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How to involve and engage patients in digital health tech innovation

An Evidence Based Guide

UNIVERSITY OF PLYMOUTH

The**AHSN**Network

Boehringer Ingelheim

Contents

Foreword

The transformation of healthcare should be done with, not to, patients. That is as relevant and essential to digital transformation as it is about the transformation of face to face care provision. We must make digital transformation a success. In order for this to be possible the public must believe in and trust the digital agenda and they must be directly involved in shaping it. Change of this sort is really difficult but is absolutely essential. We welcome this important partnership contribution to *patient and public involvement and engagement (PPIE)* in digital innovation.

The push for digital technology and modernisation is stronger than ever. Digitally enabled care is recognised as essential to healthcare delivery, and we must build on this progress to achieve a smarter, more efficient NHS. From end-to-end use of digital tools across patient pathways, to driving uptake of the NHS App and using technology to advance predictive and personalised population health management, a fundamental role for the public is essential.

Meaningful contributions from across organisations with a stake in getting this right are vital. This guide will help support change makers: the clinicians, innovators, and patient communities upon which delivering digital transformation will rely. The practical advice this guide offers innovators should ensure important standards of patient and public co-development are more readily met, facilitating adoption of digital health tech by matching supply to areas of greatest demand. We want the health innovator community to bring forward technologies that advance our healthcare goals through patient-centric inclusive tools; having the right support to do that should facilitate a wide range of entrepreneurs with diverse products to make the ecosystem flourish.

The health system and its leaders have an important role to play here too; do we build patient and community involvement into our processes consistently enough? Can we better support innovators in their efforts to meet the needs of patients by providing clear information and reflecting consistent standards in our guidance and evaluation methods?

We are also clear that digital transformation is the key to tackling health inequalities. As such, a user-friendly tool like this, accessible to innovators from across the demographic spectrum, needs to support engagement with patients and the public drawn from across our diverse communities. For the NHS to benefit from the ideas of diverse innovators, bringing forward diverse products to meet the needs of diverse communities, diverse patient involvement has to succeed and that requires collaborations and partnership efforts like this guide.

Richard Stubbs
Vice Chair of the AHSN Network and Chief Executive Officer of the Yorkshire and Humber AHSN

Matt Whitty
Director of Innovation, Research and Life Sciences at NHS England and Improvement & Chief Executive of the Accelerated Access Collaborative

Richard Stubbs

Matt Whitty

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"Like with most (if not all) transformation in healthcare, patient and public involvement is essential for the success of digital innovation. Without it, we risk widening health inequalities and losing out on harnessing its great potential to transform health and care. However, the challenge arguably lies in the awareness and understanding of the practical steps needed to achieve this most effectively.

This guide is therefore a welcome contribution, as it shares best practice on how to enable and enhance the public's role in the co-development and implementation of digital technology. Developed using a rigorous academic methodology, and in collaboration with a diverse range of stakeholders, these evidence-based principles seek to help innovators effectively and successfully involve patients in digital health innovation from start to finish, ensuring truly patient-centred transformation."

Zainab Garba-Sani, Patient Representative and NHS Clinical Innovation Manager

"Critical to the success of any efforts we undertake for patients, is to engage and actively involve them from the start. At Boehringer Ingelheim we partner with patients to not only help identify areas of unmet medical need, but crucially to help us design and execute our research, and how we bring innovation to them in clinical practice, to ensure the medicines we develop are truly patient-centric by both design and delivery. In this area of digital transformation the same rationale must apply. Industry working in true partnership with patients and the public will result in more beneficial, usable, and accessible digital tools, and I am delighted with our contribution to that important task. Now more than ever, having patient-centricity and patient partnership at the heart of digital healthcare reform is crucial; something this guide has been designed to achieve."

Uday Bose, Country General Manager, Boehringer Ingelheim UK & Ireland

"If we are serious about learning lessons from the pandemic to improve how, where and when services are delivered, taking a patient and population-centred approach must be at the heart to ensure the successful spread of technology that meets the needs of our diverse communities. England's 15 Academic Health Science Networks (AHSN) play key roles in advising, guiding and connecting innovators with health organisations, matching solutions to major health challenges. With this in mind, we welcome this practical guide for innovators, which seeks to help speed up adoption of digital health technologies and build an innovation-rich, sustainable healthcare system."

Rishi Das-Gupta, Chief Executive, Health Innovation Network

"The development of this guide has been a true partnership. The AHSN Network, BI and University of Plymouth are all clearly committed to ensuring that digital health technologies are developed with, or by patients, not done to, or for patients. Bringing together the academic rigour and expertise of organisations like ours with commercial partners like Boehringer Ingelheim (BI) is a helpful way of driving change across the NHS."

Professor Sheena Asthana, Director of the Plymouth Institute of Health Research, University of Plymouth

"This guide is an excellent resource for innovators who want to put patients at the heart of user-centred design and deliver brilliant and truly fit-for-purpose digital healthcare products. It shows how patients should be engaged early, have opinions respected and be co-designers of innovation that affects them so profoundly."

Paul Hudson, Senior Digital Innovation Manager, NHS Transformation Directorate

"We all understand the importance of including the patient and public voice during the development of digital innovations. This guide doesn't seek to tell us what we already know but to help us make this key principle a reality by offering practical steps to achieve meaningful and productive engagement."

Andrew Davies, Digital Health Lead, ABHI

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Introduction

This evidence-based guide is a first-of-its-kind review of best practice in patient and public involvement and engagement (PPIE), providing valuable advice and resources to digital health innovators.

In 2020, Boehringer Ingelheim's publication *An Innovator's Guide to the NHS: Navigating the barriers to digital health* highlighted the importance of thorough, high quality PPIE for effective adoption of digital health technologies and the successful digital transformation of healthcare. With evidence to show that patients may reject digital technology if patients and the public have not been involved in its development,[1] the success of the digital transformation agenda depends on working in true partnership with patients and the public. The Innovator's Guide acknowledged that meaningful PPIE in digital innovation is challenging, both in practice and delivery. Having learnt from a number of organisations with similar vision and values, Boehringer Ingelheim UK collaborated with the AHSN Network and the University of Plymouth to explore and share best practice in PPIE in digital health innovation and adoption.

