HOUSE OF COMMONS

# Science and Technology Committee

## Oral evidence: National Health Screening inquiry, HC 1269

## Wednesday 7 May 2014

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Written evidence from witnesses:

- Academy of Medical Sciences
- Cancer Research UK
- Warwick Medical School, University of Warwick

Watch the meeting

Members present: Andrew Miller (Chair); Jim Dowd; Mr David Heath; Stephen Metcalfe; Stephen Mosley; Pamela Nash; Graham Stringer

Questions 1-52

Witnesses: **Professor Jane Wardle**, Professor of Clinical Psychology and Director of the Health Behaviour Research Centre at University College London, representing the Academy of Medical Sciences, **Jessica Kirby**, Senior Health Information Manager, Cancer Research UK, and **Dr Sian Taylor-Phillips**, Senior Research Fellow, Warwick Medical School, University of Warwick, gave evidence.

**Q1 Chair:** Can I welcome our three witnesses? Thank you very much for coming in this morning. Perhaps you would be kind enough, for the record, to introduce yourselves.

***Professor Wardle***: I am Jane Wardle. I am a professor of clinical psychology at University College London and run a research unit for Cancer Research UK on cancer prevention, which also includes some work on the more psychosocial aspects of screening—consequences and uptake.

***Jessica Kirby***: I am Jessica Kirby. I work at Cancer Research UK as a senior health information manager. Our team does cover the whole range of prevention and early diagnosis aspects, but my particular responsibility is to keep up to date with the evidence about screening.

***Dr Taylor-Phillips***: I am Sian Taylor-Phillips. I am a senior research fellow at the University of Warwick. My research is mostly about health screening.

**Q2 Chair:** Thank you very much. First of all, is it sufficiently clear where responsibility rests for taking decisions to implement, revise and cease screening programmes within the UK?

***Jessica Kirby***: Perhaps I will start with this. I think the situation in the devolved nations is slightly clearer than the current situation in England. In the devolved nations, it appears quite clear to us that the final say for implementing or making changes to screening programmes rests with the Health Ministers in those nations, taking advice from the National Screening Committee, whereas, since the creation of NHS England and Public Health England recently, it is not quite clear to us whether the final responsibility for decision making in England rests with the Secretary of State for Health, NHS England or with Public Health England at the moment.

**Q3 Chair:** I want to explore the principle of whether health screening advice to Government ought to be independent. Do you think it ought to be independent and, if so, why?

***Dr Taylor-Phillips***: It needs to be as independent as it can be. Is the National Screening Committee independent? The National Screening Committee, from my understanding, is pretty independent in its—

**Q4 Chair:** You see that as a source of independent advice.

***Dr Taylor-Phillips***: I do, yes.

***Jessica Kirby***: If I could add to that as well, from Cancer Research UK's perspective, we would echo that and say that we do consider the National Screening Committee to be a valuable source of independent advice and we think that the existence of such a committee is very important.

***Dr Taylor-Phillips***: If I could possibly add to that, we did a systematic review looking at the UK processes versus overseas, and one of the things that came out of it is that the UK processes are very well respected internationally, with other countries looking to the National Screening Committee processes to inform their own processes.

**Q5 Chair:** The screening committee sits inside Public Health England, as I understand it. Is that the right place for it to be, or should it sit somewhere else? Does it matter?

***Jessica Kirby***: The main thing to say is that the terms of reference of the group are very clearly defined, and that is in public. The members of the group are independent academics and clinicians, which is critical. The critical thing is that the processes are very clearly set out, as Sian said, and, in our experience, that has worked well. We are not aware of situations where the National Screening Committee has recommended something which Cancer Research UK would not agree with or, conversely, where there is something that we think they ought to be recommending that they have not.

**Q6 Stephen Metcalfe:** Picking up on, or going a little deeper into, the screening committee's processes, you said that you think they are effective and independent. Can you take us through what the process is and how often they revisit the decisions that have been made? For example, if you are reviewing what cancers to screen, is that an ad hoc review or is there a regular review of that?

***Dr Taylor-Phillips***: First, there is topic selection, so you need to decide what you are going to review. In the UK, the National Screening Committee say that they will review anything that a significant stakeholder—that is, a stakeholder representing a significant community of people—recommends and can provide a case that it might meet the NSC criteria. Once it is on the books, it is taken round for review every three years. There is a sort of smaller review where they look at, "Is there any big new evidence in this area? Is this going to be a really interesting and important topic?" Then they decide whether it needs a full academic review, and they might farm that out to a university.

**Q7 Stephen Metcalfe:** When that process is under way, from whom will they gather any evidence? Is the stakeholder group wide enough, in your view?

***Jessica Kirby***: Any organisation that has an interest in the area under discussion can register to be a stakeholder and can submit evidence to be considered as part of the review, so, really, the onus is on the individual or the organisation to participate in that, but my understanding is that nobody is excluded from that process. From Cancer Research UK's perspective, we have found the process of feeding into the consultations to be acceptable.

**Q8 Stephen Metcalfe:** So you think that the whole process is transparent and anyone who would be interested in getting involved in this can and does. Are there any areas for improvement or do you think it is pretty perfect the way it is?

