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IHI JU Science & Innovation Panel (SIP)

9th Report to the IHI JU Governing Board

9th MEETING OF THE SIP

6 March 2024 (09:00 – 18:30 CET) & 7 March 2024 (08:45 – 12:00 CET)

This report summarizes the SIP opinions related to:

- IHI Progress Report
- Exploring areas for future IHI activities
- Preparing the next IHI two-stage call
- Proposed ideas by the wider health and research community

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1. IHI Progress Report

The SIP welcomed the presentation of the progress report on the activities of IHI. The SIP noted the progress and updates since last meeting regarding synergies, the planning of additional activities of members other than the Union (IKAA) and the engagement with contributing partners. The SIP welcomed the scientific achievements to date of the IMI/IHI projects portfolio[1] as well as their public-private / cross-sectorial dimension, which includes i.e. regulators, HTA bodies and patients.

2. Exploring areas for future IHI activities

Healthcare Delivery Optimisation

2.1. Joint presentation by the European Commission (DG Research & Innovation) & of the EU partnership Transforming Health and Care Systems (THCS)

The SIP acknowledged the magnitude of this partnership, its thematic priorities and building blocks and its expected outcomes aiming at people-centered health and care systems. Building on the strategic pillars of the partnership and considering synergies with other EU initiatives that are already identified, it would be relevant to consider the funding dimension of healthcare systems as investments rather than costs. Exploring relevant and new modeling approaches aiming to

[1] Discussed at this meeting: Lung cancer portfolio (OPTIMA, IDERHA, GUIDE.MRD, IMAGIO), Alzheimer's disease and other dementias portfolio (EPND, PROMINENT, AD-RIDDLE, PREDICTOM), tuberculosis (UNITE4TB), COMBACTE-CARE, EU-PEARL, CARDIATEAM

demonstrate healthcare system efficiency, namely through fiscal return of investing in prevention, could be a use as a benchmark between countries and potentially inform national policies such as the ones in line with the EU Stability and Growth Pact. Additional considerations are related to the transformation of healthcare systems due to ageing populations and increased financial pressure, as well as questions related to the use of available data regarding the share of medicines and technologies within and across healthcare systems. Finally, the inclusion of additional indicators on the use of staff and use of existing resources a well as patient perspectives would further inform on the efficiency of healthcare delivery.

2.2. Presentation of IHI portfolio by the IHI JU Programme Office

Call 6 – topic 1 (*Support healthcare system resilience through a focus on persistency in the treatment of chronic diseases*) and ***call 7 – topic 2*** (*User-centric technologies and optimised hospital workflows for a sustainable healthcare workforce*) are aligned in aiming at healthcare delivery optimization. However, call 7 – topic 2 it is mainly focused on the hospital setting. Future activities should also include the primary healthcare sector and address questions related to the adoption of new technologies including assessing their relevance and reliability.

The ***SASICU*** project (*Improving patient outcomes, and reducing cognitive load of clinical staff in intensive care, through medical-device interoperability and an open and secure IT ecosystem; IHI call 3 – topic 3*) highlights the need for interconnection between the use of existing products and technologies and the development of new approaches aiming at improving the implementation of these technologies. The adoption and implementation are important elements that depend on the capacity of hospitals to comply with technical standards (e.g. Wi-Fi, servers, connectivity issues…), but also on the adaptation of current hospital procedures to include the use of these technologies by the concerned staff. Addressing barriers to implementation by demonstrating the practical feasibility of integrating new technologies in existing working procedures in times of high workload for the staff would need to integrate assessing change management processes. Moreover, it would be relevant to consider appropriate methodologies to measure and assess the impact on workforce of these changes.

Overall, the SIP is of the opinion that in such projects the voice of involved healthcare staff is key, for instance through surveys or focus groups, as well as the relevant exploitation of technologies (e.g. virtual twin of ICU) to inform on way to improve implementation. The focus should be on healthcare system quality and efficiency. Although healthcare is a national competence, there are common challenges (e.g. fiscal sustainability has commonalities) and looking at regional level might be very informative on what would work in some areas while not in others.

