

Eindhoven MedTech Innovation Center

IMPLEMENTATION SCIENCE

Fast track to clinical innovation

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IMPLEMENTATIÓN SCIENCE IN HEALTHCARE TECHNÖLÖGY INTEGRATIÓN

Foreword

As we celebrate the fifth anniversary of the Eindhoven Medtech Innovation Center (e/MTIC), we reflect on our journey. The mission of e/MTIC is not merely to foster the development of ideas generated by doctors and nurses on the hospital floor. In collaboration with engineers from the technical university, we strive to transform these ideas into effective products and, with the aid of the business sector, bring them back to the workplace to benefit patients directly. Our motto, "the fast track to clinical innovation," is a testament to our commitment. However, we recognize that it typically takes an average of 17 years for an evidence-based innovation to be implemented in practice. Implementation science is the field that addresses the challenges of the dilemmas inherent in this process. This book aims to shed light on these complexities by giving voice to key figures involved in the journey from ideation to solution and product creation. We have chosen an example from clinical practice that encapsulates the entire trajectory from idea to product development and implementation in clinical settings. Specifically, this involves the development of a new monitoring system for mother and child during pregnancy and childbirth, but can be replaced by any other idea. Our journey in this case, as in many others, spanned 20 years, aligning with the typical 17-year timeframe for clinical implementation.





Château Lambrey in Haute Saõne

During the third Lambrey conference, we reflected with researchers from the Fundamental Perinatology Research Group, along with representatives from the hospital, technical university, business sector, and health insurers, on the journey we have made.

We hope this book not only imparts knowledge but also sparks inspiration, motivating readers to contribute positively to the healthcare sector. Embark on this enlightening journey with us and discover the intricate dance of implementation science.

Professor Guid Oei, MD PhD Máxima Medical Center Eindhoven University of Technology

OUTER SETTING

Pressure from national and local organizations to implement the hemorrhage bundle

INNER SETTING

- Social architecture of each site
- Site-specific organizational culture and implementation climate
- · Compatibility with current workflow
- Relative priority to other quality initiatives
 Engagement of site leaders

CHARACTERISTICS OF INDIVIDUALS

- · Provider of knowledge and beliefs about the hemorrhage bundle · Belief in ability to perform bundle components like QBL
- Provider of readiness for changeProvider of identification with the organization

Figure 1: Application of the consolidated framework for implementation re

THE PROMISE OF IMPLEMENTATION **SCIENCE: ENHANCING PATIENT CARE THROUGH INNOVATION**

Professor Guid Oei, Obstetrician Gynaecologist, Founder of the Fundamental Perinatology Research Group, Máxima Medical Center - Eindhoven University of Technology

Implementation science, often termed implementation research, stands at the nexus of theory and practice. This multidisciplinary arena emphasizes the systematic exploration of strategies that facilitate the seamless integration of evidence-based interventions, practices, or innovations into real-world settings, particularly in healthcare environments like hospitals.

The primary objective is to narrow the chasm between empirical research and pragmatic application. This endeavor necessitates the scrutiny of a myriad of variables, ranging from the dynamics among healthcare professionals, the interplay of institutional policies and the patients' perspectives to the overarching infrastructure of the healthcare ecosystem. The ultimate ambition is to craft strategies that accentuate the advantages of new technologies while minimizing potential impediments.

Key aspects of implementation science when rolling out new technologies in hospitals include:

- 1. Evidence Evaluation: A deep dive into the existing scientific literature to gauge the efficacy, safety, and applicability of the technology in question, identifying any gaps or lacunae that need to be addressed.
- 2. Barrier & Facilitator Identification: Recognizing potential hindrances and accelerators for implementation. These variables can range from technical details and the way in which an organization thinks and acts to the bigger picture of how the healthcare system works.
- 3. Strategizing for Implementation: Designing and validating strategies that bolster the adoption and ongoing utilization of new technologies. This often involves training modules, policy amendments, workflow tweaks, innovative study design, and enhanced communication mechanisms.
- 4. Outcome Assessment: Measuring the real-world impact of implementation strategies, gauging metrics such as adoption rate, fidelity to original design, and long-term sustainability.

strategies, the focus shifts to amplifying the technology's reach across diverse healthcare settings, buttressed by well-designed dissemination blueprints and guidelines.

5.

By embracing the methodologies of implementation science, healthcare institutions stand poised to augment patient outcomes through the adept introduction of new technological paradigms.

Real-world Case Studies & Insights

Dr. Guid Oei's own PhD research project in the 1990s, which focused on the effectiveness of the postcoital test introduced by Dr. Sims in the nineteenth century, exemplifies the challenges associated with implementation. Under the guidance of Prof. Marc Keirse, a vanguard in the evidence-based medicine domain, Oei embarked on a novel randomization approach. Though the test was found redundant and was swiftly phased out in the US, the Netherlands witnessed an 18-year lag in its discontinuation - a testament to the intricacies of de-implementation. Historically, the cholera epidemic in

PROCESS	INTERVENTION CHARACTERISTICS				
 Engagement at administrative site and individual provider level Selection of implementation champions Provision of education sessions Audit and feedback with clear goals 	 Perceptions by administration and clinicians, nurses and trainees that the bundle will improve outcomes Quantitative Blood Loss (QBL) vs. Estimated Blood Loss (EBL) Adaptability to different sites Complexity - multiple components requiring time and resources Cost of educational materials. Hemorrhage cart. QBL implementation 				
ch to the obstetric hemorrhage bundle. Invented by Dr. Sims.					

Scale-up & Dissemination: Following the identification of efficacious

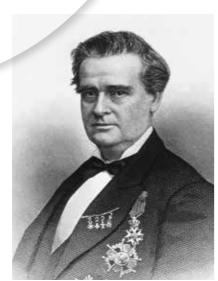


Dr. Eugene Sue, portrait by François G.G. Lepaule (1804-1886)

1844 sheds light on implementation disparities. Dr. Eugene Sue's revelations in Paris linking cholera to hygiene weren't enough to prevent an outbreak in the small village of Lambrey in the Haute Saône more than a decade later, leading to hundreds of unnecessary deaths.

It seems that local conditions where the implementation takes place play a crucial role in the speed of implementation. The delay in the Netherlands in discontinuing the postcoital test as part of fertility examinations can be





Portrait of Dr. Sims in the nineteenth century

attributed to several influential conservative fertility professors who found it challenging to let go of the postcoital test. Conversely, the later implementation of hygiene measures in rural France compared to Paris can be attributed to political decisions. More disconcertingly, cholera's presence in contemporary regions like Malawi underscores the disparity in implementation speeds based on location.

Mark Bauer's treatise on implementation science delves into the nuanced differences between controlled research environments and the unpredictable real world. Transitioning from efficacy (conceptual effectiveness) to proving its effectiveness in varied settings and finally to actual implementation demands an understanding of a multitude of external variables. The crux of implementation science pivots on not just gauging the impact of an innovation but more pertinently, on discerning the multifarious elements influencing its day-to-day adoption.

In this context, Laura Damschroder's 'Consolidated Framework for Implementation Research' (CFIR) stands out as a beacon. The CFIR meticulously demarcates potential factors under five broad domains that can influence implementation:

- + Intervention Characteristics
- + Outer Setting
- + Inner Setting
- + Characteristics of Individuals
- + Process

A case in point is Rebecca Hamm's foray into obstetrics. The introduction of an 'obstetric haemorrhage bundle' bore contrasting results in Pennsylvania and California. The defining difference? California's recourse to the CFIR framework. Apart from the CFIR, other frameworks for implementation have been developed and validated as well. It probably doesn't matter much which framework you use; what's more important is to have a framework in the first place.