***Jessica Kirby***: We are supportive of the process in general, as I have mentioned. The couple of areas that we have highlighted within our written evidence that could be marginally improved—but I would say this is not revolution and these are relatively minor points—are, first, about the availability of past documents from National Screening Committee reviews. As it stands currently, the only review document which is available on the website is the most recent, and often the National Screening Committee will have reviewed just one small aspect of a programme and it can be quite tough to track down the initial recommendation and the reasons behind that. One thing we would like to see, coming back to your transparency point, is the back-recommendations, as it were, and how we have come to this point, particularly if the latest review has not covered all of the topics.

**Q9 Stephen Metcalfe:** Is there resistance to doing that or is it a matter of getting the organisational process in place that would make them available?

***Jessica Kirby***: I have not experienced any resistance to that. It is something we would like to see, but I am not too sure on the details internally, I am afraid.

***Professor Wardle***: I have just one thing to add to that. The review process is somewhat organised, but has an ad hoc element to it in connection with the appearance of new evidence, trials or suggestions. It is also clear that the screening committees and the advisory committees—at least in the case of cancer—that sit under them take note of public interest and public attention to issues. This was obviously particularly the case in connection with the question about whether the public was given enough information about the harms of screening. That issue was taken very seriously. It was not only the general public, of course, but a whole number of health professional groups who were interested in this. That fed into a review process which fed into consideration at all the screening advisory committees and the national screening programme.

***Jessica Kirby***: The other thing, which we did highlight in our written evidence, is around the criteria which are used to assess the programmes. We think they are absolutely asking the right questions, but it can be difficult sometimes to provide an objective and very clear answer to some of them. For example, looking at the balance of benefits and harms, clearly that is absolutely central to whether or not a screening programme ought to be offered. I am sure we will come on to this a bit later on, but it can be quite difficult to nail down the exact level of harms and benefits and then, because they are very different by nature, to compare them. It is hard to give an absolutely objective answer, so one way of helping with that could be to provide a bit of guidance around how evidence will be used and interpreted within the context of some of the criteria.

**Chair:** You have pre-empted our next question. Do you have anything else on that, Stephen?

**Stephen Metcalfe:** No. My final question was a fairly open one. Aside from what you have already mentioned, is there any other way we could improve the way the National Screening Committee operates that you would like to get on the record now? Obviously not; it seems nothing leaps to mind.

**Q10 Mr Heath:** I want to come back to the criteria point, and your point, Ms Kirby, that it is difficult to interpret exactly what the criteria may mean, or there are potential inconsistencies. Do you have suggestions of how that process could be improved?

***Jessica Kirby***: There are a few different criteria for which guidance like that might be useful. One I have mentioned is about the balance of the benefits and risks. Take, for example, No. 5: "There should be a simple, safe, precise and validated screening test." The word "precise" could mean quite a number of different things in the context of a screening test. Are we talking about a particular level of sensitivity and specificity, or is there some other definition by which the precision will be—

**Q11 Mr Heath:** Do you think there is another definition? Is there a working definition, but it has simply not been published?

***Jessica Kirby***: It should consider the sensitivity and specificity, but I am not sure whether it would be appropriate or practical to come up with specific cut-off levels, because they do vary quite widely. The main measure of the benefit of screening tests is the reduction in morbidity or mortality, which is demonstrated in randomised controlled trials. I think it

would be slightly impractical to do that, but if there are ways—if there are, for example, cut-offs, or if there are considerations that the committee is using to make these judgments—then it would be good to have knowledge of what that is.

**Q12 Mr Heath:** I think you are saying that there is a slight blurriness about the criteria, but that is inevitable, given the nature of the beast. Is that right?

***Jessica Kirby***: Quite, actually. The difficulty is that, by their nature, these things do have to be judgment calls, and that is why we really value the expertise of the National Screening Committee in interpreting the mass of evidence. Sometimes it does not give an absolutely cut-and-dried, very clear picture, because evidence comes from many different sources; it can be interpreted in different ways; and studies have different strengths and limitations. It does require an expert group such as the National Screening Committee to interpret it all and to draw some clarity out of it.

**Q13 Mr Heath:** One thing that has been brought up in evidence to us from the PHG Foundation, which I think is Public Health Genomics—yes, thank you, Professor Wardle—is that there is a trade-off between the criteria. Is that something that you perceive—that there is a potential trade-off, in which you would maybe go easy on one because something is scoring above the line on another? Is that something that any of the panel recognises as being part of the process? It looks like you do not.

***Professor Wardle***: No. Are you talking about between screening programmes here, or within screening programmes?

**Q14 Mr Heath:** I think what they are saying is in the appraisal—

***Professor Wardle***—of an individual potential screening.

**Mr Heath:** For an individual screening programme, there may be a trade-off between one of the criteria and another, so that the overall outcome is positive, even though there may be inconsistencies within that across the criteria. I have to say, looking at you, that you do not look as if you agree with that view.

***Professor Wardle***: It would be hard to imagine that there are not areas where the case is much clearer and stronger, given the number of elements one is considering about a screening programme, and areas where the evidence is emerging, and there is still perhaps increased uncertainty about it. This relates to what Jessica is saying: some of the time, judgments need to be made.

**Q15 Mr Heath:** But if you are making a subjective judgment—there is an element of subjectivity there—that makes review rather difficult, does it not, because you may have bent the criteria, for all the right reasons, initially; and then when you come to review it, you are not sure quite what you are reviewing against.

