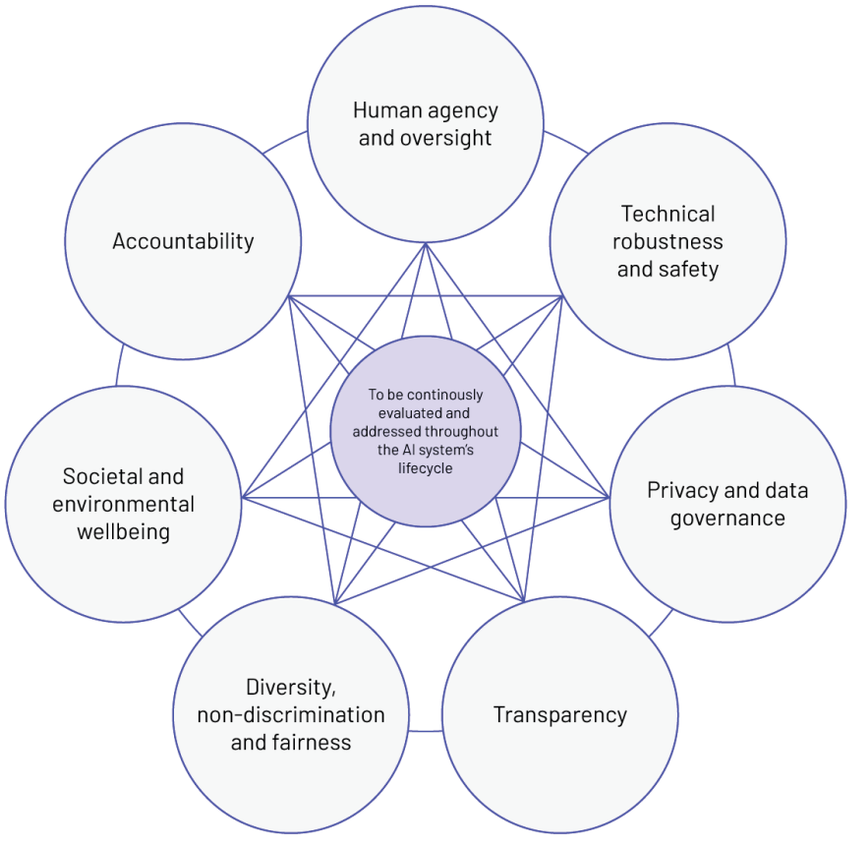


Fig. 7.12. Requirements to implement and evaluate throughout AI system´s lifecycle (Comission, 2019)

EXAMPLES AND ANALOGIES

Example 6– In the following practical course, you will be able to understand how such concepts apply: https://www.kaggle.com/learn/intro-to-machine-learning

APPLICATION AND INTEGRATION

For a hands-on practical code experience, you can visit the following open crash course:

https://machinelearningmastery.com/start-here/

REFERENCES FOR FURTHER INFORMATION AND AREAS OF INQUIRIES

Commission E. Ethics guidelines for trustworthy AI. 2019.

Magnuson J.A. DBE. Public Health Informatics and Information Systems: Springer International Publishing; 2020.

Lesson plan 3: Data-driven decision making

FOUNDATIONAL KNOWLEDGE

Principles and definition of Data Governance

There is still no consensus on a proper definition of Data Governance.

IBM defined data governance "as a discipline of quality control to add new rigour and discipline to managing, using, improving and protecting organizational information".(IBM, Data Governance) Recently, de EU splits this concept and defined firstly "data governance that entails defining, implementing and monitoring strategies, policies and shared decision-making over the management and use of data assets" and secondly, "data policies are a set of broad, high-level principles which form the guiding framework in which data assets can be managed." More specifically, both concepts" aim to provide guidance, assurance and support to transform the data-driven organization by defining clear roles and responsibilities; and introducing common principles, guidance and working practices that provide the foundation for harmonized and coordinated data management across the organization."

To this end, it is defined three hierarchical organizational levels, namely:

1. Operational
   a. Implementation of data policies and accountability for local decisions about data
   b. Whenever necessary, issues are escalated to the managerial level for resolution.
2. Managerial
   a. Responsible for developing and implementing data policies at the corporate level and local level.
   b. It monitors progress, reports to the strategic level, and refers to any issues and matters beyond its decision-making power or mandate.
3. Strategic
   a. Defines the long-term vision, gives direction, oversees progress, takes strategic decisions, and acts as the highest point of reference for issues and matters related to data governance and policies.

Overall, data governance enables greater transparency, auditability, and accountability of the organization's data assets. Therefore, a data governance program strategy should cover not only the organizational and data management priorities, but also aspects such as legislation and regulatory compliance and data culture and structures within the organization.

The principles for implementing a data governance strategy are listed below:

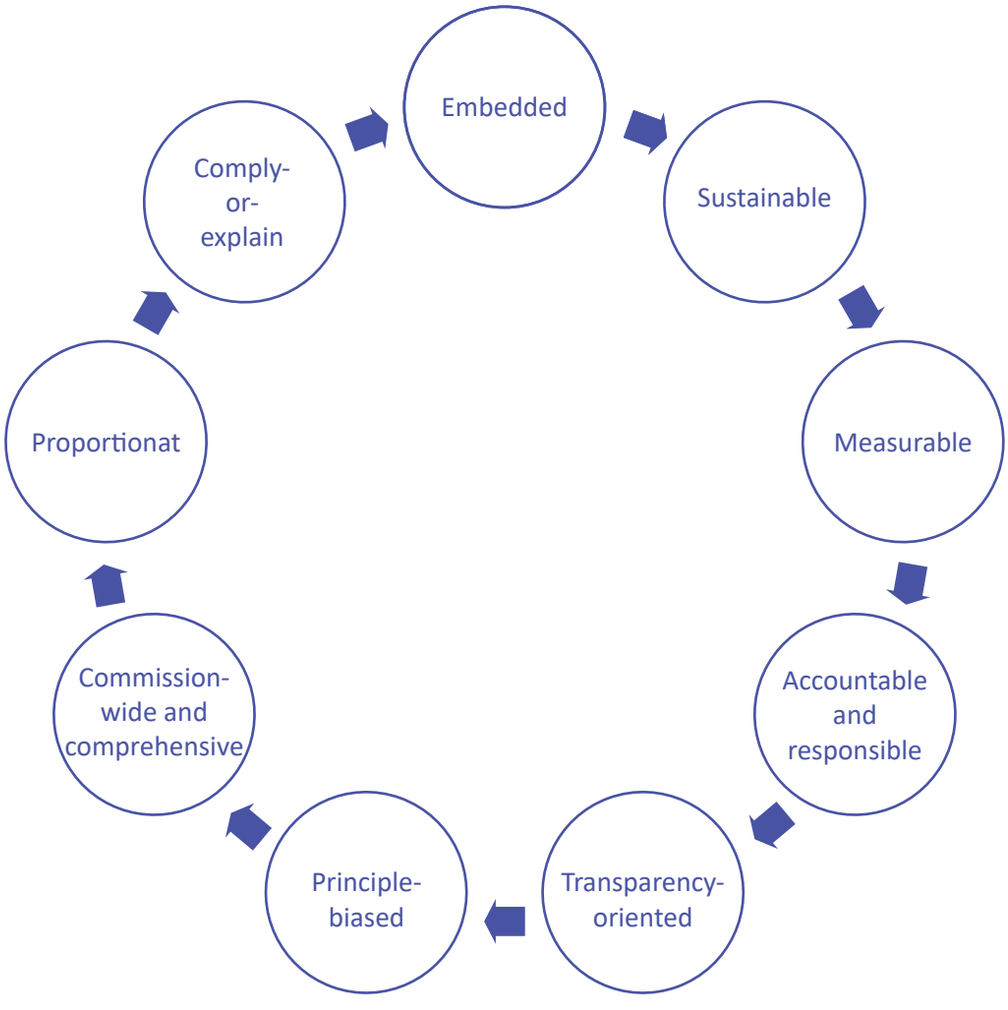


Fig. 7.13. Principles for implementing a data governance strategy (Comission, 2020)

Challenges of Data Governance (Comission, 2020)

1. Data Quality

Researchers, decision-makers and data scientists must consider possible biases and limitations regarding the accuracy and integrity of secondary data, where the six dimensions of data quality stand out:

1. Accuracy measures the degree in the which in what is measured represents a relationship with the real world;
2. Completeness represents if all necessary fields are registered;
3. Consistency is related to the frequency of filling in the various data fields;
4. Temporality measures the time difference in which the use of data is expected and in which they can effectively be used;
5. Uniqueness refers to the duplication or contradiction of records;
6. Validity is linked to the correct format, data type and consistency with pre-defined parameters.

Best practices in data quality management should focus on data quality planning, control and monitoring, assurance, and improvement.

