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 AI systems
3. Record keeping through logging capabilities by AI systems
4. Transparency and information provisions to the users
5. Human oversight of AI systems
6. Accuracy specifications for AI systems
7. Robustness specifications for AI systems
8. Cybersecurity specifications for AI systems
9. **Quality management system for providers of AI systems, including postmarket monitoring process**
10. **Conformity assessment for AI 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 ALTAI 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 AI's predictions.

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

5

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

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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 misunderstand 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 counter-intuitively, 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,

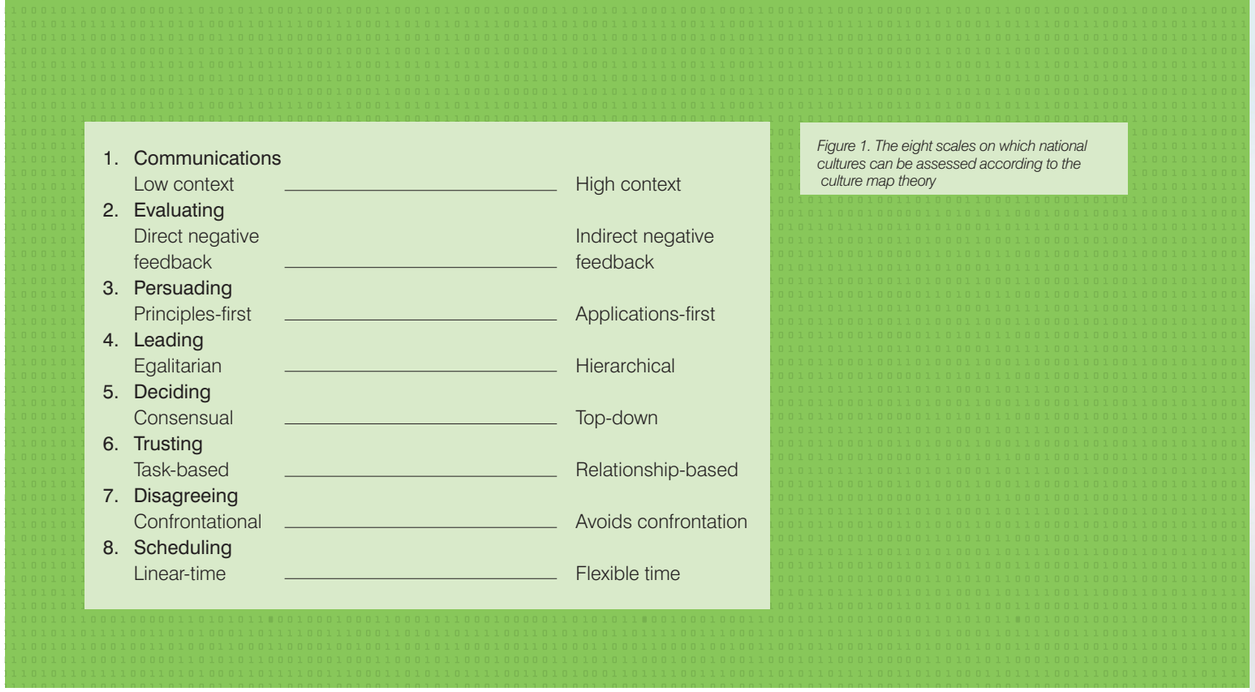

Figure 1. The eight scales on which national cultures can be assessed according to the culture map theory

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 task-based 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.

6

PIONEERING MEDICAL PROGRESS: A HEALTH COMPANY'S JOURNEY WITH HOSPITAL IMPLEMENTATION

Will Ickenroth, CEO of Nemo Healthcare

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 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.