Implementation Guidance for the Planning, Assessing, and Monitoring of Personalised Prevention Programmes

A work developed within the **PROPHET Project**.

PROPHET

a PeRsOnalized Prevention roadmap for the future HEalThcare

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This guidance, developed by the EU-funded Project "a PeRsonalised prevention roadmap for the future HEalThcare" (PROPHET) [1], provides policymakers with a structured series of steps to support the assessment, planning, and monitoring of public health personalised prevention programmes.

At the core of personalised prevention programmes are personalised prevention approaches. In line with the PROPHET conceptualisation, personalised prevention may be defined as: **an action, or a set of actions, in which the information provided by genetic and/or other omic biomarker testing, combined with demographic, environmental and behavioural characteristics, as well as the socio-economic and cultural context of individuals, guides the decision-making process regarding one or more interventions aimed at preventing the onset, progression, and recurrence of diseases [2]**.

This guidance supports the translation of such evidence-informed personalised prevention approaches into public health programmes. It is intended to help decision-makers systematically consider the key factors that may influence implementation, including population needs, available evidence, programme characteristics, health systems readiness, legal and data-governance requirements, ethical and equity implications, potential health and economic impacts, and monitoring requirements. The guidance is designed to be flexible and adaptable to different disease areas, preventive interventions, and healthcare systems. Stakeholder engagement should be considered throughout the process and not as a single implementation step, because mission-oriented policies require ongoing alignment of public, private and civil actors across the mission lifecycle [3].

STEP 1

Define the Prevention Need and Preventive Programme Scope

Key policy question: Why is this personalised prevention programme needed?

As an initial step in planning, policymakers should determine whether a personalised prevention approach could provide additional value compared with current prevention strategies in addressing a significant public health need. This step focuses on understanding the burden of disease, identifying unmet prevention needs, and defining the scope and objectives of the personalised approach and related public health programme under consideration. This assessment should be informed by the analysis of national and regional epidemiological data, including disease incidence, prevalence, mortality, risk factor distribution, inequalities, and temporal trends. It should also include a preliminary review of the scientific literature and current policies to identify existing evidence, knowledge gaps, and opportunities for improving prevention outcomes through a personalised prevention approach.

Recommended actions

- **Identify unmet prevention needs and gaps in current preventive pathways**
- **Review current policies and practices**
- **Identify opportunities for improvement in prevention delivery, access, outcomes, and equity**
- **Develop a preliminary conceptualisation of the personalised prevention approach, including the preventive objective (e.g. primary, secondary or tertiary prevention), the target condition, target population, risk-stratification strategy, test or biomarker component, and proposed intervention(s)**
- **Define preliminary objectives, scope, intended outcomes, and expected added value compared with current prevention practice**
- **Identify early "go/no-go" criteria to determine whether further assessment and programme development are justified**

Expected output: A programme concept document defining the public health need, rationale, target population, proposed scope, and the decision to proceed.

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STEP 2

Gather and Assess Evidence

Key policy question: Is there sufficient evidence to support implementation?

Implementation decisions should be informed by a comprehensive assessment of available evidence. In addition to clinical effectiveness and safety, policymakers should consider clinical utility, analytical validity where testing is involved, economic evidence, implementation experience, patient and citizen perspectives, ethical and legal implications, and existing assessments conducted at national or international level. The aim is to understand not only whether an intervention works under study conditions, but also whether it can generate value in routine public health practice. In this context, value refers to the balance between expected health outcomes and the resources required for implementation, while also considering organisational feasibility, equity and broader societal impacts. This assessment should be supported by systematic or structured reviews of the available evidence on the proposed personalised prevention approach, including evidence on effectiveness, safety, clinical utility, cost-effectiveness, acceptability, feasibility, and implementation barriers and facilitators. When the evidence base is incomplete, policymakers should explicitly identify evidence gaps and determine whether implementation should proceed, be piloted, or be deferred pending further research.

Recommended actions

- **Review scientific evidence on analytical validity, clinical validity, clinical utility, effectiveness, and safety**
- **Review clinical guidelines and public health recommendations.**
- **Review existing national or international HTA.**
- **Review economic and resource-use evidence, including cost-effectiveness and budget-impact evidence where available.**
- **Review real-world evidence and implementation studies where available.**
- **Assess evidence on implementation barriers and facilitators.**
- **Consider patient, citizen, professional, and stakeholder perspectives.**
- **Identify evidence gaps and determine whether additional local evidence generation, pilot implementation, or modelling is required.**

Expected output: An evidence dossier summarising the available evidence, its quality, key uncertainties, and recommendations regarding whether implementation, pilot testing or further evidence generation is warranted.

STEP 3

Define the Prevention Programme and Governance Model

Key policy question: How should the prevention programme be designed, organised, governed and adapted to the healthcare system?

Even when supported by strong evidence, personalised prevention approaches need to be adapted to the healthcare system in which they will be implemented. This step focuses on defining how the public health programme will operate, who will be involved, how services will be organised and financed, and how responsibilities will be distributed across the prevention pathway. Based on the evidence gathered in the previous steps, the proposed personalised prevention approach should be translated into an implementable personalised prevention programme by integrating available evidence with national and subnational contextual factors, resources, policies, regulatory requirements, organisational arrangements. Early stakeholder involvement (e.g. policymakers, healthcare providers, intended beneficiaries, public health authorities, healthcare organisations, and payers where applicable) is essential to ensure that programme design is feasible, acceptable, equitable, aligned with local needs. Particular attention should be paid to the design of the care pathway, including eligibility criteria, recruitment strategy, informed consent, testing procedures, risk communication, referral mechanisms, preventive interventions, follow-up, data collection, feedback loops. For programmes involving genetic or omic testing, additional attention should be given to laboratory quality assurance, data governance, communication of results, family implications where relevant, and access to counselling.

Recommended actions

Define the target population and eligibility criteria.	**Define the risk-stratification approach and decision rules.**
Define the care pathway and service delivery model.	**Establish governance arrangements and accountability mechanisms.**
Identify key stakeholders and clarify their roles and responsibilities.	**Identify the financing, reimbursement, procurement, contracting, and sustainability mechanisms needed to support implementation, including agreements with payers where relevant.Address legal, regulatory, ethical, and data-governance requirements.**
Define requirements for data infrastructure, interoperability, privacy, and secure data sharing.	**Adapt the programme to national and subnational contexts.**
Plan communication, training, and engagement strategies for professionals, patients, citizens, and families where relevant.	

Expected output: A programme implementation blueprint describing the operational model, governance arrangements, care pathway, stakeholder responsibilities, financing, legal framework and data governance.

STEP 4

Assess Implementation Readiness and Impact

Key policy question: Is the healthcare system ready to implement the programme, and what impact can be expected?

Successful implementation requires more than evidence and programme design. Policymakers should assess whether the healthcare system has the capacity, resources, infrastructure, workforce, data systems, and organisational conditions needed to support implementation and to manage its expected consequences. Implementation readiness and impact should be assessed following the logic of the PROPHET Framework [4], which integrates HTA and HIA and includes a monitoring phase to evaluate the effects of personalised prevention policies over time. This assessment should consider effectiveness and broader dimensions of clinical utility, including organisational feasibility, economic sustainability, patient and citizen acceptability, equity, ethical and societal implications, and long-term public health impact. This step should be informed by a review of the available literature, prioritising evidence relevant to the national or regional context where available. Where evidence is limited or context-specific estimates are required, decision-analytic modelling, budget-impact analysis, scenario analysis, and forecasting models should be considered. A multidisciplinary steering committee should guide the assessment from inception and support interpretation of findings. The information generated through this assessment should also support the development of an evidence-informed case for investment and the long-term sustainability of the proposed programme.

Recommended actions

Assess organisational feasibility and compatibility with existing pathways	**Assess workforce capacity, professional roles, and training needs**
Assess laboratory, digital, and technological infrastructure requirements	**Assess economic sustainability, budget impact, and opportunity costs**
Assess patient and citizen acceptability, awareness, health literacy, and potential uptake	**Assess equity implications, including access for underserved groups and potential for widening or reducing inequalities**
Assess stakeholder acceptability and engagement	**Assess ethical, legal, data-governance, and societal considerations**
Develop a forecasting or decision-analytic model, informed by real-world data where available, to estimate the potential health and economic impact of implementing the proposed programme compared with current prevention practice, including the likely consequences of not implementing the programme	**Identify implementation risks and mitigation strategies before scale-up**

Expected output: A readiness and impact report documenting the healthcare system's preparedness, expected health and economic impacts, implementation risks, equity implications and resource requirements.

STEP 5

Develop Recommendations and a Monitoring Framework

Key policy question: What actions should be taken, and how should implementation and impact be monitored over time?

