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From patients to partners: participant-centric initiatives in biomedical research

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Abstract

Advances in computing technology and bioinformatics mean that medical research is increasingly characterized by large international consortia of researchers that are reliant on large data sets and biobanks. These trends raise a number of challenges for obtaining consent, protecting participant privacy concerns and maintaining public trust. Participant-centred initiatives (PCIs) use social media technologies to address these immediate concerns, but they also provide the basis for long-term interactive partnerships. Here, we give an overview of this rapidly moving field by providing an analysis of the different PCI approaches, as well as the benefits and challenges of implementing PCIs.

Recent advances in digital technologies have led to increasing concern about the use of personal data, in particular about the amount of control that individuals have over their information and who may have access to it. At the same time, the ways in which individuals can choose to share personal data are exploding through the use of user-friendly tools such as social-networking sites. In the medical research domain, this 'user-centric' approach is being applied through the development of participant-centred initiatives (PCIs). These initiatives, although varied in nature, all place patients and research participants at the centre of decision making, providing an interactive information technology (IT) interface to engage and communicate with participants. The approach reflects changes in attitudes towards privacy and individual involvement, greater functionality in IT and is a response to new requirements in science. PCIs can provide the tools to help build the long-term public trust that is needed for the new ways of carrying out medical research based on global networks of shared data and samples.

In this paper, we review the rapid growth in PCIs for research purposes. We also discuss the diversity of aims and approaches of these initiatives, which are starting to become more widely integrated as essential and valuable components of the research infrastructure. The aim of this article, therefore, is to encourage a greater awareness of the way in which PCIs can address some of the ethical and legal challenges raised by innovations in research practice.

Protecting individual interests

The central concern of medical research ethics is to protect the interests of research participants while allowing beneficial research to proceed. Those who agree to take part in any form of biomedical research are required to give their consent to the use of any donated samples and associated data in the given study before the research commences, and this consent must be informed and voluntary. Informed consent is the norm, but the particular kind of consent — from broad to explicit — that is considered to be appropriate depends on the study. The requirement for consent is reinforced by a number of procedures, practices, policies and legal requirements. For example, approval to carry out biomedical research projects with human subjects must be granted by institutional review boards (IRBs) in the United States. In general, research participants are taken through a consent process that involves 'one-on-one' discussions with appropriately trained health professionals and ends with the signing of a paper-based informed consent form. The focus is on obtaining one-time consent rather than seeking to understand or to think more broadly about the interests and concerns of patients and research participants as these evolve over time. Traditionally, there has been very little use of IT mechanisms to engage with research participants to facilitate

participation in research on their terms or to encourage an interactive dialogue between research participants and researchers¹.

By contrast, health-care and biomedical research practices have been greatly facilitated by advances in computing technology and bioinformatics. The use of such technologies is providing new opportunities to accumulate, share, mine and integrate data sets for both clinical and research purposes, providing greater potential for growth in translational research. Many biomedical projects now rely on large consortia of researchers and repositories such as biobanks and, increasingly, networks of biobanks. The increase in the overall size of research initiatives is also inextricably linked to data-sharing initiatives, such as open-access policies, that are helping to facilitate the processing of the vast amounts of data by researchers. These technologies enable the linkage of detailed and heterogeneous data sets and the accumulation of the large sample sizes needed to achieve statistically significant results. This dual capability, which is unprecedented on the current scale, marks a shift from data sets that are specifically developed for a single research purpose towards samples and data sets that have more general applications. The increased ability to link data sets blurs the boundaries between clinical records and research data, and between the clinic and the research process. As a result, translational research may become more efficient².

New trends in research demand new consent models

These developments have raised great challenges for research governance and the protection of research participants. First, although consent is regarded as being of fundamental importance, there are no uniform standards of consent across all types of research, and clarity is lacking about the role of the participant's rights over the resulting data sets and biobanks³. Second, the legal, ethical and regulatory requirements may differ between jurisdictions at the regional or national level^{4,5}. Third, as whole-genome sequencing gradually becomes routine and as biobanks and data sets are ever more interconnected, it is increasingly difficult to guarantee that individuals can remain anonymous^{6,7}. Fourth, ongoing participation is required to provide more detailed information or samples; this applies to new studies but also to participation in a biobank or a longitudinal study, as existing data and samples might be used or integrated into new research studies. Consequently, there is concern within the bioethics community that the broad consent process adopted by many studies as a practical solution for unforeseen secondary research aims may actually have the effect of reducing the levels of trust between participants and researchers, despite giving the researchers the freedom to share and to use the data⁸. Although some individuals are prepared to sign up under broad consent parameters, others are quite sceptical and opt out of such practices⁹. This has implications for both the recruitment and retention of participants.