Key Takeaways:

- 1. The indispensability of a structured framework.
- 2. The imperative of stakeholder engagement.
- 3. The weightage of qualitative research.
- 4. The importance of documentation and knowledge dissemination.
- 5. Gleaning insights from real-world scenarios.

Stichting De Weijerhorst

Sponsor of the Fundamental Perinatology Research group

HARMONIZING MEDICINE AND **ENGINEERING: TEAMWORK IN CLINICAL RESEARCH AND IMPLEMENTATION**

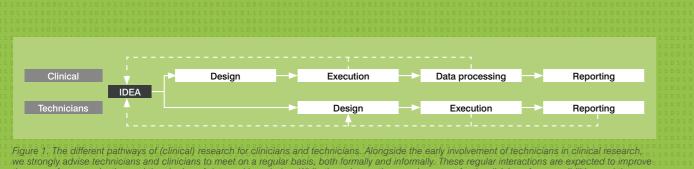
Ivar de Vries MSc, Phebe Berben MD, Nadine de Klerk MD, Midwife Physician Assistant Sofie van Weelden, Marion Frenken MD, PhD students of Máxima Medical Center and Eindhoven University of Technology

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In the world of medicine, technology is assuming an increasingly significant role. The collaboration between technician and clinician in this process is essential. This collaboration can be challenging, but when optimized it will give new opportunities. The different aspects within this collaboration will be further illustrated in order to harmonize medicine and engineering in scientific research and clinical implementation.





righter is the one-feat pairways of (clinical) research to clinicals and technicals. Addigide the early involvement of technicals in clinical research, we strongly advise technicians and clinicians to meet on a regular basis, both formally and informally. These regular interactions are expected to improve the ease of communication and the sharing of data and knowledge. While these interactions are important for the division of responsibilities and the management of expectations, they could also serve to include technical knowledge in the optimalization of the clinical research workflow or to test technical ideas for their clinical implementation. Last of all, informal meetings might result in new research ideas, as they might help to bridge the gap between technical feasibility and clinical desire.

Frequently mentioned possible barriers in the collaboration between technicians and clinicians are different communication styles (e.g., jargon), various visions and interests, different responsibilities and diverse types of knowledge. When looking at technical innovations, technicians tend to develop complex solutions whereas clinicians desire a more practical solution. Furthermore, there is a lack of awareness among clinicians of what is technically feasible. Due to this knowledge gap, technicians are often not involved in the beginning of a research project. Additionally, clinicians sometimes have a conservative mindset regarding (technical) innovations in clinical care. On the other hand, technicians sometimes come up with solutions that lack clinical insight.

Abovementioned barriers are noticeable in all research stages. The typical pathway of clinical research for a clinician consists of the following components: 1) idea, 2) design, 3) execution, 4) data processing and 5) reporting (*Figure 1*). The technician's entry point into research typically comes later, as technicians often conduct their research on clinical data. This often results in conflicts during research due to a mismatch in expectations and responsibilities in data collection. For example, technicians are often unaware of the labour intensity and clinical implications of certain procedures. In the most optimal setting, technicians are involved in the first and second stage of a clinical study.

The difference between technical and clinical research is further illuminated by the possibility of adapting or extending research with new ideas. While technicians can easily design new research questions using the collected data, clinicians often need to set up completely new research due to clinical research regulations.

Our recommendations for the advancement of clinical research implementation can be summarized as follows (*Figure 2*):

- + Communication in each stage of the research project is essential.
- + Technicians and clinicians should learn to speak the same language.
- Regular (informal) meetings could contribute to overcoming the knowledge differences between clinicians and technicians.
- + Regular (informal) meetings could result in new research ideas.



Susan Hommerson, medical/medical device research policy officer, Eindhoven University of Technology



What do you need in the regulatory domain to implement your product in the clinic? The primary requirement is the Medical Device Regulation (MDR). In this session, we will study some of the required technical documents and the logic behind them. Additionally, we will also delve into Artificial Intelligence (AI) ethics, which will soon be legislated by the EU.

The MDR is a regulation, directly applicable in all EU countries. It governs patient safety and compliance with it leads to a CE mark, which is valid throughout Europe. This MDR also applies to clinical studies. The former directive was no longer adequate, a fact that became evident through various scandals, such as the breast implant incident.

Changes in the MDR compared to the previous situation include: more clinical evidence is required, as is increased transparency; there's a greater emphasis on post-surveillance research and a shift in classifications, with many products moving to higher classes. This means there's a quicker need for a notified body. A notified body evaluates the evidence of whether a medical device is safe and meets the CE mark standards. They have the authority to award the CE mark. Every device now carries a Unique Device Identification (UDI) code. Additionally, the EU has set up Eudamed, the European database in which all medical devices are listed and where all ongoing studies are tracked.

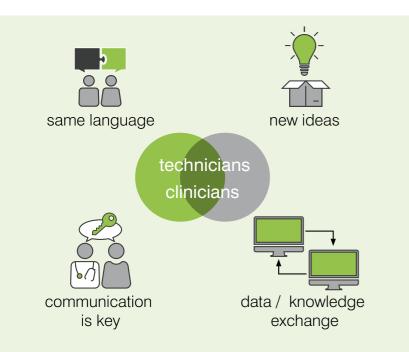


Figure 2. Key features in optimizing teamwork between technicians and clinicians

The MDR requires a quality management system for manufacturers, the ISO 13485. From this quality management system, documents such as technical documentation necessary for the Investigational Medical Device Dossier (IMDD) for clinical studies are derived.

A Medical Device (MD) is a nonpharmaceutical tool (software, implant, device, reagent, etc.) with the objective of addressing diseases (e.g., diagnosis, monitoring, treatment, etc.). It can also play a role in an injury/impairment or pertain to the investigation, replacement, or modification of anatomy/physiology, or provide information through in-vitro studies or body specimens, such as the coronavirus test.

There is a transition period for MDs to shift from the previous situation to comply with the new MDR. Making adjustments to an existing MD under the old legislation is impactful, as it then needs to meet the new MDR standards. This can be rather cumbersome, leading companies to decide against updating certain MDs and even withdrawing products from the



market. It's not only the manufacturer that is subject to the MDR, but also the supply chain partners. The implications of this can be extensive, to the point where certain MDs might no longer be available for patient care. Apart from the MDR, there are other laws, standards, and guidance documents that one may encounter, such as the ICH GCP (Good Clinical Practice), the Dutch law on medical scientific research.

EU AI Legislation is currently being developed and is aimed at ecuring fundamental rights and safety. Additionally, it is part of a digital framework including laws on the AI liability framework, safety regulations, the Cybersecurity Act, etc.

For AI, a risk classification has been established with four levels. Within this framework, risk is firstly defined across multiple high-risk domains: social, infrastructure, economic, and so forth. Secondly, an AI system is considered to be high risk if it is a safety component of products such as medical devices. .

This doesn't necessarily mean that certain activities or applications are prohibited, but that there are heightened requirements in terms of transparency. Ten standards are going to be established for AI systems:

HIGH-RISK SYSTEM STANDARDS

- 1. Risk management systems
- 2. Governance and quality of datasets used to build Al systems
- 3. Record keeping through logging capabilities by Al systems
- 4. Transparency and information provisions to the users
- 5. Human oversight of Al systems
- 6. Accuracy specifications for Al systems
- 7. Robustness specifications for Al systems
- 8. Cybersecurity specifications for AI systems
- 9. Quality management system for providers of AI systems, including postmarket monitoring process
- 10. Conformity assessment for Al systems

There is also an ethical standard comprising seven ethical principles, often used in research. It adopts a lifecycle approach, meaning that these items must be continually reviewed and addressed.

