VIEWS AND OPINIONS

PATIENT ADVOCACY

PATIENT INPUT INTO MEDICAL DEVICE DEVELOPMENT: A MISSED OPPORTUNITY

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doi: 10.54920/SCTO.2023.RAWatch.8.5

The delivery of care to people who are patients has, beyond doubt, reached the digital age. This is never more striking than in the area of medical devices and in vitro diagnostic medical devices. Patients' standard of care has risen exponentially in light of the technological and innovative advances in the medical device field. Yet, in many instances, medical device development is undertaken without patient input. This article discusses why it is important to include patients' perspective in the process of developing medical devices. In addition, it addresses several related topics, such as the issue of access to medical devices and the need for transparency with regards to the data collected by medical devices. It also provides an example of a research project aimed to better understand and promote patient engagement in medical device development.

MEDICAL DEVICE USERS: AN OVERLOOKED BUT VALUABLE SOURCE OF INPUT

The World Health Organization (**WHO**) reports an estimated two million different kinds of medical devices (**MDs**) on the world market, categorised into more than 7,000 generic device groups.[1] Currently, patients are either involved in the ideation phase or as beta testers, with little or no opportunity to provide input on how these devices will be used or how they are of value to their communities.[2] There is also a significant disconnect regarding the actual value of real-world evidence generated by the patients wearing the devices. Even though these patients have not developed the analytics to interpret the data, they still need to be consulted more often on the use or distribution of the data. Informed consent and protection has been put in place by legislation such as the EU's General Data Protection Regulation (**GDPR**); however, to be informed, one needs to be educated. There needs to be more true appreciation of and education on how and where data is valued for good and less-than-ideal situations.

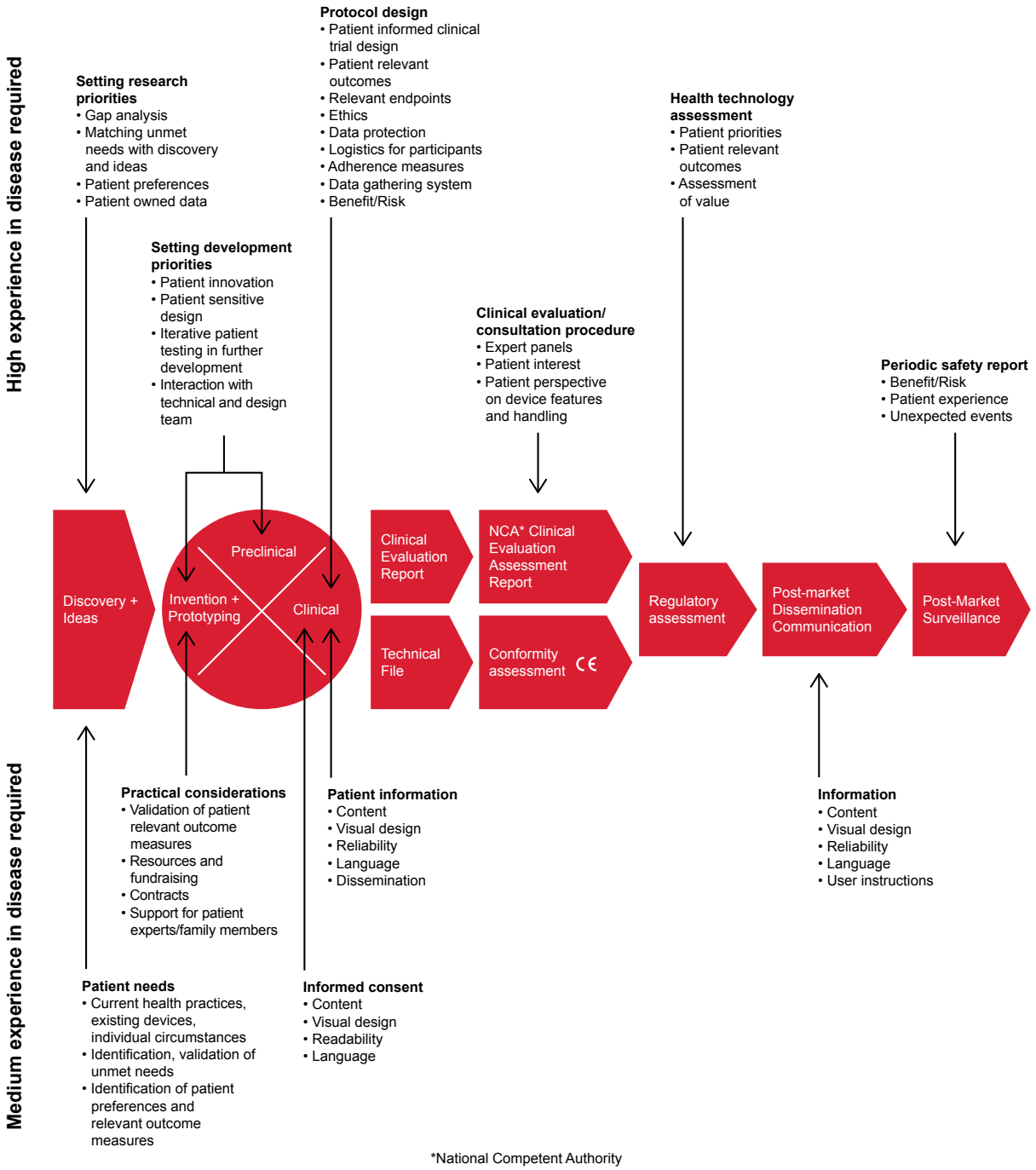
Traditionally, the main driver of in vitro devices (**IVDs**) is to advance and improve healthcare practitioners' delivery of care. The complexity and rapid pace of technology have been staggering, and this growth is reflected in the publication of the EU's 2017 Medical Device Regulation (**MDR**). However, there are a growing number of directly patient-facing devices: there are currently over 10 million digital health applications available, and by 2025 one in every three adults in America will wear a fitness tracker.[3] Some people find that including the patient's perspective will not improve devices' design, and they claim it only adds complexity and slows the agility of the development process. Thankfully, this mindset is receiving a solid challenge from patient groups and regulators. The development of medical devices should involve patients and the public throughout each stage. The inclusion of the patient's voice is essential to ensure that medical devices:

- address identified needs of patients and the public so they are useful and beneficial for those using the devices in the future and
- remain fit for purpose; a device without reference to user requirements cannot be fit for purpose in terms of ease of use, acceptability, affordability, and compatibility with other technologies.

PATIENT ENGAGEMENT EFFORTS AT THE EUROPEAN LEVEL

In its factsheet for manufacturers of medical devices, the European Commission states, "The new Regulations create a robust, transparent, and sustainable regulatory framework, recognised internationally, that improves clinical safety and creates fair market access for manufacturers."[4] Yet the practice needs to be more in sync with the European Medicines Agency (**EMA**) guidance regarding the inclusion of patients at all stages of therapeutic development.[5] Questions remain, however, about the value of including the patient's voice in the development of medical devices. Here it is essential to make a distinction between devices that are directed towards healthcare professionals and those that directly interact with patients. There are efforts at differing stages to include the voice of people who are patients across the entire product life cycle. For instance, the European Patients' Academy on Therapeutic Innovation (**EUPATI**) has recently developed a medical devices training module in its course catalogue that shows how patients can be directly involved in medical device development (see **Figure 1** for EUPATI's roadmap of patient involvement).[6]

Figure 1: Concept roadmap of patient involvement in the different phases of medical device R&D



Source: Adapted from EUPATI Open Classroom (Lesson 3, Page 2, Figure 1 of the Medical Device Development, Lifecycle Management, New Technologies, Patient Involvement course);[6] licenced under CC BY-NC-SA 4.0

MEDICAL DEVICES ARE BIG BUSINESS

The global market for medical devices is astronomical. In 2021, the global medical device market reached a value of nearly USD 488.98 billion and is likely to reach an impressive USD 718.92 billion by 2029.[7] To put that in context, it is greater than the combined gross domestic product (**GDP**) of 176 countries in the world.[8] This economic value, however, is coming at the cost of patients. And access to devices is a universal issue. Even in Switzerland, it is not 100% certain that every individual will be able to access life-changing medical devices in the future. As cost and complexity increase, the market is looking to recoup R&D investment by allowing high-end access only. The global COVID-19 pandemic demonstrated that health systems are even more fragile than assumed. And because we have an ageing population, it is inevitable that there will be great costs for devices that can increase mobility and the quality of life. These costs will be covered only partially by insurance, and economic considerations often place constraints on patients' health decisions.

