

Ask Not What Personalized Medicine Can Do for You – Ask What You Can Do for Personalized Medicine

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Key Words

Personalized medicine · Ethics and society · Citizen behavior · Genetics

Abstract

Background: Personalized medicine (PM) aims to offer tailored health care to individuals on the basis of their genetic profile. This paper explores the types of behaviors and practices that citizens are expected to adopt under PM, examines whether such expectations are realistic, and proposes strategies that could support citizens in the adoption of these behaviors. **Methods:** Recent reports from national and international medical organizations and funders of PM are reviewed to investigate the types of behaviors and practices that citizens are expected to adopt under PM. These behaviors are examined in light of the current knowledge regarding citizen involvement in health care. **Results:** Under PM, citizens are expected to be much more educated, proactive, and engaged in their health care than under conventional medical models. Actualizing such behaviors and practices may, however, be difficult or even unattainable for some groups of citizens. **Conclusions:** Educating citizens in PM, as proposed in the reports, is important but may not suffice for the adoption of new behaviors and practices by a majority of citizens. Approaches taking into consideration the heterogeneity of

backgrounds, abilities, and resources among citizens are needed and include modifying reimbursement and pricing mechanisms, diversifying research, and developing low-cost PM programs.

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Introduction

Since the mapping of the human genome in 2003, enormous progress has been made in understanding molecular and genetic pathways underpinning human health and disease. The acquisition of new knowledge coupled with rapid developments within genetic sequencing and testing as well as plummeting costs of new technologies continually improve our potential to provide better health care. Genetic and genomic information can be used to unveil disease predisposition and onset in individuals much earlier and more accurately than previously possible, and an increasing number of therapies will target disease-specific molecules and biological pathways, rather than simply treating the symptoms of diseases [1]. The traditional one-size-fits-all approach to disease prevention, diagnosis, and treatment, which has proved to be inefficient, expensive, and sometimes even hazardous, is expected to be progressively replaced by a more individu-

alized and tailor-made approach. This ‘personalization’ of health care has captured worldwide attention, with various strategies under development to facilitate its realization. For instance, precision medicine aims to create a new taxonomy of diseases based on molecular biology with the objective to improve disease classification and inform health-care treatment and decisions [2]. Stratified medicine aims to group patients based on their genetic risk of disease or response to therapy with the objective to offer treatment that specifically targets those groups [3]. Personalized medicine (PM) aims to use information about an individual’s genotype to guide decisions regarding the prevention, diagnosis, and treatment of diseases [4]. These strategies work towards the common objective to provide ‘the right patient with the right drug at the right dose at the right time’ [5].

The production, integration, and use of genetic and genomic information in health care requires significant changes in the way such care is organized and provided to individuals. Recent reports discussing precision medicine [2], stratified medicine [3], and PM [6–9] have highlighted the roles and actions that relevant stakeholders of PM should undertake to enable a smooth integration of genetic and genomic information into health care and, thus, facilitate the transition to a tailor-made approach to medicine, which we hereafter refer to as personalized medicine (PM). These reports (published by national and international medical organizations and funders) provide practical recommendations to researchers, health-care professionals, policy makers, health authorities, and pharmaceutical companies. For instance, researchers are encouraged to develop data management infrastructures to handle the growing amount of data produced from genetic sequencing, health-care suppliers are advised to reorganize their clinical services to enable the integration of genetic and molecular information in the electronic health records of patients, and pharmaceutical companies are encouraged to identify and qualify a range of new biomarkers that predict clinical response [9]. However, the successful integration of genetic and genomic information into health care also depends upon the actions of another central group of stakeholders, namely citizens. While many of the reports emphasize the importance of citizen engagement in PM and propose strategies to educate and engage citizens regarding new medical developments, they do not systematically provide recommendations for what citizens could do to enhance the realization of PM but rather describe the behaviors and actions that are important for individuals to adopt. In this paper, we scrutinize the content of these reports to identify the spe-

cific behaviors and practices that are targeted, examine obstacles that could prohibit many citizens to adopt these behaviors, and propose strategies that may facilitate such adoption.