ETHICAL STANDARDS IN AI THE ALTAL PRINCIPLES DISCUSSION

- 1. Human agency and oversight
- 2. Technical robustness and safety
- 3. Privacy and data governance
- 4. Transparency
- 5. Diversity, non-discrimination and fairness
- 6. Environmental and societal well-being
- 7. Accountability

Probably also: human rights assessment, democratic values and rule of law

For example: No. 1 addresses the role of the human being, e.g., the one who bears responsibility. No. 5 pertains to data collection, emphasizing the importance of avoiding bias, but also regarding discrimination and tackling the complexity of acting on Al's predictions.

While these principles are set, implementing them requires collaboration from all disciplines to make the right decisions, not just ethicists, for example.

IMPLEMENTATION SCIENCE: A BEACON OF HOPE FOR LOW/MIDDLE INCOME COUNTRIES' HEALTHCARE?

Anne van Tetering MD, Ella de Vries MD and Kirsten Thijssen MD, PhD students of Máxima Medical Center and Eindhoven University of Technology

Low/middle income countries with concurrent low health status of the population stand to benefit more from implementation science in healthcare than high-income countries, given the triad of high need, high potential, and low existing capacity. Nonetheless, studies about implementation science have shown that a technology (or a training course, a protocol, etc.) which works in one setting under certain conditions may not be appropriate in other circumstances. One important aspect to consider is a difference in cultures between the place where a technology was developed and where the technology is intended to be implemented. To understand differences in cultures between countries, the theory of 'the Culture Map' by Meyer can be used. In this theory, national cultures have been mapped on eight scales (Fig 1.). We will highlight three of these scales and give examples of how these differences can lead to challenges, drawing from past experiences in the Netherlands, China and Uganda.

Communicating

Meyer differentiates low-context communication from high-context communication. In countries with low-context communication, messages are expressed and understood at face value. Good communication means it is precise, simple and clear, and repetition is appreciated. In contrast, in countries with high-context communication, messages are spoken and read between the lines. They are implied but not plainly expressed and good communication is sophisticated, nuanced, and layered. As a result, people from the Netherlands, a country where low-context communication is appreciated, will often misunder-

stand people from Uganda or China, countries with high-context communication. For example, when attempting to get ethical clearance for research in Uganda, it was very unclear to the Dutch people on our team what steps had to be taken, even after asking repeatedly. Therefore, walking into a room and having to present our whole study to the board of the medical ethical committee without previous notice came as a great surprise to the Dutch. It is highly likely the Ugandan counterparts had implied this, but the message was missed by the Dutch. Another example is the tendency of people in low-context communication societies to send emails after a meeting, summarizing the discussion, recording agreements and highlighting tasks that have been assigned. In high-context communication styles, this can be seen as offensive and distrusting. It is also interesting to note that counterintuitively, the highest chance of miscommunication lies between one high-context person and another high-context person from another culture, as the messages that are conveyed between the lines are completely different.

Evaluating

In Meyer's theory, countries can range from a direct negative feedback style to an indirect one. The direct style means that feedback is provided frankly, bluntly and honestly. Negative messages are not softened by positive ones, absolute descriptors are used e.g., totally inappropriate, completely unprofessional) and criticism may be given to an individual in front of a group. On the other end of the scale,

Communications		
Low context		High context
Evaluating		
Direct negative		Indirect negative
feedback		feedback
Persuading		
0		Applications-first
		Αρριοαιοπο-πιοι
0		Hierarchical
0		Hierarchical
•		- .
		Top-down
Trusting		
Task-based		Relationship-based
Disagreeing		
Confrontational		Avoids confrontatio
Scheduling		
Linear-time		Flexible time
	Low context Evaluating Direct negative feedback Persuading Principles-first Leading Egalitarian Deciding Consensual Trusting Task-based Disagreeing Confrontational Scheduling	Low context

Figure 1. The eight scales on which national cultures can be assessed according to the culture map theory

PIÖNEERING MEDICAL PRÖGRESS: A HEALTH COMPANY'S JÖURNEY WITH HÖSPITAL IMPLEMENTATION

Will Ickenroth, CEO of Nemo Healthcare

negative feedback is provided softly, subtly and diplomatically. Positive messages are used to wrap negative ones, qualifying descriptions are often used e.g., sort of inappropriate, slightly unprofessional) and criticism is given only in private. Consequently, when Dutch people (givers of direct negative feedback) receive feedback on papers by Ugandan colleagues (givers of indirect negative feedback), it may appear to them that Ugandans feel very positive about the article and only have a minor issue that may need to be addressed. However, this issue might actually be a lot more important than it seems to the Dutch. This difference in feedback style can also have impact on the design and evaluation of a simulation-based team training program that has been implemented in Uganda, based on Dutch expertise. Part of successful learning within these training programs lies in feedback participants receive from the trainers and their peers. To the Dutch involved in the training program in Uganda, it may appear as if not enough feedback is given by the Ugandan trainers and participants or not enough emphasis on what to improve. For the Ugandan participants, the feedback may be clear on how to improve their performances.

Trusting

According to 'the Culture Map', trust can be based either more on tasks or on relationships in business. In taskbased cultures, trust is built through business-related activities and work relationships are built and dropped easily, based on the practicality of the situation. In relationship-based cultures, trust is built through sharing personal time and work relationships build up slowly over the long term. Staying in a highly relationship-based society like China for some time without completing any of the intended tasks might therefore seem like a failure for someone from the Netherlands (a task-based society). However, the success is actually in building relationships during this time, and that is essential before being able to start any tasks.

Conclusion and recommendations

National cultures can differ significantly from another, which has important consequences when working internationally. It is important to be aware of your own culture, how it might differ from others and what consequences this can have for your technology or study design. The eight scales of 'the Culture Map' can be used as a basis for reflecting on these differences. To avoid mishaps and to smoothen implementation in other countries, it is essential to involve local staff and to remain flexible and curious. Developing and successfully launching a new medical product in the market is a fantastic challenge and experience, but it is usually underestimated how much time, effort and investments it takes. A continuous drive, passion and determination is needed from everyone in the company to make it happen. But the bare truth is that most startups fail.

There are many areas to consider simultaneously when developing a new product. When analyzing the root causes why most startups fail, technology push is often mentioned. There is a sincere belief of many entrepreneurs that the market will (easily) adopt a new product and is willing to pay a lot of money for it. And this is where things often go wrong, especially when the launch of a new product requires a change in ways of working, training, education, clinical evidence, budget increase and cost reduction. Let's also not forget that there is great diversity in how healthcare systems work in different countries. Who is the customer? Who are the decision makers? Who are the informal decision makers? All these factors need to be considered from the start of a development of a new product.

Another root cause is the relatively late response and feedback on a new product of potential users in the market. Clinical studies to investigate clinical outcomes and economical benefits take a lot of time. Of course, approval from a Medical Ethical Committee (METC) is required and the product needs to be safe. But the question, however, is whether it is possible to collect feedback from the market much earlier in the development process of a new product and how to set up shorter 6

clinical studies, covered by the approval of a METC. Could a minimum viable product be defined and approved in close collaboration with potential customers that make it possible to carry out clinical studies and collect feedback from the market much faster? This is certainly an area where close collaboration between industry, hospitals and universities is needed.