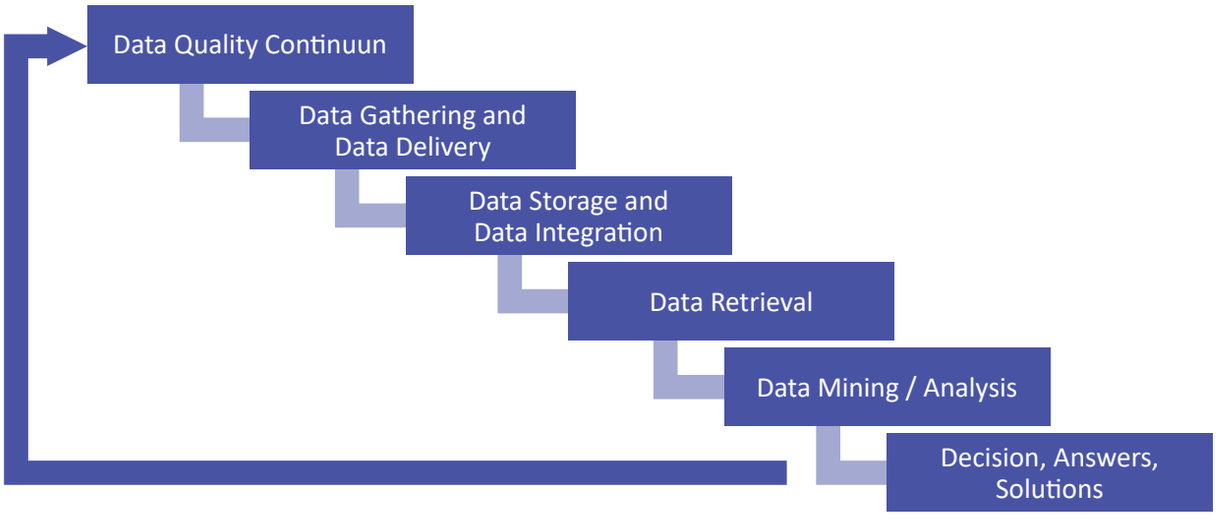


Fig. 7.14. Flow for data quality management (sursa?)

2. Protection and Information Security

Privacy and Confidentiality

With big data comes big risks and challenges, among them significant questions about patient privacy and confidentiality. To this end, the European Commission (EC) proposed a key reform of the EU legal framework, which led to the draft of new European regulation on protecting personal data.

European Data Protection Regulation (GDPR) and Health Data

In 2018, EU Regulation 2016/679 of the European Parliament of the council of 2016 states to harmonize data privacy laws across Europe (Commission, 2016). Accordingly, personal data "means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person" (Commission, 2016).

The GDPR creates a distinction between personal data and special categories of personal data, which merit higher protection, such as personal health data, including genetic data, biometric data or any data concerning health.

Personal data concerning health includes "all data pertaining to the health status of a data subject which reveal information relating to the past, current or future physical or mental health status of the data subject. This includes information about the natural person (…); a number, symbol or particular assigned to a natural person to uniquely identify the natural person for health purposes; information derived from the testing or examination of a body part or bodily substance, including from genetic data and biological samples; and any information on, for example, a disease, disability, disease risk, medical history, clinical treatment or the physiological or biomedical state of the data subject independent of its source, for example from a physician or other health professional, a hospital, a medical device or an in vitro diagnostic test" (Commission, 2016). In addition, it establishes the general principle of the prohibition of processing health data. The GDPR broadly defines processing as including operations on personal data and data collection, storage, use, disclosure, and destruction. The GDPR rules are rooted in six data processing principles defined in GDPR Article 5, which must be followed:

1. Lawfulness, fairness, and transparency— requiring lawful, fair, and transparent data processing

2. Purpose limitation—requiring data to be processed consistently with the purpose for which it was collected
3. Data minimization—limiting processing to what is necessary for a given purpose
4. Accuracy-requiring “every reasonable step” to ensure that data are accurate
5. Storage limitation—limiting the storage of identifiable data
6. Integrity and confidentiality—requiring appropriate security for processing personal data

Privacy and confidentiality

Privacy and confidentiality of protected health information (information that can be used to identify an individual) are major systems and data security drivers. Privacy is viewed from the individual’s perspective; it reflects the right to keep one’s information private (undisclosed). Confidentiality is viewed by those entrusted with that information and their duty to keep it confidential (see example 7). Confidentiality - ensuring confidentiality begins with a data classification program and requires the highest levels of protection - if disclosed, disrupted, or stolen, it would cause considerable damage to an organization. One common and effective method of ensuring confidentiality is to encrypt the data.

3. Data Interoperability and Standards

According to CDC (CDC, 2021), effective healthcare data interoperability ensures that electronic health information is appropriately shared between healthcare and public health partners in the right format, through the right channel at the right time. Data Interoperability aims to improve communication between entities and improve patient care. Some benefits include:

- Bi-directional communication between state public health departments and clinical care providers and between organizations
- Standardized data elements for data exchange
- Improved efficiency across the healthcare and public health system

But…Health data is inconsistent, unstructured, and complex, raising difficulties in applying interoperability principles!

Among the available technical specifications for achieving interoperability, HL7 is healthcare’s most widely used syntactic standard. In recent years HL7® has developed a new product called Fast Healthcare InteroperabilityResources (FHIR) - the latest development in standards for health information exchange designed by HL7.

A key strength of FHIR is that it uses an application programming interface (API) based approach to facilitate the exchange and integration of clinical data, thus facilitating interoperability.

Nevertheless, achieving interoperability still faces many challenges, highlighting funding, the sparse variety of platforms and HIE, complex legal and regulatory environment and workforce.

4. Data Governance and Management

While governing a data program, a holistic approach should set the basis for best practices. Applying core principles which govern the life cycle of information(as previously discussed) may form the basis for an efficient data management strategy in the health ecosystem.

EXAMPLES AND ANALOGIES

Example 7– Example of applying the concept of privacy and confidentiality:

"For example, a Public Health (PH) professional engaged in Sexually Transmitted Disease (STD) contact tracing might be working to identify and help the sexual partner(s) of an HIV/AIDS individual. The PH professional will inform the contact(s) that they may have been exposed to an STD and recommend testing/treatment. But if the original individual wishes to keep their information private, then the partner(s) will not be told who referred them—that information will be kept confidential."

APPLICATION AND INTEGRATION

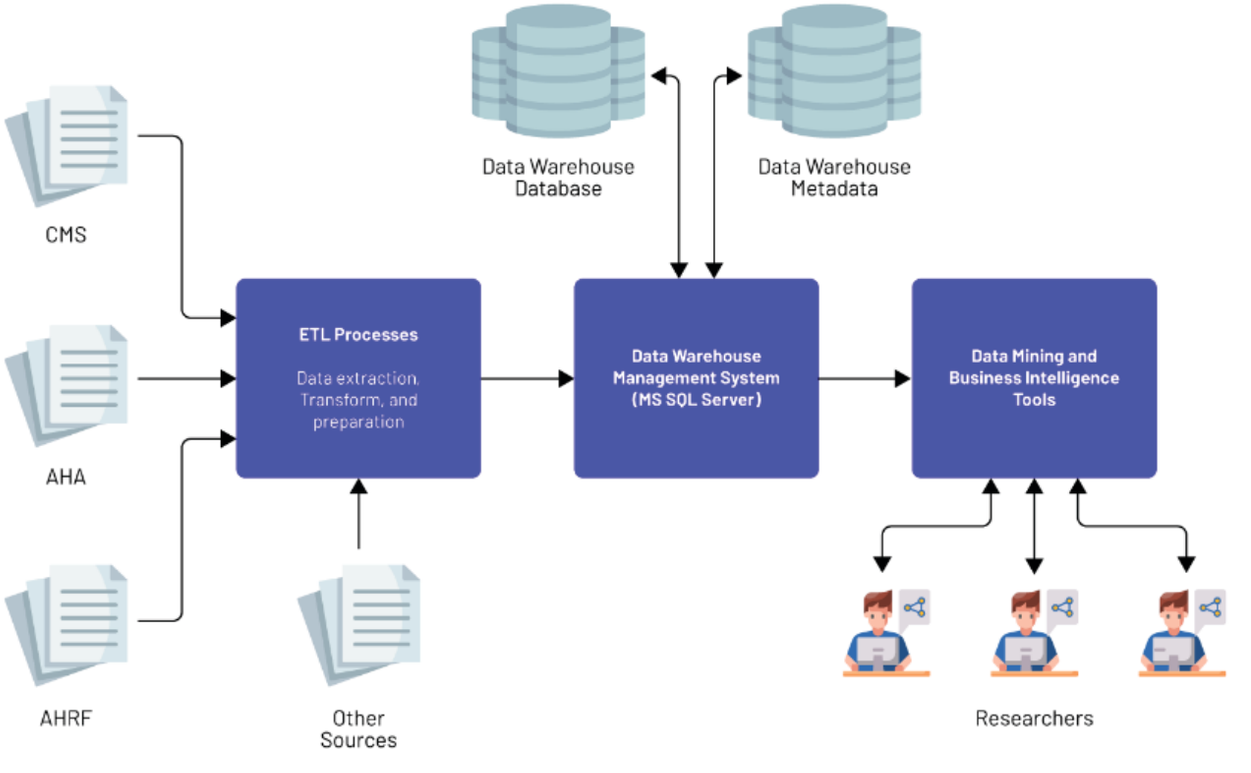
Case Study 2 (Ozaydin, Zengul, Oner, & Feldman, 2020)

As previously stated data Governance requires multiple fields of intervention. Application of such dimensions ranges from projects applied to address integration, cleansing, interpretation, and aggregation of raw data from various data sources.