Methods

In October 2013, we conducted an internet search using Google and the following search terms: [‘personalized medicine’] and/or [personalised medicine] and/or [‘stratified medicine’] and/or [‘precision medicine’] combined with [report] and [pdf] to identify publicly available reports discussing the realization of PM. Reports from national and international medical organizations and funders published between January 2008 and October 2013, written in English and providing recommendations for the adoption of PM, were selected.

The reports were reviewed using a qualitative content analysis method [10] according to the following steps. First, the content in the reports that describes behaviors and/or practices of citizens and/or patients was identified, extracted, and compiled into a list of verbatim texts. Next, the substantive content of these texts was examined in order to code and categorize it according to the type of behavior and/or practice it describes. Then, the categories were further examined to identify overarching themes into which the specific types of behaviors and practices could be grouped. Each category of behavior and/or practice was then analyzed in light of current knowledge regarding citizen and/or patient involvement in health care to determine the extent to which citizens and/or patients may realistically adopt, wholly or partly, such behaviors and practices. Hurdles that may impede such adoption were identified and discussed, and potential strategies to overcome these challenges were proposed.

Results

Eighteen publicly available reports were identified (table 1) [2, 3, 5–9, 11–21]. Importantly, these reports do not make a clear distinction regarding when expectations apply to citizens in general or to patients in particular. All the reports use the term ‘patient’ at least once to refer to the end users of PM. Eight reports either use the term ‘citizen’ or a combination of ‘citizen’ and ‘patient’. For instance, some reports emphasize the importance of patients sharing their data for research purposes [2, 6, 14], while others refer to citizens when describing this type of activity [7, 21]. Similarly, some reports mention that patients will be involved in the decision-making processes regarding treatment [2, 6, 9, 21], while other reports state that patients and citizens will be involved [7, 21]. This may reflect that PM, due to its proactive nature, will progressively blur the patient/non-patient dichotomy that has characterized traditional health-care models. For the

Table 1. PM reports

Report title [Ref]	Publisher	Year of publication
Priorities for Personalized Medicine [20]	The President's Council of Advisors on Science and Technology	2008
Public Health in an Era of Genome-Based and Personalised Medicine [12]	PHG Foundation	2010
Medical Profiling and Online Medicine: The Ethics of 'Personalised Health Care' in a Consumer Age [13]	Nuffield Council on Bioethics	2010
Personalised Medicine: Opportunities and Challenges for European Health Care [19]	European Commission Health Research Directorate	2010
Toward Precision Medicine: Building a Knowledge Network of Biomedical Research and a New Taxonomy of Disease [2]	National Research Council of the National Academies	2011
The Case for Personalised Medicine [6]	Personalized Medicine Coalition	2011
Signature Event Report: Mapping a Way Through the Double Helix [8]	Cancer Quality Council of Ontario	2011
Next Steps in the Sequence [14]	PHG Foundation	2011
Advancing Access to Personalized Medicine: A Comparative Assessment of European Reimbursement Systems [15]	Personalized Medicine Coalition	2011
Addressing Race and Genetics. Health Disparities in the Age of Personalized Medicine [17]	Science Progress	2011
European Perspectives in Personalised Medicine. Conference report [18]	European Commission	2011
Personalised Medicine: Status Quo and Challenges [9]	The European Association for Bioindustries	2012
Privacy and Progress in Whole Genome Sequencing [16]	Presidential Commission for the Study of Bioethical Issues	2012
ESF Forward Look: Personalised Medicine for the European Citizen [7]	European Science Foundation	2012
Realising the Potential of Stratified Medicine [3]	The Academy of Medical Sciences	2013
Paving the Way for Personalized Medicine [5]	U.S. Food and Drug Administration	2013
Use of '-omics' Technologies in the Development of Personalised Medicine [11]	European Commission	2013
Innovation and Patient Access to Personalised Medicine [21]	European Alliance for Personalised Medicine	2013

purpose of our analysis, we use the term 'citizen' when referring to citizens and patients; many of the behaviors and practices described in the reports do not require that the end users of PM are patients when they endorse the expected behaviors and practices.