The aim of this project was to provide a practical guide for how to bring forward innovations with the patient, instead of for the patient. How also to deploy good PPIE processes to continually improve a digital product and better communicate its value to the system. The insights in this evidence-based guide should enable innovators to develop digital products with patients front of mind, and better meet the accessibility and usability requirements set out by two important organisations; the NHS Transformation Directorate (formerly NHSX) *Digital Technology Assessment Criteria (DTAC)*[2], and the *Organisation for the Review of Care and Health Applications (ORCHA)* – two advantageous accreditations for market access. Ultimately, this should speed up the proliferation of digital technology across the health service in a patient-centric and inclusive manner, supporting a better and more sustainable health system of the future and mitigating against digital exclusion.

Academic rigour for this collaborative project was provided by the University of Plymouth's newly developed paper, Best Practice Principles of Meaningful Patient and Public Involvement in Digital Health Innovation, Implementation and Evaluation. Following a comprehensive systematic literature review of over 10,000 peer-reviewed abstracts and extensive patient input, these principles were explored in a multi-stakeholder workshop convened by all partners to the project on 30th November 2021. It was facilitated by

AHSN Network Vice-Chair and CEO of the Yorkshire and Humber Academic Health Science Network (AHSN) Richard Stubbs , as well as University of Plymouth Research Fellows Dr Rebecca Baines and Dr Sebastian Stevens, and Oxford AHSN Director of Community Involvement and Workforce Innovation, Dr Siân Rees. The workshop benefited from the insight of nearly 40 system representatives, innovators, clinicians, patients and thought-leaders. In addition, Boehringer Ingelheim (BI) conducted a comprehensive six-month period of stakeholder engagement, collecting case studies and insights to produce a Green Paper on PPIE in digital technology, providing another important pillar to the project.

The evidence based guide to PPIE that emerges here is the first of its kind, evidence based, practical toolkit specifically for digital health technology. It contains key insights and case studies from extensive partnership work. The four categories of principles are those published by the University of Plymouth in Health Expectations.[2b]

Engage
Acknowledge, value & support
Communicate
Trust and transparency

For each category, further key learnings and challenges, an illustrative case study, and a checklist of recommended actions for innovators to track their progress against, are presented. These insights were validated in a thorough feedback loop with a wide range of contributors before publication, and as such, reflect the input of a diverse and expert field. Alongside recommendations to innovators, this document will be used to engage in meaningful dialogue with system leaders on how they can respond to support patient-centric digital transformation. The more that the system makes explicit the value that it places on patient and public co-development of digital tools, the easier it will be for producers of those products to engage properly and successfully with that process.

We have designed this guide to be as user-friendly as possible, and we encourage you to dip in and out of the various sections as needed. We hope it is a truly helpful resource and serves to advance the adoption of digital health innovation in a way that drives inclusive and sustainable health and care services across the UK.

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[1]   https://academic.oup.com/eurjcn/advance-article/doi/10.1093/eurjcn/zvab103/6427445

[2]   DTAC helps the healthcare system understand the clinical safety, data protection, technical security, interoperability, usability, and accessibility standards of digital technologies.

[2b] Meaningful patient and public involvement in digital health innovation, implementation and evaluation: a systematic review, Health Expectations, DOI:10.1111/ hex.13506

Meaningful PPIE -
The EnACT Principles

Following a systematic review and Delphi methodology study led by the Centre for Health Technology at the University of Plymouth, these principles were co-designed and agreed by a range of stakeholders including patients, clinicians, regulators, digital health innovators and academics. The review and Delphi methodology team included Dr Rebecca Baines, Dr Hannah Bradwell, Dr Sebastian Stevens, Katie Edwards, Samantha Prime, Dr John Tredinnick-Rowe, Miles Sibley *(Patient Experience Library)* and Professor Arunangsu Chatterjee.

Engage	**Commit to sharing power, working in equal partnerships built on mutual trust and respect.** This can often take time, but is essential in developing meaningful collaborations, maximising innovation relevance and cultural sensitivity.
	Involve people early and throughout. This can help increase the value, relevance, and acceptability of digital health innovations.
	Work in an interactive, flexible manner, learning how to become/be open-minded and receptive to people's suggestions. This can help ensure innovations better align with stakeholder needs, helping to prevent resource expenditure and product rejection rates.
	Co-design engaging involvement activities and evaluation methods. This can help ensure activities are engaging, acceptable and appropriate.

Acknowledge, value and support	**Recognise, value and reward people's time, collaboratively discuss and agree intellectual property (IP) rights from the outset.** This can help to ensure people are sufficiently acknowledged for their contributions and avoid potential frustrations later in the innovation journey. There are several ways to acknowledge people's time including providing financial rewards, membership offers, access to digital devices/skills, creating awards/certificates and offering personal/professional development opportunities.
	Build in sufficient time and resources including time for people to familiarise themselves with new technologies, deteriorating health and unexpected delays. This can help ensure sufficient time is available to work with stakeholders in a meaningful way, explore longer-term intentions to use and ensure conclusions drawn are due to the digital innovation reviewed and no other confounding variables such as limited time, novelty, or lack of familiarity.
	Support people involved throughout the digital innovation journey. Proactively consider issues of cost, inclusivity, inequalities (particularly for 'seldom-heard' or 'easy to ignore' communities), issues of accessibility, interoperability, digital skills, connectivity and device ownership. This can help to ensure a diverse representation of end-users are able to take part in the innovation process. Costs to consider include subscription fees, connection charges, data use etc. and relevant training for facilitators and collaborators. Create accessible instructions on how to use digital innovations, provide a hotline for any technical difficulties and offer support for everyone involved.