At present, broad consent is the tool used to legitimize research endeavours and to cover future uses of data and samples. However, it is problematic in a number of ways. It is difficult for researchers to make consent forms future-proof, and participants cannot express their preferences or protect their interests over time in response to new research proposals and rapidly changing circumstances. This 'one size fits all' approach to consent also risks losing segments of the population, such as disadvantaged groups, who may have a historical but justified mistrust of the research enterprise.

From an ethical perspective, it is necessary to enable participants that have given consent under one set of circumstances to reassess this in the light of new research possibilities on the same data sets that contain their information or samples. It is also increasingly being recognized that patients are a valuable source of detailed information about their conditions and treatment regimes and that this information could be integrated into research data sets. As research capabilities and questions evolve, there is also the possibility that participants

can clinically benefit from updated or more informative data sets. Furthermore, the ability to interpret findings is evolving; findings that are not of clinical or personal use now could be useful in future years. Given the investments made in putting together these large collections for both researchers and participants, there is a need to ensure their value is well used in the future.

Giving research participants a greater choice

The major challenge is to develop ways to engage and to communicate with diverse groups over long periods of time, as personal data are used and reused for new studies. For such studies to be ethically sound, new methods are required for consent and for exercising choice over the use of samples and information in response to changing research needs while not hampering research with burdensome practices. However, interfaces also need to provide a flexible method to give participants different degrees of control according to personal preferences without placing a burden on each participant. One way to meet these challenges is through the use of social media technologies. These provide the basis to reshape the current relationships with participants and patients so that they are less passive and more interactive. This could have enormous benefits for biomedical research and clinical practice. It could also address some of the ethical, legal and regulatory challenges that are raised by new ways of carrying out research.

What is a PCI?

At the most general level, PCIs have been defined as ‘tools, programs and projects that empower participants to engage in the research process’ using IT (K.E., N.A., C. Bragg and A. Hartzler, unpublished observations presented at the EURAC International Conference in Rome, Italy, 28 Oct 2011). The use of an IT interface provides an ongoing, interactive method for obtaining consent and maintaining regular communication between participants and clinicians, researchers and other participants. The key feature of all PCI interfaces is that they are based on the principles of respect and empowerment for individuals and are orientated towards participant concerns: patients and research participants are located at the centre of decision making as equal partners in the research process.

Edwards *et al.* also proposed that current PCI approaches in research exhibit four functions (TABLE 1): matchmaking (enabling the recruitment of research participants), direct-to-consumer services (providing participants with genetic testing and analysis services, as well as opportunities for involvement in research), dynamic control (enabling an ongoing interaction between participants and researchers) and citizen science (involving participants in facilitating, designing and executing research projects).

These features distinguish PCIs from related but non-shared, non-consent-modulated initiatives, such as public engagement initiatives. More general patient and public involvement efforts can rely on the use of IT systems, the internet and social media, but conceptually they do not necessarily place patient and research participants at the heart of decision making or situate them as equal partners. Nor do we classify as PCIs those initiatives that give patients the means to provide feedback on their health care more efficiently; although some PCIs rely on features such as this, they lack a central aspect of participation and informational control. These distinctions are not rigid, and they will benefit from wider debate in the future. However, for the purposes of this paper, they serve to demonstrate our points at this stage. We summarize the features of some PCIs in TABLE 2 to highlight the variety and geographical spread of these initiatives.

Features of PCIs

Although this is still an emerging area, there are a number of PCIs that have been designed for use in research. These have a diversity of formats and aims, but they all share some common features, which are listed below and in BOX 1.