Both technology push and late market feedback make it difficult for companies to raise sufficient funding for market implementation. Many companies have limited budget when launching a new product and hope sales will increase revenue quickly. But this rarely happens and companies get in trouble. Proof of concept, clinical and economical evidence and market acceptance are required to get new sources of funding that support the company in growing the business. The earlier a company can mitigate the risks as described above, the higher the chance of getting funding and creating success.

The initiative of e/MTIC is a good example of a close collaboration between industry, hospitals and university and forms a perfect base for discussing, searching and experimenting with new ways of working.

FROM LAB TO BEDSIDE: ACCELERATING THE TRANSLATION OF RESEARCH INTO PRACTICE

Loes Monen, perinatology fellow at Máxima Medical Center, and Pascalle Wijntjes, PhD student at Eindhoven University of Technology cos 2 d = 2 cos d

To accelerate the translation from research into practice. a multidisciplinary approach is essential. To aid multidisciplinary communication, different tools can be used. One tool popular for innovation in any kind of organization is Design Thinking. This complex thinking process leads to improved and accelerated creative processes, mainly in multidisciplinary teams.

Design thinking is a non-linear, iterative process that teams use to understand users, challenge assumptions, redefine problems and create innovative solutions to prototype and test. Involving five phases (Empathize, Define, Ideate, Prototype and Test), it is most useful to tackle problems that are ill-defined or unknown.

Many well-known companies have implemented Design Thinking in their daily practice. Examples are Oral-B, GE Healthcare and Netflix. Design Thinking has also found its way into education, where the concept is taught by Design or Challenge-Based Learning. Many universities, both nationally and internationally, are currently using Design-Based Learning as their main type of project-based learning.

Until now, Design Thinking has not been used on a large scale in healthcare. However, due to many technical innovations in healthcare, the increasing involvement of patients and the necessity to reduce costs, Design Thinking is increasingly valued as an interesting concept for healthcare.

In the field of fundamental perinatology, Design Thinking could aid in innovative ideas. In fundamental perinatology, research teams are generally multidisciplinary, where the people involved have different backgrounds. Also, the new concepts that are explored are suited to this process. In this article, the Design Thinking process is described using an example from our research group.

Before the concept of Design Thinking can be explained in detail, a brief summary of the example research proposal is given.

Research proposal summary

It is often assumed that many obstetric complications are caused by placenta dysfunction. Fetal growth restriction (FGR), hypertensive disorders in pregnancy and pregnancy loss are some of the complications that can be caused by placental insufficiency. For normal placental function, adaptations to blood vessels have to be made, both on the maternal and fetal side of the placenta. Therefore, it is important that the microvasculature of the placenta is studied. Hence, placenta imaging is

discussed. So far. no satisfactory method for placenta function has been used in daily practice. One of the proposed methods is contrast-enhanced ultrasonography (CEUS)

Methods and Results

The Design Thinking process consists of five steps: Empathize, Define, Ideate, Prototype and Test. It is an iterative process, meaning that the process can (partly) be repeated after the fifth step. In this section, every step is explained based on the example of placenta microvasculature imaging.

Empathize - In this phase, the problem is explored. In a human-centered manner, all of the aspects of the problem are investigated. In this way, all of one's own assumptions are set aside and real insight is gained into the user's needs. A lot of information is gathered. Different stakeholders and experts in imaging, as well as obstetrics experts, were interviewed in this stage.

Define - The second phase is about defining the problem in a human-centered manner. For placenta vasculature imaging, it is important that the microvasculature of the placenta can be visualized, both on the maternal and fetal side. However, the safety of the mother and baby is most essential when using intravenous contrast agents.

Ideate - In this phase, ideas are generated. The problem is challenged from different directions and insights.

The goal is to generate as many ideas as possible in order to eventually select the best ideas.

For visualization of the microvasculature of the placenta, many ideas were first generated. These included Doppler ultrasound, plasticizing the placenta or the use of CEUS. After investigating the pros and cons of each method, CEUS was chosen as the best idea to proceed with. CEUS was found to be easy to implement and enough knowledge was available. Above all, it can image both the macro and microvasculature of the placenta.

Prototype - In this phase, some of the ideas from the ideate phase are tested. Thereafter they can be improved, accepted, or rejected. At the end, in the ideal situation, the best possible solution to the defined problem should be found.

For CEUS, a feasibility study has been done to analyze whether it is possible to visualize the fetal circulation. As this was the 'prototype' phase, an in-vitro approach was used in which already-born placentas were investigated. In this way, it was not too expensive and there were no safety issues for the pregnant women and the fetus. During the execution of the prototype phase, many challenges may be faced. In this case, the right setting for the contrast was not available on the right ultrasound probe. Furthermore, adjustments had to be made to the set-up.

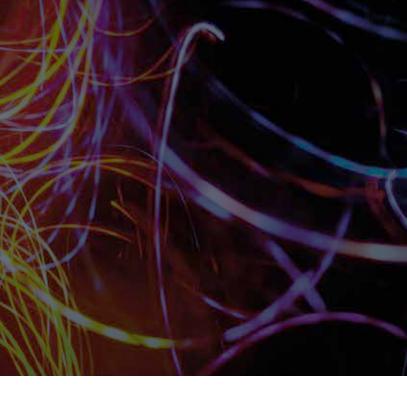
Test - This is the phase where the best solution from the prototype phase is tested. This is the last phase of the Design Thinking process, but one or more steps are usually repeated because of its iterative character.

At this stage, the vasculature of 16 cases has been shown using CEUS. Next, super localization techniques have been applied to the CEUS images. This led to the visualization of the feto-placental macroand microvasculature of the cases. At this point, the feasibility of CEUS for placenta imaging has thus been demonstrated. Now, the steps must be repeated to plan larger-scale research with CEUS to get from problem to idea to clinical use.

Discussion

Design Thinking has not been used in daily practice in healthcare. However, it is a concept that is very suitable for the implementation of innovations. It is an iterative process, although it is presented linearly in this report.

Within healthcare research, many steps of the Design Thinking process have already been taken unconsciously, but it helps to structure the brainstorming process. With previous unstructured brainstorm sessions, it is possible to miss out-of-the-box ideas. With the concept of Design Thinking, gathering as many ideas as possible in a human-centered model is key. In this way, input from all viewpoints is secured.



In our field of multidisciplinary and fundamental research in particular, this iterative process could aid in streamlining ideas.

Conclusion

Although still relatively unfamiliar, Design Thinking is a promising and valuable concept for innovations in healthcare. We would recommend implementing this process for future clinical problems with multidisciplinarv teams.

IMPLEMENTATION SCIENCE: TRANSFORMING THE LANDSCAPE OF INSURANCE OPERATIONS

Dr. Hans Kuijpens, NZa VGZ Medical Advisor

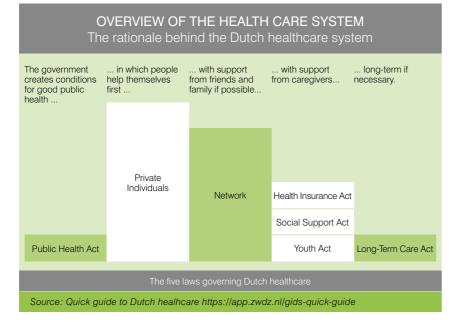
In the Dutch healthcare system, the medical advisor of a health insurer advises the insurer on whether an innovation is of interest. The primary responsibilities of health insurers in the Netherlands are twofold: improving the quality and availability of care while ensuring its longterm affordability. These objectives can sometimes be at odds.