There is no universally agreed definition of 'PPIE' as reported in the University of Plymouth's SLR (systematic literature review), with 133 terms being applicable. However, the following definition is often used although it specifically relates to research and not innovation: 'Patient and Public Involvement (PPI) means actively working in partnership with patients and members of the public to plan, manage, design and carry out research. It is *"Research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them"'. Or in this case, it is innovation being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them*'.

The principles have been colour-coded according to one of 4 categories that they sit in. Whenever you see a phrase highlighted in a colour it is because it relates to a principle from one of these categories.

Communicate

Communicate clearly, regularly and inclusively in a way that accommodates individual needs, digital skills, confidence and accessibility. This can help ensure everyone stays up to date and engaged. Ask people how, when and in what format they would like to be communicated with. Offer a choice of communication methods to ensure inclusivity and provide a main point of contact.

Develop a feedback loop. This can help maintain levels of interest and avoid people feeling like a passive participant in the digital innovation journey.

Advertise the potential benefits of being involved, not just the benefits of the digital innovation. This can help facilitate recruitment and explore people's motivations for being involved. The potential benefits and motivations for being involved may differ between stakeholder groups. Tailoring communication/marketing materials is therefore essential.

Trust and transparency

Provide clear assurances and information about patient confidentiality, data privacy and security. This is particularly important. Clearly explain how people's data will be stored, used and collected. Important questions to address include how will the data be used? Who will and won't see the data? What rights do people have to withdraw their data? And will any financial gains be made as a result of data sharing? If so, by who? Supporting people who need to relay information about data privacy and security on the 'front line' such as healthcare professionals, care managers and carers is also essential.

Manage expectations, clarifying people's roles and responsibilities. This can help ensure people are aware of what is expected of them and what can be expected of others in return. Creating a shared vision statement, memorandum of understanding, code of conduct or ground rules can be particularly helpful. Be clear and up front about: what can and cannot be achieved in the timescales, tech capacity and resources available including possible levels of involvement; intellectual property agreements; decision making processes and what will happen if not all design suggestions can be acted upon.

Engage

In the early stages of undertaking patient and public involvement and engagement (PPIE), mapping out your strategy and motivations, identifying a representative cohort, and developing inclusive engagement practices, are the three most critical elements. This approach is time intensive but will result in higher quality outputs.

The principle is to involve people early and throughout. To do that successfully, it is helpful to consider your strategy carefully: why are you conducting PPIE and how do you want people to feel during the process? The different ways of engagement should also be considered: are you looking to conduct user research, test the product, and at which phase? This can impact how people are involved.

Before starting, innovators must be clear on:
- Motivation and purpose: why you are doing it, who you need to involve, and what are your own values underpinning it. These points are explored in depth in the next sections.
- Audience: what a patient, carer, or health care professional (HCP) may want from a product can be completely different. Involving people from a diverse range of backgrounds will be necessary.
- Process and experience: how you want people to feel during and after the involvement process. It is familiar and easy to fall into the trap of doing PPIE in the same way every time. Using a variety of approaches and thinking outside the box can be helpful, for example by using emotion cards to get patients comfortable speaking about their experiences. Equally, making use of existing structures to identify and engage with patients where these approaches work well, such as through patient advocacy groups or charities, can optimise resource use.

The principle is to involve people early and throughout, so it is important to consider the full breadth of potential participants (beyond professional patients) to target a diverse, inclusive, and representative cohort.

When developing a product for a very broad population, such as patients with depression or diabetes, it can be challenging to know who to engage with, and how to do so in a representative and meaningful way. Engaging with an intersectional cohort across the patient pool is essential – experiences of people with different employment status, ethnicities and genders will vary. Here, selection bias is a common challenge. It is easy to fall into the trap of working with professionalised patients, who are familiar with PPIE practices, thereby excluding often under represented patient groups and populations. Inclusivity is key. Equally, innovators can sometimes gravitate towards people who have time to give, such as retired people, making the patient cohort not representative in age.

The *Health Equity Assessment Tool (HEAT)*[3], which can help define which populations are affected by a particular condition and if any groups are under represented may be a helpful tool in exploring this important issue. Using a *Patient Involvement Volunteer Form*[4], whereby patients can express their interest in contributing to PPIE, could also widen the search for patients outside of established PPIE networks. It could also allow patients to sign up to different levels of engagement, ranging from light touch participation such as surveys and ad hoc focus groups, all the way to more active involvement in advisory boards, or being an integrated member of the team. NICE's *Patient and Public Involvement Policy* is a great case of clear PPIE polices and transparency frameworks and provides a good example to innovators of how to involve patients. Similarly, NICE's *Public Involvement Programme* aims to help patients, carers, the public, and patient organisations involve themselves in NICE's wok, and is another excellent example for innovators to look to.

Once the established PPIE networks are identified, asking community leaders or influencers who are already in positions of trust, to help you engage with patients and families from diverse demographics (especially those often under represented in digital innovation) is advisable. *The Academic Health Science Networks* are a cohort of organisations that aim to spread innovation at pace and scale over a specific geographical region. They improve health in their regions and generate local economic growth, and more specifically provide regional support to innovators regarding market access and PPIE.

3 https://www.gov.uk/government/publications/health-equity-assessment-tool-heat/health-equity-assessment-tool-heat-executive-summary

4 https://www.uhcw.nhs.uk/download/clientfiles/files/Patient%20Involvement%20Volunteer%20Letter%20and%20Application%20Form%20Feb%202017.pdf

*The principle is to **commit to sharing power and work in equal partnerships**. That is, to empower patients and the public to share their views, and consider them equally when making decisions.*

Sharing power with patients and the public during decision-making can be challenging. You must first consider how to define power-sharing and what this definition means in practice. Power has a range of sometimes negative implications. In this context, power-sharing means equality of voice for all stakeholders such as innovators, clinicians, managers, policymakers, patients and the public. It is about considering everybody's voice fully and being transparent as to why and how decisions were taken, not patients and the public overruling decisions. Patients have historically been passive participants, and co-design is about empowerment and active engagement – doing things with, not to, patients.

