

Communicating risk in primary care

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MM, JT., DS, IR (Members of the oversight group, Academy of Medical Sciences report “Improving the use of scientific evidence to judge the potential benefits and harms of medicines”)

In 2014, NICE changed its guidelines for offering statins to patients, reducing the threshold from 20% cardiovascular risk to 10%¹. This ignited a fervent debate about the wisdom and practicality of the change and raised three key questions: *Do we really have the right evidence on which to make a decision about the risk/benefit balance? Is that evidence trustworthy when applied to patients seen in general practice? How can we communicate the best possible evidence to the people who need to make the relevant decisions: policy makers, clinicians and the public?*

These questions are not, of course, specific to the issue of statins – they go to the heart of how healthcare decisions are made and as a result were the trigger for a request from the Chief Medical Officer of England to the Academy of Medical Sciences (AMS) to examine the issues in detail. Four of the authors of this article were members of the oversight group involved in the work, and the resulting report was finally published last month².

The report presents 12 recommendations that are planned to address nothing less than the scientific basis of medicine (See Box 1): from deciding how research efforts should be targeted, to guidelines for science reporting in the media; from improving the methodology of clinical trials to the design of patient information leaflets. But what does it mean for general practitioners?

We believe that it raises a number of significant issues relating especially to **shared decision making, the capacity and capabilities of health professionals and over-medicalisation**:

Shared decision making: Making it easier to put shared decision-making at the heart of general practice

The theory of shared decision-making is wonderfully simple: a health-care professional will sit down with a patient and together they will discuss the potential benefits and risks of different treatment options, coming to a joint decision on the course of action that best suits the individual patient's needs and priorities.

The report oversight group, however, in talking to GPs and the public, identified several familiar challenges in reaching this ideal. Time, trust, and understanding were all lacking, from the perspective of both clinicians and patients.

The report tackles the issues of trust with sections on the design, implementation and interpretation of clinical research. That leaves the issues of communication of the resulting information, the skills to interpret it, and the time to do so.

The report attempts to anticipate how patients might frame their questions (Box 2a), how clinicians might prepare for such questioning (Box 2b) and how both might be supported in terms of resources. Within primary care, NHS Choices and patient information leaflets were identified as key means to share trustworthy information on the potential risks and benefits of treatments and signpost resources that tend to be on disparate sites at present.

There has been much work done on how to get information across in ways that are clear and easily understood by a majority of people – (see Box 3 and Fig 1). One example that is mentioned in the report is the use of 'Facts Boxes', originally developed in the US³. These summarise the key information that patients and healthcare professionals need to know, often using graphics alongside numbers to make comprehension easy at a glance. The report suggests that NHS Choices should consider including this sort of structured information on the potential benefits and harms of alternative options.

However, it suggests that NHS Choices carries more than this. Many patients are more than happy to trust their doctor to make decisions fully on their behalf, but others may want to know more and to take an active role in decision-making. In order to help this latter group, and their doctors, the report suggests that NHS Choices should increasingly carry not just information, but tried-and-tested decision aids.

Decision aids have been developed to help guide shared decision-making in a wide variety of fields. They range from a simple set of suggested questions for a doctor to ask a patient (and vice versa) to online sites into which a patient's personal information can be entered in order to produce individualised information and suggested considerations for the clinician and patient to discuss. Decision aids have been experimentally developed by both NICE⁴ and NHS England⁵, but the AMS report aims to put them firmly into the mainstream, suggesting that NICE co-ordinates their development, NIHR and others fund their evaluation and assess their effectiveness, and that NHS Choices hosts them. This proposed structure and clear division of responsibilities should, we hope, help make a real difference to the uptake of decision aids by GPs and patients.

The report also formulated a series of questions that it suggests patients and healthcare professionals are encouraged to consider in advance of every appointment, or to ask during it (Boxes 3a, b). The oversight group drew upon many previous initiatives, within the NHS and by specific charities, and hope to add increased support and momentum to this movement, especially for patients who may not consider questioning their doctor.

The capacity and capabilities of health professionals

The idealised view of shared decision-making is that in a comfortable consultation GPs will be able to present the evidence, discuss the pros and cons of any intervention (along the lines of Box 3) and, with the patient's involvement and agreement, proceed with an effective form of therapy or treatment to achieve the patient's goals. There would be time for reflection and the patient would return to clarify any prevalent issues. The report's oversight group recognised that none of this is easy to deliver in the current environment.

Firstly, there's the problem of access to online resources. Many GPs already use a variety of these as a source when discussing treatment options with patients⁶, but having decision aids and other resources scattered over the internet makes it difficult to know the best place to turn. As already mentioned, the report's suggestion of adding clear information summaries to a trustworthy centralised resource (e.g NHS Choices) where they can be kept up to date is – we hope - an ideal solution, if it can be funded and maintained to do this.

Secondly, though, there's the issue of training. Until very recently, much medical training has (understandably, but perhaps problematically) concentrated on the theory and practice of *medicine*, and not covered the theory and practice of *conducting research*. Thus many – if not most - practising clinicians do not feel confident assessing the reliability of the methods and statistics employed in individual research papers, and even less so in communicating this evidence to patients⁶.

The report calls for increased training at undergraduate and post-graduate levels in both the evaluation of scientific evidence and its communication, and encourages the Royal Colleges to provide continuing professional development (CPD) in both these areas for practising doctors. The RCGP already has a curriculum that includes the need to develop critical appraisal skills and its CPD programme complements the needs of speciality trainees to meet the requirements of the curriculum for the MRCGP examination. More on the communication of risk to patients may be called for, and the report recommends training in shared decision-making and the use of decision aids as part of both medical school and CPD curricula for all clinicians.

This increased training, together with the provision of clear, balanced, and up-to-date information via NHS Choices should – we hope - help doctors be confident that they can easily find and pass on the information they and their patients need.

Reducing over medicalisation, especially for patients with multimorbidity

It's thought that 44% of patients over the age of 75 attending GP practices will have more than 1 medical condition⁷. The RCGP has already raised its concerns about the way that medicines are prescribed to this group in particular⁸ and the report recognises that. Since

patients with multimorbidity are usually excluded from clinical trials, there is doubt over the scientific basis for treatment decisions in their cases, along with the concern of potential unexpected drug interactions⁹.

The report suggests that that gap in knowledge is addressed by clinical research; that planning is done to ensure that patients with multiple needs get the time they deserve; and that the focus of their treatment is on the matters of real importance to them, encompassing lifestyle as well as medical interventions, with a more personalised and self-managed approach in line with the recent NICE guidelines on dealing with multimorbidity¹⁰. Decision aids – we believe - can help with these aims.

We recognise, though, that this approach will need GPs to spend adequate time with patients (often elderly) to go through their care options, understand their priorities and values, and discuss possible alternative options with them in a considered and appropriate way. