ICPerMed
INTERNATIONAL CONSORTIUM

Challenges, Opportunities and Facilitators in Implementing Personalised Medicine

Methodology documentation
Supporting document

Working Group 2
'Personalised Medicine in Healthcare'
December 2023

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I. Background and Objectives

I.1 Background

According to the European Council, "Personalised Medicine (PM) refers to a medical model using the characterisation of individuals' phenotypes and genotypes (e.g., molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention." In terms of clinical application, Personalised Medicine is an approach to healthcare that uses genetic, molecular, and other data to tailor treatments and prevention strategies to the unique characteristics of patients within a population. This approach has the potential to improve patient outcomes and result in the more effective use of healthcare budgets.

The International Consortium for Personalised Medicine (ICPerMed) brings together around 50 funding bodies from EU Member States and beyond, in order to initiate and support communication and exchange on PM research, funding and implementation.

ICPerMed has a key role in supporting research actions related to PM and identifying requirements for suitable frameworks in terms of infrastructure, regulatory perspectives, as well as of human and financial resources to ensure a fair implementation of the concept of PM in healthcare.

ICPerMed has identified key priority areas and formed dedicated Working Groups (WG) consisting of ICPerMed members and external experts to foster reflections on those topics, to (co-)organise events and develop strategic documents. There are currently four Working Groups addressing the following topics:

- Clinical Studies in Personalised Medicine
- Personalised Medicine in Healthcare (WG2)
- Education, Empowerment, and Engagement in Personalised Medicine
- Health Economic Value of Personalised Medicine

The main objectives of the Working Groups (WG) are to contribute to the development of ICPerMed recommendations, strategic publications, reports and to ICPerMed dissemination activities (e.g. roadmap, scientific research and innovation agenda); to provide content-driven input for ICPerMed events; to exchange with stakeholders and representing ICPerMed in thematically focused events to improve the visibility and impact of ICPerMed in the respective community; and to identify and validate Best Practice PM examples.

The Working Group 'Personalised Medicine in Healthcare' (in short WG2) aims to contribute to improved diagnosis, treatment, and prevention by a better integration of PM approaches into healthcare. Its activities consist of

- mapping and analysis of the field of PM application and implementation scenarios;
- understanding the challenges and opportunities for the implementation of PM in health systems;
- contributing to the ICPerMed registry of best practices examples;
- developing and sharing of already existing strategic papers/recommendations and other communications supporting better synergies between R&I and healthcare;
- supporting the organisation of ICPerMed events.

Specifically, WG2 intends to support and disseminate ICPerMed's vision and encourage the implementation of PM into health systems by providing guidance on specific aspects of implementation processes to healthcare professionals, healthcare systems managers, decision-makers, patient organisations etc. Through the collection and analysis of PM Applications, i.e. PM approaches, processes or structures already in practise or close to implementation, as well as input provided by representatives of ICPerMed member and observer organisations, this WG developed these recommendations. The consulted and analysed PM Applications were proposed by ICPerMed member and observer organisations or previously identified as Best Practice Examples.

I.2 Objectives

The PM concept is anticipated to enable healthcare systems to maximise health through the effective use of healthcare funding but the implementation of PM approaches faces several obstacles and barriers to widespread rollout. As PM is a relatively new concept for health systems worldwide, professionals and experts may lack experience and knowledge to allow the rollout of PM concepts. Opportunities are also possible with the implementation of PM in terms of the type of stakeholders to be engaged in the ongoing implementation process, the infrastructure needed, education and training for both health professionals and patients consulting PM care, in addition to regulatory and data aspects.

The document "Challenges, Opportunities and Facilitators in Implementing Personalised Medicine" aims to develop an understanding of the challenges but also opportunities for the implementation of PM in healthcare practices through the use of expert consultation and input of the ICPerMed consortium. The results of these consultations are proposed to serve as a reference for experts and organisations aiming to implement PM into healthcare systems by profiting from and building on previous experiences. Identified challenges could be tackled and facilitators applied from the outset of the implementation process (stakeholders' meetings, setting objectives, defining logistical needs, integration into healthcare systems, ...) so that patient benefits can be realised and the effective use of healthcare budgets maximised.