Dutch Healthcare Structure

- Green blocks in the figure below: laws and regulations.
- White areas: pertain to an individual's personal responsibility. The central government manages public healthcare through the Public Health Act Furthermore, individuals are responsible for their own health. If one cannot manage on their own, they are encouraged to consult their network. Three primary support networks ensure access to quality care:
- 1. Health Insurance Act
- 2. Social Support Act (WMO) 3. Youth Act (both of which are now managed by municipalities)
- The final block represents the Long-Term Care Act for chronic illnesses.

Highlights of the Dutch Healthcare System

- + Cost, quality, and effectiveness should be as transparent as possible.
- + Healthcare growth is predetermined
- + Mandatory health insurance; free for those under 18, funded through income taxes.
- + Health insurers must accept everyone for the basic package (solidarity principle), and an individual's health doesn't affect premium cost.
- + The Minister determines the composition of the basic package, with any changes subject to government approval.



Regulatory Authorities in Dutch Healthcare

+ Dutch Healthcare Authority (NZa): Definition and tariff setting.

Health insurance

Healthcare

purchasers

- + National Healthcare Institute (ZIN): Package content.
- + Health and Youth Care Inspectorate (IG&J): Healthcare quality.
- + Authority for Consumers and Markets (ACM): Monitors competition and questions insurers about mergers and collaborations. For instance, when hospitals collaborate closely, insurers can offer advice to the ACM
- Dutch Authority for the Financial Markets (AFM) and Dutch Central Bank (DNB): Due to significant financial stakes, both monitor the system closely.

From Innovation to **Clinical Practice**

In the Netherlands, innovations often originate from industrial, technical, academic, or pharmaceutical sources. Introducing them to healthcare is more of a hurdle race than a sprint. In 2022, several relevant reports were released:

- + Integrated Care Agreement (IZA)
- + Signaling Appropriate Care for Cancer Patients (by the National Healthcare Institute)
- + Appropriate Emergency Care (by the NZa)

These reports emphasize the importance of evidence-based personalized care. The IZA centralizes "appropriate care".

It also discusses the concentration of complex care and the overall hospital care volume. More healthcare will take place at home, requiring added infrastructure and organization.

Implementing Innovations in Clinical Practice

Questions from the National Healthcare Institute and insurers:

- 1. Is the innovation truly new or is it part of an existing treatment?
 - for treatment: + Does it improve clinical
- outcomes? + Does it enhance care quality?

HEALTH INSURANCE ACT 2006 The key players

Individuals

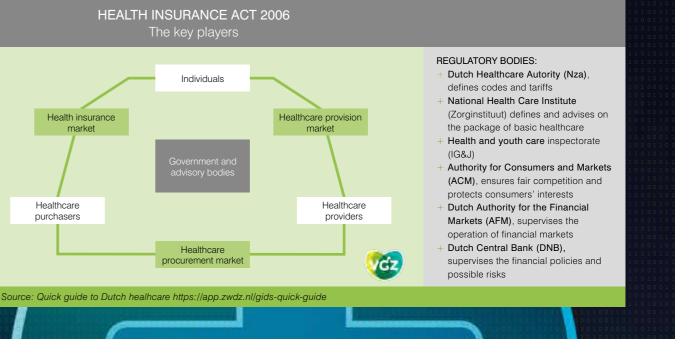
ernment ar sory bodie

Healthcare procurement marke

- life? + Are there no complex
- changes in costs?

For entirely new innovations, different criteria are considered and stakeholders must decide who should be involved. The Healthcare Institute has set evaluation criteria, indicating that insurers can conduct their evaluations. The ZIN and the NZa are the penultimate steps to approval. This is a crucial document for understanding the path from research to implementation and payment.

For a new therapy, it's essential to have cost-effectiveness (savings; non-inferiority isn't enough with rising costs). Interventions must be evidence-



+ If part of existing technology

+ Does it improve quality of

based and test performance must be known. For a new diagnostic test, it should be clear if a "new patient group" can emerge (e.g., like with the COVID test).

Every hospital now has an innovation budget 1.5 billion euros nationally; allocated proportionally between primary and secondary care institutions).



TRANSFORMING CLINICAL PRACTICE: EVIDENCE-BASED STRATEGIES AND TOOLS

Prof. Edwin van de Heuvel, Dean of the Department of Mathematics and Computer Science, Eindhoven University of Technology

Objective

To provide information on the methodology of data collection.

Comparative effectiveness research

This research often involves extensive studies to validate a hypothesis that a researcher is passionate about. An intervention is compared with either a control group or another intervention, assessing both benefits and harms. For this purpose, empirical data related to meaningful health outcomes is collected. There are various methods for this, including trials and observational studies.

Observational studies

They can be roughly divided into:

- + Case Studies: Often the starting point of a research trajectory. They provide a detailed description of a specific case, detailing the circumstances without generalizing the results. There's no comparison to a control group. Such studies can lead to fresh insights, for instance, unveiling underlying biological mechanisms.
- Ecological Studies: These studies focus on the characteristics of a group of individuals, often based on location. They establish a correlation or association between aggregated information on the group of individuals (e.g., location) and the group-level health state (e.g., number of symptoms or disease percentage).

- Cross-Sectional Studies: Sampling data from a population at a single point in time to understand associations between health-related variables. Challenges often include a low response rate and bias in collecting retrospective data, which may reduce representativeness. However, it's possible to examine multiple variables at a low cost.
- pling is done from two distinct groups: one group has a specific characteristic (i.e., the cases), like having a disease, and one group lacks this characteristic (i.e., the controls) but is very similar to the cases. A drawback is the potential ambiguity in selecting controls, which can cast doubt on how representative the study is.

COM

Association Measure Prevalence Incidence Relative risk Odds ratio Excess risk Attributable risk



Case-Control Studies: Similar to cross-sectional studies but samCohort Studies: Collecting data from a well-defined group that is being monitored over a specific duration, like a birth cohort. Challenges include high costs, difficulties in estimating prevalence accurately if sampling is not involved, and the need for large samples and extended follow-ups, especially with rare conditions. However, being prospective in nature, cohort studies facilitate comprehensive data collection and allow for the tracking of changes over time (estimation of incidence rates).

Each study design has its advantages and drawbacks, as detailed in the table.

PARATIVE EFFECTIVENESS RESEARCH Epidemiological Study Designs							
	Estimation of association measures:						
	Case Control	Cross-Sectional	Cohort				
	No	yes	population sample only				
	no	no	yes				
	rare disease only	yes	yes				
	yes	yes	yes				
	rare disease only	yes	yes				
	rare disease only	yes	population sample only				

Experimental studies

They typically compare a new treatment or intervention with an existing treatment or control on human beings. The control can be no intervention, a placebo, and care-as-usual. Experimental studies can be roughly divided into:

- Clinical Trials: Their objectives include the determination of efficacy (treatment works) and safety (treatment does not harm). Efficacy does not mean that the treatment is effective across a broader population and on each patient. Safety is often determined in a trade-off of benefit and harms. The most common clinical trial is randomized controlled trials where the treatments involved are randomized to (groups of) patients.
- Pragmatic Trials: The goal of pragmatic trial is to demonstrate effectiveness (treatment works under routine conditions). A subset of pragmatic trials that make use of cluster randomization (groups of patients are allocated to the treatments) are sometimes referred to as community trials.
- Field Trials: Experiments on healthy people grouped by different interventions to determine which keeps them healthiest.