Differing views are to be expected during the PPIE process.

Innovators should consider all views and explain the reasoning behind their changes, to all parties. These explanations should not only include reasonings behind inclusion, but also exclusion. This is known as a feedback loop. Further detail on feedback loops is provided further on in this guide.

Involving People and Communities in Digital Services, guidance published by NHS Transformation Directorate is a good example of diverse involvement best practice. NICE also has *Shared Decision Making Guidelines*, which also house resources to help people in the process of power-sharing and shared decision-making. These are two examples of resources that can help innovators as they commit to power-sharing and working in equal partnership.

*The principle is to **work in an interactive, flexible manner**, so you must be mindful that people's digital skills, willingness, and ability to engage with PPIE processes may vary over time. An empathetic and flexible approach is necessary to include patients at different stages of the patient pathway.*

Many people may not think that accessing digital health systems is relevant to them, until they are in a situation where they need to do so. Innovators and researchers should be mindful of this, and address the 'what's in it for me'. PPIE is a dynamic and evolving process, and digital technology means different things to different people at different stages of their healthcare journey. The public engages in digital health frequently, without even realising it: health apps on smart phones or watches and use of the NHS app are two good examples of this. Digital innovation touches almost everyone

in some shape or form, not just patients receiving care.

How people access digital health will also be dynamic. For example, if a sudden diagnosis throws a patient into a crisis, their interest or ability to learn digital skills may drop. Some communities are hesitant to use digital technology, hindering the PPIE process. Innovators should approach PPIE empathetically and be mindful of people's individual circumstances and the ecosystem around them, while recognising that these may change over time.

*The principle is **co-design evaluation methods**, which involves assessing and sharing the positive and negative outcomes from the PPIE process as learnings for everyone involved.*

Part of being transparent and trustworthy is evaluating the success of the PPIE process and sharing learnings as well as best practice with others. In addition to standardised measures, there is scope for the usage of subjective measurements. An assessment equivalent to the anxiety and depression scales in mental health could include qualitative questions, such as:
- How have you found your PPIE experience?
- What benefits have you experienced as a result of your involvement? Is your wellbeing better as a result of your involvement?
- How empowered does this PPIE process make you feel?
- What challenges, if any, have you found?

Another potential measure of PPIE's impact could be how inclusive is the digital health technology. If a wide variety of patients can use the technology, that should be indicative of inclusive and representative PPIE practices. However, this may not apply to niche products with narrow patient populations. A broader outcome of effective PPIE would be adaptations that are made to the product, which would

provide useful information alongside the value proposition, for people considering it in procurement processes.

However, developing evaluation frameworks, while remaining sensitive to how different people process motivation and purpose, may be challenging and would benefit from expert input. Here, it is crucial that patients are involved as well, so that PPIE is partially evaluated on what matters to all parties involved. Both the innovator and patient perspectives need to be represented in evaluation methods and content.

Evaluation and PPIE processes should also be aligned with evidence generation requirements for innovators and their technologies. A strong evidence base aids in the adoption of technologies into the system with its proven ability to be efficient, safe, and impactful. NHS England's *Innovation Service* acts as an 'information gateway' to support innovators in understanding the evidence standards and requirements needed for NHS procurement processes.

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Reaching out to digitally excluded populations

Non Hill, an independent peer researcher supported by Healthwatch Surrey, described her experience of resuming PPIE after the first coronavirus lockdown in 2020. She worked within a Surrey Heartlands team who reached out to digitally excluded and under-represented populations, including people with mental health challenges, additional needs, in temporary or secure accommodation and from the travelling community. In order to engage meaningfully with these groups, the team visited them in person. This facilitated them developing a genuine connection and obtaining meaningful feedback. She noted that these individuals really appreciated the team making the effort to meet them in person and found this a more familiar and human experience than completing a survey online.

Hill noted that digital exclusion is often quite an emotive thing, underpinned by fear. It can be based on fear of technology, such as forgetting passwords, or past humiliating experiences. Sometimes digital health can seem very alienating from normal life, and it can be helpful to contextualise its use. If people do online banking, or online shopping, digital health is the next step. Familiarity can help to alleviate fears. Equally, establishing a human connection is crucial to discuss these sensitive matters. Innovators or researchers must be particularly mindful of not sounding patronising or showing implicit biases.

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"Ability and access are more straightforward to identify and should be possible to address with enough resources. Understanding people's hesitance and supporting them to be less fearful of digital health technology is more challenging."

Non Hill, Healthwatch Surrey/Public member of Thames Valley and Surrey Care Records Partnership Ethics and Engagement Group

Recommendations

Recommended steps for innovators

- Take time to consider your strategy: why are you conducting PPIE and how do you want people to feel during the process? Consider what good looks like.

- Consider the full breadth of potential participants (beyond professional patients). Use the Health Equity Assessment Tool *(HEAT)* or widely disseminated patient volunteer forms to ensure diversity and breadth of different backgrounds, including ethnic minorities, are also well represented.

- Empower patients and the public to share their views, and ensure these are considered equally when making decisions.

- Be empathetic and have a flexible approach to include patients with different digital skills, at different stages of the patient pathway.

- Build relationships with community leaders/influencers who are already in positions of trust, to support your engagement with patients and families in under-represented demographics, as patients and the public are more likely to trust members of their own community.

- Document positive and negative outcomes from the PPIE process as learnings for anyone involved.

Acknowledge, value, support

It is important to show you value patients' and the public's contribution. Showing value involves ongoing, transparent communication, any necessary training and potentially, financial reimbursement. Innovators and researchers also need support to conduct PPIE, particularly clarity regarding intellectual property (IP).