This section will use the article to provide an overview of the health life cycle.

Current uncoordinated and isolated efforts on such disparate datasets can be wasteful due to the inability to reproduce findings. Information technology (IT) infrastructure is crucial to unveil the potential of analytics and address data governance constraints in terms of interoperability. This is especially important when multiple databases are available, and a proper infrastructure architecture design may improve data delivery to health services researchers – thus, enabling collaboration on innovative and rigorous research. Data warehouses usually serve as the infrastructure for running institutional data analytics and business intelligence (BI) systems.

This case study provides theoretical underpinnings of the processes and methodologies in developing a data warehouse system as an infrastructure to support health services research.



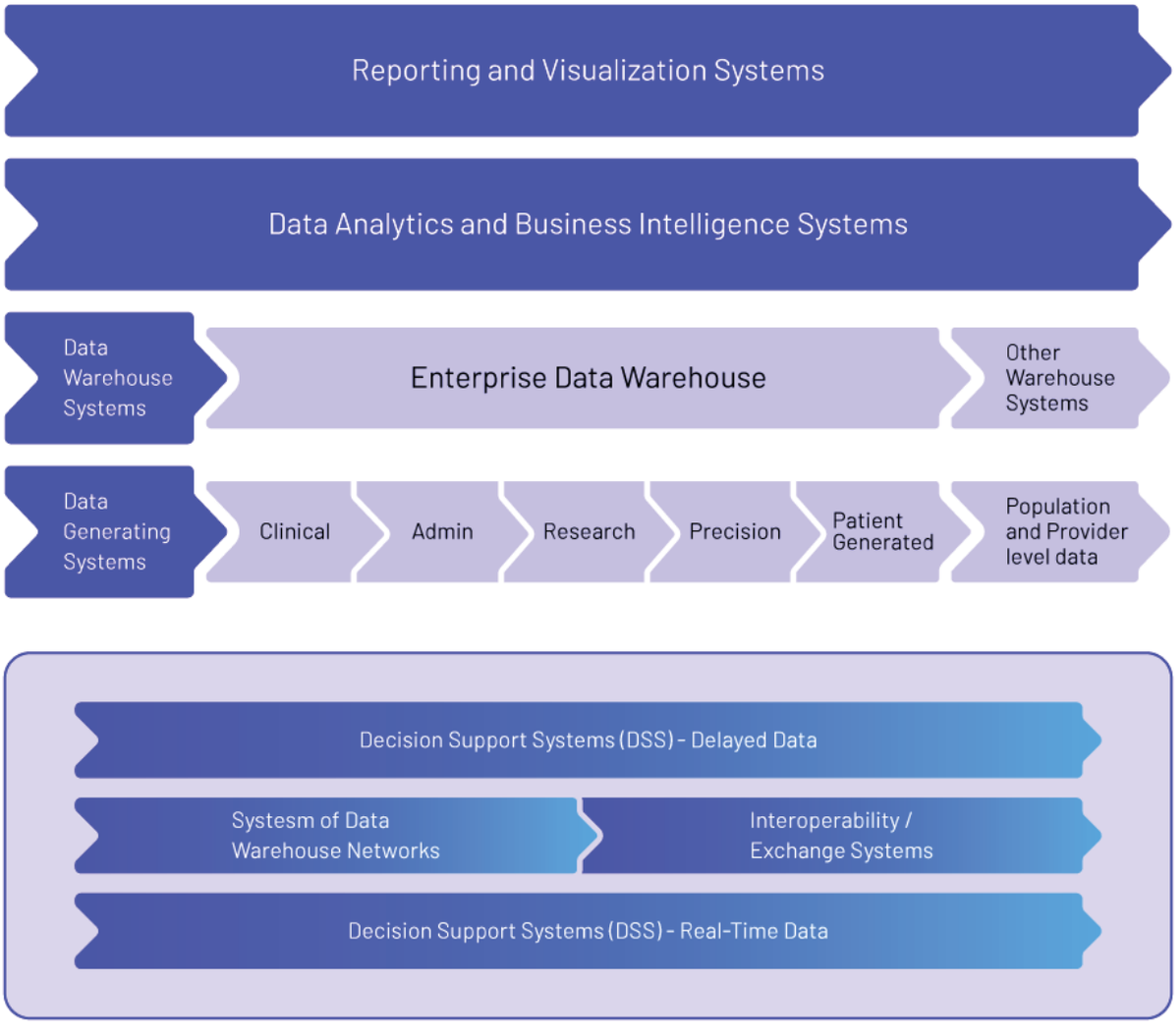


Fig 7.15. Processes and methodologies for developing a data warehouse system as an infrastructure to support health services research. Images extracted from the paper of Case Study 2.

It addresses existing constraints in data quality (e.g., inefficiencies, disparate and unnecessary duplication of efforts, and the lack of harmony among health services researchers) during all health data lifecycle. To this end, it is presented and discusses a design process (the application of 4 phases of a conceptual iterative process model) for the implementation of HRADIS - a full-service data warehouse integrating frequently used health services research data sources, processes, and methods along with a variety of data analytics and visualization tools.

Another example that has been gaining attention from the scientific community is the FAIR4Health. For more information, visit https://www.fair4health.eu/.

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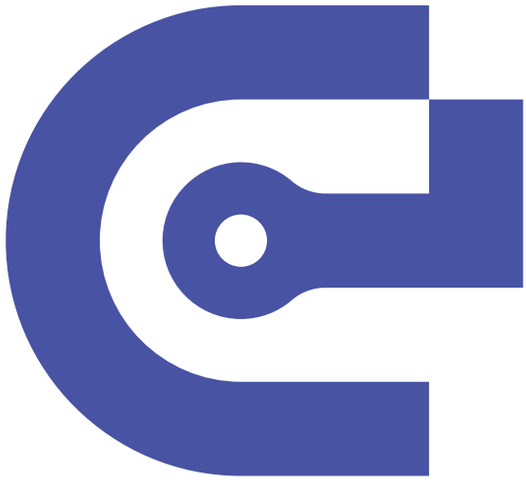

Module 8: Electronic Health Records

Learning objectives of the Electronic Health Records module

1. Understand and explain concepts, principles and methodologies related to EHR
2. Describe how the implementation of the EHR improves the healthcare system
3. Identify ways in which EHR implementation improves workflows
4. Understand the importance of patient data privacy
5. Apply relevant safety, privacy, and policy concepts to the use of EHR's within the clinical/hospital setting
6. Gain hands-on experience using digital solutions that satisfy the functionalities of the EHR.

Foundational knowledge of the Electronic Health Records module

Electronic health records (EHR) are real-time, patient-centred records that make information available instantly and securely to authorized users. While an EHR contains patients' medical and treatment histories, 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. EHRs are a vital part of health IT and can:

- Contain a patient's medical history, diagnoses, medications, treatment plans, immunization dates, allergies, radiology images, and laboratory and test results
- Allow access to evidence-based tools that providers can use to make decisions about a patient's care
- Automate and streamline provider workflow

One of the key features of an EHR is that authorised providers can create and manage health information in a digital format capable of being shared with providers across more than one health care organization. EHRs are built on sharing information with other health care providers and organizations – such as laboratories, specialists, medical imaging facilities, pharmacies, emergency facilities, and school and workplace clinics – so they contain information from all clinicians involved in a patient's care. EHRs are also useful for patients as a tool to keep them engaged with their medical data, view their medical history and have easy access to their data (Healthit.gov, 2021).