The final step translates evidence and assessment findings into actionable recommendations. Policymakers should identify priority actions, define responsibilities, establish implementation timelines, and specify the conditions required for successful implementation or scale-up. Recommendations should distinguish between actions required before implementation, actions required during early implementation, and actions required for long-term sustainability. Monitoring should support continuous learning and enable programme adaptation as new evidence becomes available. Where possible, monitoring frameworks should include indicators covering programme inputs, processes, outputs, outcomes, equity, costs, and long-term impacts. Examples of monitoring indicators may include programme coverage, uptake of testing and preventive interventions, equity of access, public acceptance, health outcomes and resource utilisation. Monitoring should also include mechanisms for periodic reassessment of the evidence base, programme performance, and unintended consequences.

Recommended actions

Develop implementation recommendations based on evidence, feasibility, impact, and equity considerations

Define implementation priorities, responsibilities, timelines, and governance mechanisms

Identify measurable indicators across inputs, processes, outputs, outcomes, costs, and impacts

Include equity-sensitive indicators to monitor access, uptake, and outcomes across population subgroups

Establish monitoring, evaluation, and reporting mechanisms

Plan periodic reassessment as new evidence, technologies, costs, or policy priorities emerge

Use monitoring results to support continuous improvement, adaptation, de-implementation of ineffective components, or scale-up of successful components

Expected output: An implementation and monitoring plan including policy recommendations, implementation roadmap, monitoring indicators, evaluation strategy and mechanisms for programme review and adaptation.

BRCA1/2 Case Study: Steps 1 & 2

The table below illustrates how the implementation guidance was operationalised in a PROPHET Project case study on ***BRCA* cascade screening for breast and ovarian cancer prevention in Italy** [5].

Step	Key Policy Question	Example from the *BRCA1/2* Case Study [5]
Define the Prevention Need and Preventive Programme Scope	Why is this personalised prevention programme needed?	The public health need was identified in hereditary breast and ovarian cancer prevention, where access to preventive *BRCA1/2* testing and cascade screening varies across Italian regions. Regional diagnostic and therapeutic care pathways (PDTAs) were mapped to compare current practice with an ideal national scenario. The programme focused on preventive *BRCA1/2* testing in healthy high-risk individuals identified through cascade screening.
Gather and Assess Evidence	Is there sufficient evidence to support implementation?	Evidence was gathered through narrative literature reviews and consultation with a multidisciplinary Steering Committee (medical geneticist, oncologist, radiologist, surgeon, regional public health official, laboratory professional, patient organisation representative, and private-sector representative). The assessment covered effectiveness, safety, clinical guidelines, economic evidence, and Italian real-world evidence on acceptability, organisational feasibility, and implementation barriers and facilitators.

BRCA1/2 Case Study: Step 3

Step	Key Policy Question	Example from the *BRCA1/2* Case Study [5]
Define the Prevention Programme and Governance Model	How should the prevention programme be designed, organised, and adapted to the healthcare system?	Evidence was translated into a structured cascade screening programme for preventive *BRCA1/2* testing, adapted to the Italian healthcare context. The target population included healthy high-risk individuals identified through index patients with breast, ovarian, prostate, or pancreatic cancer meeting national guideline-based eligibility criteria. The pathway included *BRCA1/2* testing of eligible index cases, cascade testing of healthy relatives, and personalised preventive options for female carriers (risk-reducing surgery or active surveillance). Governance was formalised through the same multidisciplinary Steering Committee.

BRCA1/2 Case Study: Steps 4 & 5

Step	Key Policy Question	Example from the *BRCA1/2* Case Study [5]
Assess Implementation Readiness and Impact	Is the healthcare system ready to implement the programme?	A Health Impact Assessment was structured around four domains: population health and well-being, economic sustainability, patient acceptability and awareness, and organisational feasibility. A simulation model compared the current heterogeneous regional scenario with an ideal standardised national programme, combining a decision tree with a Markov model estimating long-term breast and ovarian cancer incidence, cancer-related deaths, and costs over 10, 20, and 30 years.
Develop Recommendations and a Monitoring Framework	What actions should be taken and how should progress be monitored?	Evidence from literature reviews, stakeholder consultation, and simulation modelling was synthesised into recommendations to improve *BRCA1/2* cascade screening implementation in Italy, validated through the multidisciplinary governance process. The study identified measurable indicators for future evaluation, including: eligible individuals, individuals tested, cascade screening uptake, uptake of preventive strategies, cancer cases and deaths avoided, total costs, and incremental cost per event avoided.

References

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