

Involving patients
and citizens:

**I Statements for
research and
innovation**



Review of innovative medicines and medical technologies
supported by Wellcome Trust

Overview

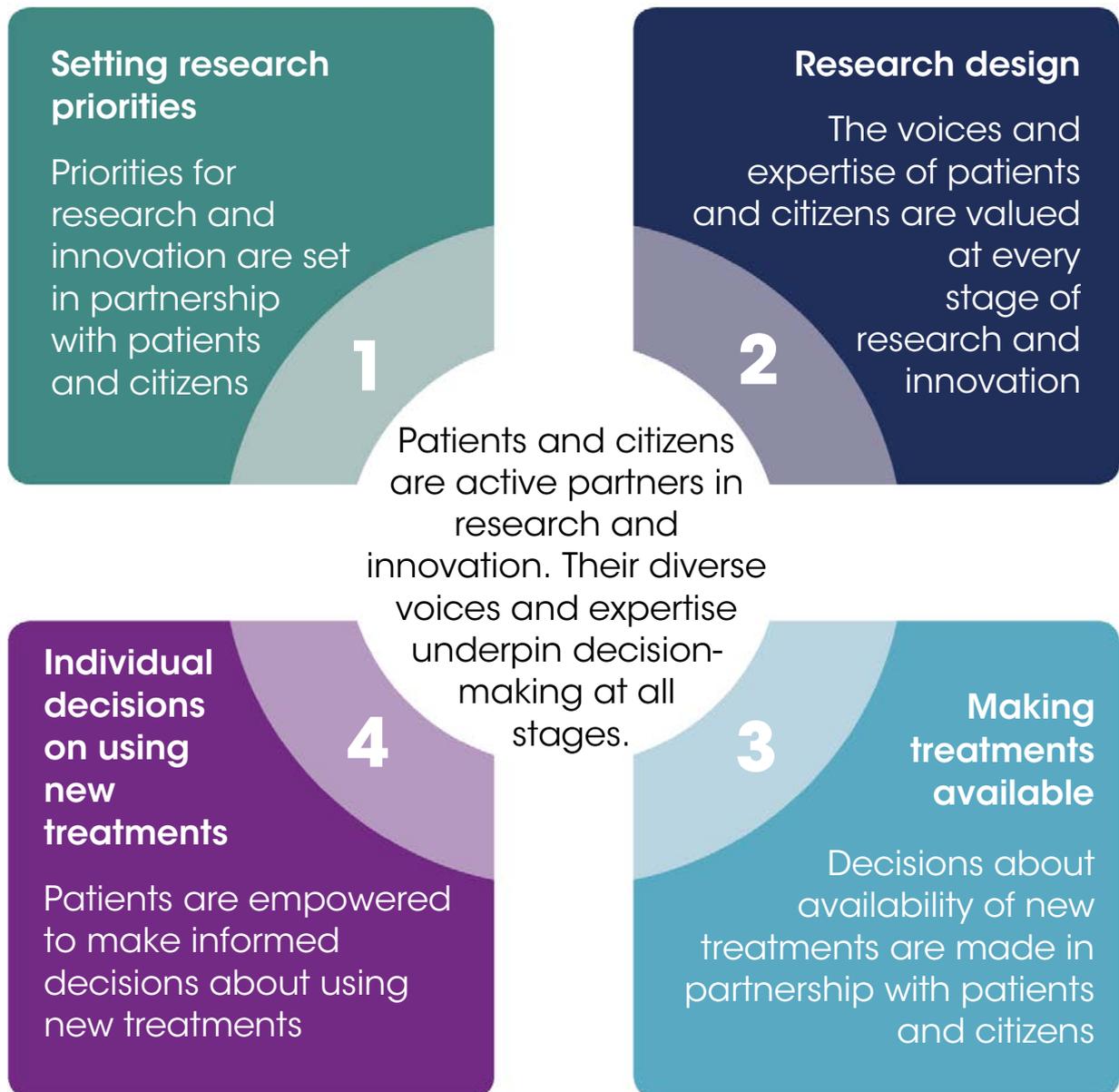


Figure 1: An overview of the I Statements for research and innovation

Introduction

The Accelerated Access Review was established to speed up access to innovative products for NHS patients. National Voices was invited to provide advice on how patients and citizens should be involved, and Hilary Newiss, chair of National Voices, acted as patient champion in the review.