***Professor Wardle***: So long as that information was clearly documented at the time— "We were aware of the limited evidence base in this domain"—

***Dr Taylor-Phillips***: My understanding of how it works in practice is that you would look at all of the NSC criteria, and for it to be implementable as a screening programme it would have to reach a certain level for every single criterion. What happens in a lot of the reviews is that, because it is reviewed against the criteria, it might say, "It has met all of these criteria, but there is not enough evidence about this and this." Three years later, the next review cycles round, and they might review, say, more about the test performance, if that was what it fell down on. That is probably what you are getting at, in terms of wanting to see the older reviews.

**Q16 Mr Heath:** If there is one outcome that is absolutely the gold star, as it were, would it be reduced overall mortality, disease-specific mortality, or morbidity? What would be the one thing that would tell you whether a screening test was working?

***Jessica Kirby***: I would say that all-cause mortality would be the ideal.

**Q17 Mr Heath:** Professor Wardle does not agree. Let us hear you first. We like disagreement.

***Jessica Kirby***: I was going to follow that by saying that while that may be the ideal, it is also absolutely essential to recognise that that is quite impractical in many situations. It is extraordinarily difficult to design a trial such that you would have even a hope of detecting an impact on all-cause mortality. With that in mind, disease-specific mortality does tend to be pragmatically the gold standard, in terms of measuring the benefit of screening programmes. It is also absolutely critical to consider the level of morbidity. With some screening programmes, either by preventing cancers from occurring in the first place or by detecting them at an earlier stage, possibly you may end up with a less intensive intervention. That is important to measure. However, screening tests can also increase morbidity, on the other hand, through over-diagnosis—again, I am sure that we will come on to that a bit later on—which can lead to unnecessary treatment. Weighing that morbidity is important, but I would say that the gold standard for a cancer-screening programme would be, practically, disease-specific mortality with the ideal of all-cause mortality, recognising that that is not possible in many cases.

**Q18 Mr Heath:** Professor Wardle, do you now agree a little bit more?

***Professor Wardle***: It seemed to me that it would be impossible to argue that our outcome on the positive side should be all-cause mortality, just because of the practical difficulty—nay, impossibility—of asking that kind of question. We do not in general ask that kind of question about any health-protective action we recommend, from seat belts to other things. We recommend that we show that the intervention reduces the hazard that we are considering at that moment. Equally, as Jessica has said, we recognise perhaps more than we used to—more than the public—that that has to be weighed against the harm, so it is

no longer possible to say there is one primary outcome. It is how benefits and harms stack up against one another.

**Q19 Mr Heath:** Dr Taylor-Phillips, do you want to adjudicate?

***Dr Taylor-Phillips***: Yes, I agree. I agree that it is a net gain in mortality and morbidity—for the individual screened, rather than other people, because that can complicate things. The other issue is that it should be from RCT evidence—high-quality randomised controlled trial evidence.

**Q20 Mr Heath:** Can I stop you? That is interesting; you are saying that the test is for the individual screened, rather than the cohort—the population.

***Dr Taylor-Phillips***: Yes. In a normal population screening programme—it comes in a lot with antenatal and newborn screening—there are considerations; for example, you might find out about carriers or the health of siblings, particularly in the US, where they screen for a wide range of conditions in the newborn blood spot test. They then have to deal with all the issues around revealing that information. In the UK, it is a clearer definition of benefit, and I think the effect of that is that you are more likely to keep people's faith in the screening programmes.

**Mr Heath:** Thank you.

**Q21 Jim Dowd:** I want to dig down on a lot of what we have covered already, certainly in harms versus benefits, and just look at the ethical considerations, though I am always slightly wary of doing so because ethics and morality are not universal. Everyone has an individual code, so it will depend. Is it your feeling that the screening committee have strong enough mechanisms in place for scrutinising ethical acceptability of screening programmes? Even though they may be adequate, could they be improved? If, of course, they are inadequate, do tell us.

***Jessica Kirby***: The main ethical consideration around offering screening is that screening is a medical intervention which has both benefits and harms associated with it and it is offered to healthy people. The balance of benefits and harms, and trying to minimise the level of harms while maximising the benefits, is obviously one of the critical points to tackle. Another really central one is related to that: it is about respecting individual autonomy in making decisions about whether or not to be screened. That is something which we are really moving much more towards now—and we are getting there, I think—with an informed choice position when offering screening to people. In terms of whether the National Screening Committee considers these, there are criteria that speak to these, absolutely. Regarding the benefits and harms, criterion 15 looks at that: does the benefit outweigh the harm? There is another one about informed choice, which looks like it is number 20, which asks for information laying out the full range of outcomes—benefits and harms—to be made available to people to help them in making an informed choice. In that respect, I think the main ethical considerations are dealt with within the criteria.

***Dr Taylor-Phillips***: I would just add to that. There is a specific criterion, 14, that it must be "clinically, socially and ethically acceptable to health professionals and the public." We have found that other countries had more specific ethical statements: they talked about human rights, confidentiality, autonomy, equity and access. In other countries, the only difference is that they are a bit more explicit, but it is certainly considered in ours.

**Q22 Jim Dowd:** Is that because it is more individualised, as opposed to the collective good, and it has to be more specific—there has to be an individual benefit?

***Dr Taylor-Phillips***: Yes, because for ethics there is a population-level consideration and an individual-level consideration. Screening programmes have to consider both ethically, and marrying the two up can be quite difficult. It is something that is considered at the moment, but it does not have its own specific ethics committee or anything like that.