Mental health

2.3. Overview of the IHI portfolio in mental health presented by the IHI JU Programme Office

The SIP appreciated the large portfolio of research activities under IMI (more than twenty projects) and IHI concerning mental health / “brain” / neurology, as well their strong links with global initiatives,

in particular in the areas of autism spectrum disorders, dementias and neurodegenerative diseases.[2] The projects cover a broad range of research, e.g., molecular underpinnings, novel outcomes / endpoints, treatment target identification, efficient trial designs, patient engagement, data and biosample sharing.[3] Interactions with regulators have taken place to discuss and seek support. Increasingly, new projects build on and leverage previous projects' outputs, and coordinators of different projects in the portfolio are connected and collaborating. Further outputs are anticipated from ongoing projects in the IMI / IHI mental health portfolio, including several research and drug development tools and solutions for patient care.

2.4. Overview of the EU support for mental health research, presented by the European Commission, Directorate General Research

The SIP noted that mental disorders are among the top ten causes of global disease burden, with no evidence of reduction since 1990. The EU's comprehensive approach to mental health addresses it at the same level as physical health, as a new pillar of the European Health Union, in a cross-sectoral approach and with an investment of over 1.2 billion €. Funding of mental health research and innovation covers a range of target populations, specific contexts, settings and approaches; examples are call topics and projects in Horizon Europe Work Programmes 2021-2022 and 2023-2024 (in particular 'Health cluster', 'Culture, Creativity and Inclusive Society'). As Flagship initiative, a European Partnership on brain and mental health is planned. The activities will capitalize on existing initiatives, strengthen links with key entities and consider global initiatives.

The SIP appreciated and supports these activities. In the context of mental health, SIP members flagged the importance of addressing alcohol abuse and more broadly addiction, considering a high portion of the population is reported to be at risk. Examples of research needs can be markers of risks and abuse, elucidation of causes and effects, long-term clinical outcomes beyond assessments for depression, impact of healthcare systems' structure, financing and access. SIP members also flagged the need: for activities addressing mental health from a prevention perspective, for a unified pathway that broadly integrates diagnostic and therapeutic options across disciplines, and for new effective therapeutics and interventions. The SIP noted that children and adolescents should be in the focus of mental health activities, as well as people lacking access to healthcare or being 'invisible' to the healthcare system. Rapidly developments related to mental health should also be considered, such as anxiety related to climate change and dependence on gaming or digital devices, the SIP noted.

Industry Think Big initiative

The SIP welcomed the presentation by the IHI Industry founding members of the active IHI projects and proposals mapped to therapeutic areas/themes and the Think Big status overview and its developments. Although the themes covered in this process are mapped comprehensively, the

[2] See https://www.frontiersin.org/research-topics/33451/impacts-of-public-private-collaborative-research-on-alzheimers-disease-the-case-of-the-innovative-medicines-initiative/magazine

[3] Find a list of projects here: https://www.ihi.europa.eu/projects-results/project-factsheets?disease_areas=DA5

prevention dimension seems to be missing. It would be relevant to address living conditions rather than the individual lifestyle. In that regard, potential gaps in primary care should be addressed in each of the thematic pillars, including healthcare workforce issues. Moreover, it would be worthwhile considering mental health and musculo-skeletal disorders, osteo-arthritis, respiratory and infectious diseases as well as social determinants of health (e.g. considering war and migration, poverty and displacement). The psychiatric dimension remains an important element to consider. Other elements related to maternal and child health and adolescents could also be considered.

Overall, the connectivity between the thematic pillars including the regulatory aspects and sustainability are essential, including tackling questions about technology adoption (with inclusion of women and ethnic groups), affordability, patient access, remote monitoring and remote care as well as staffing issues. A more in-depth identification of key stakeholders to engage with would better inform on existing initiatives within hospitals or professional associations that could lead to synergies and new partnerships.

Early idea - Perfluorinated Polymers Exposure: emissions and end of life management in the healthcare sector including risk management measures, prevention, and reduction

The presentation of the idea by the industry IHI founding members included an overview of the IMI/IHI portfolio with a mapping of PFAs use, a lifecycle approach to PFAS and awareness. The SIP sees this idea as a potential large-scale prevention topic, looking at environmental elements and is of the opinion to encourage focusing within this vast topic, since mapping alone will not be sufficient. For instance, this could pinpoint to disposables to start somewhere and continue with other materials further on. This idea could generate a first call of a series to come allowing identifying EU partnerships in this area and other types of relevant partners (public, academic, SME associations, and companies in the chemical sector).

3. Preparing the next two-stage call 8

Idea 1 – Piloting a Regulatory Sandbox mechanism

SIP members feedback / general position:

1. Not clear yet what is actually the question (framing) and targets of these sandboxes proposed in the idea.; elements of the idea appeared vague ("alignment of understanding") or of limited impact / utility ("roadmap")
2. tricky topic to understand, SIP not sure to understand the aim – text to be clarified to ensure notably the aim to ensure that sandbox would be consequential and successful.
3. Refer to the EMA horizon scanning paper for new technologies coming in[4]. For the case studies 3D printing could be considered, a member suggested.