Lesson plans for the Electronic Health Records module

Lesson plan 1: Introduction to Electronic Health Records

FOUNDATIONAL KNOWLEDGE

Definition:

Electronic Health Records (EHR) is a health information technology database that is being widely adopted in the healthcare industry. An EHR is a comprehensive, real-time record of an individual's health/healthcare information in a digitized format. EHR data is recorded and maintained by healthcare providers over time and includes information on a patient's medical history, treatments, medication, immunizations, radiology images, lab and test results, progress notes, demographic data, and insurance information. In addition to storing heath data, the EHR system automates access to information, streamlines providers' workflow and includes evidence-based decision support, outcome reporting and quality management interfaces. The purpose of EHR is to support improvements in the delivery of efficient and quality health care by consolidating a patient's clinical information

into a single interface that can be readily accessed by authorized users and securely exchanged across healthcare providers (HealthIT, 2021).

Critical Features:
There are three critical features of EHR (Bastias-Butler & Ulrich, 2019).

1. EHR's are longitudinal - EHR allows for health-related information to be recorded over time and from various systems (Bastias-Butler & Ulrich, 2019). This is because an EHR system is a single interface for all medical encounters to be documented throughout an individual's lifetime, regardless of where or by whom the patient is seen. In this sense, an EHR is longitudinal because each encounter in any care setting generates the information in the record, and the record is continuously being added to.
2. EHRs are interoperable - According to the 21st Century Cures Act, interoperability in healthcare technology, is health technology that "(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; "(B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and "(C) does not constitute information blocking as defined in section 3022(a) (HealthIT, 2019)." Thus, interoperability for an EHR is the ability of two or more EHR systems to exchange information and to use the information that has been exchanged (Green, 2019). Interoperability is important in EHRs because EHRs are intended to improve patient outcomes through better healthcare communication.

Because there are numerous EHR systems with various interfaces and technical specifications, EHR interoperability is achieved through national and international standards developed by organizations such as Healthcare Information and Management Systems Society (HIMSS), and H level 7 (HL7). The standards ensure that an EHR system can share data across clinical environments, labs, hospitals, pharmacies, and patients regardless of the technology or the vendor (HealthIT, 2021).

There are currently several standards in place regarding the terminology, healthcare messaging, documents, frameworks, applications, and architecture of EHR (HealthIT, 2021).

For example:

- HL7 V2.X and HL7 V3 is a standards for the exchange of demographic, clinical, and administrative data.
- ASC-X12 provides design for exchange procedures, patient eligibility, and benefit payments.
- ICD-10 (International Classification of Diseases) defines a catalogue of diagnoses and procedures for statistical purposes, billing, costs, and paperwork.
- HL7 CDA (Clinical Document Architecture), CCDA (Consolidated CDA) and CCR (Continuity of Care Record) provide standards for documents used to indicate the type of information included in a report.

3. EHRs facilitate the involvement of different healthcare organizations and levels of care in the information exchange process (Bastias-Butler & Ulrich, 2019). This feature of the EHR is achieved through a combination of it being a single interface for all healthcare interactions to be documented and its interoperability. Any healthcare provider, whether a physician, pharmacist, or lab technician, can input data into an individual's EHR. Further, this data can be equally accessed by any of the healthcare providers mentioned above. In this regard, EHRs allow for the involvement of providers at different levels of healthcare. EHRs allow for participation from various organizations through their interoperability standards, which mandate that data from an EHR must be cable of being shared across healthcare organizations, rather than limiting data to a single office, hospital or state.

There are different models in place that aim to assess the proper implementation and adoption of EHR by hospitals and health systems everywhere. One of the most comprehensive models is the HIMSS Electronic Medical Record Adoption Model (EMRAM), currently being used to improve person-enabled health and governance and workforce dimensions of digital health in the acute care setting. Using the model, patient satisfaction and safety are increased, data is secured, and clinicians are supported in their day-to-day work.

Increase patient safety: Optimizing EHR implementation will lead to better access to critical information when and where clinicians need it, therefore better patient safety.

Increase patient satisfaction: Having the right information at the right time for both the patient and the clinician will lead to enhanced care delivery. Therefore, it will reduce time and errors in care delivery and increase patient satisfaction.

Secure data: EMRAM guides the organization in policymaking for the appropriate use of the data the EHR stores and the level of access available to clinician teams and others within the organization.

Support clinicians: EMRAM ensures the workflow and content in the digital tool meet the needs of the clinical teams while monitoring compliance with approved standards.

EMRAM has eight stages of implementation. Information about each stage can be found here.

Lesson plan 2: EHR today

FOUNDATIONAL KNOWLEDGE

Who EHR is used by

EHR data is recorded and maintained by healthcare providers over time and can be shared across practices and organizations (clinicians, laboratories, pharmacies, e.g.) EHRs are only accessible by authorized personnel. This includes primary health care providers, specialists, nurses, radiologists, laboratory technicians, pharmacists, radiographers, administrative staff, etc. Additionally, EHR is accessible by the patient (and their parents if under 18) through a patient portal.

A person who contributes to a medical record is called a documenter (DeVore, 2015). Although many different members of a healthcare facility can contribute to a patient's EHR, how an EHR is used in a given healthcare setting, for instance, what kind of information is being documented and reviewed, often depends on the staff member's position. For example, administrative staff, such as the front-desk receptionist, will use an EHR to document data about the patient in preparation for their examination (DeVore, 2015). This information is gathered using a patient information form (PIF) in the EHR system. The information documented can include the (patient) reason for the visit, copayments, request for prescription refills and authorization to obtain or release medical records from other physicians (DeVore, 2015).

Additionally, the administrative staff may document appointment information, such as no-shows or cancellations (DeVore, 2015). Another common documenter is the medical assistant. The medical assistant is the staff member who accompanies the patient in the examination room and is responsible for measuring the patient's weight, height, and vital signs (DeVore, 2015). The medical assistant will record this information into the EHR. Additionally, the medical assistant will use the EHR to take notes of any preliminary health information, such as why the patient is visiting, their current medications, allergies etc. (DeVore, 2015). Lastly, the physician is the main documenter for the patients' medical charts. The physician will use the medical chart portion of the EHR

during and after the examination to document the examination findings, care plans and any other observations made during the patient counter (DeVore, 2015). The physician must approve all additions to a patient's medical chart (DeVore, 2015). In addition to the medical record, the physician will also use additional functions of the EHR, such as clinical decision support (CDS) and the computerized physician order entry, allowing physicians to order medications electronically. These systems are described later in the text.

Healthcare providers are the key documenters in the EHR; however, as seen earlier with the administrative staff, other people within the healthcare system can access an individual's EHR. For example, a medical biller may use an induvial EHR to document insurance information (DeVore, 2015). Generally, the function of the EHR system (e.g. medical or administrative) that a given staff member is using to document or review information corresponds to their work responsibilities.

In addition to healthcare providers and staff, the patients have access to their EHR through a patient portal. The patient portal allows patients direct access to their medical records and tools that can support their health and treatment and enable them to share their information with other providers. In their patient portal, patients will find information regarding (HealthIT, 2017):

- Recent doctor visits
- Discharge summaries
- Medications
- Immunizations
- Allergies
- Lab results

Some patient portals also allow patients to (HealthIT, 2017):

- Securely message their doctor
- Request prescription refills
- Schedule non-urgent appointments
- Check benefits and coverage
- Update contact information
- Make payments
- Download and complete forms
- View educational materials

EMRAM implementation around the world

HIMSS Analytics developed a map for assessing the hospitals that adopted the EMRAM model to track the achievement of maturity levels (stages 6 and 7) for each hospital. The map is constantly updated and can be consulted here: https://www.himssanalytics.org/europe/stage-6-7-achievement.

Since it was founded in 2005, more hospitals have started adopting it. According to HIMSS data, the United States and Canada are leading in this domain, with over 6000 hospitals using EMRAM. Most have very high maturity levels (stages 6 and 7) (Analytics, 2009). Moreover, countries like Ireland, UK, Netherlands, France, Spain, Italy, Switzerland, Belgium, Finland, Sweden, Turkey, KSA, UAE, India, Malaysia, Brazil, Singapore, Australia, and China also attained stage six maturity levels according to HIMSS data (Analytics, 2009).

There are several examples of the implementation of EMRAM in hospitals across the world, such as in US (Furukawa & Pollack, 2020), US (Kharrazi et al., 2018), Canada (Sulkers et al., 2019), Turkey (Kose et al., 2020).

EHR System structure

The structure and content of EHRs have varied over time. EHRs include both unstructured free text and coded data. The most recent widely accepted structure encompasses three main elements of EHR: time-oriented, problem-oriented and source-oriented EHRs (Häyrinen et al., 2008). The data are presented in chronological order in the time-oriented electronic medical record. In the problem-oriented medical history, notes are taken for each problem assigned to the patient. Each issue is described according to the personal information, objective information, assessments and plan (SOAP). In the source-oriented record, the record's content is arranged according to the method by which the information was obtained (e.g. notes of visits, X-ray reports and blood tests). Within each section, the data are reported in chronological order (Häyrinen et al., 2008).