Stages in experimental studies

There are often different stages in experimental studies to obtain specific evidence of the new treatment. These stages are common practice in the pharmaceutical industry.

- + Preclinical: Animal testing for efficacy and safety.
- + Phase I: Conducted on healthy volunteers or sometimes on patients who have no other treatment options left in order to determine relevant doses of the new treatment.

- Phase II: Focuses on evaluating biological activity. It usually doesn't study clinical events but instead observes proxies due to keeping the study size limited.
- Phase III: Comparative trials assessing clinical effects.
- Phase IV: Examines long-term adverse consequences.

Hierarchy of epidemiological studies

Several medical journals use a specific hierarchy of study designs to quantify the importance of evidence on treatment effects. The most trustworthy evidence of treatment effects is determined with a systematic review, preferably using randomized controlled trials. This type of evidence combines multiple studies and therefore is most reliable. Second in rank is clinical trials, since they have more control over possible biases than observational study, particularly when randomization is applied. The next type of studies is cohort studies, since they are mostly prospective and therefore provide real time evidence of certain effects. Case-control studies are then often considered the most reliable evidence. since they sample from both the cases and controls. When controls can be matched with cases using certain relevant characteristics of the patients, this provides a more reliable piece of evidence than crosssectional studies. The lowest levels of evidence are determined by casereport studies and ecological studies. Case-report studies have no generalizability at all, while ecological studies only have generalizability at a helicopter or aggregated level.

Biases

There are many different biases that could creep into a study and that would cause a disturbance in the estimation of the benefit and harm of new treatments. Here, we mention just four of them, often being the most important biases that can occur in studies:

- Selection Bias: The difference between participants and nonparticipants in terms of exposure and outcome. This would occurs when the process of collecting participants is affected by factors that also influence the outcome and it is usually irreparable due to insufficient data.
- Recall Bias: People with different outcomes might recall and report information differently. This type of bias is relevant when retrospective information is being collected.
- Observer Bias: Judgment can be swaved by the observer's information. This bias may be eliminated when the observer is blinded from the treatment.
- Confounding Bias: The relationship between exposure and outcome can be disturbed by another variable, making it challenging to observe the true effect. Typically present in observational studies.

Blindina

In clinical trials, it is often recommended to make use of blinding. First-level blinding is making participants unaware of the treatment they receive. This would eliminate the placebo effect. There is quite some research on placebo effects through which it has been demonstrated that some participants are more susceptible to placebo than others. Second-level blinding means that the researchers and doctors are also unaware of who received which treatment. As we just stated, this is to prevent observer bias. It is preferable to include secondlevel blinding, but not all clinical trials can implement this since the treatment cannot be disquised.

Foundation of randomized controlled trials

The most important element in clinical trial is randomization, i.e., the process of randomly assigning interventions to individuals. Randomization is crucial to eliminating confounding bias. Typical randomization techniques are complete randomization, random allocation rule, and permuted block randomization. Randomization is also the foundation for demonstrating that there is a benefit to the treatment.

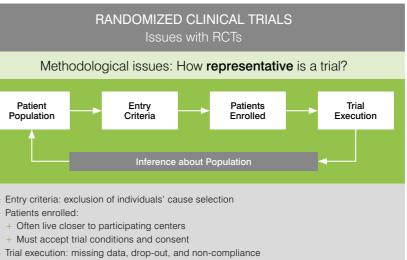
A randomized controlled trial is, in essence, a statistical hypothesis testing study. The fundamental test statistic to demonstrate that there is a benefit beyond reasonable doubt is called the permutation test. Based on a measure of effect (e.g., a mean difference or odds ratio). the permutation tests calculate all values of the measure of effect for all possible permuted allocations of treatments that could also have been the outcome for the randomized controlled trial. The outcomes of the participants are considered given, but the treatments are permuted among the participants. This leads to a large set of values of the measure of effect and, when the observed value of the measure of

effect from the trial is away from this set, it is unlikely that the treatment does not contribute.

Issues with randomized controlled trials

Although there is a high level of trust in randomized clinical trials, they do pose several huge challenges. One issue is that there is the vast variability among people, affecting generalizability. Other issues include participants dropping out, non-compliance, and other factors that might compromise the reliability of randomized controlled trials. These effects aren't always considered in the analyses. Ultimately, the representativeness of a trial is a question of utmost importance. There's often a significant discrepancy between the research question, aimed at a population, and the data resulting from the actual included population sample.

One study is often not enough. By pooling data from multiple studies, you can achieve consistent results, regardless of whether it's an RCT or observational study. In essence, comprehensive research requires multiple studies conducted in diverse settings, and pooling this data offers



more reliable conclusions. However, this doesn't mandate the exclusive use of RCTs; observational studies can also contribute to this pool. Thus, we may be much more flexible in the type of studies that we can use to demonstrate the benefit and harm of new treatments. This is also because causal inference can be conducted from observational studies.

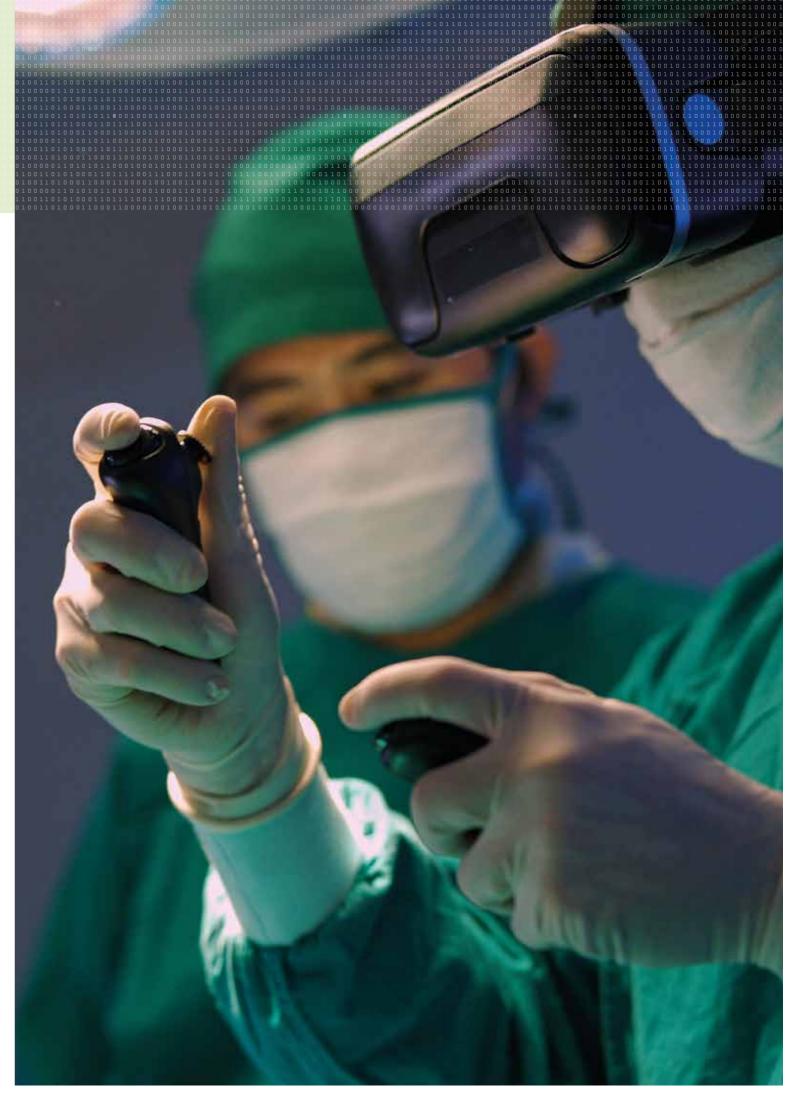
From efficacy to implementation

There is often a gap in comparative effectiveness research (CER) where the focus on process thinking is missing. Implementing findings into practice necessitates a process-oriented approach. This means:

- Clearly defining the intended outcomes of each activity.
- Identifying and following steps that facilitate practical implementation.
- + Adopting a phased approach.
- + Making adjustments based on accumulated knowledge.
- Continuously monitoring and overseeing all activities.