The principle is to collaboratively discuss and agree intellectual property (IP) rights from the outset, so you must be clear on who owns the IP and how contributions will be governed.

Innovators and the public may benefit from external or facilitated support to understand the implications of power sharing on IP, which pertains to the ownership of intellectual ideas, such as inventions or symbols used in commerce. IP is protected in law by, for example, patents, copyright or trademarks.[5] There are several challenges and concerns here:

- Definition of IP is poorly understood
- Concern over ownership of IP, particularly if a patient provides rich insights during the product development process
- Concern around sharing sensitive information or 'trade secrets' with patients, particularly if competitors exist that may tap into the same pool of patients.

These risks can be mitigated by:

- Seeking advice on IP before starting the PPIE process, such as from UK Research and Innovation (UKRI)[6]
- Putting a commercial non-disclosure agreement in place
- Having a clear agreement on who owns the IP from the beginning.

National guidance, resources and sharing of best practice on IP would be helpful for innovators and could encourage transparent information-sharing with patients and the public.

The principles are to recognise, value and reward people's time and advertise the potential benefits of being involved in PPIE. You could offer to compensate patients for their time as a way to acknowledge their contributions and be transparent about how much you are willing to reimburse.

As a general norm, people want to be helpful and support the development of digital technologies that improve the standard of care for patients and communities alike. Some form of reimbursement and the existence of a feedback loop can express recognition for the contribution of patients and the public, and be helpful to maintain engagement over the long term. Patients should receive value from their involvement with innovators, even if the product does not make it to market. (Many products do not.) Offering financial compensation is one way to do this.

However, it is difficult to determine what a fair compensation rate is. Innovators typically want to do what is normal and fair, and for this to be standardised. NHS England's *Expenses Policy* and the *Involve Framework*, used widely by the National Institute for Health and Care Research (NIHR), provides payment guidance for researchers and professionals in this area, ranging from £12.50 to £300 depending on the nature of the activity[7]. It is crucial to plan this from the very start and communicate transparently with patients, so that everyone understands what innovators will gain from PPIE.

Introducing financial incentives should not reduce PPIE to a transaction, or influence the feedback received – there is a question about whether paying people will make them more likely to say what they think you want to hear. Some financial incentives may also result in tax issues or affect benefits and health insurance payment claims, so more than one way of acknowledging people's involvement, beyond financial recognition, will be needed.

Another way to encourage patients to actively participate is to ensure that the process around financial compensation runs smoothly and does not become a stressful and cumbersome experience.

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[5] https://www.wipo.int/about-ip/en/
[6] https://www.ukri.org/councils/epsrc/guidance-for-applicants/what-to-include-in-your-proposal/health-technologies-impact-and-translation-toolkit/showing-value-in-healthcare-technologies/intellectual-property/
[7] https://www.nihr.ac.uk/documents/payment-guidance-for-researchers-and-professionals/27392

The principles are to support people involved throughout the digital innovation journey and allow enough time for people to familiarise themselves with new technologies. To do this, it is important to provide access to sufficient digital support, such as digital training days, technological equipment and access to the internet, to ensure patients can use the technology for your research purposes.

Formal support and upskilling mechanisms for patients involved in product development should reduce health inequalities and the digital divide. There could be a lot to learn from patients' upskilling needs, in terms of what end-users would need by way of digital development to enable them to use the technology.

Formal support mechanisms might include a material component, giving access to the basic hardware, connectivity, and infrastructure needed to engage with digital interfaces, as well as a training component, such as reading materials, training sessions or physical demonstrations showing how to engage with digital technology. Here, healthcare professionals should also be trained to support patients.

Offering a wide programme of support is crucial because there is a spectrum of ability required to use digital technologies – some technologies only require a login, while others require more engagement. Equally, people do not always have a good idea of how digitally literate they are. Health systems must have mobility and heterogeneity of process to support people to use the full spectrum of digital technologies, from rudimentary to complex, while recognising people will likely become more digitally skilled over time and with more experience.

ORCHA's Digital Health Academy is an online training centre that aims to give all health and care professionals the knowledge, skills and confidence to safely use digital health in practice, and is an example of an excellent resource for upskilling people to help them use digital health technologies. Health Education England also has *The Digital Readiness Education Programme* which increases the digital skills, knowledge, understanding and awareness across the health and social care workforce.

The principle is to build in sufficient time and resources, an important part of which is to secure internal buy-in with budget holders to ensure sufficient funding and resources are allocated to conduct PPIE appropriately.

It is crucial to communicate internally about the purpose and necessity of PPIE. Having senior buy-in from the beginning can help set the tone for the project and relationships between different stakeholders moving forward. Communicating clearly over the budget and resources required can help minimise the risk of underfunding or disruption to the project if priorities change. PPIE requires significant planning and administration, so having a dedicated project manager would be helpful to coordinate this aspect, ensure timelines are met and manage stakeholder relationships, such as with GPs, charities, and volunteers.

One way to secure this resource is to make the case for PPIE internally. NHS England's operational priorities around mitigating against digital exclusion mean that innovators and implementers must be confident that the technology will not contribute to digital exclusion[8].

In addition, the NICE Digital Health Technology Evidence Standard outlines evidence expectations around accessibility and usability which could be demonstrated through effective PPIE.

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8 https://www.england.nhs.uk/wp-content/uploads/2021/03/B0468-implementation-guidance-21-22-priorities-and-operational-planning-guidance.pdf

Case Study

Nathan Moore, founder of Primum Digital, shared his experiences reimbursing patients for their time during the PPIE process. He followed up afterwards and offered payment but felt uncertain of what a fair reimbursement rate would be. It would be helpful to define fair reimbursement, both in terms of financial and other means of compensation, to be an established policy across the board.

Moore suggested that a flat rate for PPIE compensation, set by the NHS and updated according to the financial environment, would help guide decision-making and reassure innovators they are following the industry standard. Anyone receiving payment should be able to check that this does not have a negative implication on their finances, by for example, creating tax or welfare issues. This may also involve the education of participants on this topic prior to involvement, to ensure they are aware of what to consider when receiving money for their participation.