Our review of the reports reveals that citizens are expected to adopt a range of new behaviors and practices in relation to their health care. These are grouped into three overarching themes as described below and summarized in table 2.

(1) Citizens Are Expected to Actively Engage in Their Health Care

Citizens are expected to increasingly participate in the decision-making process regarding prevention, diagnosis, and treatment [2, 6, 7, 9, 13, 14, 21]. For instance, they may discuss information about their individual genetic risk predisposition with their health-care provider and contribute to the design of tailor-made prevention strategies to reduce their risk of becoming ill [7, 13, 14, 21]. One report mentions that they may also discuss the choice of genetic tests and therapeutic options [9]. To ensure that prevention strategies are efficient, citizens may regularly enrich and update their personal health information, in-

cluding genetic risk predisposition information, through the use of technologies such as web-based interfaces, self-tracking systems, personal health records, smart phone applications, and biofeedback systems [6, 7, 9, 13, 14, 21]. They may decide to voluntarily share information about their genetic predisposition with their relatives in order to increase the possibility that their relatives also take necessary measures to prevent disease onset [7, 16]. Some reports foresee that groups of citizens will purchase services from direct-to-consumer genetic testing companies and seek help from their public health-care services to interpret the results of genetic tests [13–14]. Finally, one report assumes that citizens will endorse targeted treatment strategies and understand that access to conventional treatment may be restricted when no positive effect for the individual's specific genetic profile is documented [18].

(2) Citizens Are Expected to Actively Contribute to the Research Endeavor

Citizens are expected to contribute many different types of data about themselves such as '-omics' data and imaging, clinical, environmental, behavioral, and socio-economic data [2, 6, 7, 16, 17, 21]. To do so, citizens may

Table 2. Behaviors and practices expected of citizens as described in the reports

Citizens engage in their own health care

- ✓ Participate in the decision-making process regarding prevention, diagnosis, and treatment [2, 5–7, 9, 13, 14, 21]
- ✓ Use new technology to manage their health information (including genetic risk predisposition information) [6, 7, 9, 13, 14, 21]
- ✓ Share their genetic risk predisposition information with family members [7, 16]
- ✓ Purchase genetic services and health-care products online [13, 14]
- ✓ Endorse targeted treatment strategies based on their genetic profile [18]

Citizens contribute to the research endeavor

- ✓ Consent to research uses of their biological samples and health-related data [2, 6, 7, 16, 17, 21]
- ✓ Participate in research projects [2, 6, 7, 16, 17, 21]
- ✓ Join citizen-led and health social networks data-sharing initiatives [2, 5, 7]
- ✓ Contribute to the establishment of patient registries [2, 13, 16, 22–24]
- ✓ Report health data to public health authorities [7, 12]
- ✓ Communicate with researchers about patient values [11, 18]

Citizens engage in the design of PM

- ✓ Participate in public consultations and debates on PM [3, 7, 13, 14, 16, 18, 19]
- ✓ Collaborate with health professionals and drug manufacturers through involvement in patient advocacy groups, advisory boards and health technology assessment bodies [5, 7, 8, 13, 16, 18–21]

consent to participation in research projects, for instance population health surveys or biobank projects, or agree that their biological samples and data collected through clinical and research settings be used for future research [2, 6, 7, 16, 17, 21]. Some reports mention that citizens may also take the initiative to share their personal health data through citizen-led initiatives and health social networks [2, 5, 7], as already practiced within some communities of patients and health-care users [22–24], and may contribute to the establishment of patient registries that are made available to the research community [2, 13, 16, 22–24]. One report emphasizes that contributions from citizens with rare genotypes and phenotypes are particularly useful [2]. Additionally, as stated in two reports, citizens may take the initiative to report health data to public health authorities in case of potential infection or contamination in the community [7, 13]. Finally, two reports mention that citizens may communicate with researchers about patient values, informing them of their expectations regarding the translation of research discoveries into clinical practice [11, 18].

