

# Precision Medicine

DATA SCIENCE - MULTIOMICS - BIOMARKERS - TARGETED THERAPY

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# Socio-Political Costs of Implementing Precision Medicine

The benefits of precision medicine, the challenges associated with it and the impact of its use on healthcare costs, testing and monitoring, and the inequality in access to healthcare services.

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## key points

- Precision medicine personalises disease treatment and preventive care by taking into account individual characteristics.
- Precision medicine will improve treatment outcomes, but its high costs and uncertainties about cost-saving measures pose challenges.
- Precision medicine raises concerns about healthcare costs, over-testing, and unequal access to services, challenging the principle of equal healthcare access.
- Precision medicine shows great potential, but important steps remain needed to ensure development and implementation are realised in a clinically useful and socially robust way.

Precision medicine holds great promise in revolutionising healthcare by leveraging new technologies in genomics and beyond to develop more precise biomedical models for understanding, treating, and predicting human diseases. This visionary approach aims to personalise disease treatment and preventive care by taking into account individual characteristics such as genetic variation, environmental factors, and lifestyle. Unlike traditional evidence-based medicine, which relies on statistical evidence from large populations, precision medicine seeks to improve treatment effectiveness by predicting individual responses. However, while precision medicine offers potential benefits such as improved treatment outcomes and better management of rare diseases, it also presents challenges. Concerns arise regarding its impact on healthcare costs, the risk of over-testing and over-monitoring, and the potential for increased inequality in access to healthcare services. Additionally, the principle of solidarity and equal access to healthcare services may be challenged by the implementation of precision medicine, highlighting the

need for careful consideration and inclusive practices in its development and deployment.

## ***How is precision medicine expected to revolutionise healthcare?***

Precision medicine, often called personalised medicine in the European context, can be considered a vision to utilise new technologies in genomics and beyond to construct more precise and detailed biomedical models for comprehending, addressing, and forecasting human diseases. The goal is to tailor disease treatment and preventive care to the specific characteristics of each individual by considering factors such as genetic variation and other molecular markers, environmental factors, and lifestyle. Traditional evidence-based medicine has emphasised statistical evidence based on large populations, but being right on average does not always predict what is best for the individual. By improving the ability to predict treatment response at the individual level, it is hoped that medicine can improve the effectiveness of treatments and reduce

adverse effects experienced with current treatment forms. Precision medicine also holds the potential to improve the treatment of rare diseases that are highly influenced by specific molecular traits. Another aspect of precision medicine that holds many promises is individualised risk profiling, which is hoped to enable healthcare professionals to improve disease prevention and early intervention. It is envisioned that precision medicine will identify individuals at high risk for certain health conditions and that returning such risk information to them will motivate their commitment to adopt preventive measures. The underlying assumption is that informing individuals about their genetic risk motivates them to change their lifestyle more than general health recommendations. It is too early to tell which of these hopes can be realised, but important discussions have already started on which attainable priorities should be investigated first and what it takes to realise these promises from what we already know about the challenges.

The philosophy of science is a crucial asset to approach questions about whether and how medical uncertainty can be overcome with new scientific developments and also to understand challenges beyond science and technology. Realising the aims of precision medicine also means facing the social complexity of specific healthcare structures where socio-economic issues and data biases can greatly impact who will benefit from the new developments.

for different stakeholders. Precision medicine requires substantial investments in large data infrastructures, omics technologies, workforce training, clinical trials, and development and price setting of targeted therapies. Rather than blockbuster drugs developed for large populations, the precision approach requires pharmaceutical companies to invest in smaller niche markets of patients with specific molecular variants. This means that the increased efficacy for individual patients often comes with a much higher price tag. As a result, precision medicine treatments are often very expensive and may significantly increase the spending of public healthcare systems and health insurance premiums. It is, therefore, important not to equate higher effectiveness with overall higher cost-efficiency. Whether precision medicine will decrease or increase healthcare costs ultimately depends on how drug pricing models will develop at the regulatory level. Uncertainties also exist in the context of preventive precision medicine. If disease prevention can be improved for those at the highest risk, it is clear that cost savings would occur due to a reduction of downstream treatments of developed diseases, making investments in data collection and analysis worthwhile. However, there are substantial uncertainties about whether data-intensive risk profiling will succeed in identifying and helping those at the highest risk while avoiding overmedicalisation of others due to over-testing. These problems can only be addressed by governance bodies providing a robust pricing and reimbursement framework and healthcare

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### ***Is the higher effectiveness of precision medicine a reliable indicator of future cost-efficiency?***

Policy reports often give the impression that precision medicine will inevitably lead to reduced healthcare costs. If successful, precision medicine can indeed reduce the administration of ineffective or unnecessary interventions. However, this approach also requires large-scale investments that may have uneven returns

research providing benefit-risk insights on generalised risk profiling.