Moreover, sustainable business models need to be developed to create value for a healthcare provider and the patient, looking at both the costs and benefits of e-Health. Therefore, EHR is a good business model for healthcare providers and patients. Here are some examples of successful EHR business models: https://www.businessinsider.com/ehr-systems-vendors. There is also evidence that EHR can be further improved: https://hbr.org/2020/06/its-time-for-a-new-kind-of-electronic-health-record.

Lesson plan 3: EHR Technology

FOUNDATIONAL KNOWLEDGE

System software:

Most EHR systems are cloud-based; however, an EHR system can be offered in the cloud or a server-based method. In a cloud-based EHR system, the system software and clinical data are stored on off-site servers, which can be accessed through the web (Green, 2020). For server-based EHR software, "system software and clinical data are stored on local servers (Green, 2020)".

There is numerous commercial EHR software available on the market, as there is currently no universal EHR system. However, each EHR system must comply with implemented standards at a national and international level. For example, the most recognized international nonprofit standard organization is called H level 7 (HL7). HL7 develops electronic standards that ensure that each component of an EHR (e.g. billing and clinic information) can communicate more easily (Atherton, 2011). Because a different vendor can develop each part of an EHR, HL7 create a standard that specifies what kind of language the computer will use (Atherton, 2011). Standards like this ensure an interconnection among software and aid in the interoperability of EHRs. In addition, each EHR system must be certified by the Certification Commission for Healthcare Information (CCHIT). The CCHIT imposes standards for what each EHR software should be able to accomplish (DeVore, 2015). Further, the Institute of Medicine (IMO), a branch of the National Academy of Sciences, has outlined eight core functions that each EHR system should be capable of.

Core Functions of EHR:

1. Health information and data: the primary function of an EHR system is collecting health information and data from various healthcare sources. This includes a patient's medical history, treatments, medication, immunizations, vital signs, radiology images, lab and test results, as well as progress notes, demographic data, and insurance information
2. Result management: EHR systems must ensure that test/lab results are easily accessible to healthcare providers across different settings or locations and the patient.
3. Order Management: All EHR must include a system known as computerized physician order entry (CPOE). CPOE allows physicians to enter, store and order prescriptions, tests and other services, such as radiology or physical therapy (Menachemi & Collum, 2011).
4. Clinical Decision Support (CDS): all EHR software must include an evidence-based tool that assists providers in making patient care decisions.
5. Electronic Communication and Connectivity: All EHR software should include a secure messaging system that allows providers and organizations involved in patient care to communicate and share data.
6. Patient support: EHR software includes a patient portal. The patient portal gives the patients direct access to their medical records and tools that support their health and treatment. Tools can include educational materials such as wound care instructions or resources for monitoring their health at home.
7. Administrative process and reporting: EHRs include tools that allow for administrative tasks, such as scheduling, billing etc. task to be automated.
8. Reporting and population health: EHR system should be able to store and transmit clinical data (e.g. diagnoses of infectious diseases) to public health entities (e.g. Center for Disease Control). Researchers can also access the EHR database to gather epidemiological statistics (DeVore, 2015).

Basic Functions of EHR:

Aside from these eight core functions, each EHR system generally has the same basic functionality. The differences between EHR systems typically are seen in navigation, task execution, workflow etc. (DeVore, 2015). However, because the fundamental features of all EHR systems are similar, users can adapt to different systems with little difficulty (DeVore, 2015).

The basic functions of an EHR system include (DeVore, 2015, p.12):

- Progress notes function
- Documentation using free text, predefined clinical templates, user-defined clinical templets, or clinical macros
- Provider review of incoming lab data, reports
- Patient correspondence
- Storage of office forms (incident reports, inventory, petty cases)
- Images and report attachment function
- Electronic signature insertion
- Prescription templates that provide dosage suggest alternatives, list prices and cross-check prescriptions for drug interactions, patient allergies and availability in the formulary
- Fax and messaging functions to transmit prescriptions directly from the EHR to the patient's pharmacy
- Reminders that the patient is due for a screening or other health maintenance test or procedure

- Vital signs data capture
- Patient portal
- Importation of lab data from the outside or in-house lab, using industry-standard formats
- Automatic flagging of abnormal data and test results
- Intraoffice messaging and email functions
- Summary and print functions

EHR Architecture:

There is no standard architecture for EHR systems; however, there is a basic model for current hospital EHR systems. EHR systems used in hospitals are created by pooling and sharing data between many components. The ability of an EHR to support advanced features such as the CDS, depends on the level of integration of its component systems. For a system to qualify as an EHR it must be on the level of data integration (Carter, 2008).

Data integration: is required for proper EHR functionality. "Data-level integration requires that all system components use a consistent scheme for coding data elements and that a mechanism be present for movement of data between systems (Carter, 2008, p. 8)." The hospital's central system is a large database called a clinical data repository (CDR). The CDR acts as a major information source for the entire EHR system. The goal of this system is to provide a common pool of data that all applications can access. The ideal CDR would implement departments such as laboratory, radiology, and pharmacy, as well as other functions of the EHR, such as CPOE and advance reporting (Carter, 2008).

The most common method for populating the CDR is through interfaces to link each component system. This is called the interfaced system: best of breed (Carter, 2008).

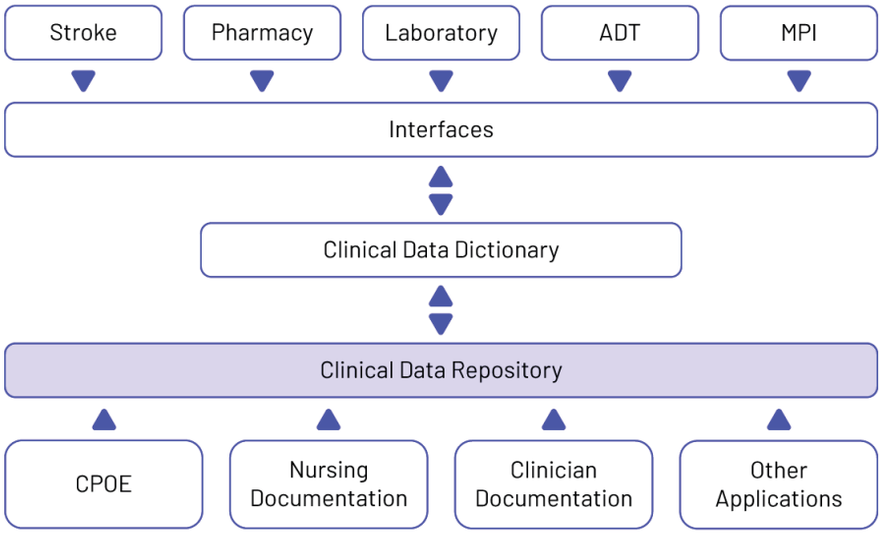

Fig. 8.1. Best-of-Breed(interfaced) HER (Carter, 2008)

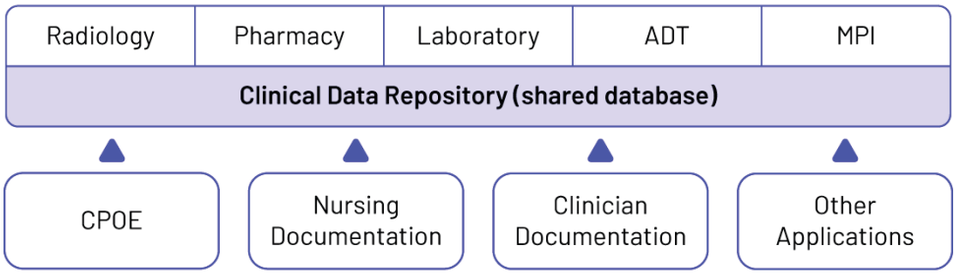

Fig. 8.2. Unified Database(integrated) EHR (Carter, 2008)

However, the ideal system for EHR functionality is the integrated system: a unified database. Unified database systems share a single underlying database. This system design minimizes or potentially eliminates the need for interfaces by providing true data-level integration. To achieve this system, all components of an EHR must be purchased from the same vendor (Carter, 2008).

System Structure of EHR:

Generally, an EHR system is structured into two large components, clinical software and administrative software. The clinical software includes the medical report, which is used by physicians and other direct care providers (Physician assistants, Nurses, Physical therapists etc.) to enter any notes pretraining to a patient's health. This clinical software will also include information such as (DeVore, 2015, p. 4):

- Medication list
- Allergies list
- Immunization records
- Laboratory reports
- Surgical reports
- Hospital records
- History and physical assessment findings
- Risk assessment
- Preventative services
- Progress notes
- Vital signs and growth charts
- Imaging test results

Another key component of the clinical software in EHRs is the CDS software. The CDS software is an evidence-based tool that assists providers in making patient care decisions. The CDS system includes "providing the latest information about a drug, cross-referencing a patient allergy to a medication and alerts for drug interactions and other potential patient issues that are flagged by the computer" (Menachemi & Collum, 2011). These functions allow the providers to (DeVore, 2015, p.13):

- Ensure that a patient's care complies with established screening recommendations for the disease they are at risk. This is because the CDS system automatically analyzes patients' data, such as age and gender, to produce automated reminders for mammograms, pap smears, coloscopies and other exams and screening tests and procedures.

