PROPHET
a PeRsOnalized Prevention roadmap for the future HEalThcare

PROPHET FOR ALL - FACTSHEET#4

PROPHET FRAMEWORK

WHY WAS A SPECIAL FRAMEWORK CREATED?

The PROPHET Project created a special framework to help use personalized prevention in healthcare.

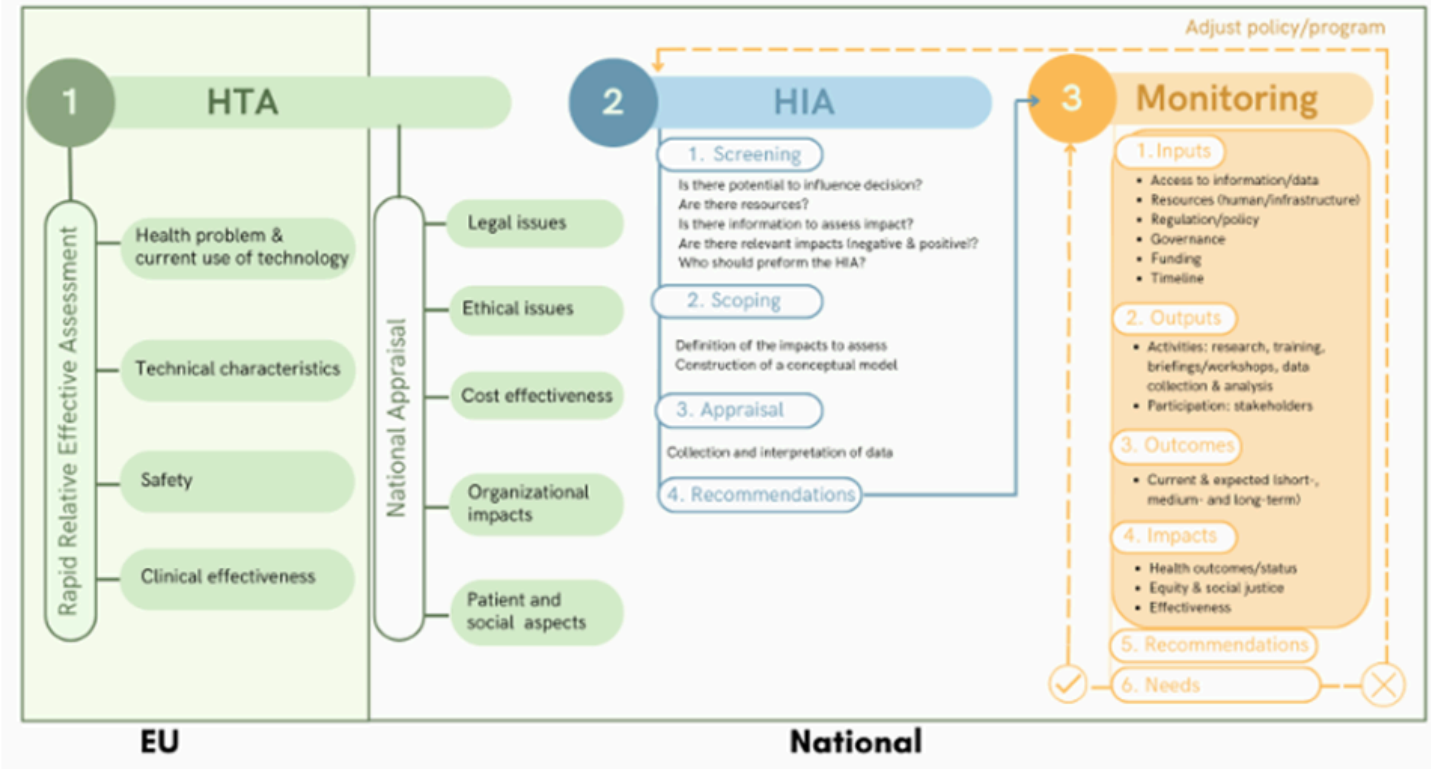
Although interest in personalized prevention is growing fast, existing evaluation frameworks (based on, for example, ACCE which assesses how genetic tests work and their effects using factors like '**A**nalytic validity', '**C**linical validity', '**C**linical utility', and **'E**thical, legal, and social consequences') are strong in evaluating individual tests or technologies, but are not designed to assess the broader impact on health or the healthcare system. For instance, they may not include the views of important stakeholders, such as patients, or evaluate if everybody has access to testing or treatment.