(3) Citizens Are Expected to Actively Engage in the Design of PM

Citizens are expected to participate in the design of PM by discussing its development and contributing to setting up priorities. This may be achieved through participation in public debates and deliberations, for instance to discuss the use of new technologies in health care or policies for reimbursement of targeted treatments [3, 7, 13, 14, 16,

18, 19]. Some reports also describe expectations that citizens may participate in corporations and advisory bodies and work in close cooperation with public health authorities and drug manufacturers [5, 7, 8, 18, 21], for instance to advocate for the development of targeted drugs [5, 13] or participate in the choice and validation of new diagnostics and therapeutics [5]. Citizens may also be involved in the design and development of educational tools to inform diverse publics about genetics and PM [8]. Examples of educational projects in which citizens play an active role are provided in some reports, such as the National Institute for Health and Care Excellence (NICE) project in the UK [3]. Patient advocacy groups may be central drivers of citizen engagement [2, 21], and two reports mention that strong public engagement from ethnic groups and minorities, which traditionally have been underrepresented, is particularly important [7, 21].

Discussion

The data we reviewed reveal that citizens are expected to adopt a whole range of behaviors and practices considered to be critical for the realization of PM. Citizens are seen as proactive, engaged, educated, responsible, and contributing partners of PM. These knowledgeable, rational, and resourceful citizens not only engage in healthful behaviors by following early prevention strategies, participating in the decision-making process regarding their medical follow-up, and sharing their genetic information

with relatives and public health authorities, they also actively contribute to the development of PM by, for instance, providing access to their health data, taking the initiative to produce more data to feed both their own health records and research databases, and participating in public debates to discuss the design and development of PM. Additionally, they actively seek to access more comprehensive information about their health by using the services of direct-to-consumer genetic testing companies and buying technological devices and applications to manage personal health information in real time.

These new behaviors and practices represent a radical change in the role of citizens compared with the way citizens traditionally have been involved in their health care. This change echoes recent developments which encourage a move away from the rather paternalistic model, under which citizens are primarily passive recipients of health care, to a participatory model of health care under which citizens are responsible drivers of their health, contributors to the health-care system, and partners sharing decisions with health-care providers [25].

Although PM offers the opportunity for citizens to be more proactive and engaged in their own health care, there are several challenges towards the realization of such citizen engagement as described below.

Challenges towards the Realization of Citizen Engagement in PM

Health Literacy

Citizens must have sufficient health literacy to be able to actively engage in their health care. However, such literacy is not widespread in the population. As an illustration, a recent comparative study on health literacy in 8 European Union member states reports that nearly every second respondent has limited health literacy and that a majority of respondents find it easier to follow instructions from their health-care provider than to make their own decisions or judgments [26]. Empirical data show that individuals who receive information about their personal genetic risk predisposition often fail to interpret it, either overestimating or minimizing it [27], and may prefer more intuitive, experience-based types of evidence [28]. The same individuals often do not change their lifestyle [29], either because they do not understand the information provided, do not want to change their life style, cannot afford to change it, or because genetic counseling protocols fail to raise some groups' awareness of risk predisposition [30]. Educational interventions developed to improve risk perception do not seem to influence the way people understand their genetic risk [31]. The lack of

health literacy is worrisome knowing that citizens are not always accompanied by professionals to interpret their genetic information. For instance, citizens who decide to order genetic tests through commercial companies may not be able to assess the validity and clinical utility of these tests and may make misguided health-related decisions. The recent US Food and Drug Administration's [32] ban on 23andme personal genetic tests demonstrates that information produced through commercial genetic tests may not be reliable.