- Plan treatment following evidence-based treatment guidelines. The provider can make timely and accurate diagnoses with the aid of advice automatically generated by the EHR system based on the patient's clinical data
- Generate patient data reports and summaries
- Complete documentation templates specific to the patients diagnoses
- Perform database searches to identify patients who meet specific criteria, such as those within a certain age range who have a given diagnosis, to ensure they are receiving the recommended care and screening

In addition to the Medical record and CDS system, the clinical component also includes the computerized physician order entry (CPOE). As stated earlier, CPOE allows physicians to enter, store and order prescriptions, tests and other services, such as radiology or physical therapy (Menachemi & Collum, 2011).

The administrative component is utilized by administrative staff, such as receptionists and medical billers. Information in this component will include DeVore, 2015, p.13):

- Patient demographics
- Name of the emergency contact person
- Patient correspondence
- Referral and consultation letters
- Prior authorizations
- Insurance information, copies of insurance cards
- Health insurance portability and accountability act (HIPPA) 5010 Claim status
- Billing account ledgers
- Superbills
- Day sheets
- Appointment history
- Diagnosis and procedure codes

This component of the EHR includes practice management software (PMS). The PMS enables the electronic management of the business components of healthcare (DeVore, 2015). The PMS includes (DeVore, 2015)

- Information about the patient demographics, socioeconomic data, occupation, education etc. Information found on the patient information form (PIF), such as contact information, emergency contacts and insurance information, are also stored in this software. Further, this software will provide this information in three separate tabs: patient, guarantor, and insurance
- Billing and insurance information, including scanned copies of a patient's medical insurance cards
- An appointment scheduling function that allows for a quick search of available appointments, the option to reschedule appoints and a documented record of cancelations. This function will also include a link to a patient's clinical records.
- Advance accounting procedures are incorporated in the PMS. This includes the management and creation of patient statements, generation of day sheets (a register of daily business transactions), and the completion of HIPPA 5010 claim format

Information structure:

EHR systems utilize unstructured free text and structured or templets (Hoerbst & Ammenwerth, 2010). Physicians record data freely via a text box in the unstructured free text option. The structured text option selects data from a fixed field or template (DeVore, 2015). The structured format requires physicians to choose options such as "diagnosis, medications and symptoms from a list and completing onscreen forms" (AMA J Ethics, 2017).

The information in the EHR is usually organized in a combination of elements, time-oriented, data is presented in chronological order; problem-oriented, notes are taken for each problem, and each problem is described according to subjective information, objective information, assessments and plans; Source- oriented, the information is arranged by the method of which it was received (e.g. clinician notes, x-rays, lab test etc.). Within each section, the data is arranged in chronological order (Hoerbst & Ammenwerth, 2010).

Useful tools for EHR Implementation

According to the Health IT Playbook, the implementation of EHR consists of 4 main steps:

1. Planning and selection;
2. Adoption & Implementation
3. Optimization & Workflow Redesign
4. EHR Replacement & Data Migration

To aid the development of each step, guidelines and frameworks were created, among which the American Medical Association's Electronic Health Records Optimization: Strategies to help organizations maximize benefits and minimize burdens, a useful tool for optimizing EHR processes.

Lesson plan 3: Challenges in EHR adoption

FOUNDATIONAL KNOWLEDGE

Paper records vs EHR:

Several benefits associated with EHR make it more advantageous than standard paper health records. As stated earlier, these benefits are seen in the eight-core functions of EHR. Foremost, EHR improves the availability of accurate, up-to-date health information. Patients' health information is usually generated from various locations and across health care providers—for instance, hospitals, pharmacies, emergency departments etc. Historically, healthcare providers rely on faxing or mailing each other pertinent information (Menachemi & Collum, 2011). Paper records make it difficult for providers to access "real-time" information, especially in a time-sensitive manner. With EHR, this information is stored in one interface, making it easily and readily accessible to any healthcare provider at any given time. Providers have access to a compressive record of their patient's prior tests, treatments, health issues etc. The availability of accurate and up-to-date information generally leads to better coordination among health care providers, leading to improved patient care and reduced diagnosing errors. It also enables care to be provided more efficiently because, in addition to having immediate access to health information, it also reduces redundant diagnostic testing. As stated earlier, EHR system will include all of an individual's testing. Redundant testing is costly and may lead to more false-positive results (Menachemi & Collum, 2011). In this scope, EHR is more advantageous than paper records for the provider and the patient.

Yielding similar benefits is the CPOE system. The CPOE system can reduce medication errors and improve patient safety by 1) eliminating the use of hand-written prescriptions, this reduces the occurrence of prescription errors

caused by poor penmanship, and 2) this system automatically checks for potentially dangerous drug interactions. Studies have suggested that when a CPOE system is used, medication errors can be reduced by as much as 55% and by as much as 83% when used with a CDS system (Menachemi & Collum, 2011). In addition, CPOE system improves efficiency in the ordering process because it allows for direct communication between a physician and a pharmacy, thereby reducing the need for staff to seek clarification or "solicit missing information from illegible or incomplete orders" (Menachemi & Collum, 2011).

Security and Privacy of EHR

The digital version of health records has considerably improved the quality of care by simplifying the data storage process, patient follow-up, data tracking over time, more precise medical decisions, and overall lowering the cost of care (Menachemi & Collum, 2011). However, with the rise of EHR a series of data protection issues arise. Storing health data is very important in the HER business. Weak health data protection may lead to identity theft, obtaining sensitive information about patients that may stigmatise receiving medical care at the expense of others, ordering expensive drugs for resale, and fraudulent insurance claims (Farhadi et al., 2019). Several solutions were identified for data security and privacy by developing and implementing standards and measures and recently using blockchain technology (Wang et al., 2019; Shi et al., 2020).

Read the following paper on Privacy and Security issues: Security and Privacy in the Era of Electronic Health Records (EHRs)

EHR applications are guided by measures to ensure confidentiality, integrity, and availability to protect patient data. Examples of such actions are Health Insurance Portability and Accountability Act (HIPAA), Health Level Seven International (HL7), and The General Data Protection Regulation (GDPR). All these measures offer information and guidance to protect personal data when working with EHR.

Health Insurance Portability and Accountability Act (HIPAA): In 2003, HIIPA developed the Security Rule, establishing national standards to protect individuals' electronic personal health information that is created, received, used, or maintained by a covered entity. The Security Rule requires appropriate administrative, physical and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information. Since its creation. The Security Rule suffered alterations and modifications to stay relevant to modern days.

Health Level Seven International (HL7): Founded in 1987, Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems. HL7 standards support clinical practice and the management, delivery, and evaluation of health services and are recognized as the most commonly used in the world. HL7 is supported by more than 1,600 members from over 50 countries, including 500+ corporate members representing healthcare providers, government stakeholders, payers, pharmaceutical companies, vendors/suppliers, and consulting firms. **Romania has an HL7 Association and has implemented HL7 as a standard in current Hospital Software Platforms (such as AtlasMed, InfoWorld, etc.)**

The General Data Protection Regulation (GDPR): The GDPR standards were built based on the EU Charter of Fundamental Rights, which stipulates that EU citizens have the right to protection of their data. The GDPR data protection package adopted in May 2018 aims at making Europe fit for the digital age. The regulation is essential to strengthen individuals' fundamental rights in the digital age and facilitate business by clarifying rules for companies and public bodies in the single digital market.

Lesson plan 5: Operating EHR today

FOUNDATIONAL KNOWLEDGE

Advancing security and privacy of EHR in the present day

A series of measures are currently being taken to standardize the development and use of EHR in the present day. The authorities responsible for developing standards for HER development and service have also developed different tools to help EHR producers and users. Some examples include:

Health Level Seven International (HL7) developed some implementation guides to help organisations properly implement the HL7 standards.

GDPR also established the European Data ProtectionBoard (EDPB), an independent European body that shall ensure the consistent application of data protection rules throughout the European Union. The EDPB comprises the representatives of the national data protection authorities of the EU/EEA countries and the European Data Protection Supervisor. The EDPB tasks consist primarily in providing general guidance on key concepts of the GDPR and the Law Enforcement Directive, advising the European Commission on issues related to the protection of personal data and new proposed legislation in the European Union, and adopting binding decisions in disputes between national supervisory authorities. The GDPR tool also offers a checklist that helps organizations to be more secure, protect customers' data, and avoid costly fines for non-compliance.