[4] Vignali V, Hines PA, Cruz AG, Zi˛etek B and Herold R (2022) Health horizons: Future trends and technologies from the European Medicines Agency's horizon scanning collaborations. Front. Med. 9:1064003. doi:10.3389/fmed.2022.1064003

4. the goals are specific end to end - but maybe this should be part of the project; on the other hand, “end to end” is likely premature at this time with uncertainties as to the final text and timepoint of the novel pharmaceutical legislation coming into force, and until then projects could work on developing enabling environments for safe experimentation and introduction of disruptive innovations into the health system.
5. Multidisciplinary aspects to be emphasised – sharing risks (acceptance high level of risks by everybody).
6. importance of rules of engagement and of quality indicators (KPIs) – to be considered by the project.

A member flagged that there are new ISO standards that may need to be considered for the regulatory sandbox ISO/TS 9491-1:2023 - Biotechnology — Predictive computational models in personalized medicine research — Part 1: Constructing, verifying and validating models.

Idea 2 – Unified Standards for Combining PPI, PROMs, and Patient-Centred Digital Measures

SIP members feedback:

1. Emphasize the necessity of patient involvement from project inception and highlight the continuous engagement of patients throughout the research process, proposing the integration of a European patient group(s)/organisation(s) as an active partner(s), not merely as consulting entity.
2. Stress the importance of ethical considerations and diversity in patient data collection and the need to address challenges such as potential discrepancies between collected data and patients' actual conditions.
3. Consider implementing an immediate feedback loop for patient adaptation to therapy or treatment continuation.
4. Patient preferences are not outcome measures such as PROMs so clarify the concepts underlying the idea.
5. Standardise and clarify terminology to enhance understanding and coherence.
6. Emphasise in the objectives to assess how the collected data contribute to identifying clinically meaningful change.
7. Emphasize the expectation to contribute to a greater incorporation of Patient Reported Outcomes (PROs) and patient preferences in healthcare and clarify protocols needed for collecting patient-reported outcomes.
8. Highlight that the goal is not to standardize measures but to assess the utility of PROs or digital health technologies in indicating clinical program changes and providing unique insights. Thus, shift the emphasis from standardization of devices (not needed as already done by the market) towards creating core outcome sets for enhanced research comparability.
9. Refine objectives to underscore the innovative aspects of the topic.
10. Consider adding in the topic to look at how outcomes and measures align with other relevant endpoints, especially since an integrated approach is needed as there is no unifying approach currently to summarise intervention effects on different endpoints (e.g. tumour shrinkage and patient functioning).
11. Clarify for this idea what is meant by validation (in particular what is ‘valid’ from a patient perspective; note that various levels and actors are concerned with ‘validation’) and how the project should contribute to this validation process.

Idea 3 – Non-communicable Chronic Diseases: Understand osteoarthritis and develop new assessment tools and regulatory pathways for integrated health care solutions in an ageing society

SIP feedback:

1. Broader on other treatment options beyond drugs
2. Include patients in the consortium
3. Functional measures
4. Clarify if the biomarkers have to be developed or also validated
5. Consider adding prosthetics/sports equipment expertise
6. Need to ensure that the data has to be harmonised vs a federated database
7. Consider 3D imaging/implants
8. Consider other gait measures, muscle tension, balance coordination

Idea 4 – Non-communicable Chronic Diseases: Cities @ Heart

SIP feedback:

1. The choice of cities and not regions is not clear.
2. Prevention should be better reflected in the topic text.
3. People in cities are healthier than people in rural areas depending on the country – there is a potential bias in selecting cities.
4. What are city health systems? In many countries, cities are not responsible of healthcare.
5. Consider the impact of infectious diseases on CVD, maybe bringing on board a company (vaccines or infections)
6. A gap analysis should be done to identify the unmet need that needs to be fulfilled with this topic.
7. Patients should be part of the applicant consortium.
8. The 30% reduction is overambitious and not clearly justified.
9. How are the cities chosen? Are there any criteria?
10. Suggestion to have a look at other initiatives/projects under H2020 and HE include the Mission on cities.

4. Ideas submitted by the wider health and research community

The SIP reviewed the recently submitted ideas in order to finalise its opinion (the summary will be published on the IHI website).