Placing participants in control

The need to place the individual at the centre of decision making is embedded in the design of the IT interface for PCIs. It is also implicit in all initiatives that involvement is purely voluntary and is aimed at empowering participants.

Using social media technology

A common element across these approaches is the use of individual IT interfaces that use social media technology and approaches. In most cases, this allows participants to record all of their research activity in one place and to manage this when it suits them best and in response to changing situations.

Promoting active participation

The new way of doing research exemplified by PCI demands an ongoing active interaction between participants and researchers; this requires reciprocity and commitment on both sides⁷. Researchers must commit to transparency and veracity in all interactions with participants, particularly during recruitment and the provision of information. Participants must commit themselves to research and to acting altruistically for others.

Facilitating communication

Through various social media tools, such as individual participant interfaces, blogs, online experts and webcasts, PCIs can inform participants and keep in regular contact. This enables individuals to choose the communication tools that are best suited to their needs and has the effect of being able to reach a broad range of different constituencies.

Appealing to public goods

PCIs focus on empowering the individual but also have more ambitious aims, such as accelerating research and improving clinical outcomes, as well as increasing public knowledge about genomics.

Benefits of adopting a PCI approach

There are several ways in which using a PCI approach can improve research governance: by ensuring conformity with basic principles of medical ethics and privacy law; by improving recruitment methods and retention of participants and thereby cutting down costs; by enhancing understanding and first-hand knowledge of the research process; and by encouraging and sustaining public confidence through greater transparency and involvement. This can result in research that demonstrates high standards of research integrity but also an involvement by patients and participants that is more active and richer than more conventional approaches.

Streamlining the consent process

First, using a PCI approach makes it easier to obtain consent and ensures compliance with data privacy legislation in most jurisdictions. Efficiently obtaining consent for research through an IT interface could transform and streamline governance systems for research.

Removing the need for anonymized data

Second, a PCI approach avoids the requirement to anonymize data and samples for secondary uses, as participants can be directly approached for consent to the use of their identifiable information for new research purposes. Anonymizing data has often been used as a means of protecting individual privacy and dealing with the impracticalities of obtaining consent. It has also had the effect of removing research from external oversight and from the requirements of data protection and privacy law. However, the ability to anonymize the rich, detailed and well-characterized data sets effectively while retaining usefulness to research is increasingly being brought into question. It is also evident that it is far better scientifically to have access to individual-level data⁸. Therefore, using a PCI approach enables consent to be obtained as the research is being planned, removing the need to anonymize data fully through techniques such as aggregation.

Facilitating participant recruitment

Third, PCI approaches have a positive effect on participant recruitment. PCI projects open up the possibility for ongoing and easy contact with participants for further involvement in existing projects or enrolment in new ones. Having sufficiently high numbers of participants is crucial to successful research, and projects such as [UK Biobank](#) demonstrate that large numbers of participants are capable of being recruited on the basis of altruism.

Facilitating participant retention

Fourth, PCIs are an important means of retaining participants. If participants are keen to be kept informed and made to feel a part of research — or at least to be given the option of setting preferences for communication and notification about research — then there is every chance that meaningful contact with participants can be maintained. This can have real benefits to the quality of research, as retention of existing participants will become increasingly relevant to scientific research as population-based association studies move to the consideration of genetic associations with longitudinal changes in health status. Furthermore, there could be benefits in the clinical setting if research information could be used. It has been demonstrated that many participants expect that researchers act as ‘responsible stewards’ of samples and data, and they believe that permission should be sought or notification be given before these are shared with other researchers⁹. Similarly, proponents of PCIs are keen to show that there is a desire on behalf of patients and participants to have a degree of control over their medical records and research donations^{10,11}.

Promoting the delivery of better quality and more cost-effective health care

Fifth, in the clinic, patients’ use of personally controlled health records¹² have been argued to lead to a reduction in medical errors¹³, providing better quality data¹⁴, greater efficiency and safety in the provision of medical care¹⁵, and, in a US context, reduced health-care costs^{16,17,18}. Opening up access to health data to include patients can also lead to positive changes: more ‘activated’ patients take on more responsibility and manage their own health care as partners¹⁹. A research facility is a natural addition to this interface as in the CuraRata and Indivo models.