The processes of research and innovation in health can be complex, opaque, and are driven by a mix of scientific, commercial and regulatory factors that do not necessarily align with what really matters to people. National Voices' aim was to bring real people and "what matters" into the heart of innovation. We worked with patients, patient organisations and charities, research organisers and central government to develop a clear and shared view of how this should be done.

The result is a set of 'I Statements'. They set out patient and citizen expectations, and can be used by those involved in research and innovation to help meet these expectations. They set a standard for what good looks and feels like.

How do we best describe people when they are affected by illness and disability? There is never consensus about language and various terms are in use. For simplicity, in this document we have used "patient" throughout as a short-hand for patients; users of health and social care services; people with direct experience of living with particular illnesses, health conditions and disabilities; and their informal carers, families and significant others. We use citizen to describe anyone, whether or not they are a patient and as a term with more empowering connotations than "the public".

Similarly, there is a confusing array of terms associated with the outputs of research and innovation. For simplicity, we have used the term "treatment" to stand in for drugs, devices, diagnostics and other technologies used in the context of health and care, whether new in themselves or applied in new ways.

The I Statements in summary

The I Statements can be summarised by an overarching statement:

“Patients and citizens are active partners in research and innovation. Their diverse experiences and expertise underpin decision-making at all stages.”

The statements are grouped to reflect the different stages of research and innovation; (1) priority setting, (2) the research process, (3) decisions about the availability of new treatments and (4) decisions taken by individual users of treatments.

It is vital that patients and citizens are involved in all of these stages. And involvement must be meaningful, in the sense that people have the information they need, have a voice, are listened to, and are able to shape what happens.

How to use the I Statements

Articulating the “good” not the status quo

The statements articulate what matters to people and what good looks like when it comes to their involvement in innovation. The statements do not attempt to describe current conditions – they are a standard to which everyone involved in research and innovation should aspire.

The statements are not prescriptive. Rather, they offer a set of standards that focus attention on what is most important to people and against which progress can be tracked.

The statements should help those driving innovations in health to develop and evaluate ways of meaningfully involving people and ensuring that their experience is positive.

Being inclusive

When decisions are taken, the interests of all those who may be affected should be represented. This means engaging with patients and relevant organisations, for example, health charities. In some cases it means engaging with a broader range of citizens too.

Involvement must reach beyond those with the loudest voices – it must encompass people with a wide range of health conditions, characteristics and backgrounds, including those with very rare conditions and those who may struggle to make their voices heard.

There must be sensitivity to diverse needs and some people will need to be supported to be involved at each stage. For example, accessible information in pictorial form will be vital for some people with disabilities. Approaches to engaging people need to be sensitive to cultural, ethnic and other differences. Organisations working with particular groups of people and communities are valuable sources of support and advice to enable effective involvement, as was highlighted consistently in the work to develop these statements.

Beyond research and innovation

While the I Statements were developed in the context of research and innovation, people involved in this exercise emphasised the importance of being partners in decision-making about health and care in the broadest sense. This included having choice and control over all aspects of their care and support, not just questions about access to innovations. Such expectations are well expressed in a suite of I Statements previously produced by National Voices, the 'Narrative for Person Centred Coordinated Care'.

A broader set of considerations about working in partnership with people on matters of health and care is also well articulated in the 'Six principles for engaging people and communities', a document produced with support from National Voices, helping to underpin the NHS Five Year Forward View.

Phase 1: Setting research priorities

Priorities for research and innovation are set in partnership with people

- I know that people with a wide range of characteristics and backgrounds will be included in, and benefit from, research and innovation.
- I know that patients and citizens are involved in deciding priorities for research, including decisions about funding.
- I know that what matters most to patients and citizens is taken into account in setting priorities for research and developing innovations.
- I get accessible information and support that helps me to understand how priorities for research and innovation are set.
- I get accessible information and support that helps me to understand how I can get involved in decision making about research and innovation.

