ABPI Consultation on industry principles for use of health data

Response from use MY data

10 March 2022

Introductory Note

This response has been coordinated by the Secretariat, on behalf of the Advisory Group. Our Advisory Group acts on behalf of **use MY data's** Members – patients, relatives and carers who want patient data to be used for research.

For consultations, the Secretariat would usually consult with all of our Members to seek their views and include all of these in our response - we believe there is strength in presenting a wide range of patient views about the use of patient data. Unfortunately, we did not find out about the consultation in time to do this. Our Advisory Group Members provided their views, all of which have been included and collated into this single document, from which the online form was populated - https://www.surveymonkey.co.uk/r/ABPI_Health_Data_Principles.

We hope our response is useful and we thank you for the opportunity to contribute. We are happy for **use MY data**'s response to be used or shared without restriction.

Contact details and follow-up

If you would like to follow-up with **use MY data**, or ask any questions about our response, please contact the Coordinator, Alison Stone - alison@useMYdata.org.uk

Principle 1: Transparency of purpose
Industry will be clear and open about what company researchers aim to do with health data; how the data will be analysed, what the expected benefits are and how risk will be managed.

Background: Considering the complex process of research, discovery, development and deployment of new medicines, analyses of health data can help move the process forward at all stages. For example, analysis of various health datasets can help any of the following:

o Understanding disease processes and progression, identifying which patients respond best to different approaches and interventions, and defining current 'unmet need'

o Identifying new biological targets, and designing new medicinal interventions

o Stratifying and selecting the right patients for clinical trials to develop new medicines

o Supporting delivery of precision medicines to the right patients

o Assessing the performance and cost effectiveness of medicines in routine clinical practice, and identifying indicators of variable response

o Analysing and refining patient pathways to ensure the best patient outcomes for different patient groups, and to support equality of access to the best pathways for the best patient outcomes

All industry data analysis projects will be described in a short abstract covering aims, approach, anticipated benefits and risks that can be posted on a public database or website hosted by the data custodian and/or the researching organisation.

Do you have any specific comments on this proposed principle?

Response from use MY data to Principle 1

use MY data agrees that transparency is a crucial underpinning if we are to build trust in the way that patient data is used, the purposes and the benefits to those using that data, to patients and to the NHS. But we would stress that this should be about benefits to the NHS and/or patients.

Being transparent about the purpose is not the same as having an acceptable purpose. As written, this principle has missed the point of why research should be conducted. Good worthwhile research starts with the question "How does this help a patient?" It is good that throughout these principles the ABPI strives to be transparent, but we hear regularly from our Membership that "we need to avoid the type of research that is interesting and doesn't end up helping anyone".

We would like the ABPI to be explicit in saying that all research should have the purpose of finding something of benefit to the people who contributed (or collected, in the case of the NHS) the data.

As a patient movement we have developed principles of transparency around using patient data. These principles were written by our Members (patients, relatives and carers) and have been adopted by groups such as Understanding Patient Data and Health Data Research UK. We recommend that the ABPI adopts the principles.

Our Principles of Transparency are available here, and are shown below:

use MY data Principles of Transparency

Transparency should underpin everything and is essential if the trust and support of patients and the public is to be maintained and developed. Transparency means operating in such a way that it is easy for others to see what actions are performed. In a nutshell – Say what you do, do what you say.

Our guiding principles for transparency:

- Accessible* – easy access to information
- Understandable – the right language for the audience
- Relevant – addresses audience concerns
- Useable – in a form that meets the audience needs
- Assessable* – is checkable/provides sufficient detail
- Being as pro-active with 'bad news' as with 'good news'
- Being timely with communication

*What do we mean by:

Accessible:

- Easily see what data/information is there
- Meta-information i.e., the rules about what is there, how it is held, what are the rules/processes for access etc
- Must also be clearly available, must be understandable, and adherence to the rules stated (both the legal ones and the self-imposed ones) must be checkable
- There must be a clear statement on what rules are used to check that the data is eligible for inclusion.
- These must be around the sources of the information, what processes are used to validate the information, why data might be excluded (e.g., someone's opted out, we don't include children……)

Assessable:

- Bland 'PR' statements tell the audience nothing
- If it's personal information how you can dispute the content and what processes they would use to check, correct or exclude disputed info.

We recommend: that the ABPIs adopts use MY data's principles of transparency for the use of patient data. We would be happy to work through these with the ABPI, so that the ABPI can demonstrate that the views of patients have been listened to and acted upon.

The ABPI principle is heavily focused towards potential benefits but does not describe where the actual benefits are reported.

Ideally, we would like the first principle to be something that encourages patient benefit to be the guiding star of any research.

We recommend: that the ABPI extends Principle 1 to recognise that actual benefits (over time) should also be clear. These will be important in helping with the dialogue and wider understanding of the benefits of using patient data for research.

Principle 2: Clarity of arrangements
Contractual arrangements with data custodians will be designed to return 'fair value' as agreed by both parties, with the goal of contributing to the sustainability of the system (recognising the costs associated with collecting, validating, curating, storing, and analysing the data), regardless of whether the outcomes of individual projects are positive or negative.