INCREASING DATA TRANSPARENCY

It has become clear that at-home and personal devices play a central role in expanding the range of medical devices. Moreover, the device explosion has led to a vast array of data generated by each individual. This data has considerable value, but to whom? Primarily, its value is reaped by the organisations that have developed the digital tools designed for health interaction, including medical devices. Citizens and people who are patients need to be made aware of how and when their data can be used. And a more transparent system is needed for demonstrating the value of data. The transparency of the systems is not only for financial gain but also for societal good. Data is a long-term asset, a fact that was recently highlighted by how public health epidemiological data can impact global health decisions. It is not only necessary that a person should actively own the data he or she generates, but there should also be a requirement to proactively demonstrate how and when a person's data is accessed and utilised.

INCLUDING THE PATIENT'S PERSPECTIVE IN MEDICAL DEVICE DEVELOPMENT

The inclusion of the patient's voice is becoming much more embedded in therapeutic development, with a wealth of guidance available from the past twenty years. Both the US Food and Drug Administration (FDA) and the EMA have worked with patients to develop guidance on how to include patients in the decision-making process of therapeutic R&D.[5,9] This is not the case with medical devices. There is a need for a more balanced approach to including the patient's voice in this most critical of health sectors since it safeguards the usability and safety of medical devices.[10] The FDA has started this patient engagement process and demands evidence of end-user engagement in health technology design when reviewing market pre-submissions.[11]

In order to deliver impactful patient engagement, evidence-based research is required which delivers a systematic inclusion of patients at all stages of digital and medical device design and development. As a first step, the patient empowerment consulting firm Personal Pulse GmbH teamed up with Dr Christine Jacob of the University of Applied Sciences and Arts Northwestern Switzerland (FHNW) and undertook a research project designed to address two important areas: (1) better understand the challenges and opportunities for including patients in the development of e-health technologies and (2) create a research-based, end-to-end, practical blueprint that can guide relevant stakeholders through how to successfully engage patients as co-creators in all human-centred design phases instead of viewing them as mere testers of pre-planned prototypes.[2] **Figure 2** depicts the first iteration of a blueprint that helps stakeholders understand how to include the voice of patients in all stages of human-centred development in e-health. These research findings can be applied throughout the medical device community.

Figure 2: Proposed blueprint for engaging patients as co-creators of e-health technologies

	Specify context	Define user requirements	Produce design	Prototype	Deliver solution
Maturity	2.5 ★ average rating ★★½☆☆ SD 0.8	2.7 ★ average rating ★★½☆☆ SD 1.2	2.3 ★ average rating ★★½☆☆ SD 0.9	3.3 ★ average rating ★★★½☆ SD 1.0	3.7 ★ average rating ★★★★½ SD 0.8
Sample considerations	Diversify your sample to capture the different gaps and unmet needs	Involve patient experts in these phases as they require sophisticated skills and technical expertise		Diversify your sample again to ensure an inclusive design	
Potential patient engagement approaches	Online patient communities	Ideation and design thinking	A/B testing	Interactive diaries and checklists	Real-life testing or piloting
	Patient complaints or requests	Benchmark existing apps	Cocreate by embedding patients in all iteration rounds		Beta testing
	Workshops or focus groups	Moderated workshops or focus group to translate technical language to nontechnical users, and translate health care info to the technical teams			User analytics and platform metrics (hypercare)
	One-on-one interviews, if possible at their place			Lab or in-field testing (simulation)	