II. Materials and Methods

II.1 Materials

PM Application examples were collected based on the suggestions of the ICPerMed members and observers. Furthermore, representatives of best practices examples previously selected by ICPerMed (see the website) were invited to fill in the PM Application form and provide further information about their approach. In this way, WG2 revised the collected PM Applications and verified their level of implementation before further starting in depth analysis.

A semi-structured data collection form was developed in order to collect information from PM Application representatives using interviews (individual or group). The questionnaire covered several aspects regarding the implementation process of PM applications (see section III. for further details):

- Engaging relevant stakeholders
- Collaborations
- Infrastructure
- Education and Training
- Resource allocation
- Ethical considerations
- Data
- Regulations and Legislations

II.2 Methods

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 with the support of the ICPerMed Secretariat and under consultation of the WG2 members and review of interviewed stakeholders as well as consultation of the ICPerMed Advisory Board.

Relevant PM Application stakeholders were interviewed through group or individual one-to-one interviews. The interview sessions were conducted between March and April 2023.

A total of nine (9) external stakeholders participated in the interviews, representing in total ten (10) PM Applications previously collected by WG2 (see table 1). The interview questions were shared with the stakeholders prior to the interviews for information and to be filled in beforehand, if possible, in order to ease the interview flow and the analysis of the discussion outcome afterwards. Interview sessions were recorded upon confirmation of the participants in order to develop this analysis.

Full name of Participant	Organisation	PMA title
Angel Alonso	NavarraBiomed SPAIN	NAGEN 1,000: The 1,000 Genomes Project of Navarra NAGEN Mx_Personalized Breast Cancer Screening
Amalia Gastadelli	Institute of Clinical Physiology, CNR Pisa ITALY	MEchanisms for increased risk of DIabetes in chronic LIver Diseases
Valérie Barbié	SIB Swiss Institute of Bioinformatics SWITZERLAND	Swiss Variant Interpretation Platform for Oncology (SVIP-O)
Katrin Crameri	Personalized Health Informatics Group SIB Swiss Institute of Bioinformatics, Director SPHN Data Coordination Center SWITZERLAND	Federated Query System of the Swiss Personalized Health Network (SPHN)
Thomas Geiger	Managing Director SPHN, Swiss Academy of Medical Sciences SWITZERLAND	
Hege Russness	Oslo university hospital, NORWAY	National Infrastructure for Precision Diagnostics – InPreD National knowledge sharing network, personalised medicine – NorPreM
Adrián Llerena	Instituto Universitario de Investigación Biosanitaria de Extremadura (INUBE). Servicio Extremeño de Salud (SES). SPAIN	MedeA Initiative (Medicina Personalizada Aplicada, Applied Personalised Medicine)
Peter Schirmacher	Institute of Pathology, University Hospital Heidelberg, Im Neuenheimer Feld 224, 69120 Heidelberg, GERMANY	Centers for Personalized Medicine (ZPM), Germany
Andreas Wicki	University of Zurich SWITZERLAND	Swiss Molecular Tumorboard

Template: Collection of Personalised Medicine Application

This template aims to facilitate the collection of Personalised Medicine (PM) application that are already implemented or at least in a pilot stage. We aim to collect implementation approaches on all levels (from clinical settings to healthcare systems, further outlined below).

Title

You are invited to indicate the Acronym of the PM application AND the full title.

Short description

Please indicate a short description of the PM application (max. 2000 characters without spaces).

Timeframe

Please indicate the start (year), the running time (if available) or information about the timeframe needed for the development and implementation of the approachdevelopment and implementation of the approach.

Contact details

Please indicate the responsible person/organisation for this PM application example.

Last Name:

First Name:

Organisation:

Email:

Telephone number:

Website of the PM application (if available):

Any other information that could be interesting for this PM application example.

Further indications for the PM application

Scope of application

Please indicate what applies	YES	No
Prevention		
Early detection/disease risk		
Diagnostic		
Decision support (e.g. tools)		
Treatment		
Disease trajectory		
Monitoring/Managing of follow-up (after treatment, ongoing disease monitoring/management)		
Recovery/Rehabilitation (e.g. against toxicity/side effects, post-treatment therapy)		
Relapse		
Infrastructure (e.g. biobanks)		
Development of processes/standards (e.g. data sharing, standards in genomics, etc.)		
Multidisciplinary collaboration (e.g. collaboration of research/clinic/industry, etc.)		
Others Please specify:		

Disease field

Please indicate what applies	YES	No
Cancer		
Neuroscience		
Diagnostic		
Infectious diseases		
Cardiovascular diseases		
Genetic disorders		
Rare diseases		
Others Please specify:		

Level of application

Please indicate what applies	YES	No
Local level (e.g. one or several hospital/s involved)		
Municipal level		
Regional level		
Interregional level		
National level		
Supra-National level (e.g. European level)		
International level		
Others Please specify:		

Information to outline the added value for Personalised Medicine and support its implementation

Please outline the personalised approach of the PM application example presented (max. 2000 characters without spaces):

Please outline the benefit for healthcare/healthcare systems for the PM application example presented (max. 2000 characters without spaces):

Please outline the benefit for the patients/citizens for the PM application example presented (max. 2000 characters without spaces):

Please specify if any health economic analysis of the PM application example presented is available (e.g. budget impact on the healthcare system, economic benefits for the society, etc.) and, if available, please describe shortly the approach and the main outcome (max. 2000 characters without spaces):

Please specify if any analysis of the impacts of the PM application example on the socio-economic burden presented has been conducted to demonstrate and quantify the benefits to patients and relatives (e.g. loss of income/education, early retirement, isolation/missing community and cultural events, cost of medication and devices, out-of-pocket healthcare expenses, at-home care, etc.). If available, please describe shortly the approach and the main outcome (max. 2000 characters without spaces):

Please specify if the PM application example presented is considering diversity aspects (e.g. sex as a biological variable, gender as a socio-cultural factor, other identity factors, age-specific considerations, genetic diversity, socio-economic status; max. 2000 characters without spaces):

Organisation behind the PM application example

Please indicate the different stakeholders involved in the PM application example.
If you cannot complete this section, WG2 will contact the representative of this application example to collect the respective information.

Organisation of the PM application example

Please complete and indicate the responsible instance	Organised by
Governance (organisation of the approach)	
Infrastructure	
Funding / investment	
Regulation	
Legislation	
Communication	
Others Please specify:	

Please outline obstacles faced during the implementation process:

Please outline the prerequisites (e.g. governance, infrastructure, funding/investment, regulatory, legislation) needed for the implementation:

Please outline the different instances passed during the implementation process:

Please indicate potential levers you identified:

Please outline to what extent economic effects were considered when making decision to implement the PM application presented:

Collection of Personalised Medicine Applications Explanatory note

Introduction

The questionnaire on Personalised Medicine Applications (PMA) intends to collect implemented personalised medicine (PM) practices in care or those being under experimentation. Furthermore, approaches contributing to establish the adequate environment to allow PM application into practice are also welcome.

The PMA questionnaire is running in parallel to the collection of PM Best Practices Examples and the ICPerMed Recognition that aim to identify or recognise examples of innovative PM programmes, strategic plans or PM research projects.

Aims

The PMA collection will serve as basis for a further analysis to identify priorities and frameworks required for the implementation of PM by healthcare professionals, organisations (healthcare facilities, infrastructures as biobanks) or by health authorities and regulators. The analysis, by outlining hurdles and facilitations for PM implementation, can provide guidance to healthcare systems' roadmap and support the successful uptake of PM practices in care.

Additionally, the PMA collection could provide input to ICPerMed Events.

Principles

This survey will help to demonstrate the large panel of PM applications already set in place or close to application. The PMA collected can concern any aspect of a medical intervention from prevention, diagnostic, treatment, etc. or be related to the environment favouring the implementation of the approach (e.g. infrastructure, standards, regulatory frameworks, etc.).

PMAs can include applications at local level (healthcare facility), regional/national or supra- national/international level.

We aim, to understand how the PMAs integrated reflections on the benefits for patients, the citizens and the society, as better health outcomes, socio-economic advantages or the engagement of patients and citizens in their own health and care, as well as reflections on the cost-effectiveness for healthcare systems and economics benefits for the society.

Finally, the PMA collection intends to provide a better understanding on how to build up successful PM approaches that should be considered for the implementation of PM practices.

To this end, the PMA questionnaire aims to collect information about the framework, methodologies or activities that allowed the implementation by outlining obstacles and levers, prerequisites (e.g. governance, infrastructure, funding/investment, regulatory, legislation) and instances to interact with.

Roles

The ICPerMed Working Group 2 is responsible for the collection and analysis of the PMA.

The entire Executive Committee of ICPerMed is invited to participate to this questionnaire that will be closed in October 2021.

In the case of questions, please contact: Monika Frenzel (ICPerMed@agencerecherche.fr).

Data

Data provided within the questionnaire are dedicated only for the internal use within ICPerMed and in particular to feed the work of the ICPerMed Working Groups (e.g. analysis of PM implementation strategies by Working Group 2; analysis of data on health economics value of PM by Working Group 5).

No information about PM applications will be published without further consent.

No personal data of the contact person indicated within the questionnaire will be published.

The participating organisations have the right of access their personal data provided within this survey and the right to rectify any such data. In the case of queries concerning the processing of his/her provided data, s/he shall address them to Monika Frenzel (ICPerMed@agencerecherche.fr).

Set of GUIDING Questions/Remarks for the Interview

Personalised medicine is an approach to healthcare that uses genetic, molecular, and other data to tailor treatments and prevention strategies to the unique characteristics of individual patients. This approach has the potential to improve patient outcomes and reduce healthcare costs, but implementing personalised medicine in a real-world setting can be challenging. In order to realise the full potential of personalised medicine, it is essential to better understand the various factors that can impact its implementation and to develop effective strategies for addressing these challenges. This includes understanding the role of stakeholders such as patients, healthcare providers, researchers, and policymakers, as well as understanding the need for robust infrastructure, education and training, and appropriate regulations and legislation. Additionally, it is important to consider the ethical, social and economic implications of personalised medicine. A better understanding of these factors can support the development of effective strategies for implementing personalised medicine and ensuring its success in the clinic.

Engaging relevant stakeholders:

It is essential to engage a diverse group of stakeholders, including patients, healthcare providers, researchers, policy makers, and industry partners, in the implementation of personalised medicine. This can help to ensure that the needs and concerns of all stakeholders are considered and that there is strong support for the implementation.

- Who are the key stakeholders that should be involved in the implementation of personalised medicine, and how and when can their input and involvement be effectively solicited?
- What are the most effective ways to engage with patients and to ensure that their preferences and needs are considered in the implementation of personalised medicine?
- How can we ensure that there is strong leadership and support for the implementation of personalised medicine from key stakeholders, such as policy makers and healthcare providers? How can we ensure a good flow of project implementation?

Collaborations:

Personalised medicine often requires collaboration and partnerships across sectors and disciplines. This can include collaborations between healthcare providers and researchers, as well as partnerships with industry and other organisations.

