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INTERNATIONAL CONSORTIUM

Challenges, Opportunities and Facilitators in Implementing Personalised Medicine

The International Consortium for Personalised Medicine (ICPerMed), developed a document "Challenges, Opportunities, and Facilitators in Implementing Personalised Medicine" that outlines strategies for integrating personalised medicine (PM) into healthcare systems, aiming to improve health outcomes and create sustainable healthcare systems through research, development, innovation, and implementation. It identifies significant hurdles to implementing PM and offers actionable recommendations for stakeholders, including healthcare professionals, policy makers, patient organisations, and researchers.

Eight major facilitators were identified:

- Engaging relevant stakeholders in the implementation process of personalised medicine
- Collaboration between relevant stakeholders during the implementation process of personalised medicine
- Establishment of a national or regional common strategy
- Infrastructure needed during the implementation process of personalised medicine
- Education and training in personalised medicine
- Resource allocation during the implementation process of personalised medicine
- Regulations and legislations for personalised medicine approaches
- Ethical considerations

Engaging relevant stakeholders in the implementation process of personalised medicine

There is a need for a multidisciplinary approach, involving collaboration between policy makers, healthcare professionals, researchers, and patient advocacy groups. It is essential to bridge the gap by integrating these diverse perspectives to foster an effective strategy for PM development and implementation. Healthcare professionals should be involved in policy discussions related to PM to provide practical insights and ensure that policies are aligned with clinical realities. While participation of patients and citizens could be detrimental in PM implementation processes and in policy discussions to influence decision-makers.

Engagement of patients or patient representatives and citizens is crucial, as their input contributes to the development and acceptance of patient-centred approaches. The education of patients about the benefits, risks, and potential outcomes of PM is important. This could involve developing patient-focused materials and programmes that explain complex PM concepts in an accessible manner. Additionally, to foster a broader understanding of PM, ICPerMed suggests public awareness campaigns. These campaigns could demystify PM technologies and treatments, address common misconceptions, and highlight the potential benefits of PM for individual and public health.

For policy makers and healthcare administrators, understanding the implications of PM for healthcare policy, funding, and regulation is crucial. Training in this area could focus on the economic, legal, and ethical aspects of PM. ICPerMed suggests to increase the awareness of policy maker about PM, provide evidence-based information on its benefits, and encourage international collaborations to streamline PM practices globally and harmonise PM care delivery. This should also equip policy makers and healthcare administrators with the skills to make informed decisions about PM integration into healthcare systems, including resource allocation, regulatory oversight, and healthcare delivery models.

Specifically, the role of healthcare professionals in the successful implementation of PM is essential. Engaging these professionals effectively is seen as crucial, given their direct role in patient care and their influence on the adoption and integration of PM practices. ICPerMed advocates for the creation of regular meetings where healthcare professionals from various disciplines can share knowledge, experiences, best practices and develop consensus on implementation strategies related to PM. Additionally, acknowledging and rewarding the efforts of healthcare professionals in PM research, development, and implementation can encourage

further participation and innovation in the field. ICPerMed suggests providing incentives to healthcare professionals who actively engage in PM initiatives. These could include recognition programmes, career advancement opportunities, or financial incentives.

Collaboration between relevant stakeholders during the implementation process of personalised medicine

Successful PM implementation hinges on the synergistic efforts of a wide array of stakeholders. Hence, ICPerMed recommends establishing formal governance structures to facilitate collaboration. This can include steering committees, working groups, and task forces that bring together representatives from different sectors. Clear delineation of roles and responsibilities within these collaborative structures is necessary to ensure effective coordination and decision-making. Additionally, the creation of formal collaboration agreements with a common and clear goal between institutions, organisations, and other entities is encouraged. These agreements can outline objectives, shared resources, and mechanisms for conflict resolution. Collaborations between the public and private sectors, academia, and healthcare institutions are also highlighted as critical for advancing PM research and implementation.

Establishment of a national or regional common strategy

Establish a national steering committee comprising representatives from healthcare providers, research institutions, policy makers, healthcare professionals, patient advocacy groups, and other key stakeholders to develop in a collaborative approach a common strategy and framework for PM implementation. Regional and local variations should be considered since the beginning and flexibility should be built into the framework to accommodate diverse health systems and resources.

Infrastructure needed during the implementation process of personalised medicine

In terms of infrastructure, particularly IT infrastructures, biobanks, genomic and molecular diagnostics, and platforms for patient engagement are identified as crucial for PM implementation. ICPerMed emphasises the need for advanced data management systems capable of handling large volumes of diverse data types, including genomic, clinical, and lifestyle data. The adoption of federated data models is recommended. These models enable data sharing and collaboration across different organisations while maintaining data privacy and security. Ensuring that healthcare professionals have access to necessary resources, including advanced diagnostic tools, patient data, and decision-support systems, is critical for effective PM practice. Additionally, the development of advanced diagnostic facilities equipped with the latest technologies for genomic and molecular analysis or imaging data is a key infrastructure requirement for PM. Lastly, the creation of digital platforms that enable patient engagement in PM is recommended. These tools can facilitate patient education, consent processes, participation in decision-making regarding their treatment and allow patients to provide feedbacks on their treatment outcomes for monitoring the effectiveness of PM interventions and for continuous improvement.

