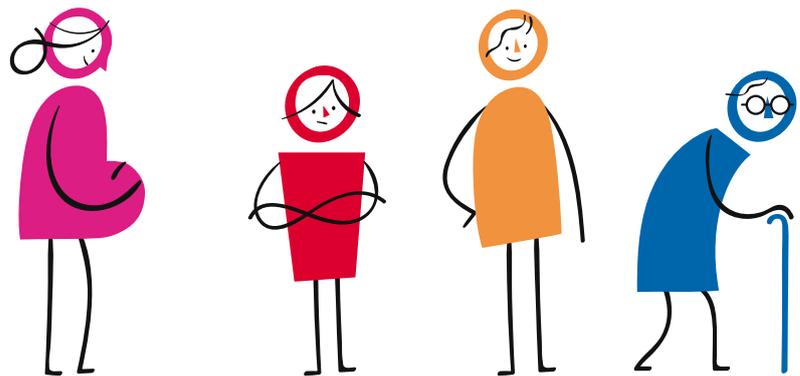


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My healthy future

discussion notes on
overdiagnosis



Roundtable on overdiagnosis

Overdiagnosis is the worry that expansion of risk measurement and early diagnosis (for example, in the context of personalised prevention) may be harmful to individuals and put undue strain on health services and resources.

The *My healthy future* roundtable on overdiagnosis brought together experts from clinical medicine, health services research, cancer epidemiology, law and history and philosophy of science/public health. Participants considered whether the introduction of new technologies will inevitably lead to overdiagnosis and, if so, how potential harms can be reduced and benefits increased. The discussion addressed the general debate, difficulties in evidencing overdiagnosis, the role of the commercial sector and implications for the health sector.

The roundtable was held at King's College, Cambridge on 27 November 2018.

This document presents a summary of the discussion, which has fed into the *My healthy future* project and final report.

The views expressed are not necessarily those of the PHG Foundation.

The narrative

Concerns about overdiagnosis have their origins in the growing awareness of the negative aspects of diagnosis. Specifically, these are anxiety, unnecessary and potentially harmful action intended for the prevention of disease, and additional cost to the health system arising from follow-up consultations, investigations or treatments. Much of that concern arose in the US where early studies had shown large variation in medical practice leading to overdiagnosis and overtreatment.

In the UK the 'overdiagnosis movement' has taken a different form, partly stimulated by the presence of guidelines and financial incentives in primary care that prioritised certain diagnostic categories and associated treatments - described in the workshop as 'the opposite of trying to explain to patients what that label means and giving them options'. The current UK debate was initiated by a series of conferences on 'Too Much Medicine' prompted by the BMJ and takes the form of an active social movement.

The debate on overdiagnosis occupies a challenging space both at a policy level and for individual patients. At a policy level it competes with the positivity of the scientific and commercial sectors, which are underpinned by complicated and intersecting drivers.

Innovative technological and research programmes such as Genomics England, for example, seek to satisfy a set of different agendas - the ambition to 'create a legacy for the NHS', to generate individual patient benefit and to promote 'UK PLC'.

- Overdiagnosis 'is very common in the US health system' and 'often associated with people being frightened into having treatments that they may not need'
- Often, those advocating technological change aimed at identification of risk or early diagnosis imply a general presumption of benefit so that those who question this presumption are labeled luddites, criticised for negativity or accused of simply trying to save money
- The intervention narrative includes forceful ideas including that 'prevention is better than cure', metaphors of 'beating' and 'winning', being involved in a 'battle' against disease and that 'knowledge is power'. Overdiagnosis is also described as 'a lousy narrative'. The public may perceive interventions as strongly positive through upbeat narratives such as that from Stephen Fry on the early diagnosis of his prostate cancer. In contrast, the overdiagnosis narrative is held back by the difficulty in identifying (and getting a compelling story) from an individual who has been 'overdiagnosed'

Suggestions for ways in which the debate could be more constructive and expresses the real challenges presented by overdiagnosis:

- Acknowledge the different agendas at work in major health-related projects
- Reframe the overdiagnosis agenda as a general campaign to understand the issues that will drive patient benefit
- Always discuss benefits and harms together
- Those concerned with minimising harm from overdiagnosis should pay careful attention to how rhetoric is used: particularly the importance of ordering what is presented and starting with what matters most to people
- Working with the commercial sector may help to refine the narrative

Finding evidence

Collecting good quality evidence regarding overdiagnosis is extremely difficult due to several factors (as reviewed in the overdiagnosis briefing document). Randomised controlled trials (RCT) are the gold standard method to test and evaluate interventions for effectiveness and for potentially beneficial or detrimental outcomes. However, they are usually expensive, laborious and time consuming; they often begin with test populations (in early phases) which do not reflect real life populations; and can take many years to yield useful results.

Specific challenges for evidence in disease prevention include:

- There are likely to be numerous interventions that offer small, incremental benefits
- The benefits may accrue across a broad group of individuals and may be difficult to characterise

The benefits of prevention are therefore much harder to assess than the benefits of a treatment. In these circumstances, RCTs do not provide an appropriate means of assessing effectiveness.