**Q23 Jim Dowd:** Fine. That leads us on to another aspect. It is well known that one of the problems with screening programmes is that the take-up, as you go through the social scale, is much higher at the top than at the bottom. What efforts have been made, and whose responsibility is it, to minimise those discrepancies to ensure that the adoption of a screening programme does not actually widen health inequalities?

***Professor Wardle***: Maybe I could address that. The National Screening Committee and the advisory committees collect and look at data on inequalities in uptake and are concerned about the strategies that might be implemented to reduce inequalities, but I think one would have to say that in a highly organised programme such as ours in the UK, that is probably one of the things that is difficult to address, because we do not have, at present, tailored invitation procedures, for example, for different groups who might benefit from differently presented information. I think that the committees, as I understand it, and Public Health England and the NIHR on behalf of the national health service, are open to any kinds of research proposals that might be able to develop methods that are implementable within the screening programmes to reduce inequalities.

**Q24 Jim Dowd:** Is there not a glaring, obvious answer to the potential for inequality, in that the areas of the harder-to-reach groups need more resource to get a response than other groups? If you simply have a uniform national scheme, it is not localised enough to address that, surely.

***Professor Wardle***: I think you and I agree that that is a limitation of providing an organised screening programme in the national format that we provide in the UK. We do not really see evidence from screening programmes in other countries that offer them more opportunistically that they have any systematic approaches to promoting uptake in harder-to-reach groups. That is one of the responses I would make to that. The second is that what we actually see in uptake of screening is, if you like, a gradient across groups, whether we measure them by education, income or area-level characteristics. That makes it somewhat harder to say, "These are the groups that we need specifically to invest more activity in." Certainly, speaking as a researcher who is funded both by Cancer Research

UK and NIHR, we need to try to develop methods which would dovetail with the routine procedures and, none the less, try to give more of an uplift as you are talking about people with progressively more difficulty, for example, in understanding written information or having the time and resources to get themselves to the place they need to get to and so on.

**Jim Dowd:** Sure.

***Jessica Kirby***: Perhaps I could bring in an example from some work that Cancer Research UK has done in respect of the bowel screening programme. We have been running a pilot project over the first few months of this year within some boroughs in north-east London with the aim of trying to go some way towards at least learning how we might address some of the inequalities in bowel screening uptake. The campaign included posters with a Cancer Research UK recommendation and some pictures of people that the local audience may identify with. Also, some people were mailed what we called a "helper pack" to help them with the physical process of collecting the sample for bowel screening. That is still being evaluated and we have not had the results through yet, but we have had a very few pieces of anecdotal feedback indicating that people have found the kits helpful in taking their samples. I would say it is something that everybody ought to get involved in because health inequalities, as Jane has highlighted, are central—it is not just a problem of screening, actually—across many different areas. It is something that Cancer Research UK can help with, through information, and through campaigns, where we can do them. It is something that research can help with, to help understand what techniques are effective at raising uptake, but I do not think it is limited to just those two.

***Dr Taylor-Phillips***: Can I add that I agree that the localised solutions for uptake are important? We have a national quality-assured programme that it is really important to maintain. That has massive benefits, even if it does make these localised uptake initiatives a bit more difficult.

**Q25 Jim Dowd:** Thank you. Finally, is there any need for a specific advisory group on the ethical aspects of screening? Can you see any advantages or disadvantages were there to be such an entity?

***Dr Taylor-Phillips***: We are just finishing a systematic review where we have looked at the ethical implications of extending the newborn blood spot test, and it has come up with a lot of complex ethical issues, particularly as we move towards more genomic-type screening. The literature tends to say that people have specific concerns about screening that might contain their genetic information. There could be a case for that sort of thing.

***Professor Wardle***: I can see that perhaps consideration of ethical and social issues might increasingly be a standing item on the committee's reports, because as things stand, they kind of enter opportunistically into it when there has been a particular issue that raises attention. One of the things that we all experience, in connection particularly with the cancer screening programmes, is that we are talking about a very feared disease—the most feared disease that there is—and the public's attitude towards cancer screening programmes is overwhelmingly positive. Their enthusiasm for it is documented again and again across different countries, and we see this, at least partly, as being because something is being done to them to help with this dreaded disease. They find it very hard

to understand. Intuitively, it is non-obvious what the hazards are going to be. It stands to reason that finding cancer earlier is a good thing. If you talk about changing the date at which screening begins or the frequency of screening, people tend to think the explanations for those kinds of changes are economic. It makes, I think, a social and ethical debate important, because this is the public's perception.

**Q26 Jim Dowd:** I have one final point. Is that not quite easy to understand, given the prevalence of cancer and the fact there is barely a family in the country that has not been touched by it in some way?

***Professor Wardle***: Indeed. I think we can understand it, but what we have realised over the past 10 years, I suppose, is the extreme difficulty of providing balanced benefit and risk information at an individual level to the public who have this kind of uniformly rosy view of a screening programme. Even those who do not go to them regard the screening programmes positively and as a great benefit of service provision to them.

**Q27 Pamela Nash:** We received evidence from a GP who suggested that "copious evidence about screening has been gathered without careful attention to the harms generated." Is this something that each of you agree with? Do you recognise this as a problem?