Lifecycle management

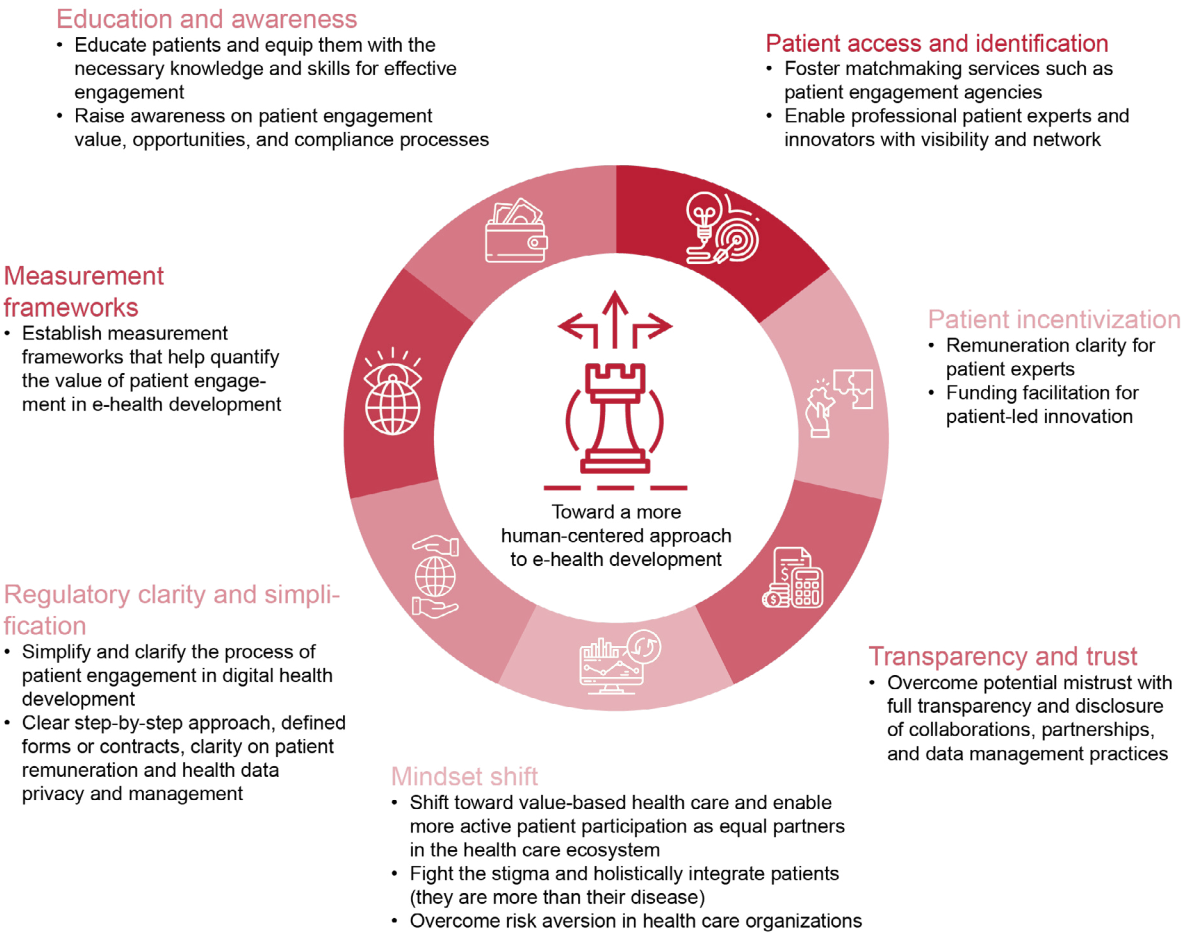
2.2 ★ average rating ★★½☆☆ SD 0.8

- Engage key opinion leaders and patient experts to periodically get their input
- Facilitate, promote, and monitor support line and email
- Monitor and respond to app store feedback
- Establish a drip email system to constantly seek feedback
- Transparently communicate about new iterations

Source: Adapted from Jacob C, Bourke S, and Heuss S (2022), Figure 4[2]

Figure 3 has been developed to help device manufacturers understand the practical, real-world implications and value of including patients at all stages of medical device development. It contains concrete examples for having a proactive discussion with stakeholders about including people who are patients.

Figure 3: Practical implications of the From Testers to Cocreators study and its recommendations for more patient-driven e-health development



Source: Adapted from Jacob C, Bourke S, and Heuss S (2022), Figure 5[2]

In conclusion, the development of medical devices – such as robotics, wearables, implants, and bionics – has turned the world of science fiction into reality. In order to ensure that medical devices serve the individual users as well as they are designed to do, we need to actively seek the opportunity to engage with people who are patients. Let's not allow the value of patients to slip through our fingers.

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