On 28 August 2020 the WHO opened a public consultation for review of the draft Global Patient Safety Action Plan 2021-2030 [1]. This document presents HOFMI WG response, submitted with the support of IMIA HFE WG on 27 September 2020.

European Federation for Medical Informatics' (EFMI) Human and Organizational Factors of Medical Informatics (HOFMI) working group response to the WHO 'Global Patient Safety Action Plan 2021–2030. Towards Zero Patient Harm in Health care' consultation

With the support of the International Medical Informatics Association's (IMIA) Human Factors Engineering working group

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This strategic Action Plan opens up the possibility for transformational change in how we strive to achieve the safety of patients worldwide. We fully support this Action Plan. We particularly welcome making Human Factors (ergonomics), and human-centred technology key strategies in this plan.

We believe it is important to stress that while Human Factors has historically focused upon psychological, physical and behavioural aspects of individuals, it is now widely recognised that it is a health-system science with environmental and organizational dimensions. It is this wider definition of Human Factors which we support.

The Action Plan emphasizes Human Factors as foundational to patient safety, by calling for person-centred, participatory, evidence-based, design-driven, interdisciplinary and systems approaches all with the aim of continuous learning and refinement. The Plan acknowledges the need for patient safety specialists, organizational leaders, informaticians, and front-line healthcare professionals who are knowledgeable in Human Factors. It also operationalizes strategies for governments, health care facilities and other stakeholders, including academic institutions, to promote attention to Human Factors approaches. The targets set in this Action Plan seek to substantially improve patient safety globally by 2030, and to create new infrastructures to promote durable socio-technical change, such as building Human Factors skills, into licensing and accreditation programmes. These points represent huge progress in increasing awareness of the important role that Human Factors can play in patient safety at an international level. We encourage and support this endeavour.

On behalf of the European Federation for Medical Informatics (EFMI) Human and Organizational Factors Medical Informatics (HOFMI) working group, we offer herewith our response to each of the Strategic Objectives and plan for implementation, focusing on Human Factors' contribution to each objective.

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[1]WHO consultation call: https://www.who.int/news-room/articles-detail/public-consultation-for-review-of-draft-global-patient-safety-action-plan-2021-2030/ - Last Accessed 27 September 2020
Draft Action Plan: https://www.who.int/docs/default-source/patient-safety/1st-draft-global-patient-safety-action-plan-august-2020.pdf?sfvrsn=9b1552d2_4 - - Last Accessed 27 September 2020

* Strategic Objective 1: Policies for zero patient harm

Human Factors is not explicitly discussed in Objective 1 of the Action Plan. Human Factors is underpinned by a participatory, systemic 'view of the world', as highlighted and explained in page 23 of the Plan (Objective 2). Thus, it is our belief that a Human Factors approach to healthcare delivery fits well with Objective 1 and will contribute to the change in 'state of mind and rule of engagement' envisaged in this objective.

The Action Plan disambiguates harm from error; human error is "something to be mitigated and prevented rather than eliminated entirely" (p2). We agree with this perspective.

* Strategic Objective 2: High reliability systems

Human Factors is key to this objective, as made explicit by the section dedicated to describing what Human Factors is and how it can support the creation of high reliability health systems as well as their continuous improvement over time (p23).

- Strategy 2.3 focuses on the development of leadership and capabilities towards supporting high reliability health systems. Actions envisaged for health care facilities include appointment of Human Factors experts at board level. It is absolutely essential that these are dedicated Human Factors roles. We propose that governments should facilitate this by including Human Factors training in the national leadership academy for patient safety curriculum (also advocated for in Strategy 2.3). Additionally, it is crucial to empower leaders with the assets, finances, and regulatory machinery to execute and enforce Human Factors principles and expectations.
- Strategy 2.4. is central to the Action Plan. As HOFMI, we welcome a collaboration with the WHO to foster the development of a global network with expertise, knowledge, and experience in Human Factors (cf. Actions for the WHO – page 26). We strongly support the recommendation to incorporate Human Factors approaches in the design, purchase, deployment, and evaluation of health devices and information technologies, as well as in the design of tasks and procedures.