Technology Literacy

Citizens must also have sufficient technology literacy to be able to fully benefit from PM. However, groups of citizens, for instance the elderly, who are the heaviest users of health-care services, often do not have the necessary skills and abilities to use new technologies such as web-based health platforms or self-tracking devices, or are reluctant to use them [13]. Other groups, although more interested in technology, may not have access to it if the e-infrastructures are missing or if the technology is too expensive.

Lack of Economic Resources

Interfacing regularly with health-care provider, purchasing genetic tests, and endorsing the prescription of targeted therapies require economic resources that some groups may not have. This may be particularly true in countries where health care is funded through a variety of private insurers that can decide to restrict access to genetic tests and targeted therapies if considered too expensive or 'investigational' [21, 33]. Even in countries where health care is publicly funded, public payers may decide not to cover additional costs of targeted drugs and require that the patients cover such costs themselves. To illustrate our point, we refer to ongoing plans in the UK to modify pricing systems with the objective to increase prices for targeted drugs [34] and allow drug producers to achieve sufficient return on investment [35]. For the time being, it is still unclear who will cover potential additional costs related to the use of targeted drugs.

Other Barriers to Contribution

Citizen contribution to the research endeavor, for instance through participation in research trials, may be impeded by traditional research practices. For instance, ethnic groups and minorities are often excluded from research and deprived of the opportunity to contribute and benefit from medical progress [17]. As an illustration, 9 out of 10 genome-wide association studies are reported to

be conducted on populations of European descent, unveiled gene-disease correlations therefore primarily applying to Caucasians [17]. Paradoxically, groups of population who are given the opportunity to contribute to the scientific endeavor may not be willing to do so. For instance, 44% of Europeans are not willing to provide personal information to a biobank, and 67% prefer being asked to consent to every new piece of research instead of consenting only once to a broad range of research uses [36].

Finally, broad citizen engagement in the public debate may be difficult to realize in practice. Current initiatives to engage a variety of citizen groups – other than the white and educated – in the design of research and health care often fail to reach groups which are usually underrepresented. As an illustration, a recent review of citizens' juries – a frequently used tool for engaging citizens in health policy decision-making – demonstrates that even when the organizers intend to recruit juries that are representative of the community, such juries primarily gather the most privileged groups of populations and fail to engage less advantaged groups [37].

Numerous initiatives are currently being developed which may make it possible for groups of citizens to adopt the new behaviors and practices that are needed for the realization of PM. For instance, patient-activated social networks such as the 'quantified self' [38] network offer individuals the opportunity to use simple technological devices to take their own health measurements [39], disease-oriented social networks such as 'Patients like me' [23] offer patients the opportunity to share experiences and even launch research projects [39], and participant-centric initiatives in biomedical research enable research participants to actively engage in the research process [40]. More and more citizens are taking the initiative to collect and gather medical information through the use of web-based technologies and participation in e-patient networks [22–24]. However, a general concern is that the early adopters of PM may primarily be citizens who are resourceful, highly educated, and socioeconomically advantaged. Adopting new behaviors and practices may be much more challenging for those who have lower levels of education and fewer socioeconomic resources. Some of the reports we have reviewed acknowledge this challenge but propose few solutions to address it. Instead, the focus is put on the importance of educating citizens in PM [2, 3, 7, 8, 13, 14, 16, 20, 21]. Citizen education, for instance, encompasses introducing genetics and genomics in the educational program of students, developing web-sites and television channels to inform citizens about ge-

netics and the use of genetic tests, and organizing public forums and debates. These strategies are of great importance but may not suffice to address the socioeconomic, cultural, and generational challenges we have described.

In recognition of these challenges, we review below recently proposed strategies which may enable larger groups of citizens to participate in PM. At first glance, some of these strategies may seem too expensive and resource-demanding to implement. However, the current resources of health-care systems are allocated inefficiently [41–43]. If such resources can be used in a more efficient and coherent manner, implementing the strategies we describe may not be unrealistic or insurmountable.