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"When it comes to reimbursing patients for their time, innovators want to do what's fair and normal, and we want what's normal to be established."

Nathan Moore, Founder of Primum Digital

Recommendations

Recommended steps for innovators

- Be clear on who owns the IP from the outset and how contributions will be governed.

- Offer to reimburse patients for their time as a way to acknowledge their contributions and be transparent about the levels and types of reimbursement available and what considerations they need to be aware about.

- Provide access to sufficient digital support, such as digital training days, to ensure patients can be fully involved in the testing, development, use and/or evaluation of technologies.

- Secure internal buy-in with budget holders to ensure sufficient funding and resources are allocated to conduct PPIE appropriately.

Communicate

Tailored external communication and open feedback channels are crucial to maintaining engagement and accountability by all parties.

The principle is to **develop a feedback loop**. *This should be an iterative process which entails communicating with participants often about how and why their contributions have been included (or not) and provides the foundation to build meaningful relationships.*

Arguably, one of the biggest thank yous innovators can offer is to keep in touch with participants after their initial engagement, showing what has happened with their feedback – this is what you said, this is how we changed the product, and this is why it was a meaningful change. Where patient and the public's feedback has not been incorporated, one must explain why this was not the case. This also speaks to the fact that PPIE is an ongoing process, and transparent communication will help to ensure participants feel valued for their contributions and therefore remain engaged. Feedback loops help reassure patients that their voices are being heard and valued throughout the entire process and not just at particular and isolated instances.

The principle is to **communicate clearly, regularly, and inclusively**, *which entails tailoring your communication style to address your audience needs. It may be necessary to seek support or input from the community you are trying to target to get this right.*

Innovators undertaking PPIE must be mindful that different people like to be approached in different ways. It is most effective to tailor communication approaches to suit the audience you wish to work with. For example, when approaching someone who is partially sighted, it may be best to engage in-person or over the phone, or send emails with a very large font. These simple tweaks can make a big difference and need to be communicated and planned for in advance. One NHS stakeholder reflected on preparing for six months before starting PPIE. The outputs and engagement rates were of much higher quality as a result. It may therefore be necessary to work with patient representatives as advisers, validating the language and approach for a particular group of patients

This kind of constant feedback loop from inception to development to implementation is one tangible way to ensure patients feel engaged throughout the PPIE process. This is important because there are data[9] to show that the effectiveness of any digital intervention is determined by the level of active patient involvement.

The principle is to **develop a feedback loop** *and* **create a safe space where people feel supported in sharing their views**. *It is important that you open a communication channel enabling patients to voice their grievances about the PPIE process and that you commit to addressing their feedback.*

It is crucial for patients to be able to feedback on the process of PPIE. Introducing a whistleblowing mechanism would allow the public to complain if an organisation has not engaged with them appropriately, and act as an additional incentive for organisations to get PPIE right.

Such a mechanism could operate in multiple ways. It could be codified into central NHS standards, a self-regulated code of practice, or be an addition to trade body codes, such as the ABPI (The Association of the British Pharmaceutical Industry). Alternatively, it may be possible to have a more informal Trustpilot-style approach, where patients review the quality of engagement online. The success of such an approach would rely on people engaging with it. Importantly, it may be necessary for the whistleblowing mechanism to change at different stages of PPIE, such as concept to product launch, or product launch to market growth.

Until a formal, centralised mechanism is put in place, it is up to individual organisations to put processes exist that will enable patients and the public to discuss their experiences openly and safely.

Case Study

Feedback loops in the digital health technology PPIE process

Abraham Hijazeen, Lead Product Designer for patientMpower, previously worked at a company that produced phones and explained that feedback loops and the product development process can be much more straightforward in the telecommunications industry. In his previous role, it was not uncommon to stop people in the street and offer them compensation for their feedback on a new product or app, with minimal forethought given to the recruitment and engagement process. *"We could go back into the office and make a few changes over a couple of days and follow the same feedback process again the next week."*

This is not comparable to the healthcare industry where technologies must be regulated and clinically proven to have a positive impact on users. PPIE therefore has a different function, in that it needs to prove not just the usability of the product, but also help companies meet regulatory and clinical standards. For this, it may be necessary to engage with multiple groups (not just patients) at once, meaning the feedback loop is not always linear.

Recommendations

Recommended steps for innovators

- To build meaningful relationships, construct iterative feedback loops and communicate with patients and the public often about how and why their contributions have been included (or not).

- Consider the correct communication style for engaging with different people and recognise not all forms of communication work for everyone.

- Seek out the right support to communicate effectively from the offset.

- Open a communication channel enabling patients to voice their grievances about the PPIE process and commit to addressing their feedback.

> "
>
> *"It is much harder to develop a feedback loop in healthcare because it is not a linear process. It is easy to get a lot of patient input at the start, but the developments made to the product from these suggestions need to be validated by clinical experts as well, to ensure it does not impact the digital technology's efficacy or increase clinical risk. This complicates the process enormously compared to other industries."*
>
> *Abraham Hijazeen, Lead Product Designer for patientMpower*

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Trust and transparency

In order to gain patients' trust, organisations conducting PPIE should be trustworthy and transparent about potential risks.

The principle is to provide clear assurances and information about patient confidentiality, data privacy and security which requires being transparent, no matter what. If you want to be perceived as trustworthy, be open about risks and respect people's decisions.

In order to be transparent and maintain trust during the whole PPIE process, it is crucial to be honest, realistic and manage stakeholder expectations. This is particularly important when discussing patient concerns, such as information governance or data privacy. Organisations should not provide 'empty reassurances' or make promises they are unable to keep. It is precisely this lack of transparency that can damage trust.