***Jessica Kirby***: I would say that in some of the older screening trials—the ones conducted a few decades ago—they were not really set up to measure some of the harms of screening in the same way as modern screening trials are. That is partially, at least, because the existence of those harms has become appreciated over the time that screening has been an issue that we have considered. Some of those very old trials did not really address the harms in the same way. In fact, there was a study only towards the end of last year that looked at the level of harm reporting in screening trials. They looked at 57 screening trials and showed that only a minority of them reported some of the most significant harms. However, those were some of the very old trials, and I think that the trials set up these days—some of the lung screening trials, for example, and the ovarian ones—are explicitly set up with the aim of gathering all of the outcomes of screening, both beneficial and harmful. I would also say that, for some of the screening programmes based on those older trials, many researchers have gone back to that trial data and used other sources of data to make estimates of the levels of harms, and particularly of over-diagnosis. For breast screening, for example, that culminated recently in the independent breast screening review, chaired by Michael Marmot. It was an independent panel receiving evidence from many different researchers and people with different perspectives on breast screening, to try to come to some estimation of the harms. I would say that while some of the very old screening trials probably did not adequately assess it, we do, for all of the national screening programmes, have an enormous amount of evidence—

**Q28 Pamela Nash:** Just to be clear, you said "all", and earlier in your answer you said "some" several times—"some screening." Can I be clear and ask all the witnesses: are we at a

stage now at which all trials for screening do fully take into consideration the harms, and collect evidence on the harms as well as the benefits?

***Dr Taylor-Phillips***: I do not think I can answer that for all trials. I am conducting a trial, and I do not think I would have got it funded, or through ethics, without looking at the full spectrum, but I have not reviewed all of the evidence.

***Jessica Kirby***: For all screening trials, again, as you said, it is very difficult to answer. Certainly, the ones I have encountered—the modern trials that I know about—are set up to measure the harms.

**Q29 Pamela Nash:** Would you agree?

***Professor Wardle***: I would agree that in contemporary cancer screening trials, I cannot imagine anything being funded in this country that would not examine harms.

**Q30 Pamela Nash:** Is it fair to say that the culture has changed round this? I am not expecting you to have knowledge of every single trial, but would it surprise you more if it was not looked at than if it was?

***Professor Wardle***: My view would be that in medicine generally there has been a progressive acknowledgment of the potential for harm of medical treatment, rather than a primary focus on the benefit of medical treatments. In fact, cancer screening programmes are probably ahead of the curve in trying to look at the risks—harms, if you like, rather than risks— and benefits that might go along with screening. There are other things that go on, by way of checks and tests in medicine, which do not actually consider these kinds of issues as strongly. I see this all as being a progression within medicine. We were so grateful once that anyone could do anything for anything; now we are realising that some of the things we do, we actually overdo, and harm.

***Jessica Kirby***: I think you put it well: I would be surprised if I saw a trial now that did not collect the harms. It would surprise me. Obviously, I cannot speak for everyone.

**Q31 Pamela Nash:** Can I ask about Cancer Research UK in particular? When trials are funded by Cancer Research UK, how do they ensure that the harms are being analysed as well as the benefits?

***Jessica Kirby***: My actual area of expertise is not within the research funding side. However, I would say that all research proposals to Cancer Research UK are fully scrutinised by expert panels and committees within the areas that are relevant to the research proposal.

**Q32 Pamela Nash:** Are there public criteria?

***Jessica Kirby***: I am afraid all I know about the process is that they are thoroughly scrutinised, but perhaps Professor Wardle will be able to elaborate more on the process for research funding.

***Professor Wardle***: I do not think I can say that, but I can say that, when you are asked as a reviewer to examine and make comments on a grant, it would always involve a question about ethical issues and harms having been considered, so that element of the process is certainly being fed into screening committees. I am also aware that over the past 20 years there has been more call on the kinds of researchers—epidemiologists, statisticians, psychologists or sociologists—who might look at some of the important harms; they are becoming full members of research teams.

**Q33 Mr Heath:** There is one area of potential risk as we move to, rather than screening for evidence of disease, screening for propensity for disease—genomics, particularly. Is the legal and economic risk of a positive screening result considered as part of that ethical dimension? Clearly, there are issues in terms of insurance cover and of, possibly, civil liabilities in some cases. I wondered whether a lawyer ever gets involved in this ethical discussion.

***Dr Taylor-Phillips***: Not that I know of. When we have reviewed the ethics, we have also reviewed a little bit on the legal side and, yes, the legal situation does appear to be becoming more complex, particularly if your definition of benefit goes beyond mortality and morbidity for the individual screened.

**Mr Heath:** Thank you.

**Q34 Pamela Nash:** I have a final point. Jessica, you mentioned in your first answer experts going back and looking at previous trials with harms in mind. Is there sufficient access to raw data from older trials, and also current trials, for experts to do that? I am interested in the views of all of you in this. In trials now, is there sufficient evidence published in order for experts to analyse that data?

***Jessica Kirby***: The independent breast screening review that I mentioned did go through the process of getting hold of various trials. Unfortunately, I was not a part of that, so I cannot really speak too much to whether they actually got hold of the individual-level trial data, but my understanding is that, on occasions, that can be shared and re-analysed. What I would say is that the published trials have all been analysed and new studies have been done off the back of that data as well, which has led to the knowledge that we have these days about the levels of harms of screening. Unfortunately, I am not an expert on the absolute details of it.

**Q35 Stephen Mosley:** Could I move on to communicating the benefits and risks of screening with the general public? Are each of you confident that each screening programme across the UK is producing clear, unbiased and consistent information about both the risks and the benefits?