* Strategic Objective 3: Safety of clinical processes

We agree that clinical processes are safer when supported by an infrastructure of resources, procedures and tools designed for safety. Human Factors provides an epistemology and methodology to design, test, validate, and instruct on procedures and tools. The packaging of medications is an exemplar case of how Human Factors can assist in error prevention.

- Strategy 3.1 calls for Standard Operating Procedures (SOPs). While we agree that SOPs are an essential foundation for safety in many high-risk contexts, we must not forget that procedures tend to be designed for 'work as imagined', and strict adherence is often not feasible in all contexts of care. To contribute to safety, SOPs must be co-designed with clinicians into each context of use, to account for local constraints and organisational culture.
  Furthermore, SOPs must be constantly revised and assessed in the specific contexts in which they are applied. In this respect, creating a static database of procedures (as recommended

in Strategy 3.1. among the actions for Governments), may be counterproductive, unless there are clear roles and responsibilities for maintaining the database up-to-date.

- Strategy 3.4 calls for the safety of devices and medications. Avoidable harm from medication is an ongoing problem for all healthcare settings, and technology designed with a Human Factors approach can significantly contribute to reducing patient safety risks in this area. As medications are tested for potential harm to patients, so devices and health information technology must also be tested before being approved for use. Human Factors evaluations of the risks associated with the use of devices should be performed before release.

* Strategic Objective 4: Patient and family engagement

Engaging individuals, families, and communities requires a participatory vision of the health system and strategies for engagement. Health information and healthcare interfaces (both real and virtual) must be co-designed to align with the language, mental models, and cultural sensibilities of the communities they serve. Information materials for patients and the public, and patient-facing technologies, must be designed with a Human Factors approach, and be evaluated with representative users. As patient demographics and direct-to-consumer marketing transform the digital ecosystem, we need a Human Factors lens to understand how to leverage, connect, and enrich communication and health quality within this framework.

Implicit bias, institutionalized racism, and socio-economic gaps reinforce social inequities and foster an environment of health-related social needs. As a foundational part of health-systems science and population medicine, Human Factors provides the theory and methods to address social determinants of health. Human Factors research methods can be applied to identify engagement issues and barriers to care. For example, needs assessment, user empathy, and Design Thinking can be applied to improve and enrich telemedicine among vulnerable and marginalized populations.

- Strategy 4.3 calls for greater awareness of patient safety issues. We also recommend greater public awareness of Human Factors and the role of poor design of technologies and workflows in causing incidents. There is an increasing number of healthcare devices and treatments that patients use on their own at home, and it is essential that patients and families are able to assess the effectiveness and risks associated with these devices. The Action Plan should give greater attention to patient safety outside healthcare organisations, in patients' home, including the safety of home-based technologies and devices.
- Strategy 4.4 calls for greater transparency. We strongly agree that for greater safety, patients should be given access to their records and be given capabilities to effectively and securely share information in their records with care-givers across different settings, such as test results and prescriptions, or data they collect through their (wearable) devices. We should not forget that transparency is dependent on a number of factors, including patient literacy.

* Strategic Objective 5: Health worker education and skills

Healthcare professionals training and education rarely includes formalized instruction in patient safety methods and almost never includes topics on Human Factors. We propose that there may be a risk of inadequate training in Human Factors if it is covered only as a stand-alone topic. We suggest

that this Human Factors training should be provided not only as a separate topic, but also embedded in all training in the use of devices, technologies, or procedures.

It is also important to provide, fund and resource networked simulation labs where clinicians can test technologies, acquire experience, and develop competencies without harming patients.

