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IMPLEMENTATION SCIENCE IN MEDICAL DEVICES AND TECHNOLOGY: CHALLENGES AND OPPORTUNITIES

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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.

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.