***Professor Wardle***: I can only speak for the cancer screening programmes. I sat on the independent group that was responsible for revising the information leaflets that were sent to the public when they were invited to take part in these screening programmes. I would have to say that there was a great deal of debate within the committee always about how best to communicate the information that we wanted to communicate, because, on the whole, it is quite hard to communicate, for example, the issue of over-diagnosis, which has been mentioned. I have been involved in running some focus groups with the public about their understanding of over-diagnosis. I explained to them that some cancers may be found at screening that would probably never have done them harm, but that at the moment we cannot tell which is a cancer that might subsequently do harm and which is not, so if a cancer is discovered, at least in the case of the breast screening programme, the person goes down the treatment route. The public find it extraordinarily difficult to understand both how there could be a cancer that might not have done you harm, and how it could possibly be that, if there is such a thing, we do not already know. One is communicating difficult information.

On every iteration of the materials that we produced, which were seen by people with a very wide range of expertises, people had quite strong views: "I do not think the public can quite understand that, or that"; "I think that is misleading,"; "That makes it too long." You had a constant trade-off between giving people so much material that they would be overwhelmed by it and including all the caveats and information you wanted. Within all the constraints that this situation obviously poses, I think—I am obviously not speaking independently here, because I was on the committee—this was a heroic and largely, in principle, successful activity. What we do not yet know is whether these particular materials that people are getting for screening make a difference to the way they feel about the information they get about screening, or to what they are doing, in terms of taking up screening.

***Jessica Kirby***: I would absolutely echo all of that, and I was also involved in the development of the new breast screening materials. Jane has given a wonderful description of the challenges that we faced while doing that. Like her, I feel that we did the best we possibly could in the situation, and I think it is effective, although, as Jane said, we do not have any evaluation results from that yet. All I have see in is a very few pieces of anecdotal feedback, and a few newspaper articles. "My mother's friend told me something"—that is the level of anecdote we are talking about here. But people have told me that they like it. It was also tested extensively with members of the public. The concepts were tested as part of a citizens' jury, and we received extensive feedback throughout the whole of the development process from experts, clinicians and researchers from a wide range of viewpoints.

I think this is probably the first example within the national screening programme of a piece of information material that is explicitly on informed choice, which is a great achievement. I am sure there will be many improvements that we can make to this in future. I would very much welcome more information from other countries and from the NHS programme about how information like this is perceived and used, in order to improve that further in the future.

The other side of that is that this is the new information material for the breast screening programme. We also revised the cervical screening materials through this informed choice

process and, as far as I understand it, those have not yet been launched to women. The bowel screening materials had not been developed through this process, apart from the bowel scope—the new flexible sigmoidoscopy—leaflet. So I think there is a range across the screening programmes and also within the breast screening programme. There is one legacy leaflet, aimed at woman over 70 and dating from 2006 or 2007, that is still available to people and does not, I would say, fulfil the principles of informed choice.

**Q36 Stephen Mosley:** We have had some evidence given to us, specifically on breast screening. Advocates for Honesty and Transparency in Breast Screening have said that health professionals' focus seems to be on increasing the uptake of the programme through "a mixture of misinformation, pressure and propaganda." Healthwatch has said that "information on screening supplied by the NHS is often poorly explained and subject to bias", and Professor Bewley, when talking about the breast cancer screening programme, said it was being "marketed using persuasive techniques". Could you answer those sorts of criticisms that we have had put to us?

***Jessica Kirby***: I would say this is absolutely representative of the kinds of opinions that we were dealing with throughout the development of the process, and I understand that the individuals involved in that have given their feedback as part of the process. Perhaps you wanted to say something further, Jane.

***Professor Wardle***: As a consequence of the range of opinions, the committee that produced these materials obviously explored this issue a great deal. There was certainly concern in the committee that some of the information that we were giving might be more of a deterrent to people with lower levels of numeracy and literacy; they would just see these words about bad effects, and it would be off-putting overall. I think the consensual view of the committee was that we had ended up with something that was about as transparent as it could be. You have all, no doubt, seen or can see the materials for yourselves. I certainly anticipated, as a consequence of these materials, that we would see some drop-off in screening uptake rates; I felt that we were being very up-front about the downsides.

***Jessica Kirby***: I would say as well that the approach that has been taken with these materials is to treat the invitation letter and the leaflet together. We reworked the invitation letter as well as the leaflet. The approach that we were aiming for was the so-called "consider an offer" approach, which is making an offer of screening, saying, "We think this is, overall, beneficial and outweighs the harms. Therefore we, as the NHS, are offering you this screening," and having the information leaflet be factual, balanced and non-persuasive. That is not to say that the letter is persuasive; it says, "Here is the offer." The interpretation of that, in this "consider an offer" model, is that the offer is made because somebody considers it worth while. Perhaps that might help in understanding a little bit more about where the persuasiveness is—I would not say it is persuasiveness, but the offer is in the letter, and the leaflet should be completely factually based.

**Q37 Stephen Mosley:** Thank you. We had received the submission; I just wanted to make sure that you had an opportunity to respond to it. Can I move on to Dr Taylor-Phillips? I

know that you put in a written submission in which you said that screening is sometimes poorly understood by clinicians. Could you explain why that is the case, please?