HIIPA developed a Security Risk Assessment Tool to assist small and medium-sized health care practices and business associates as they perform risk assessments. The tool helps organizations comply with HIPAA's administrative, physical, and technical safeguards. A risk assessment also helps reveal areas where the organization's protected health information (PHI) could be at risk. A HIPAA Security Toolkit Application also exists, which is a self-assessment survey intended to help organizations better understand the HIPAA Security Rule (HSR) requirements, implement those requirements, and assess those implementations in their operational environment. A comprehensive user guide and instructions for using the application are available along with the HSR application.

Advancing EHR knowledge and education in the present day

Educational: EHR Core competencies

The American health information management association and the American medical informatics association developed core competencies for individuals working with electronic health records. The core competencies are intended to be used for educational purposes by educators, trainees, or any healthcare worker creating, accessing, or using EHR. The competencies are divided into four domains; within each field, a set of skills/abilities that a user of EHR should be cable of.

1. **Health information literacy and skills**

a. Differentiate data versus information.

b. Describe the principles of structure, design, and use of health information (such as individual, comparative reports, and trended data).

c. Use health record data collection tools (such as input screens and document templates).

d. Apply standard data definitions, vocabularies, terminologies, and/or relevant healthcare data sets (such as OASIS, HEDIS, UHDDS) as used in the organization's health information systems.

e. Differentiate between the types and content of patient health records (such as paper-based, electronic, and personal health records).
f. Adhere to health record documentation requirements of external agencies and organizations (such as those specified by the Joint Commission, regulatory bodies, professional review organizations, licensure, reimbursement, and discipline-specific "good practice").
g. Adhere to internal organizational health record documentation requirements, policies, and procedures.
h. Ensure that documentation in the health record reflects timeliness, completeness, accuracy, appropriateness, quality, integrity, and authenticity as required.
i. Adhere to information systems policies and procedures as required by national health information initiatives from national, state, local, and organizational levels.
j. Write or update policies and procedures related to health data and information in daily work.
k. Identify incorrect data and take corrective action.
l. Identify methods and types of data collected in health care.
m. Maintain professional standards in all documentation activities. Health information skills using the EHR
n. Create and update documents within the electronic health record (EHR) and the personal health record (PHR).
o. Locate and retrieve information in the electronic health record for various purposes.
p. Perform data entry of narrative information.
q. Locate and retrieve information from a variety of electronic sources.
r. Differentiate between primary and secondary health data sources and databases.
s. Know the architecture and data standards of health information systems.
t. Identify classification and systematic health-related terminologies for coding and information retrieval.
u. Know the policies and procedures for populating and using the health data content within primary and secondary health data sources and databases.
v. Apply appropriate documentation management principles to ensure data quality and integrity.
w. Use software applications to generate reports.
x. Know and apply appropriate methods to ensure the authenticity of health data entries in electronic information systems.
y. Use electronic tools and applications for scheduling patients

2. **Privacy and confidentiality of health information**

a. Explain legal responsibility, limitations, and implications of actions.
b. Apply the fundamentals of privacy and confidentiality policies and procedures.
c. Follow legal aspects and regulations of documentation in requests for information.
d. Identify legal and regulatory requirements related to the use of personal health information.
e. Identify and apply policies and procedures for access and disclosure of personal health information
f. Identify policies and procedures for releasing patient-specific data to authorized users.
g. Identify what constitutes authorized use of personal health data.
h. Participate in privacy and confidentiality training programs.
i. Follow security and privacy policies and procedures for using networks, including intranet and Internet.

j. Follow confidentiality and security measures to protect electronic health information.
k. Maintain data integrity and validity within an information system.
l. Report any possible breaches of confidentiality by organizational policies.
m. Describe the possible consequences of inappropriate use of health data in terms of disciplinary action.
n. Describe monetary and prison penalties for breaches.
o. Document profession-specific information in an electronic health record.
p. Know appropriate methods to correct inaccurate information/errors personally entered in an electronic health record.
q. Authenticate information entered in an electronic health record.
r. Access reference material available through an electronic health record.
s. Identify the source of information entered in an electronic health record.
t. Identify, evaluate, select, and appropriately use computer systems for patient information documentation.
u. Teach others health record concepts, laws, documentation requirements and organizational policies and procedures as it applies to your work

3. **Health information/data technical security**

a. Implement administrative, physical, and technical safeguards.
b. Develop security policies and procedures.
c. Resolve minor technology problems associated with using an electronic health record.
d. Follow access protocols for entry to an electronic health record.
e. Enforce access and security measures to protect electronic health information.
f. Recommend elements that must be included in the design of audit trails and data quality monitoring programs.
g. Implement policies, procedures, and training for health data security.
h. Apply departmental and organizational data and information system security policies.

4. **Basic computer literacy skills**

a. Apply basic computer concepts and terminology to use computers and peripheral devices, computer communications systems, general-purpose and organization-specific system applications, and patient care/health-related software applications.
b. Demonstrate use of the essential aspects of file organization, information storage (such as disk or flash drive), protection from data loss, and basic computer skills.
c. Use basic word processing, spreadsheet, database, and desktop presentation applications as applicable to your work.
d. Identify, evaluate, and use Web-based literature resources, CD-ROMs, and Internet resources.
e. Conduct basic file organization and management for routine storage and protection from data loss.
f. Use statistical analysis packages.
g. Use portable computing devices to facilitate data input and management.
h. Demonstrate basic computer operating procedures such as logging in the computer and logoff, opening, closure and saving files.
i. Demonstrate proficiency in the Windows operating environment.

j. Resolve minor technical problems associated with the use of computers.
k. Demonstrate Internet/intranet communication skills.
l. Access and use a Web browsing application.
m. Demonstrate use of email, addressing, forwarding, attachments, and netiquette.
n. Identify and use icons, windows, and menus.
o. Create and name or rename subdirectories and folders.
p. Open and work with more than one application at a time.
q. Demonstrate how to save work to a computer and print and copy a file.
r. Create and edit a formatted document using tables and graphs.

Educational: AGME Core Competencies:

The ACGME's core competencies are guidelines used in medical schools to assess the educational progression of residents during clinical training (Habboush et al., 2018). When teaching EHR, educators can cross-reference these six core competencies with the activities a trainee performs in the EHR to evaluate the trainee's EHR learning progress. This can also help identify gaps in knowledge, problem solving, and skills that can be targeted and remediated (Habboush et al., 2018). Below is a list of the six core competencies and examples of activities an individual can do in EHR, as it relates to the core competencies Habboush et al., 2018).

1. **Patient Care**
   To achieve a person-centred stance in the EHR, patients should be able to read physician notes. When using an EHR, users should limit the number of abbreviations and avoid scientific jargon, especially in the assessment and plan section of the note.
2. **Medical Knowledge**
   To promote an evidence-based medicine (EMB) documentation, an EBM note can be added to the assessment and plan section of clinical notes using the CDS support tool.
3. **Practice-Based Learning and improvement**
   The data available in an EHR data can be extracted to a population health spreadsheet and used as an example of practice-based learning and improvement to expose trainees
4. **Interpersonal and communication skills**
   Exam rooms should be set up patient-centred to support interpersonal and communication skills. An EHR can be displayed on a large monitor. This would limit a physician's time on a separate computer away from the patient reviewing or documenting notes in the EHR. Additionally, patients can become active in their medical notes and health education.
5. **Professionalism**
   Professionalism-related issues in the EHR can be related to incomplete notes, unsigned notes, spelling and grammatical errors, and problems with organisation and structure. Professionalism while using EHR requires a balance between using the EHR and interacting with the patients.
6. **System-based practices**
   "System-based practices is the process of providing cost-effective healthcare through integrating a team approach to patient care". EHR can be used to identify safety errors and quality-improvement gaps in the EHR. EHR can also provide outcome-based knowledge by assessing specific cohorts (identify patients who need immunizations etc.).

Educational: Frameworks, related concepts and tools

Habboush et al., 2018 developed a conceptual CCM framework for using EHR as an educational tool in residency programs. The purpose of this framework is to provide a "visual guide for accessing resident progression during training from an EHR perspective" The CCM framework combines different educational concepts and tools to enhance the learning experience of medical students. For instance, the framework incorporates the ACGME's core competencies and the Reporter-Interpreter-Manager-Educator (RIME) framework. RIME is an assessment framework used to evaluate a medical student's progression through four stages: reporter, interpreter, manager, and educator. "The EHR can provide educators with a feedback tool to monitor a trainees progression." As trainees progress through RIME stages, the way they use and document in the EHR will also progress. For example, a trainee will use the EHR at the reporter stage to gather and document clinical facts. At an educator level, the "trainee" would be able to document and seek an answer to medical questions based on evidence-based medicine (as an EBM tool is available in the EHR.). "This framework places a high importance on quality notes as a foundational means to assess trainees' activities in the EHR and correlate these activates to their level of training (Habboush et al., 2018, p.1)." Essentially, the educator can track a trainee's progression within the RIME framework by observing how the trainee is documenting notes in the EHR. The QNOTE tool is also incorporated into this conceptual framework. "QNOTE uses a spreadsheet form to assess medical documentation notes for quality, completeness and efficiency. QNOTE can generate a quantitative score for clinical notes and assists with identifying the gaps in documentation skills (Habboush et al., 2018, p.3)."