For example, it is impossible to ascertain whether a patient's sensitive and confidential data will ever be breached. What organisations can and should do to allay patient fears is be transparent about what measures are being put in place to mitigate risks, and help patients understand the consequences. If there ever was a breach, how would that affect patients and their health?

Part of being transparent is accepting that some patients will not be willing to accept the degree of risks involved in undertaking PPIE for digital technologies. It is crucial that organisations give people freedom to choose and respect individuals' decisions. People need to come on board in their own time (if at all). If you pressure people into doing something, they will most likely withdraw.

Additionally, when engaging with patients and utilising their shared experiences, it is critical that stringent information governance protocols are followed. Data protection impact assessment (DPIA)[9] is a process designed to help systematically analyse, identify and minimise the data protection risk of a project. Utilising this when managing data shared by patients, especially about their medical condition,

is key to ensure that innovators are following the correct legal processes, but also builds trust with the patient that their data is being protected and used correctly. A DPIA is not required in all cases, but where it is not there still must be evidence to show that it was considered and ruled out.

Appointing an information governance officer to ensure that data is stored and managed correctly, and potential breaches are identified and mitigated before occurring, is one way to instil trust in patients when it comes to their data. Having direct access to this person is also important. Additionally, the *Information Commissioner's Office*, which upholds information rights in the public interest, promoting openness by public bodies and data privacy for individuals, houses many good resources for use by innovators. Companies that store and process personal data will also have to pay a fee to this body, the amount of which is set by Parliament and reflects the risks posed by the processing of personal data by the organisation. A number of private information governance expert advisors exist in this field, and seeking their advice and support early is likely to be advantageous down the line.

Appointing an information governance officer to ensure that data is stored and managed correctly, and potential breaches are identified and mitigated before occurring, is one way to build trust with patients when using their data.

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[9] https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/accountability-and-governance/data-protection-impact-assessments/

Case Study

Kevin Auton, Managing Director of Aseptika, described the importance of conducting patient engagement throughout the product development process. "We have beta tested our products with typical end-users as part of our development process to get feedback and to improve the product continuously throughout its life. The PPIE process gives a formal way of doing this and reporting the outcomes, all of which goes into the product file, which is used to support certification as a medical device. The introduction of the EU's Medical Devices Regulation (MDR) 2017/745 CE standard and the NHS' *Digital Technology Assessment Criteria*, now makes continuous PPIE part of the body of evidence submitted to regulatory authorities through Notified Bodies and the NHS DTAC assessment for entry into NHS procurement. DTAC helps the system understand the clinical safety, data protection, technical security, interoperability, usability, and accessibility standards of digital technologies.

DTAC includes a section on usability and accessibility, where companies must provide evidence of their previous PPIE activities and Aseptika's Active+me REMOTE App scored 100% for this because they had been undertaking PPIE for over a decade, and therefore had a wealth of information and internal resources to draw from for the DTAC submission.

Dr Auton recommends that other companies looking to go through DTAC, CE marking under the EU's MDR 2017/745 and UKCA marking, engage early with NHS England and NHS Improvement and their Notified Body to gain clarity on the type of evidence they should collect during the PPIE, or seek support from other companies that have already gone through the process. A process of constant reference to patients and clinical staff throughout product development is vital to make a good product, and appropriate PPIE practices are now needed to evidence this has been undertaken and was effective. A structured way of presenting the wealth of feedback that is often collected during PPIE process to both the regulatory authorities and NHS DTAC assessors would also be helpful to smoothing the pathway through the many accreditation processes a medical device must now successfully undergo before it can be commercialised in the UK and EU and the many other nations now adopting MDR 2017/745.

Recommendations

Recommended steps for innovators

- ■ To be perceived as trustworthy, be open about risks and respect people's decisions on PPIE.

- ■ Use the tools offered by arm's length bodies like NICE and NHS England & NHS Improvement, and seek support from them if these tools prove challenging.

- ■ Seek advice from data privacy consultants on which processes you are required to follow and how to ensure you have the evidence to show that these processes were considered.

"

A digital transformation lead was told by a patient
"I don't care what it is or how it works, I need to know what it will do for me"

Anonymous

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Undertaking patient and public involvement and engagement well will help to ensure that new digital technologies meet the needs that matter most to patients and society as a whole. It has an important role to play in tackling health inequalities and enabling products that are accessible and acceptable to the whole target population, by highlighting barriers to uptake during product development. Even though undertaking PPIE can lengthen the product development process, Simon Denegri, NIHR National Director for Patients, Carers, and the Public believes it is a key driver for innovation. *"It will be [patients'] insights, experiences and ideas that will help drive forward innovation. They will be important agent provocateurs in ensuring innovation is adopted."* [10] In order to make the digital transformation of the NHS a success, the public must trust and buy in to the digital agenda.

> *PPIE has an important role to play in tackling health inequalities and enabling products that are accessible and acceptable to the whole target population, by highlighting barriers to uptake during product development.*

Digitally-enabled technology has the power to enhance the care people receive, saving resources, driving efficiency, and improving patient outcomes. However, it also has the power to deepen health inequalities by failing to be accessible and inclusive to all potential end-users, creating barriers to access or biased technology. Health inequalities can also be entrenched further by unrepresentative input in the development phase, causing algorithmic biases or discriminative decision models on a technical level. Having the right PPIE practices in place is a key step in mitigating this risk. Good PPIE should support innovators to break down silos and work in partnerships with patients and the public. It also provides another layer of validation. NICE's guidance on *Community Engagement: Improving Health and Wellbeing and Reducing Health Inequalities* is a prime example of good work in this space, to ensure all developments put tackling health inequalities at the heart of digital transformation. For the system, it is helpful to understand which technologies are needed, usable and accessible. If an innovation has PPIE data to demonstrate that the needs of all communities it would serve have been considered, it is fair to assume that it will have better uptake and a more positive impact in those communities, thus offering great potential to achieve the desired outcome. Additionally, to support a demand-led culture at the NHS, patients can highlight needs and help create ideas for future technologies, through the power of patient-driven innovation.