Sustaining public confidence in research

Sixth, greater involvement in research has the dual effect of improving knowledge about the research process but also of ensuring greater transparency and accountability on behalf of researchers. This can lead to greater public confidence in the research process and higher standards of research integrity but also to research that is more in tune with societal expectations and concerns.

Improving the quality of research

Seventh, PCIs allow research to be carried out more efficiently and using new methods. PatientsLikeMe used an online survey to validate the findings of a clinical trial that demonstrated lithium carbonate had no effect on the progress of amyotrophic lateral sclerosis (ALS)²⁰. The benefits of undertaking this through an organization such as PatientsLikeMe were the speed and lower cost of the research, because both participants and controls could reasonably easily be recruited. Similarly, 23andMe was able to identify two novel genetic associations and to replicate a total of 20 previously described associations for Parkinson's disease. At the time, the 3,400 cases and 29,000 controls constituted the largest single Parkinson's disease cohort that had been used in a genome-wide association study²¹.

Challenges of adopting PCIs

In the current research context, the implementation of PCI approaches has been variable. Initiatives have been taken by private companies (such as 23andMe) — some of which are not for profit (such as PrivateAccess and PatientsLikeMe) — or in health settings (such as CHRIS, Indivo, CuraRata and EnCoRe). In this new field, there are still a number of challenges to the wide-scale adoption of PCIs in the research context.

First, adoption requires a shift in current attitudes and approaches towards patients and research participants^{22,23}. This requires researchers to respect research participants as partners in the research rather than to see them as patients or passive providers of information and samples. This also requires the development of new procedures and policies to integrate PCI models and approaches into existing research governance frameworks.

Second, as the bulk of consent efforts are still paper-based, there are difficulties in making the transition to effective electronic consent models that allow consent to be managed online without considerable support from institutional leadership and the investment of resources. It remains costly for a research group to adopt a new approach, both in the time that is required to gain appropriate approval for such mechanisms and because of the cost that is involved to assess, implement and sustain such processes.

Third, broader implementation in research will be hampered by the lack of a common reference ontology that can accurately capture a continuum of patient consent states, which would be a valuable standard to ensure that patients interacting with PCIs in multiple settings were responding based on similar semantic questions and terms. This feature will be crucial when the need to audit the history of a participants' interaction with a tool is required to ensure that the meaning of a particular interaction is the same, regardless of the point in time in which it was taken.

Fourth, the implementation of PCIs also requires a change for research participants, as PCIs alter the nature of involvement in research. For some, this may involve the development of IT skills or gaining access to a secure computer. Care needs to be taken to ensure that the use of PCIs does not prohibit or discourage certain groups from involvement in research, such as older people, those with less education or disadvantaged groups. The development of applications for mobile phones and the use of interactive screens using videos — instead of text — located in waiting rooms and public areas may help to address some of these concerns.

Fifth, although the greater use of PCIs may lead to greater empowerment of participants and better control over personal information and samples, certain lines of research may not be possible if many participants opt out, and PCI-empowered participants may not be wholly

representative of the population at large. Further research is needed to determine how best to introduce PCI approaches while still allowing expedited research to continue.

Conclusions

Taking a PCI approach requires a substantial cultural shift in current research and clinical practice. In addition, it may not be appropriate or practical for some types of research. However, the use of electronic health records^{24,25,26,27,28} and the development of communities such as PatientsLikeMe and 23andMe²⁹ have demonstrated that individuals are sufficiently motivated to engage with researchers in novel ways and to be active partners in the research process. The appearance and range of functions in a PCI can be finely tuned to suit the needs of stakeholders, such as those in the developing world. By using a PCI, mainstream consent processes and processes of notification are more intuitive and dynamic, rather than being locked in time at the beginning of the research process. Obtaining consent for many different research activities becomes a streamlined and efficient process that is appropriate for the new way in which medical research is carried out. Therefore, PCIs should not be seen as obstacles to research but rather as enabling and empowering approaches that facilitate innovative research and safeguard public trust.

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Box 1 | Examples of the different features of participant-centred initiatives

Placing participants in control

Participants in Genomes Unzipped have set up their own website, where they are in control of their own information by making their genome sequence publicly available for others.