***Dr Taylor-Phillips***: Yes. That part of my submission was not based on research evidence. I teach screening to masters students who are from a vast range of backgrounds—clinicians, policy makers, and so on—and also to medical students. I am often astounded by their baseline knowledge, in terms of test performance, over-diagnosis and over-treatment. Certainly, doctors are becoming more aware of the issues around over-diagnosis and over-treatment because there has been a lot in the *BMJ* about it, but I am often shocked by how little people in the general public understand. I guess it ties in with what you said: cancer is thought of as this uniformly awful disease, rather than a range in which some cancers have a very good prognosis; some, if you had them, you would not want to know about; and some you cannot have any treatment for. There is not that understanding, and on that basis, it is very difficult to understand over-diagnosis and over-treatment. This does not go for the people I teach, but certainly in conversation with people, they are not necessarily that interested. I know that is unscientific, but people believe in screening and cancer screening, and obviously cancer is a massive health problem, but they have jobs and lives and do not have time, maybe, to think about all of this.

***Professor Wardle***: There was a recent study that looked at which bits of information health professionals thought was most relevant in trying to decide whether a particular form of screening was a good idea or not. What came out of it was that, if you like, non-specialist health professionals particularly valued information telling them that screening would improve survival from cancer, whereas the professionals concerned with the screening programme considered that the key beneficial outcome has to be measured in terms of mortality, because you can obviously, if you like, illusorily improve the situation by diagnosing a cancer a bit earlier. Just saying that people live longer after the moment the cancer has been diagnosed is not necessarily changing the age at which anyone is dying—sorry, I should say the length of time they have the disease for. It is just bringing back in time the moment at which they first know about this disease. This has come up time and again in terms of health professionals' understanding of benefits: an over-emphasis on survival, rather than mortality.

**Q38 Mr Heath:** Going back to evidence on review, there is a difference of opinion, I think it is fair to say, among some of the submissions we have received as to whether a randomised controlled trial is the only way of getting proper evidence, or whether observational data are as valuable in some circumstances, or perhaps better, than a badly designed or poorly constituted randomised controlled trial. I invite your views on that, and I will start with Professor Wardle.

***Professor Wardle***: I am not an epidemiologist and a trialist by background, so I cannot respond with that level of expertise on this. I think that, like many people who work in medical fields, we value randomised controlled trials for their ability to remove particular forms of bias from our outcome evaluation. Indeed, we know that, for example, the breast screening review took the randomised controlled trial data as particularly key in reaching their conclusions. None the less—

**Q39 Mr Heath:** Can I interrupt you there? That is known, is it? We know what is taken into account and what weight it is given.

***Professor Wardle***: Yes. They also looked at observational data in it from some large observational datasets, but my opinion, and the general opinion, is that we also need to be looking at observational data, and indeed we need to be recording outcomes at an individual level within screening programmes—I mean, within the population, who is electing to be screened and not screened, and who is getting different kinds of outcomes—so that we are, in an ongoing fashion, collecting data which can help us see that the screening programme, as it is being delivered to the general public, is working in the way we expected it to work, based on this randomised controlled trial data. I think most people would say that you have to have both.

**Q40 Mr Heath:** Are there other views?

***Dr Taylor-Phillips***: Yes. After you have implemented, it is essential to look at the observational data to see if you are achieving what you thought you were going to achieve, but the only way to really know if a screening programme is effective is a randomised controlled trial, because it takes out biases. In every area of medicine, you have biases that are taken out by randomised controlled trial. Screening has extra biases in length and lead time. The example I gave in my submission was neuroblastoma screening, implemented in Japan. Their survival rate before screening for neuroblastoma was 50%. The screening detected 337 cases and the survival rate was 97%. If you tell a lay person that, they say, "Wow, brilliant, screening!", but the randomised controlled trials showed no evidence whatsoever, so that is really the gold standard. Having said that, there are certain conditions for which you could never do a randomised controlled trial. For example, with a very rare condition, you would never get a sample size big enough. Perhaps you could have international co-operation, but then, if you are looking at a rare disease, given the cost of actually doing the study, would it be worth while? It is difficult.

***Jessica Kirby***: I would echo all the points made on this so far. We think it is absolutely right that randomised controlled trials are relied on by the National Screening Committee as the gold standard, particularly, as you mentioned, for the initial decision to implement a screening programme, because of the elimination of biases by those and the opportunity it gives you to measure all of the outcomes within the population. Observational data, and many other types of data that can be used to inform screening, can be very useful as well. All evidence needs to be interpreted with a mind to the strengths and limitations of that evidence, and while observational data can be very useful, for example, in determining age ranges and screening intervals and that kind of thing, modelling studies can also be very valuable in that, although, of course, that comes with the consideration that the assumptions put into the model quite clearly affect the results that come out. I think the main message is that all of these pieces of evidence need to be interpreted in light of their strengths and limitations. That is one reason why you value the independent expertise of the National Screening Committee in being able to interpret all this evidence from various perspectives, with different strengths and limitations, to inform their position.

**Q41 Mr Heath:** Are there any gaps in the evidence base for programmes that are ongoing at the moment—any examples of perceived gaps?

***Dr Taylor-Phillips***: The difficulty is that once you have implemented a programme, it is almost impossible to run a randomised controlled trial. The historical programmes—the oldest programmes—sometimes have the weakest trial data, just because of when the trials were done. Actually, a screening trial is quite difficult methodologically anyway, because you have to have a long follow-up, and in that long follow-up, people tend to say, "Why am I not being offered screening?" and maybe go and get it themselves.