Erica Pitini, Medical Doctor at Sapienza University of Rome, and fellow researchers found 30 different frameworks to assess genetic and genomic tests (for more information on genetic and genomic testing, check Factsheet 1 on Personalized Prevention Concepts and Levels). They suggested using the European Network for Health Technology Assessment (EUnetHTA) as a standard.

These frameworks, however, do not look at how policies affect health or involve important people in policy decision-making.

METHODOLOGY

The PROPHET Framework has three parts: Health Technology Assessment (HTA), Health Impact Assessment (HIA), and Monitoring. This structure guarantees that personalized prevention policies are effective, fair and work well in the long-term in healthcare.



Health Technology Assessment (HTA)

Health Technology Assessments (HTA) check if treatment tools like medicines or medical devices (which are considered 'technologies' here) are effective and safe. Apart from safety and effectiveness, they look at many things, including if it is worth the money, how it affects organisations, and what the ethical, legal and social effects are.

Many experts support the idea that HTAs should be used to assess genetic tests, especially for personalized prevention. Researchers have found that HTA is the most often used framework to assess genetic and genomic tests in personalized prevention. This framework follows the new European Union law on HTA.

Health Impact Assessment (HIA)

While Health *Technology* Assessments look at many things, they do not measure the wider impact of policies on the population. This is where Health *Impact* Assessments (HIA) come in: they show how personalized prevention policies affect, for example, fairness of healthcare among different population groups and how acceptable these groups find the policies.

HIA focuses on an all-round view of health, fairness, voices from different communities and interest groups, ethical use of proof, and long-term effects - usually *before* policies are put into practice (but they can also be done *afterwards*).

To make our work in PROPHET meaningful for the future, we have included both HTA and HIAs in the PROPHET Framework.

HIA has five important principles:

- **Comprehensive approach to healthcare:** Looking at all aspects of health and care
- **Sustainability:** Sustainability for the future
- **Participation:** Participation of the public
- **Ethical use of evidence:** Ethical use of proof
- **Equity & equality**: Fairness

The PROPHET Framework divides a HIA into five steps:

- **Screening:** Decide if HIA is needed.
- **Scoping:** Identify important issues and priorities and make a plan. A group of experts should be created to make sure that views and needs from diverse populations are included.

- **Assessment:** Analyse health effects using data and information.
- **Reporting:** Summarize findings and recommendations in a report.
- **Monitoring and Evaluation:** Identify what needs ongoing oversight and how to track it.

This framework can be changed to fit the needs in different countries. It can also be applied during different stages of policymaking, for instance in the design phase or after a policy has been applied in the real world.

The use of HIAs specifically for personalized prevention is completely new and has not been done before.

Monitoring

The PROPHET Framework includes monitoring to make sure that personalized prevention policies stay effective and flexible over time. It evaluates results, resources, changes, and impacts in society.

The PROPHET Framework checks:

- **Outputs:** Immediate results of a policy like how many people got a test for personalized prevention or how many doctors got trained in personalized prevention topics.
- **Inputs:** Resources and data needed for monitoring.
- **Outcomes:** Expected short-, medium-, and long-term effects and benefits like more awareness.
- **Impacts:** Broad effects on society like better quality of life and healthcare systems that work well.

Indicators, which measure success, should be set before policies are put into practice. This helps track progress and fix problems early on. Relevant communities and interest groups should work together to define shared priorities and goals when setting success indicators.

Key Strengths

- The Framework **combines different aspects** - medical, social, organisational, and ethical.
- It **involves key communities and interest groups** like doctors, patients, and policy decision-makers.
- It **analyses policies both before and after** they are put in place.
- It **can be adapted** for use in different countries and regions.

The PROPHET Framework was tested in Portugal, Italy, and Finland by looking at how doctors use genetic tests to make cancer treatment safer. One medical test for prevention, called *DPYD,* checks if a person's body can safely process certain medications used for colorectal cancer. In Italy, the Framework was tested through two examples: One looked at so-called *BRCA1* and *BRCA2* tests, which help identify people at higher risk of breast and ovarian cancer. Another looked at a "pharmacogenetic passport" — a personal record of important genetic information that helps doctors choose the right medicines and doses for each person.

Why it matters for policy ?

The PROPHET Framework gives policy decision-makers and healthcare leaders a practical tool to evaluate new personalized prevention programmes in Europe. It helps make sure these programmes are built on solid science, respect ethical standards, are affordable, and can be smoothly integrated into healthcare systems in a lasting way.

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More about the project on our website: https://prophetproject.eu/
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