The conceptual CCM framework follows a 36-month timeline. The timeline outlines the educational milestones a resident should accomplish every three months. The framework also highlights what competencies the trainees will be working on and what tools will be available. Additionally, the tasks and skills are outline with the RIME and indicates what level the trainee should be at any given point in the timeline. Further, the framework highlights the educator's tools to track the trainee's progression.

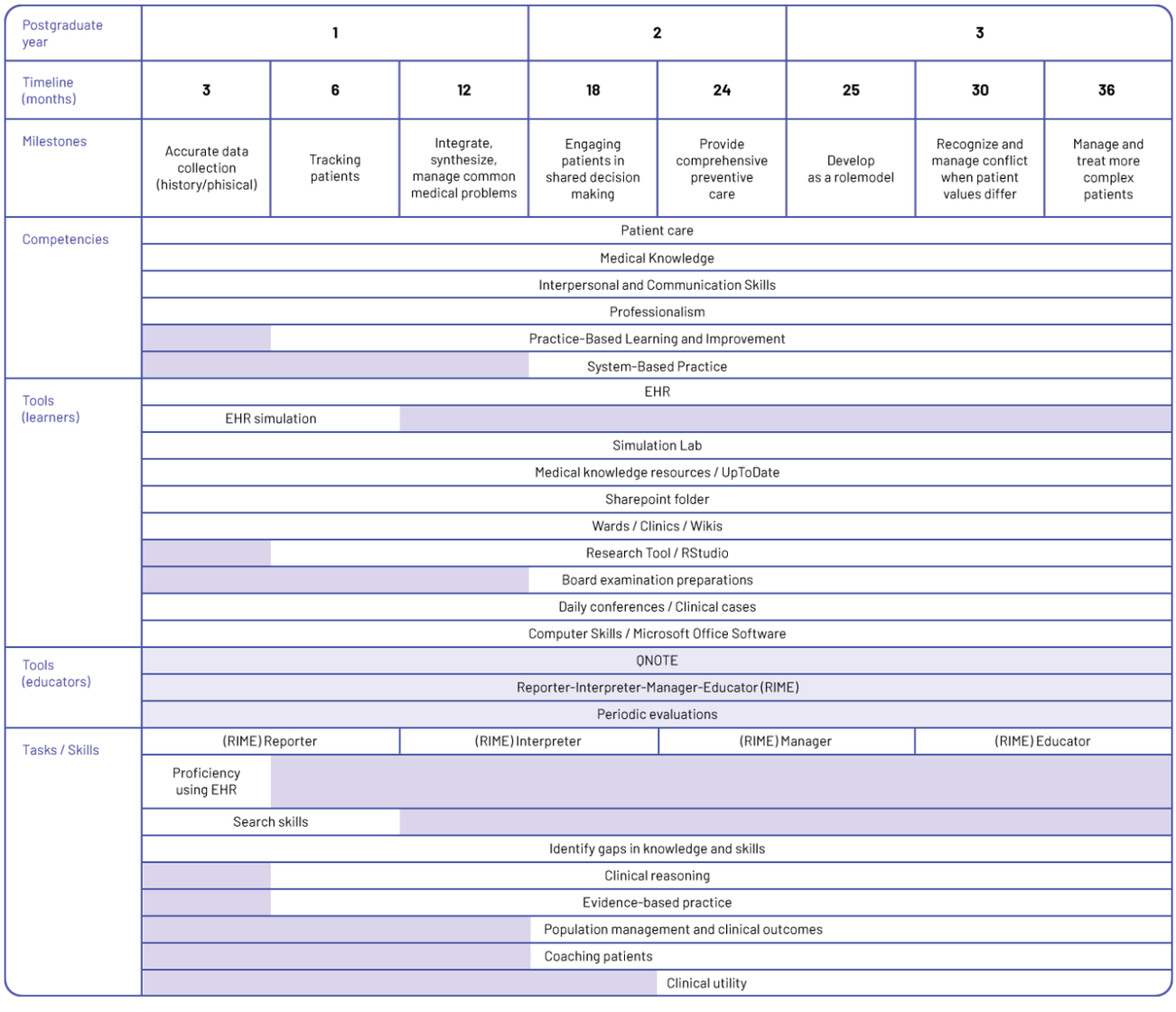

Fig. 8.3. Pilot conceptual framework. EHR: electronic health record: RIME: Reporter- Interpreter-Manager-Educator (Habboush et al., 2018).

Educational: Terminology

Clinical Decision Support (CDS): a set of patient-centred tools embedded within EHR software that can improve patient safety, ensure that care conforms to the published protocol for specific conditions, and reduce duplicating unnecessary care and its associated cost.

Computerized provider order entry (CPOE): An EHR function that allows a physician or other prescribers to order medications and tests using an automated format; CPOE can reduce prescribing errors, delays and duplication and simplify inventory and billing processes

Practice management software (PMS): software used in a medical office to accomplish the administrative task, including entry of patient demographics, record-keeping for insurance and other billing transactions, appointment scheduling and advance accounting functions

Patient information form (PIF): A form used to gather data about the patient, including basic demographic information, medical insurance data and emergency contact

Documentation: process of recording data about a patient's health history and status, including clinical observations and progress notes, diagnoses of illnesses and injuries, plans of care, patient education and self-care instructions given, vital signs taken, physical assessment findings, lab and imaging test results, medical treatments prescribed or administered, surgeries performed, and outcomes

Documenter: A person who contributes to a medical record is called a documenter

Structured data entry: documentation using controlled vocabulary via preloaded data drop-down options, radio buttons and sentence builders

Interoperability: the ability of separate EHR systems to share information in a compatible format

Single source: all systems within the EHR were purchased from the same vendor

Unified database: systems that share a single underlying database

Interface: software programs that move data between systems.

EXAMPLES AND ANALOGIES

Scanadu video (https://www.youtube.com/watch?v=xtqnaXmGjFs) – an example of where we will perhaps arrive in a few years and with the appropriate valorization of the EHR functionalities

The digitalization of healthcare can, however, be an intrusive and obnoxious way to deliver care, and it is suitable to offer an example of how digital healthcare and EHR should be – Uninvited guests video (https://vimeo.com/128873380)

APPLICATION AND INTEGRATION

The EHR module will contain 2.5 hours of individual study as a practical exercise to build up a conceptual integration of the EHR in a hospital. This will be done in interdisciplinary teams of at least two students (with different backgrounds, ideally one medical student and one IT/business student). The starting point will be the concept of a hospital that has zero digital technologies, apart from the medical equipment used to perform procedures on patients. The teams will have to include several layers of digitalization, resulting in a total adoption of the EHR in the hospital. This will be done by abiding by the EMRAM framework proposed by HIMSS. The main challenge for the student teams will be to use existing IT solutions readily on the market and available through individual research.

Therefore, the practical component of this module is to identify appropriate digital solutions that satisfy the functionalities of the EHR, building up a modular digital infrastructure for a hospital and its patients. Once identified, the answers have to be theoretically synergized to ensure data and flow interoperability within the proposed hospital. To choose the correct digital solutions, students can access openly available information concerning adopting electronic health records. Resources to be provided to students by teaching staff for the practical exercise.

The pool of digital solutions from which to select appropriate ones can be completely open (therefore requesting students to research solution viability and feasibility), or it can be closed, where student teams can choose from a pre-selected pool of digital solutions to achieve EMRAM stage 7 for the conceptual hospital. The exercise is meant to ensure students apply the principles of EHR functionalities and interoperability while leaving space for creativity in choosing solutions and ways to integrate them. It is possible to allow students to add so-called "connectors". Where a digital solution is not readily available to satisfy a process within the greater scheme of

hospital features and functionalities, teams can conceptualize one and propose it. However, for the sake of the principles of the exercise, this will be limited to a maximum of two connectors per project.

REFERENCES FOR FURTHER INFORMATION AND AREAS OF INQUIRIES

The students will use all the resources provided in Lessons 1-5 (articles mentioned, standards and tools that are hyperlinked) to understand the EHR-related concepts better. This knowledge will help them to solve the practical application for the EHR module.

Appendices

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