### ***Can the generalisation of individualised risk profiling lead to over-testing and over-monitoring?***

Data-intensive risk profiling tends to not only pick out high-risk individuals who will benefit from preventive



interventions but also to redefine many as being “at risk”. As pilot projects in precision medicine show, big data screening identifies some risk factors among all individuals (Vogt et al. 2019). However, that does not mean that we all would benefit from having that information and taking preventive actions, especially if the latter involves medical treatments. We all have risk factors for developing various diseases, but many abnormalities will not develop into significant, symptomatic health problems. For example, not all individuals with hypertension will experience cardiovascular problems later in life, and not all people with cellular changes identified as cancer will develop symptoms or die from it. The problem of overdiagnosis is

increasing number of risk factors for common diseases in the general population, both in greater detail and via continuous monitoring, more anomalies are often identified. This will often lead to an increase in follow-up testing and the need for healthcare counselling, thus increasing healthcare utilisation and cost impact, often with unclear benefits. Because individuals can be harmed by “too much medicine”, it is crucial to establish more firm evidence for the benefits of data-intensive risk profiling instead of assuming that risk information will straightforwardly lead to better health outcomes. This is particularly important because risk information can be experienced as both empowering and disempowering, depending on the context of the individual receiving it.

## Precision information is only beneficial if it gives the individual access to better healthcare preventative and treatment services

the risk of unnecessarily turning healthy individuals into patients with diagnoses or “at-risk individuals”. Precision Medicine efficiency in this context revolves around the difficult balance of estimating how many individuals we are willing to overdiagnose per each successful case of prevention. Healthcare professionals refer to this as “the number needed to treat” to have a positive impact on one person, i.e., how many we – statistically – have to unnecessarily diagnose to prevent one death or disease case (e.g., stroke). The problem is, therefore, that good intentions to catch more diseases at earlier stages can come with the drawback of overmedicalising and overtreating patients who will not benefit from the interventions.

Overdiagnosis is a persistent problem in the history of medicine, and it is a very interesting question whether precision medicine can help reduce overdiagnosis or whether the problem may be aggravated through over-testing. This question may not have a simple answer. For hereditary diseases with strong genetic causes, precision medicine can provide more accurate risk predictions (e.g., ovarian cancer), which can help stratify which populations would benefit from earlier intervention. However, whenever we start measuring an

### ***What are the concerns regarding increased inequality in access to healthcare due to precision medicine?***

Generally speaking, precision information is only beneficial if it gives the individual access to better healthcare preventative and treatment services, such as more effective precision treatments or targeted interventions for disease prevention. However, not everyone has equal access to healthcare services or options for complying with the imperative of health optimisation. This is particularly the case in countries like the US, where access to healthcare is largely based on private health insurance plans and where expensive targeted treatments or preventive tests may increase health disparities. Healthcare systems with universal coverage, such as many EU countries, can mitigate this risk by ensuring that individuals have the same level of access, regardless of their financial status. However, the increasing prices of precision treatments can also cause problems in public healthcare systems, as they make it increasingly important to prioritise treatment access to those that benefit the most. In some cases, this can result in only some patients with a specific disease being offered a new treatment because their relative predicted

gain is higher. Thus, with limited price regulation, existing systems can also be put under pressure to increase treatment costs (Green et al. 2023; Green et al. 2024).

Moreover, it is crucial to ask whether the suggested strategies for individualised disease prevention cater to the relevant patient group. There are currently several important initiatives to increase inclusivity in research by involving underserved populations in data donation. This is crucial for mitigating the problem of data biases that negatively impact the accuracy of diagnostic tests and evidence of treatments for some population groups. But addressing the problem of unrepresentative data is insufficient, as it is deeply tied to issues of trust and reciprocal gains for data donors (Sabatello et al. 2018). We also have to ask who will have access to the products of precision medicine, the technologies and treatments that were developed from all the data and work that is currently being done. Thus, developers and policymakers must work together with health professionals to ensure that health technologies are developed in a way that also improves healthcare access for underserved populations.