Phase 2: Research design

The voices and expertise of patients and citizens are valued at every stage of research and innovation

- I know that people's involvement in research is valued; when designing research, through feedback to participants, and in sharing findings to inform future research and treatment.
- I am confident that all research is carried out ethically. This means those involved have made an informed decision to participate, are treated with dignity and respect throughout, and know they are free to withdraw any time. Their information is kept confidential and secure and is only used in ways that they know about, with their consent.
- I know that when people take part in research their full views and experiences are recorded, acted on, and made available for others to learn from.
- I know that evaluation criteria and outcome measures for research are developed in partnership with, and reflect what matters most to, patients and citizens.
- I am confident that I will have access to information about relevant research and opportunities to get involved.
- I am supported at every step to understand potential risks and benefits of getting involved in research, and to put this into the context of me, my situation and how I manage my health in order to decide if taking part is right for me.

Phase 3: Making treatments available

Decisions about availability of treatments are made in partnership with patients and citizens

- I know what decisions have been taken about access to treatments, by whom, how and why.
- I can easily find out about available and emerging treatments, who can access them, and how and when they can be accessed.
- I feel confident that access to treatments is not restricted because of where I live, who I am or the clinic I attend.
- I feel confident that there will be no unnecessary delays in making treatments available.
- I know patients and citizens have been involved and our interests have been considered in making decisions about what treatments should be available.
- I know how I can challenge decisions about access to treatments – both decisions that affect me personally, and decisions that affect patients and citizens in general.
- I know in advance when and how decisions will be made about access to treatments, and how patients and citizens can be involved.

Phase 4:

Individual decisions on using new treatments

Patients are empowered to make informed decisions about using treatments

- I make decisions about new treatments in partnership with professionals and others involved in my care.
- My knowledge of myself and my health and care is recognised and respected in decision making.
- I know that professionals involved in my care will ensure that they have up-to-date knowledge and information about all the treatments that may be available to me and will provide me with the opportunity to find out about this.
- I get all of the information I need to make a decision about whether or not to use a treatment, as well as any support or advice I need to help make the decision.
- I know that all of the potential risks and benefits of accessing a treatment will be clearly explained.
- I know that professionals involved in my care will seek out the information they need to help me understand the risks of benefits of trying new treatments, in the context of me, my situation and how I manage my health.
- If I am following a treatment I am supported at every step of the way and am able to review options and change my mind at any time.
- When I have made a decision about treatment, all the professionals around me are aware of and respect my decision.

How the I Statements were developed

More than 230 individuals and organisations were involved in developing these I Statements between September 2015 and February 2016.

The Accelerated Access Review team gathered views on an initial set of I Statements in the first phase of the review. Based on comments from this round of engagement, National Voices developed a revised set of statements, and launched an online survey to gather further feedback. People were asked to rank the statements within sections, grouped by theme, to try to identify whether some were clearly more important than others. Respondents were also given the opportunity to provide comments on each of the themes, as well as any overarching points.

Two hundred and thirty four people responded to the survey in December 2015 and January 2016. Respondents were a mixture of individuals and organisations. Of the organisations that identified themselves, most were charities providing support to patients; a smaller number were universities.

The statements were then revised in light of comments made in the survey. The revised statements were explored at a workshop on 26 January 2016, facilitated by National Voices and attended by a mixture of patients, patient organisations and representatives from the Accelerated Access Review. The revised set of statements was then circulated to those who had attended or shown interest in the workshop for final comments and feedback.

National Voices has carried out previous work on innovation issues. The 2013 publication '[Teeth in the NHS Constitution](#)' found that patients' legal right to treatments and therapies was insufficiently understood, acted upon, and monitored. In 2015 National Voices published a [joint guide](#) with the Association of the British Pharmaceutical Industry on collaborations between health charities and pharmaceutical companies. National Voices is also a supporter of the AllTrials campaign which calls for all clinical trials to be registered and all results reported.

Acknowledgements

Many thanks to everyone who contributed to the development of these I Statements.

National Voices

National Voices is the leading coalition of health and social care charities in England. We work together to strengthen the voice of patients, service users, carers, their families and the voluntary organisations that work for them. We have more than 160 members covering a diverse range of health conditions and communities, and connecting us with the experiences of millions of people.

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