Therefore, PPIE plays an important role in helping innovators evidence and demonstrate the value of their product. The value of patient involvement in bringing products to market is two-fold: to help innovators develop patient-centric technologies with a clear and co-produced value proposition thereby boosting uptake and spread across the NHS; and, by consequence, to expedite digital transformation and the emergence of our rich health innovation ecosystem. Demonstrating that a product has been robustly validated throughout its development as a result of effective PPIE, brings a strong addition to a value proposition.

According to our pre-publication feedback, innovators have found guidance on reimbursing patients for their time and involving an inclusive patient cohort some of the most useful insights in this guide. We also recognise that there is scope for more information such as further guidance on whistleblowing mechanisms, personalisation, and intellectual property. This guide could also provide policy-makers with an understanding of the key areas to focus on moving forward, and where their input is integral to further quality PPIE in the context of health within the UK.

Following the advice set out in this evidence-based guide, we would welcome readers' feedback and suggestions on how to develop it further. It is our hope to continue to encourage sharing of best practice, so that innovators are well equipped to conduct meaningful PPIE in digital technology. If you have any thoughts on how to keep this resource as usable and insightful as possible, have any feedback on how to improve it, or want to talk to us about your PPIE experiences, please contact us at *communications.bra@boehringer-ingelheim.com* with your ideas and suggestions.

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10 https://www.ahsnnetwork.com/app/uploads/2018/12/Patient-and-public-involvement-PPI-in-a-digital-world-May-2018.pdf
    https://www.ahsnnetwork.com/app/uploads/2018/12/Patient-and-public-invCoudolvement-PPI-in-a-digital-world-May-2018.pdf

Summary of recommendations

Engage

Take time to consider your strategy: why are you conducting PPIE, how do you want people to feel during the process, and how can you measure a successful outcome.

Consider the full breadth of potential participants (beyond professional patients). Use the Health Equity Assessment Tool *(HEAT)* or widely disseminated patient volunteer forms.

Empower patients and the public to share their views, and ensure these are considered equally when making decisions.

Be empathetic and have a flexible approach to include patients with different digital skills, at different stages of the patient pathway.

Build relationships with community leaders who are already in positions of trust, to support your engagement with patients and families in hard-to-reach demographics, as patients and the public are more likely to trust members of their own community.

Document positive and negative outcomes from the PPIE process as learnings for anyone involved.

Acknowledge, value, support

Be clear on who owns the IP from the outset and how contributions will be governed.

Offer to reimburse patients for their time as a way to acknowledge their contributions and be transparent about the levels and types of reimbursement available.

Provide access to sufficient digital support, such as digital training days, to ensure patients can use technologies suitable for your research purposes.

Secure internal buy-in with budget holders to ensure sufficient funding and resources are allocated to conduct PPIE appropriately.

Communicate

To build meaningful relationships, construct iterative feedback loops and communicate with patients and the public often about how and why their contributions have been included (or not).

Consider the correct communication style for engaging with different people and recognise not

all forms of communication work for everyone. Seek out the right support to communicate effectively from the start.

Open a communication channel enabling patients to voice their grievances about the PPIE process and commit to addressing their feedback.

Trust and transparency

To be perceived as trustworthy, be open about risks and respect people's decisions on PPIE.

Use the tools offered by arm's length bodies like NICE and NHS England, and seek support from them if these tools prove challenging.

Seek advice from data privacy consultants on which processes you are required to follow and how to ensure you have the evidence to show that these processes were considered.

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Boehringer Ingelheim and the partners to this project are extremely grateful for the expertise and insight of the many contributors who gave their time so generously.

Being able to centre the project on academic work whose core study participants were patients and the public, was an essential tenet to a piece of work about the centrality of patient involvement in digital technology development. For the purposes of that research, the term patient is used to refer to consumers, clients, citizens, carers, users, end users, stakeholders, community and service-users of any age, gender, ethnicity or health care status.

In addition, nearly 40 participants at the patient and public involvement workshop stress-tested the University of Plymouth's principles, sharing best practice and the real-life challenges of undertaking meaningful PPIE in the context of digital health innovation. As well as numerous other people who helped this project take shape over many months, their commitment and contributions were invaluable.

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Resources (in order of appearance in document)

- NIHR's Involve Framework provides payment guidance for researchers and professionals conducting PPIE.

- NHS England's Patient and Public Reimbursement Policy.

- ORCHA's Digital Health Academy is an online training centre that aims to give all health and care professionals the knowledge, skills and confidence to safely use digital health in practice.

- Health Education England's Digital Readiness Education Programme which increases the digital skills, knowledge understanding and awareness across the health and social care workforce.

- UKRI's Showing Value in Healthcare Technology explains the challenges of intellectual property for innovators in health tech, and signposts to a number of useful resources.

- NHS England's Innovation Service acts as an 'information gateway' to support innovators in understanding the evidence standards and requirements needed for NHS procurement processes.

- Using a Patient Involvement Volunteer Form, (page 5 onwards) allows patients to express an interest in participating in PPIE and allows innovators to build a bank of potential contributors.

- Public Health England's Health Equity Assessment Tool (HEAT) has been designed to address health inequalities, and can be used to identify and engage with patients from across the demographic spectrum.

- The Academic Health Science Networks provide regional support to innovators on market access and PPIE processes.

- NICE's Patient and Public Involvement Policy outlines the principles of patient and public engagement that NICE's approach is based on, and lists the opportunities for patient and public involvement within each of the NICE processes. NICE also has its Public Involvement Programme that aims to help patients, carers, the public, and patient organisations involve themselves in NICE's work.

- NICE also has guidance on Community Engagement: Improving Health and Wellbeing and Reducing Health Inequalities, which are integral principles innovators should consider when developing their digital health technologies. Evidence Standards Framework for Digital Health Technologies provide insight into system perception of DHT.

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