**Q42 Mr Heath:** So there are gaps, but they are gaps that can ostensibly be filled.

***Dr Taylor-Phillips***: Yes.

**Q43 Mr Heath:** Does anyone disagree with that view?

***Professor Wardle***: No. I think there are always emerging questions, and one that is clearly coming up at the moment is the changes in the bowel cancer screening programme by the addition of flexible sigmoidoscopy at an age point before the faecal occult blood testing begins. We should be already considering—

**Q44 Mr Heath:** "Should be," but should not somebody be commissioning that, and if so, who?

***Professor Wardle***: It is an active item for discussion on the bowel cancer screening advisory committee, so my assumption will be that it will be commissioned shortly, but I can only—

**Q45 Mr Heath:** Is there a mechanism for funding the research if it is necessary, or do they just say, "This is something that should be done," and hope somebody will do it?

***Professor Wardle***: There are a number of mechanisms for funding it. The Department of Health funds the policy research committee. Again, I should disclose that I am the assistant director of the policy research unit, which includes cancer screening and its remit, but I would not be the person who would do this sort of thing. There is responsive-mode funding included there; that could be used precisely to fund a question of this sort. There are also additional funds available for commissioning extra reviews that are required.

**Q46 Graham Stringer:** I want to go back to David's question about screening for rare diseases. If you cannot have randomised controlled trials, what conclusion do you come to about screening for rare diseases? Do you not screen for them because they are rare and we cannot hit the gold standard on controls? What is the answer to that?

***Dr Taylor-Phillips***: Historically, if you look at a rare disease, it would almost always not fulfil the NSC criteria anyway. The reason is, the rarer the disease, the better the test you need to reach the same positive repeat value. That means for a rare disease, unless your test is absolutely perfect, you will be recalling lots of people for each case you detect, whereas if it is a more common disease, with the same quality of test, you are recalling fewer false positives. It is a kind of mechanism of test performance. It is hard to have a test that performs well enough for rare diseases, plus you have to factor in the cost of the screening test. If it is a rare disease, then there are fewer people's lives that you could potentially save, so the screening test would also have to be very cheap, because you are screening lots of people for the few cases. For a lot of rare diseases, it is just not feasible anyway, so no matter what the evidence, it just would not meet the criteria.

However, there are some rare diseases that you could add to existing tests—for example, the newborn blood spot test—and that would take out some of the costs. You would not have to pay for the extra testing; you would pay for the rest of the programme and the education and so on. So, yes, it is a difficulty for those cases. Having a randomised controlled trial of the outcome, as in the mortality and morbidity benefit, would be very difficult. You could have a randomised controlled trial of, say, the over-treatment elements, because that would require fewer people, or you could look at other countries that have implemented it and see what has happened. There are conditions under which it is very difficult.

**Q47 Graham Stringer:** Can you give us some examples of rare diseases that could be added to current screening tests? You said there are occasions.

***Dr Taylor-Phillips***: The National Screening Committee I think are considering—there is a panel of five and another panel of three—maple syrup urine disease, things like that. I do not know much about the conditions themselves, but a few rare—

**Q48 Graham Stringer:** If you could drop us a note on those, that would be helpful.

***Dr Taylor-Phillips***: Certainly, yes.

**Q49 Graham Stringer:** There have been criticisms that the NHS's Health Check programme is not based on sound evidence. The Academy of Medical Sciences, among others, has made that criticism. Do you think that is fair, and can you run us through the arguments, or the case, that it is not evidentially based? Professor Wardle?

***Professor Wardle***: I do not have enough expertise on the decision making that went into the Health Check programme, I am afraid, because obviously its primary concern has been cardiometabolic disorders and that is not my area of expertise. I note from the evidence presented by the Academy of Medical Sciences—I speak as someone who is on the Academy of Medical Sciences—that its view is that the Health Check programme has not been based on rigorous randomised controlled trial data as a basis for implementing it as part of the national screening programme.

**Q50 Graham Stringer:** Anyone else?

***Jessica Kirby***: Unfortunately, as it is not a cancer screening programme, it is not something that Cancer Research UK is particularly well placed to comment on.

***Dr Taylor-Phillips***: It is not my area of expertise. My understanding is that it is not a National Screening Committee programme, though, is it? It has not been through the system—all of the processes—we have talked about today. I do not know what system it has been through.

**Q51 Graham Stringer:** When doubts have been raised about it, do you think there should be an independent check and assessment on a programme?

***Dr Taylor-Phillips***: It seems sensible.

***Professor Wardle***: It would seem extremely sensible to do that. I think all screening programmes raise controversy. There are always adherents and opponents, and it seems to me that in connection with the Health Check programme we should not just be hearing sporadically from adherents and opponents, who often speak quite impressively either in favour or against the programmes, but should implement a review.

**Q52 Graham Stringer:** Thank you. Finally—and this really is a repeat of the randomised controlled question in a different form, I suppose—are there ever any cases where there should be screening where the evidential base is either non-existent or weak?

***Jessica Kirby***: The main thing that we learn from the understanding of screening that we have developed over the last few years and decades is that screening is complex, that all of the outcomes cannot necessarily be predicted, and that in some cases, even when something may seem to the public, as Jane has mentioned in this session already, to be entirely excellent and without fault, sometimes unintended consequences can occur. As far as cancer goes, we would support evidence being behind screening programmes and a National Screening Committee review for any new programmes that were introduced in the field of cancer.

**Chair:** Thank you very much for your evidence this morning. That is a good start to our inquiry.