Using social media technology

In the EnCoRe ‘[Dynamic Consent](#)’ prototype, individuals can express choices, change their choices, track and audit any changes made and, importantly, choose when and how they are contacted in cases in which recontact is needed for secondary research purposes²⁹. The use of ‘sticky policies’ or machine-readable disclosure policies that attach to data²⁹ means that these preferences can travel with their samples so that when new uses are requested through the biobank, it is clear what form of consent is attached to them.

The Indivo interface developed by the Boston Children’s Hospital Informatics Program system gives participants control over access through a Web-based medical record.

In the case of PrivateAccess, which facilitates clinical trial recruitment, a Web interface allows registered users to grant access individually to their personal information by specific people or groups and under specific circumstances or conditions. This setup enables its users to establish and to maintain their own privacy preferences.

Promoting active participation

As a part of this reciprocal partnership, individuals who contribute clinical information or who take part in surveys receive information on their own health status. This approach is taken by the following: CuraRata, CHRIS, 23andMe, Indivo and PatientsLikeMe.

The CuraRata model for personalized medicine facilitates patient-tailored, prevention-orientated treatment by integrating individual care in a research setting. Therefore, in exchange for the storage of anonymous medical data and collection of biomaterials, an infrastructure is created for each patient, who receives regular feedback on data outcomes and analysis.

This is also the basis for 23andWe, which encourages participation in a research project that is open-ended, using online surveys and then feeding this knowledge back to customers.

In the EnCoRe Dynamic Consent model, participants are informed as to how their samples and information are used in research and can monitor use.

Facilitating communication

In the TuAnalyze partnership, information sharing and self-management of disease is encouraged through enhanced conversations through online forums, blogposts and members’ profile pages. Participants can sign up to TuAnalyze through their Facebook, Twitter, Google or Yahoo accounts.

During the signing up process for PrivateAccess, it is possible for aspiring members to choose a more experienced patient advocate to guide them in the setting up of their privacy preferences. The website also includes promotional and explanatory videos to facilitate registration and member uptake.

In the EnCoRE Dynamic Consent model, plans are underway to integrate video clips about biobanking users’ own stories, in collaboration with the [Healthtalkonline](#) project.

Appealing to public goods

Genomes Unzipped seeks to promote open-access science, to encourage constructive public discussion on the benefits of genetic technologies and to dispel fears about potential risks.

The philosophy underpinning TuAnalyze is to encourage individuals to share their clinical results with the aim of improving clinical outcomes in diabetes.

Private Access is aimed at accelerating research findings by improving recruitment to clinical trials, thereby cutting down costs.

Table 1

Key functions of participant-centred initiatives

Function	Characteristics	Examples
Matchmaking	<ul style="list-style-type: none"> Brings together participants and researchers by either promoting communication or facilitating recruitment 	<ul style="list-style-type: none"> PrivateAccess (USA)
Direct-to-consumer services	<ul style="list-style-type: none"> Provides participants with services as well as social-networking capabilities Provides opportunities for involvement in research 	<ul style="list-style-type: none"> 23andWe (USA)
Dynamic negotiation	<ul style="list-style-type: none"> Enables an ongoing discourse and negotiation between researchers and participants Enables participants to manage their preferences for personal data sharing while facilitating more accountable research governance 	<ul style="list-style-type: none"> CuraRata and String of Pearls Initiative (Netherlands) CHRIS — Cooperative Health Research in South Tyrol (Italy) EnCoRe and the Oxford Radcliffe Biobank (UK)
Citizen science	<ul style="list-style-type: none"> Allows participants to provide and to control the samples and data and, in so doing, to have an active involvement in facilitating research Allows participants to drive the research agenda and to carry out their own research projects 	<ul style="list-style-type: none"> PatientsLikeMe (USA) TuAnalyze (USA) Genomes Unzipped (UK) Genomera (USA)