The apparent abundance of innovation in medicine, especially relating to personalised prevention, suggests it is necessary to become faster at evaluating new technologies. This is vital to ensure that patients are able to receive benefit from effective technologies in a timely manner, and that potentially harmful interventions are rejected. Evaluation must be proportionate. Where practical issues demand, less certain but faster assessments may be appropriate. Similarly it is often important to conduct research in such a manner as to rapidly show those interventions that lack utility, although this might be counterintuitive to many current marketing and research programmes.

Considerations

- Defining, describing and measuring the harms of overdiagnosis in medical, social, psychological and emotional terms is currently under-researched
- As diagnostics and medicines become more personalised and when assessing incrementally small gains from personalised preventative interventions, there is also a need to develop new methodologies that allows us to value trials on single patients as well as those with a broader population view
- Commercial providers of health innovations may accumulate vast amounts of data that could be used to inform personalised medicine. However, developing, accessing and using this data may be problematic because of a lack of transparency and proprietary rights over those data
- New trial designs need to be developed, including those that enable more systematic collection of observational data, designs for complex service delivery changes or policy interventions delivered at the level of a cluster and methods that enable a longer follow-up to generate outcomes evidence

Access to data for research

Health innovations in the public and commercial sectors result in the production of data that could be useful for advancing personalised medicine. Such data could also be useful for examining and reducing the levels or impacts of overdiagnosis. However, there are concerns that person/patient data for which access is controlled by commercial entities may not be available for these uses.

With respect to overdiagnosis, there are several additional issues with these data:

- There is often little incentive for commercial providers to make these data accessible
- Where there are multiple independent commercial providers of healthcare or related technologies, it is difficult to collect and collate data in a way that is useful for assessing overdiagnosis
- If public health services were to gain access to data collected by private companies with the above aims in mind, it is unclear how that data would be managed and utilised

In September 2018, the Department of Health and Social Care published a new voluntary initial code of conduct surrounding the use of 'data-driven health and care technology'. This voluntary code provides a set of principles, including transparency, defining a value proposition and other high level principles, aimed at manufacturers and developers to guide them in the development process. The aim of this is to clarify the expectations from suppliers of data-driven technologies and to outline what the government will do to support and encourage innovators in health and care. Roundtable participants remarked that it is "too early to know if they will be helpful and adhered to".

Interactions with commercial sector

In the future, large companies may be the ones driving how we provide care. It is therefore important to ensure that agenda setting is strongly informed by the needs of patients rather than industry.

Many innovations in, or related to, health are now being developed in the commercial sector, with a substantial proportion intended for use outside traditional healthcare environments (such as hospitals and GP surgeries). This trend is likely to continue and may escalate over the next 20 years - with negative consequences for overdiagnosis, especially where health or health-related data driven innovations are not bound by the same regulatory control as medical devices.

- Individuals can purchase devices or access technologies that have implications for health, or the perception of health, even where manufacturers do not claim clinical utility
- The intention of the manufacturer is key to determining whether or not a device is regulated as a medical device
- Examples of direct to consumer devices include genetic testing kits providing information about genetic markers that could be linked to disease and wearable devices which may alert the wearer to instances of atrial fibrillation
- The abundance and sophistication of such tests and devices is likely to increase. People will act on the resulting information in a variety of ways, such as through discussions with their GP, lifestyle changes, taking medications or even undergoing surgery.
- Negative consequences might include those consistent with many cases of overdiagnosis, such as anxiety, unnecessary and potentially harmful action intended for the prevention of disease, and additional cost to the health system arising from follow-up consultations, investigations or treatments. These additional costs are borne by the individuals and the health service rather than by the companies selling the products.

Considerations

- Encourage dialogue with the commercial sector: It is clear that the commercial sector is providing something that individuals and patients want. In determining how to meet individuals' needs in a way that results in the best outcomes for all it was noted that 'the health system has to learn to work with the commercial sector in a way that emphasises transparency.'
- Recognise flaws on both sides: In the future, large companies are likely to heavily influence the direction of health provision. In order to shape a narrative for health alongside industry and the commercial sector, the healthcare system needs to identify what lessons can be learnt from the success of commercial entities, especially regarding patient or individual wants and needs.
- Ideally, commercial companies should be held more accountable for the impacts of the devices and tests they sell
- There is a need to ensure responsible accounting for overdiagnosis in the commercial sector: Ensuring that private companies "pick up the pieces", including downstream costs of any test they market could mean that commercial companies would provide or contribute to any additional care that would not have been recommended through the application of standard procedures on the NHS

- Standards should be set for evidencing clinical utility. Companies may develop ideas first and then conduct trials in order to provide proof of clinical utility. This can take a long time and in the meantime, health services may incur significant costs in providing early access of patients to interventions that do not have proven utility

Transparency

There is a lack of transparency in interactions with the commercial sector. This arises in the context of:

- Drivers and incentives available to commercial companies
- Commercial sensitivity, which limits and reduces the availability of independent reviews that test the scientific and clinical validity and scientific utility of devices and technologies
- Conflicts of interest arising from the multiple roles of individuals involved in device development, which might include a clinical role as well as being a commercial advisor

The thresholds for placing devices on the market are getting more challenging. However, new regulations such as the Medical Devices Regulation and In Vitro Diagnostic Medical Devices Regulation will only apply if the manufacturer of a device determines that the device is intended for a medical purpose. In practice, manufacturers retain discretion as to whether or not the Regulations will apply.