* Strategic Objective 6: Information and research

Good data and effective information systems are essential for evaluating processes and interventions, optimizing design, sharing generalizable knowledge, and further improve systems. The quality of data often depends on the design of the systems that collect them, including incident reporting systems. Thus, also in relation to Strategic Objective 6, about systems for learning, we propose that a Human Factors approach should be used in their design, to contribute to more effective and usable systems. Furthermore, Human factors items should be included in the reporting of incidents – their absence is a weakness of current systems.

Partnerships among healthcare organisations and Human Factors researchers, or embedding Human Factors researchers within organisations, are useful ways to contribute to a learning organisation.

- Strategy 6.5. Develop a digital strategy to improve the safety of health care

Human-centred technology can make an enormous contribution to patient safety. Digital strategies addressing foundational issues of standardization, interoperability, performance, needs assessment, and growth should be developed and implemented at local, national and international levels. A Human Factors approach should be required to the design and evaluation of standards, hardware and software applications. In medicine, well-studied and effective therapies have side effects. While health information systems have certainly advanced patient safety, we must be vigilant to identify and address the unintended safety consequences of new technology. This consideration is especially important for the most advanced systems with high level of automation and loss of human control. National digital strategies should include independent formative evaluation programmes. Evaluations should also seek to understand non-use of digital systems, as this is as essential for technology adoption and patient safety as it is understanding use. As systems are usually developed and updated after initial implementation, there should be ongoing monitoring of the changes introduced and their consequences. Human Factors analysis of reported safety incidents can contribute to this ongoing monitoring.

In this Strategy, Actions for Stakeholders seem to be focused on private sectors innovators. Academic institutions also have an important role to play in the human-centred development, design and evaluation of innovative technologies, as well as in developing the basic science that informs them.

* Strategic Objective 7: Synergies, partnerships and solidarity

HOFMI Working Group fully supports the call for partnerships and solidarity for improvements in patient safety. We are ready to share our European expertise and resources with other regions, and are looking forward to learning from these collaborations.

Implementing the Action Plan and its recommendations in low income countries may be particularly challenging. It is especially important to focus efforts on international collaborations, sharing knowledge and expertise across countries with different levels of resources.

A specific challenge applies to the worthy desire for Human Factors methods/approaches to be integrated at all levels of decision-making (international, national, regional, local). Human Factors insight and guidance cannot be easily transposed across contexts. The local context must always be considered before implementing a strategy or transposing a strategy that works elsewhere. Thus, it is necessary that local experts in Human Factors understand the 'work system' in context, to implement purportedly 'generalizable' solutions locally. This work requires experience and expertise, and represents a significant cost. How to assist low-income countries in developing these skills is a challenge for the community of Human Factors researchers and practitioners. The 2030 target "all countries have included human factors design and training requirements in their licensing and accreditation programme" seems very ambitious. To be achievable, funding, training and collaborations are needed. The WHO could support the creation of a Human Factors-version of Doctors Without Borders as an international coalition of volunteers, bolstered by private foundations, academic grants, and government subsidies.

* Global Patient Safety Targets (Chapter 7)

The Target for Objective 2, that by 2030 'all countries have included human factors design and training requirements in their licensing and accreditation programme' is capable of kickstarting a cascade of worthwhile investments in Human Factors, and receives our strong support.

Targets for Objective 3 are measurements that require data at a baseline; it is unclear with respect to what baseline these targets are to be achieved. Such measurements may not be feasible or accurate in all settings or countries. We would recommend modifying targets for Objective 3 to make them consistent with those provided for the other objectives. For example, a target may include that all healthcare settings in all countries have SOPs for high risk procedures by 2030 and that all devices have a Human Factors evaluation performed before being released or put into use.

Targets for Objective 6 should also include that all countries by 2030 have a healthcare digital strategy; the strategy should include provisions for organisational learning and patient safety improvements.

To conclude, we congratulate and extend our gratitude to the WHO and the World Alliance for Patient Safety for their contribution to safety improvements worldwide and their efforts to change the worldview on how best to achieve safety. We particularly appreciate how the Action Plan highlights the role of Human Factors in this endeavour.

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