Table 2

Participant-centred initiatives (PCIs) used for research purposes

Name of PCI (country; URL)	Key aims and features	Activity
23andMe (USA; https://www.23andme.com/research)	This is the research arm of 23andMe. Customers can leverage their data by contributing it to studies of genetics to “produce revolutionary findings that will benefit us all” but that can also be used to “discover new genetic associations that could shed more light on your data”	It gives customers the opportunity to contribute their genetic test results to research studies of their choosing and to be involved in specific online research projects
CHRIS — Cooperative Health Research in South Tyrol (Italy; http://www.chrisstudy.it)	Aims to use the research findings to improve the health of all people living in the Tyrol region in Italy. It ensures continuous, interactive consent and communication with participants by traditional methods as well as novel online tools	Through online tools, participants can: manage their consent in relation to subprojects; restrict the use of information in different studies; determine the extent to which they receive follow-up contact and updates; and opt out of the initiative. The options are explained to participants through a range of media
CuraRata (Netherlands; http://www.curarata.nl/uk/3/patients/home.html) and String of Pearls Initiative (Netherlands; http://www.string-of-pearls.org)	A unique data-sharing partnership between eight teaching hospitals in the Netherlands. CuraRata aims to use novel IT systems to use pooled clinical information and biomaterials and to link clinical and research data. The aim is to develop high-quality health-care provision that is innovative and affordable by encouraging participant involvement. It is essentially a personalized medical approach, and the process is dependent on active patient participation	Through the Home Care interface “the patient is able to obtain access to healthcare via his or her own electronic patient file from home or from work. Home Care also offers the opportunity of monitoring the patient’s disease, use of medication and quality of life, of undertaking laboratory research from home and of planning or changing appointments with healthcare providers”
EnCoRe and Oxford Radcliffe Biobank (UK; http://www.encore-project.info/index.html)	A collaborative initiative between academia, industry and the Oxford Radcliffe Biobank based in the Oxford University Hospital, UK	The ‘dynamic consent’ interface allows patients and research participants access to IT systems that allow them to modify consent choices on an ongoing basis. These choices will determine how the samples in the biobank, and the associated data, are used in future research
Genomera (USA; http://genomera.com/about)	A company that provides a platform for personal health collaboration by connecting people with similar medical problems. It has developed a platform for crowd-sourced health science, enabling groups to operate open health studies	Individuals can share both genomic and phenotypic information and opt in to clinical trials. The trials are designed by the participants, who then work with the researchers to analyse the results
Genomes Unzipped (UK; http://www.genomesunzipped.org)	A research project involving members who have had their	Volunteers and collaborators can use the

Name of PCI (country; URL)	Key aims and features	Activity
	DNA tested using various commercially available products. The results are open to the public, both as raw data and in a customized online genome browser. It publicizes the experiences of genetic testing and has an educational purpose	sequence data to develop new tools for exploring genetic data. The goals of the project are achieved via online dialogue, discussion of personal experiences of genetic testing, review of available products and blog posts by participants
Indivo Personally Controlled Health Records (USA; http://indivohealth.org/research)	A free, customizable and open-source system that enables an individual to own and manage a complete, secure, digital copy of their health record. It relies on open, unencumbered standards and integrates health information across sites of care and over time	The medical record resides with the patient, who can grant access permissions to institutions, clinicians, researchers and other users of medical information. Through this integrated system, individuals can also be approached to be involved in research or to provide feedback on information that relates to their health
PatientsLikeMe (USA; http://www.patientslikeme.com)	A private company committed to enabling individuals to share health information. It uses a platform for collecting and sharing real-world, outcome-based patient data and is establishing data-sharing partnerships within the health and biomedical sectors	Individuals can share information on their conditions using a social media interface as well as become involved in research projects
PrivateAccess (USA; https://www.privateaccess.info)	A private company that has developed a consumer-centric technology platform to allow individual users to grant 'private access' to all or to portions of their personal information through the expression of personal privacy preferences. It aims to create an "essential environment of trust, built by and for patients"	Patients are empowered to share their personal medical information safely so that they can be approached to become involved in research, such as clinical trials
TuAnalyze (USA; http://www.tudiabetes.org/forum/topics/tuanalyze-is-here)	A research project that collects and shares basic information on the experience of having diabetes in a way that can inform public health endeavours and research	Individuals provide information in a secure, structured way, allowing them to share with other patients but also to be a part of a research project