The overarching idea is that while efficacy research can highlight what works in a controlled environment. the journey to actual implementation in the real world requires a comprehensive, phased, and adaptive strategy that takes various factors into account.

When adopting a process-oriented approach, the likelihood of a type I error might exceed the conventional 5% threshold defined in typical studies. This risk should be mitigated through methods such as intensive simulation studies and the use of diaital twins. There's a pressing need for new evidence-based methodological studies. The emphasis on randomization might decrease and study designs could be seamlessly integrated into daily routines. However, this inte-



gration complicates statistical analyses, necessitating sophisticated bias correction methods. Frequent interim evaluations become crucial, as does the application of AI and the need to estimate individual causal effects due to population heterogeneity. Future studies should be pragmatic, eliminating exclusive criteria. Moreover, these novel study designs should also provide insights into:

- 1. Details of Effectiveness: This should encompass both a general overview and an understanding of individual outcomes.
- 2. Understanding of Causal Effects: Specifically, understanding the impact of the new intervention in relation to other factors and conditions.
- 3. Practical Application: This would involve insights into how the clinical setting can accommodate or adapt to the new intervention.

Currently, there's scarcely a trial design that meets all these criteria. Therefore, there's a compelling case for transitioning to adaptive trial designs. An adaptive trial designs. is one that allows for modifications to the trial procedures (like dose adjustments) based on interim results. The main advantage of adaptive designs is their flexibility. They can provide a more efficient and ethical approach to determining the clinical benefits of an intervention, especially when there's uncertainty about the best treatment approach. With the advent of sophisticated statistical software and an increasing emphasis on patient-centric research, adaptive designs are becoming more prevalent. They allow researchers to 'learn' from the data as the trial progresses, potentially reducing the number of participants exposed to an inferior treatment and potentially accelerating the clinical development timeline.

Switch Designs are often more effective than RCTs since they are immediately implemented in the routine clinical practices. By the end of these studies, evidence is presented to determine whether a particular intervention has worked or not. Data analytic methodology has been worked out in the last decade to effectively make use of these designs compared to more traditional randomized controlled trials. Switch designs can also be more powerful than traditional randomized controlled trials.

Single Patient Trials: This approach involves testing multiple treatments within a single patient, searching for the most effective treatment for one person, which can be particularly applicable in fields like psychology. The results of

IMPLEMENTATION SCIENCE Background Process Thinking: Accumulating Evidence Accumulated Data and Information Flow Adaptive Study Study Study Evidence block Adaptive Study Analysis and Evaluation Adaptive Study Adaptive Stu these individual trials can then be aggregated for broader analysis.

Space RCTs: Experiments are conducted within a cohort, with every member of the cohort participating in the study. A major advantage of this method is the abundance of control subjects available. A random sample of participants is taken from within the cohort (note: this is different from randomization). As choices are made at various points, multiple groups emerge. This design allows researchers to explore the impact of different attributes, such as an individual's intrinsic motivation to participate, on the outcomes. This strategy permits both individual matching (to determine individual effects) and comparisons between different intervention groups.

Conclusion

The ultimate success of a study is when it culminates in full implementation at the workplace. Naturally, this encompasses all other aspects of implementation science, including understanding the contextual factors, barriers, and facilitators to implementation. It's essential to take a multi-dimensional approach involving stakeholders, adapting to local conditions, and evaluating both the process and outcomes of implementation. This holistic approach ensures that the findings of a study aren't just theoretically significant, but they also bring about change. Thus we advocate the development of process thinking in comparative effectiveness research and making use of different studies to accumulate evidence.

IMPLEMENTATIÓN SCIENCE IN MEDICAL DEVICES AND TECHNÓLÓGY: CHALLENGES AND OPPORTUNITIES

Prof. dr. ir. Carola van Pul, Clinical Physicist at Máxima Medical Center

Clinical Physics at Máxima MC is responsible for the policy on the quality and safety of the introduction and use of medical technology. The policy's execution, quality checks, and maintenance are carried out in conjunction with the Medical Technology department. Clinical Physics is always involved in the implementation of new medical technology, including medical software systems.

There is a wealth of (local) knowledge about implementing medical technology in the hospital. Often, a new method is also evaluated after 100 days. But when does implementation become implementation science? According to one definition, implementation science concerns "the study of methods to promote the integration of research results and evidence into policy and practice" and focuses on the process of implementation, the innovation itself, the context, influencing factors, strategies, and evaluations. Implementation science is essential to bridging the gap between what we know and what we do, addressing barriers that slow down or halt proven improvements. Even if they are effectively implemented, interventions and practice changes sometimes do not yield the expected health benefits if effectiveness is lost during implementation.

However, this remains rather theoretical, which is why there is a need in the Netherlands for a practical translation. This was created by the Dutch Implementation Collective. In this 2022 knowledge agenda on implementation, it is stated that more attention is needed regarding implementation strategies and determinants: context, complexity, and inclusivity. There is a strong need for practical tools: how then?! Additionally, it's crucial to realize that acquiring implementation knowledge is not just a desk activity: research and practice need each other, but implementation also requires capacity.

In the Netherlands, guidelines from the Federation of Medical Specialists are available for the implementation of new clinical interventions, providing a good starting point for implementing a new innovation in the hospital or even in the Netherlands. Additionally, the Medical Device Regulation applies to the entire process surrounding medical devices in the hospital, and there is a Covenant on Medical Technology specifying the procedures that hospitals must set up, including procedures for admission and control of new medical devices, as well as the use, management, training, and decommissioning of the medical devices. The Health and Youth Care Inspectorate evaluates these.

For implementing new technology, guidelines exist and new technologies can be used after a risk analysis and deemed to be sufficient risk-mitigating measures that limit the residual risk. This is determined by clinical physics together with the responsible doctor/ user and often also a manager. Using medical technology in complex care chains is almost never completely risk-free, but it is in the patient's interest because the benefits of use outweigh the possible risks. For a scientific study, permission from an Ethics Committee is required and the patient becomes a test subject, for which the risk-benefit ratio is critically examined, especially if the study does not immediately offer a demonstrable benefit for the individual test subject. This ratio is crucial in determining whether permission is granted for the study. For a scientific study, test subject insurance is also required, as a test subject is sometimes exposed to an extra risk that is not part of a regular process. To get an exemption from test subject insurance, negligible risk is required.