- There is a need for more transparency about the purposes for which tests would be used, to reflect the potential liability that manufacturers and developers might have to test users
- The Medical Devices and In Vitro Diagnostic Medical Devices Regulations are limited in that they regulate the assay rather than the clinical utility associated with a test (i.e. determining the population and purpose for which the test is used). Determining clinical utility remains within the judgment of the health professional
- Regardless of whether the manufacturer's intent is to diagnose or not, that is what the product may be used for. Disclaimers allow companies to cover themselves, regardless of the consequences for individuals/patients. However, health professionals may owe a duty of care to their patients: If clinical utility is not claimed, then there is no burden of proof, regardless of how the product is then used. If manufacturers do not claim clinical utility, then they do not have to prove it exists when placing a product on the market

Developing the health sector

Reducing potential harms from overdiagnosis will require supporting health professionals to improve their understanding of risk and to improve the way they communicate risk to patients and the public.

Understanding risk and uncertainty

There needs to be greater understanding of the boundary between risk and disease which should include clarity on the difference between having the 'gene for' a condition such as Huntington's disease and actually having the disease. Participants made the point that if healthcare professionals are unsure of these boundaries this will affect how they interact and communicate with patients.

Even where there is certainty about the epidemiological effects of a test, there is often uncertainty about its relevance for an individual. In genetics, for example, laboratories may spend large amounts of time and resources on deciding whether a variant is pathogenic or not but then fail to discuss the risk associated with that particular mutation, which may be quite small.

Labelling and communication

- Ensuring effective communication between the healthcare professional and the patient is key to forming a shared understanding of the patient as a whole person and their perspective on particular benefits and harms that might arise from testing
- Presenting evidence in a clear manner with a balanced approach to benefits and harms enables patient understanding and decision making
- Discussions should be situated within the context of what is meaningful to patients
- Healthcare professionals should pay particular attention to medical terminology, such as disease labels, which might be frightening and unhelpful

Engagement with the public

Participants expressed the view that there should be more engagement between the health system and the wider public about the value and potential harms from testing in the context of prevention. Important areas to include were:

- Aiming for more realism in the face of a dominant narrative that 'prevention is better than cure'
- The public should be encouraged to trust the health system. There were concerns about the increasing availability of direct-to-consumer testing. In the context of genomics the public discourse was thought 'to be misleadingly clear cut' with individuals being told that 'knowledge is power' and with products being pitched as extremely innovative and raising consumer expectations
- Patients may have a genetic test from the commercial sector even when the clinician has voiced doubts about its utility or when there are concerns that the patient may not gain clinical value from the result or might even suffer psychological or social harm from the new knowledge
- Sometimes the patient has greater trust in the DTC test, simply because it has been paid for

Final comments

Take away messages from the workshop included:

- When does a genetic label become a disease?
- Professionalism is related to professional identity, which goes back to trust and communicating uncertainty
- Given the increase in complex genetic information, healthcare professionals need updated training on the communication of risk, and new skills and tools to better enable them to do this
- There is a need to shape the narrative and a requirement to address how to make the argument about the risks and benefits of tests in a way that policy makers and public understand
- There is a need to counteract the presumption people have that they will benefit from interventions
- There must be a balanced approach which gives information about both benefits and harms. [It may be necessary at times to emphasise the harms and counteract what people already think to begin with]
- The narrative should include that benefits are typically associated with some potential harms
- We should learn to work with industry and to help shape the policy narrative
- Strategic and technological development raises questions about who is in charge (or otherwise providing the necessary leadership and who gets to choose at various points (eg what diseases to study, and what patient groups, what are important outcomes for patients)

Delegates

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- Anneke Lucassen - Professor of Clinical Genetics, University of Southampton
- David Warriner - Cardiology Registrar, Leeds Teaching Hospital
- Emma Johnson - Policy Analyst, PHG Foundation
- Fiona Adshead - Associate, PHG Foundation
- Hilary Burton – Consultant in Public Health, PHG Foundation
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- Joseph Wu - PhD student in History and Philosophy of Science, University of Cambridge
- Julian Treadwell - GP and NIHR Doctoral Research Fellow, Nuffield Department of Primary Health Care Sciences
- Nora Pashayan - Clinical Reader in Applied Health Research, University College London
- Paul Pharoah - Professor of Cancer Epidemiology, University of Cambridge
- Richard Lehman - Professor of the Shared Understanding of Medicine, University of Birmingham
- Ron Zimmern - Chairman, PHG Foundation
- Stephen John - Hatton Trust Senior Lecturer in Philosophy of Public Health, University of Cambridge
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