are genetically disposed to develop cardiac problems, earlier interventions might save you from downstream health problems and give you more equal opportunities for improved health outcomes. But the crucial question is how to ensure that these technologies can target the right audience and in the right way (Prainsack 2017). Precision medicine must help those at the highest risk to have a real impact. It is well known in public health research that high-risk individuals often have complex problems that are not easily solved by giving them more information about their disease risk. It is not empowering to know your individual risk if you do not have access to genetic counselling and other preventive healthcare services, or if you do not have the resources to implement lifestyle challenges. There is a risk that precision prevention increases the responsibilities of individuals while invisibilising factors that the individual has no or limited control over. Therefore, we must take sufficient time to understand the problem we want to solve before expecting too much of the potential of the new tools. This does not mean that precision medicine does not have the potential to revolutionise healthcare, but turning this promise into measurable action requires

## Developers and policymakers must work together with health professionals to ensure that health technologies are developed in a way that improves healthcare access for underserved populations

### ***Can you provide an example of how precision medicine challenges the principle of solidarity and equal access to healthcare services?***

Solidarity in healthcare means a collective share of risks and costs despite the fact that each person has different risks and capacities for contributing. It is well known that some are at higher risk for developing diseases, either because they have specific genetic risk factors or because of the way they live their lives. But a solidaristic system should even out such differences by collectively sharing healthcare resources. From one perspective, precision medicine may have an equalising effect because some risks can be identified and intervened on before they develop into a health problem. If you

thinking carefully about how we can implement it in a socially robust and economically sustainable way.

A related challenge has to do with opportunity costs and how we prioritise healthcare resources. In our research project, called [PROMISE](#), we interviewed Danish and American primary care doctors (GPs), who often face the difficult challenge of evaluating whether or not to act on their patients' worries. In addition to experienced symptoms, worries can come from the results of online genetic tests or anomalies detected by wearables such as smart watches (e.g., irregular heart rhythm). Acting on all detected anomalies is not advisable as it can lead to overdiagnosis and overtreatment. It can also lead to a waste of healthcare





resources and opportunity costs, as there will be less time for other patients and other tasks in primary care. The current marketing of health technologies, such as wearables and online testing, speaks primarily to consumers with the resources to invest - financially and through lifestyle changes - in health optimisation. They are often also inaccessible to certain marginalised populations, such as blind/low vision people, who would have wanted to make behavioural and lifestyle changes. While it is great if technologies can further support a healthy lifestyle, increasing testing and monitoring often give rise to new worries even among healthy individuals. This is partly a development also caused by the opportunities of various health tech companies capitalising on the hope and hype of precision medicine. Companies behind wellness technologies are not required to document the clinical benefits of their devices as long as they are not marketed as diagnostic devices, but they often encourage patients to consult with their physicians if they have concerns about their results. This could cause the increased burden of counselling demands on GPs or other health professions, a demand they are unprepared for and do not have sufficient resources to meet. Therefore, we need awareness of the risk of “medical Matthew effects”, where healthcare resources are shifted further towards those already well.

The Matthew effect, also known as the Matthew principle, refers to the tendency for individuals to accumulate social or economic success based on their initial level of popularity, friends, and wealth. In other words, those who already have more will get more. Coined by sociologists Robert K. Merton and Harriet Zuckerman in 1968, this phenomenon can largely be attributed to preferential attachment. This means that attention, wealth, or credit is distributed among individuals based on their existing level of resources.

Consequently, it becomes increasingly challenging for individuals with lower rankings to increase their resources over time, as they have fewer to start with. Conversely, those with higher rankings find it easier to maintain their advantage due to their larger initial resources.

Mitigating these problems is not easy. Important steps could include making more transparency about which applications are backed by evidence of health benefits and are properly validated, as the current market and product promises are difficult to navigate for consumers and health professionals alike. Moreover, for evidence-backed applications, there is a need for proper guidelines and procedures to implement these in healthcare systems so that more patients can benefit, regardless of their financial status. Finally, I would highlight the importance of including health professionals in the development phase of new technologies and policymaking. Policy reports that initiate large-scale investments are often written by consultant companies with limited insight into what is most needed and what is feasible in practice. As a result, we may fail to address the most pressing clinical problems or end up with unrealistic expectations of precision medicine. There is no doubt that precision medicine holds great potential, but important steps remain needed to ensure that the development and implementation are realised in a clinically useful and socially robust way.

### Conflict of Interest

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