For a regular purchasing process, even for a new medical device that has not yet been used in MMC, the process starts with a budget request. After the budget is allocated, a schedule is made for when the project can start and a multidisciplinary working group is set up. This working group starts working on a set of requirements according to the MMC purchasing procedure. All relevant internal services are involved and it is taken into account in the project planning of each of these services. When determining the set of requirements, all details are thought of, not only for purchase and commissioning, but also regarding training and maintenance. There are many implementation barriers in this that are addressed and mitigated through a checklist at the front end. The risk analysis is also drawn up at this stage because many of the risks can already be identified at the outset and measures can be taken to mitigate these risks. After implementation, there is usually a qualitative evaluation. Sometimes, there is a quantitative evaluation. This can lead to adjustments in the setup.

F

So when do you make the step from implementation to implementation science? On the one hand, implementation science is about researching the method of implementation. But if you look at articles published in the journal Implementation Science, research and extensive evaluations of an implementation also seem to fall under implementation science, provided the results are generalizable, i.e., when you can make the step to scaling up and it also works in other settings. With an implementation trajectory, the evaluation naturally depends on the conditions of the implementation circumstances itself.

During the lecture, a few specific examples were discussed, including alarm optimization for patient monitoring in the NICU and implementation of eCTG within the delivery room monitoring system ISP. These are not included in the abstract, but further information can be requested.

Take-home message

Implementation science versus implementation of new technology: learn from practice, including from other hospitals, increase awareness.

Implementation methodology & barriers & technology: ensure early detection of barriers by involving everyone in time and addressing the bottlenecks.



UNDERSTANDING AND OVERCOMING BARRIERS TO IMPLEMENTING EVIDENCE-BASED PRACTICE

Dr. Bas van Rijn, gynaecologist-perinatologist at Máxima Medical Centrum, and Dr. Hilde Perdok, midwife and midwifery coordinator at Consortium Brabant and ZonMw Implementatie Science Practitioner fellow

To implement changes into clinical practice, leaders of change projects are faced with numerous challenges. Examples of challenging implementation programs in pregnancy and childbirth care include the use of a shared electronic medical record system for primary and secondary maternity care, implementing telemedicine and value-based healthcare strategies and many other healthcare improvement initiatives.

Some barriers to implementation are easily recognizable and visible to all, others are more hidden or subtle. Factors that contribute to successful or unsuccessful implementations include familiarity with existing knowledge, differences in clinical setting and variation among practitioners' standards of care. To overcome barriers, it is advisable to use a framework for implementation (as has been discussed by others). But then the hard work starts: how do you lead the actual change within the team and among the stakeholders? What tools are there to make sure implementation actually happens?

In this workshop, a number of strategies for hands-on change management are taught using an approach derived from the 'science of improvement', originally developed by W. Edwards Deming to improve outcomes of changes in manufacturing processes and adapted by Langley et al. in their seminal work "The Improvement Guide" (1997) to aid leaders of implementation projects to achieve measurable change.

Methods

A stepwise approach to the casebased workshop includes four critical steps to guide any change project with the purpose of healthcare improvement:

- 1. Define your strategy
- 2. Do a stakeholder analysis
- 3. Start a series of improvement cycles
- 4. Use data to monitor outcomes

In summary

The model for improvement proposed by Langley proposes the use of the three change questions at the start of each cycle of improvement:

- + What are we trying to accomplish?
- + How will we know that a change is an improvement?
- + What change can we make that will result in improvement?

It is advisable to use data-over-time (process control) to monitor the outcomes of your implementation project and to include outcomes that not just show that a technology or strategy is being used but that is has also led to the desired (clinical) improvement. There is a tendency to include only process measures in implementation projects (e.g., "is the protocol being followed?", "is the new technology being used?") while the actual purpose is not being monitored (e.g., "does the new protocol lead to fewer infections?", "does the new technology lead to improvements in clinical outcomes?").

Critical to the improvement framework is working in short, measurable and preferably iterative PDSA cycles to allow for continuous learning. An important element of implementing for improvement is making a sharp distinction between testing and implementation. The essential feature of testing is to reassure the stakeholders that the new change (e.g., technology, protocol) is not implemented before critical adaptations are made. Usually, this is not a one-step approach due to unpredictable real-world barriers and facilitators. For instance, if a clinical trial shows a clear advantage of a new treatment strategy over existing standard treatment, implementing the protocol for the new treatment in your own setting may not show the same effect or may require additional training, resources, etc. This can be easily figured out in short test cycles focused on identifying and improving the factors needed for successful implementation.

Take-home message

An important part of implementation is planning for change. This is best done using a stepwise PDSA-supported process which allows for change leaders to gain trust and adapt to the setting. Well-guided change projects turn adversaries (those who do not trust the new change) into opponents (those who trust you, but are not yet enthusiastic about the change) into allies (high trust, high agreement).



TAKING IMPLEMENTATION SCIENCE FORWARD: A SHARED RESPONSIBILITY

Prof. Guid Oei, Obstetrician Gynaecologist, Founder of the Fundamental Perinatology Research Group, Máxima Medical Center - Eindhoven University of Technology

As this e/MTIC Fundamental Perinatology Conference in Lambrey dedicated to implementation science concludes, we reflect on the myriad insights, challenges, and novel ideas discussed. Special thanks to Nadine de Klerk for her excellent chairmanship and to Beatrijs van der Hout for her meticulous note-taking throughout the presentations, which significantly contributed to the development of this book's chapters.

Each chapter has imparted valuable lessons:

- The collaborative work of the multidisciplinary PhD team exemplified the synergy between medicine and engineering, underscoring the importance of cross-disciplinary collaboration in research and practical application.
- Susan Hommerson, a policy officer for medical devices, highlighted the ethical dilemmas in rapidly

transitioning clinical device concepts into tangible products, emphasizing the need for careful navigation of these challenges.

- Hedical professionals Anne van Tetering, Kirsten Thijssen, and Ella de Vries illuminated how implementation science can elevate healthcare, particularly in resource-constrained environments, offering hopeful and actionable strategies.
- Will Ickenroth, CEO of a healthcare technology company, shared candid experiences about the challenges and triumphs of implementing new ideas in hospital settings.
- Obstetrician Loes Monen and engineer Pascalle Wijntjes advocated for simplifying the application of research findings in real-world healthcare, ensuring that innovations reach those in need.
- Insurer Dr. Hans Kuijpens examined the broader impact of implementa-





tion science on insurance, extending beyond hospital settings.

Statistician Professor Edwin van de Heuvel discussed researchsupported tools and methods and their potential to revolutionize clinical practices. Professor Carola van Pul, a clinical physicist, provided insights into the integration of medical devices, highlighting both the possibilities and challenges.
 Obstetrician Dr. Bas van Rijn and midwife Hilde Perdok underscored difficulties in translating evidencebased practices into healthcare applications.

the importance of addressing the

Collectively, these chapters underscore the transformative potential of implementation science. They call for the adoption of evidence-based methods in healthcare and beyond. As we conclude, let us carry forward these lessons to enhance healthcare and improve patient care.

We hope the insights shared in this book will inspire and guide your endeavors in implementation science.

RECOMMENDATIONS FOR ADVANCING IMPLEMENTATION **SCIENCE**

- 1. Collaboration Over Competition: Foster cross-disciplinary collaboration to navigate challenges effectively and magnify successes.
- 2. Education and Training: Emphasize continuous learning and retraining to equip stakeholders with the latest knowledge and tools.
- 3. Adapting to Change: Remain adaptable to the evolving landscapes of healthcare, technology, and implementation science.
- 4. Overcoming Barriers: Identify and strategize to overcome both anticipated and unforeseen challenges.
- 5. Shared Vision: Commit to a collective goal of improved healthcare outcomes and patient experiences.

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