Background: There is a huge potential variety of projects analysing health datasets for different purposes. These can range from a single analysis at a point in time, to a regular follow-up at specified intervals to explore trends, to analysis of linked datasets through to a partnership with a custodian to explore detailed understanding of disease over a period. The costs associated with curating and managing the data vary, depending upon the scale, detail and duration of longitudinal follow-up. It will be important that the custodian(s) and researchers can efficiently reach a common understanding of what any project seeks to achieve, share the legal basis for data use and analysis, the model of commercial arrangements, and the data architecture including whether or not a Trusted Research Environment (TRE) is used. This should be publicly available including:

o The legal basis for data use and analysis

o The commercial model (e.g., fee for service, license of data, shared benefit/risk) excluding pricing

o The data architecture (e.g., where the data will be stored, processed and analysed and how access will be controlled)

Do you have any specific comments on this proposed principle?

Response from use MY data to Principle 2

Language is really important. Either the term "data custodians" should be explained, or more commonly used terms, which have a specific legal context (e.g., data controller, data processor) should be used. Using precise language is essential for transparency and public confidence in the use of their patient data.

The concept of "fair value" is described as something which has to be agreed between "both parties". We question this approach, as it does not recognise that the views of the public/patients must also be brought into this decision. We support the use of practical solutions such as patient panels, patient review teams or patient assessors in this, and we believe that this should become standard practice.

We are also aware that in some cases, where the potential commercial use of patient data is being proposed, patients have an ultimate power of veto over the use of the data for this purpose. This direct manifestation of patient-power is something that we strongly encourage.

"Fair value" should be described not just in financial terms, but in terms of the wider benefits to society, as viewed by patients and the public. However, for a purely financial view of "fairness" to be made, there needs to be greater transparency about financial flows, investments and planned benefits, for all those involved.

On the three specifics as described in the "Background" bullet points, we would add a link to Principle 1 (Transparency) and make the publication of a publicly accessible data-use register mandatory. We would like to see a consistent, industry-standard data use register, updated at the commencement of the research, including:

- Lay description of the research
- Data to be used
- Source(s) of the data
- Body/bodies authorising access to the data (where specific authority is required)
- Planned benefits – health, financial and to which organisation(s) those financial benefits will accrue

- Legal entities that will own any ensuing intellectual property (hopefully the Department for Business, Energy and Industrial Strategy will come up with rules that will ensure intellectual property and financial benefits are within the UK)
- Timescale for planned results and benefits.

We recommend linking to the work which has been done by the Health Data Research UK Alliance to examine the formats of data release and usage registers. For both data release and data usage registers, we would expect, at the end of that timescale, a report back on actual results and benefits. That report back should not only include successful results but also information about negative results and no results. This is important for learning which can be built on, or at minimum can help other people avoid repeating the same fruitless research.

We emphasise that there is a growing need for a retrospective review of whether the "fairness" assessment was actually realised, as proposed/planned. Unless this happens, the potential to learn from previous assessments (good and bad) will be lost.

Principle 3: Patient and Public Involvement and Engagement (PPIE)
Industry will support the trend towards efficient involvement of patient/public representatives in the design and approval of health data projects, whether within their organisations or when projects are reviewed by data custodians.

Background: Data custodians are now more frequently involving patient and public representatives in reviewing applications from data 'users' – those who wish to research and analyse their datasets. There is a wide range of types of data analysis project supporting research, discovery, development and evaluation of medicines, and these projects may be undertaken by researchers and analysts in biopharmaceutical companies as well as from academia, the NHS and charities etc.

As PPIE becomes increasingly embedded in the overall design of development programmes for new medicines, involvement of patients in design of individual data projects should become increasingly routine; and demonstrating such PPIE should help ensure projects are accepted first-time by data custodians' review panels.

Do you have any specific comments on this proposed principle?

Response from use MY data to Principle 3

As a movement of patients, relatives and carers, focused on the benefits of using patient data to drive research, we support the intention of this Principle to adopt an approach of PPIE throughout.

We think that clarity is required though, as the Principle will need to be supported by clear, practical methods of how to include effective and impactful PPIE, which can be adopted by organisations.

Additionally, there is benefit in having a wider, independent, informed and engaged patient community, such as ours. Having PPIE embedded within all organisations is a positive step, but members of PPIE teams will need peer support and a community of learning. We would like to see the ABPI principles recognise not just the need for organisational PPIE, but the value that could be seen from the support of a wider PPIE community around the uses of data.

For patient data usage, we already have a network of Caldicott Guardians, a network of Data Managers, a network of data analysts; there is a pressing need for a network of patients.

use MY data would be keen to discuss this model with the ABPI.

Principle 4: Non-exclusivity of arrangements
Benefits accruing will be applied across the UK health service, for the benefit of all appropriate patients, hence supporting the principle that any dataset should be available for analysis by any bona fide researchers at any time.