Education and training in personalised medicine

ICPerMed emphasises education and training as pivotal components in the successful implementation of PM. This focus is directed towards ensuring that all relevant stakeholders, including healthcare professionals, researchers, patients, and the general public, have a thorough understanding of PM concepts and practices. In particular, ICPerMed advocates for the integration of PM topics into the curricula of medical and healthcare-related educational programmes and, given the rapidly evolving nature of PM, ICPerMed emphasises the need for ongoing education and professional development for current healthcare professionals and for researchers and technical staff. Those programmes should not only include the latest developments in genomics, pharmacogenomics, bioinformatics, and other relevant fields but should also cover aspects like data management, ethical considerations, and patient communication. Training healthcare professionals in effective communication skills is crucial

for discussing PM options with patients, including explaining the benefits, risks, and potential outcomes of PM-based treatments. This will encourage a shared decision-making approach, where healthcare professionals and patients collaborate to make healthcare decisions.

Resource allocation during the implementation process of personalised medicine

Resource allocation is highlighted as a critical aspect, with recommendations for financial, logistical, and human resources to support PM integration. This resource allocation must be guided by strong health technology assessment evidence maximise the added value of PM approaches for the healthcare system and the society. However, this requires a substantial change in the approach to health economic evaluations of PM interventions to factor in the model both the uncertainty but also the potential of long-term benefit of the most innovative interventions such as gene and cell therapies.

It is suggested exploring various funding sources, including government budgets, private investments, and public-private partnerships. Efficient logistical frameworks are necessary to manage the complex operations involved in PM. This includes the development of data management systems, supply chain logistics for pharmaceuticals and diagnostic tools, and the establishment of patient data registries. The need for skilled personnel is highlighted, spanning a range of professionals from healthcare providers to researchers, IT specialists, and administrative staff. Training and retaining these professionals are key to the sustainable implementation of PM. The recommendations developed advocate for workforce development strategies that include specialised training programmes and career development opportunities in PM.

Regulations and legislations for personalised medicine approaches

ICPerMed acknowledges the complexity of the regulatory landscape specifically when it comes to PM, e.g. due to small sample sizes, emphasising the need for clear, interlinked, and adaptable regulations to guide PM implementation, protect patient data privacy, and ensure informed consent. With PM's reliance on large datasets, including genetic information, ICPerMed stresses the importance of stringent data privacy regulations. This involves creating regulations that protect patient information, ensure data security, and maintain confidentiality. The evolving nature of PM necessitates adaptive informed consent processes and adaptable regulations. ICPerMed recommends developing consent frameworks that are flexible and comprehensive, allowing patients to understand the implications of their participation in PM, including potential risks and benefits. In addition, creating mechanisms for regular review and revision of regulations to keep pace with technological and scientific advancements in PM is also necessary. This document highlights the need for international collaboration to harmonise regulatory standards. This would facilitate cross-border research and collaboration, ensuring consistency in the quality and safety of PM practices but also equal access to new technologies and PM approaches worldwide.

Ethical considerations

Finally, the need for ethical considerations surrounding the implementation of PM was identified. These considerations are fundamental to ensuring that PM is developed and applied in a manner that is equitable, respectful of individual rights, and socially responsible. ICPerMed emphasises the importance of addressing disparities in access to PM. This includes ensuring that PM technologies and treatments are accessible to all segments of the population, regardless of socioeconomic status, geographic location, or demographic factors. Stakeholders should ensure that market forces do not create barriers to access and that PM solutions are affordably priced and widely available. Additionally, prioritisation of healthcare strategies could ensure that PM is integrated into the healthcare system in a way that promotes the common good and does not neglect other important areas of healthcare. Last but not least, ethical considerations extend to the realm of research, where there is a need for inclusive study designs that represent diverse populations. This is crucial to ensure that the findings and benefits of PM are applicable and beneficial to a broad range of individuals, not just a subset of the population.

Conclusion

This document comprehensively outlines the multifaceted approach required for the successful implementation of PM. It underscores the necessity of an integrated infrastructure, encompassing advanced IT systems, biobanks, and diagnostic tools, alongside robust patient engagement platforms. The emphasis on multi-stakeholder collaboration highlights the need for synergy between healthcare professionals, policy makers, researchers, and patients. Education and training emerge as key themes, stressing the importance of continuous learning and adaptability across all levels, from medical professionals to the general public. Ethical considerations, particularly in terms of equitable access and patient consent, are crucial in guiding the responsible development and application of PM. Significant challenges were identified, including the need for sustainable resource allocation, adaptive regulatory frameworks, and the maintenance of public trust and ethical standards in a rapidly evolving field.

Methodology for the development of this document

The "Challenges, Opportunities and Facilitators in Implementing Personalised Medicine" document presents a review of challenges and the identification of facilitators for PM implementation in healthcare practices formulated as recommendations, both elaborated through dedicated interviews conducted with representatives of identified PM application examples, with the support of the ICPerMed Secretariat and under consultation of members of the ICPerMed working group "Personalised Medicine in Healthcare" as well as consultation of the ICPerMed Advisory Board.

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Conflict of interest

The authors declared no competing interest for this work.

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