Reach Out to Larger Groups of Population

Alliances may be developed with local media, community representatives, and advocacy groups [44] to reach out to groups that usually are underrepresented in research and health care, such as low-income groups, ethnic minorities, and groups living in rural areas [17]. These groups could be involved in the design of educational tools and interventions that they know will be useful to them [30]. Similarly, research programs may be developed in close cooperation with local communities to include a wider variety of populations. For instance, clinical trials which focus on genetic variation instead of 'race' or 'ethnicity' could be designed [17]. Community-based participatory research programs under which communities and researchers work together in all phases of research may be particularly fruitful [45].

Rethink Financial Schemes

Approval and reimbursement processes may be modified to provide quicker access to genetic tests and targeted treatments [15]. For instance, patient outcome and risk-sharing models [46] could be more systematically used to document the efficiency of biomarkers and companion diagnostics rather than stringent clinical data [47]. Limitations may also be put on the pricing of targeted drugs [35]. Such limitations, albeit controversial, can be more acceptable for pharmaceutical companies if financial incentives are offered, for instance through internationally financed funds [48], for the development of targeted drugs that benefit large numbers of people, such as drugs used for the treatment of infectious diseases and cancer [49].

Develop Low-Cost Programs and Tools

Free or low-cost programs offering access to genetic tests and targeted therapies may be proposed to groups

that are susceptible of not being able to afford those or may not want to use them [50]. Such programs may, for instance, consist of publicly funded annual health check including mapping of genetic risk predisposition and lifestyle intervention provided free of charge [51]. In general, low-cost solutions should be preferred to expensive solutions. For instance, health-care providers may prioritize investment in wireless medicine, which is cheaper than traditional technology and offers the possibility to perform medical tests remotely and at reduced cost while simultaneously limiting the number of medical consultations [13].

Develop Alternative Solutions

Extensive health and technology literacy among large groups of citizens may be difficult to achieve. Alternative solutions could be proposed to citizens who do not have the ability to assess their own health or use modern technology but may benefit from personalized strategies. For instance, personal accompaniment and counselling could be proposed to senior citizens.

Finally, systematically mapping disparities in the access and use of genetic tests and targeted therapies and making the results publicly available may motivate changes in policy in areas where disparities are the most striking [50].

One may question whether these strategies can guarantee that citizens will make the necessary efforts to adopt new behaviors and practices. Although no guarantee can ever be provided that people will behave in certain ways, investing in programs which target specific groups of populations may be the helping hand that is needed to motivate the adoption of new behaviors among specific groups. For instance, publicly funded programs which offer genetic risk mapping and lifestyle intervention free of charge have proved to increase the participation rate of high-risk patients in prevention programs while simultaneously potentially reducing future treatment costs [51].

Conclusion

The reports we have reviewed envision citizens as educated, engaged, resourceful, and responsible partners rather than passive recipients of health care. This new role of citizens offers exciting opportunities but requires levels of health and technology literacy as well as socioeconomic resources that some groups of citizens may not have. Although some of the reports acknowledge that educational, technological, and socioeconomic hurdles may be encountered, they primarily focus on the importance of educating citizens in PM and propose few other solutions to address such challenges. Education in PM is critical. However, we suggest that the promoters of PM take into greater consideration the heterogeneity of citizens and develop policies and programs which specifically address the needs of the less educated and resourceful citizens. In Europe, discussions are currently taking place to reduce inequalities in access to PM [21]. Such discussions should particularly be encouraged in countries where health is financed by a variety of private actors and individual access to PM may be depending on the socioeconomic resources of each individual. Citizens will be more receptive to adopting new behaviors and practices and contribute to the realization of PM only if educational, socioeconomic, cultural, and generational hurdles are properly addressed.

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