Background: Industry supports the principle that all health data collected in and by organisations within the NHS should be readily and equally available for all bona fide research projects. Given that the anticipated benefits of analysing health data will be improving individual patient outcomes; and/or improving patient pathways and hence the efficiency of the NHS; and/or supporting development of new medicines with improved efficacy/safety profiles, all of these benefits should become available to all relevant patients across the whole NHS. Analyses of Real World Data has the potential to significantly help in addressing health inequalities. To ensure this can be achieved, companies will not 'buy' or 'own' specific datasets (i.e., become a data custodian) at the expense of these datasets being readily available to other researchers, or for the purpose of the company being the sole beneficiary (commercial or otherwise) of the insights gained.

Do you have any specific comments on this proposed principle?

Response from use MY data to Principle 4

We strongly support the principle that benefits should be seen across the (UK) NHS, and not just in specific localities where research investment is highest. Without that clear principle, the use of data would simply perpetuate existing health inequalities. We want to see patient data being used to address and reduce inequality and inequity.

The phrase "readily and equally available for all bona fide research projects" also needs to reflect that projects must comply with patient choice, such as that enacted through the National Data Opt-out in England.

Principle 5: Compliance with prevailing laws and regulations
All projects and arrangements will adhere to national level legal, regulatory, privacy and security obligations.

Background: All researchers will collaborate fully with data custodians to ensure that all analyses of health datasets are conducted within existing national laws and regulations. Each project must be clear as to the legal basis for undertaking the data analysis. While the basis for managing data within traditional clinical trials has always been that of 'informed consent', many analyses of health data are now conducted on different legal bases. The way this is covered under the UK GDPR provisions is currently the subject of a DCMS consultation; industry commits to comply with whatever laws and regulations are current at any given time.

The NHS offers patients the opportunity to opt out of data re-use. Industry supports the right of patients to opt out and will consult with data controllers to ensure that no datasets analysed include data from patients who have opted out.

Do you have any specific comments on this proposed principle?

Response from use MY data to Principle 5

The requirement to comply with "existing national laws and regulations" should be a given. Whilst we understand the purpose of restating this, it would be helpful if the wording could be changed to reflect that this is not optional, and that it has always been the case that laws and regulations have to be followed. Without this clarity, a reader may assume that following laws and regulations was not always the case.

Some explanation of the difference between "laws" and "regulations" as described in the consultation, would be helpful to the lay reader.

The commitment to honour opt-outs is welcomed, although clarity is needed as to whether this relates just to "confidential patient information". There is general confusion about whether "opting out" prevents your data being used for research and planning, or whether data which does not include confidential data can be used. Clarity in areas such as this links back to Principle 1 (Transparency).

Do you have any general comments about these draft principles?

use MY data's have written Position Statements on the use of patient data and we would like to highlight those which are relevant to the ABPI's draft principles and which you may find helpful.

Expectations of organisations which use our patient data - available here

Highlighting the benefits of using patient data - available here

Acknowledging and raising awareness of patient data - available here
We strongly recommend the mandation and adoption of the Patient Data Citation, as described in this Position Statement, The Citation, developed by the Members of use MY data, is a way of acknowledging that patients are the source of the data for research and analysis:

"This work uses data provided by patients and collected by the NHS as part of their care and support".

The Citation has already been adopted widely by data controlling bodies, who have mandated its use in many of their data releases, by national research organisations such as Health Data Research UK, funders such as Cancer Research UK, the Office for National Statistics, academic institutions and commercial data services providers.

We envisage the draft principles as a key way to move towards a standard use of the Patient Data Citation across the ABPI and its members; clearly demonstrating the ABPI'S commitment to transparency and highlighting the many ways in which patient data is used to drive innovation and research.

The only independent UK movement of patients, relatives and carers focussed on the use of patient data to save lives and improve outcomes

Our vision

Our vision is of every patient willingly giving their data to help others, knowing that effective safeguards to maintain the confidentiality and anonymity of their data are applied consistently, transparently and rigorously.

Our mission statement

- use MY data is a movement of patients, carers and relatives.
- use MY data endeavours to highlight the many benefits that appropriate usage of healthcare data can make, to save lives and improve care for all.
- use MY data aims to educate and harness the patient voice to understand aspirations and concerns around the use of data in healthcare delivery, in service improvement and in research, aimed at improving patient decision making, treatment and experience.
- use MY data supports and promotes the protection of individual choice, freedom and privacy in the sharing of healthcare data to improve patient treatments and outcomes.

What we do

- We promote the benefits of collecting and using patient data to improve patient outcomes with sensible safeguards against misuse.
- We work to bring a patient voice to all conversations about patient data.
- We have developed the Patient Data Citation, which acknowledges that patients are the source of the data. Details are available here.
- We act as a sounding board for patient concerns and aspirations over the sharing and using of data in healthcare and health research.

❖ We provide learning resources for patient advocates on patient data issues, including:
  - Hosting events for patients and the public, focussing on patient data topics
  - a library of resources of data security, consent
  - narratives from individuals about the value of collecting and using patient data.

❖ We advocate public policy that supports the effective use of patient data within appropriate frameworks of consent, security and privacy, and with the aim of providing benefit to patients and their health care services.