- What are the main challenges and barriers that hinder multidisciplinary collaboration in personalised medicine and how can these be overcome?
- How can collaborations between healthcare providers, researchers, patients, industry partners, policy-makers and other stakeholders be fostered, established or improved to advance the implementation of personalised medicine? What model of collaboration would be the most effective to use in the implementation process of PM?
- How can the involvement and participation of patients and patient advocacy groups be improved to ensure that their needs and preferences are considered in the implementation of personalised medicine?

Infrastructure:

Personalised medicine often requires robust infrastructure, including diagnostics and testing technologies, digital health tools, data analytics capabilities, and secure data storage and sharing systems etc. Ensuring that the necessary infrastructure is in place is essential for the successful implementation of personalised medicine.

- What types of infrastructures, services, tools and technologies are necessary for the successful implementation of personalised medicine, and how can these be established and accessed? (e.g. genetic counselling, clinical decision support, diagnostics and testing services, patient engagement and education services, bioinformatics or data management services).
- How can we address any barriers or challenges that may arise in the development of the necessary infrastructure for personalised medicine?
- What are the strengths, weaknesses, opportunities and threats of your local/regional/national infrastructure?

Education & Training:

It is important to ensure that healthcare providers and other stakeholders have the necessary knowledge, skills, and

resources to implement personalised medicine effectively. This may include training on new technologies, approaches, and tools, as well as education on the ethical and legal considerations involved in personalised medicine.

- What types of education and training are necessary for healthcare providers and other stakeholders?
- What are the needs for specialised training? In which area?
- What role can patient advocacy groups and other organisations play in educating the public about personalised medicine and its potential benefits?

Resource allocation:

Implementing personalised medicine may require significant financial and human resources. It is important to consider how these resources will be allocated and managed to ensure that personalised medicine is implemented effectively.

- What are the most critical resources needed for successful implementation of personalised medicine and how can these resources be effectively allocated and managed?

Ethical considerations:

Personalised medicine raises a number of ethical considerations, including issues related to privacy, discrimination, and unequal access. It is important to address these ethical concerns and ensure that personalised medicine is implemented in a responsible and equitable manner.

- How can we ensure that personalised medicine is implemented in an equitable and responsible manner, and that the rights and interests of all stakeholders are protected?

Public awareness and acceptance:

Personalised medicine may be a new or unfamiliar concept to many people, and it is important to consider how to effectively communicate about it and address any concerns or misinformation making it accessible to everyone. This may involve engaging with researchers, healthcare providers, patient advocacy groups, policy-makers and other stakeholders to increase public awareness and acceptance of personalised medicine.

- What strategies can be employed to ensure that personalised medicine is inclusive and accessible to all?

Data:

Personalised medicine relies on the availability of high-quality data, including clinical and genetic data. Ensuring the privacy and security of this data, as well as addressing any barriers to data sharing, is essential for the successful implementation of personalised medicine.

- What steps have been taken, e.g. with data providers, to ensure/incentivise quality and relevance
- What are the barriers and solutions to allow access from diverse sectors (public vs. private) and regions (cross-border)?

Regulations & Legislations:

Adequate regulations and standards are necessary to ensure the safety and efficacy of personalised medicine and to protect the rights and interests of patients. It is important to consider the regulatory landscape and identify any potential barriers to the implementation of personalised medicine.

- What are the key regulations and standards that need to be considered to enable implementation of personalised medicine?
- What are the strengths, weaknesses, opportunities and threats of the regulatory framework for PM in clinics?
- How to foster the adoption and uptake of PM in policy and practice?

Outcomes and impact:

It is important to consider how the effectiveness and impact of personalised medicine will be measured and evaluated. This may involve collecting data on patient outcomes and cost-effectiveness, as well as conducting research studies to assess the impact of personalised medicine.

- Have you set in place a monitoring system following the implementation and/or the outcomes of the PM practice?

VI. List of abbreviations

List of abbreviations	
ICPerMed	International Consortium for Personalised Medicine
PM	Personalised Medicine
PMA	Personalised Medicine Applications
R&I	Research and Innovation
WG	Working Group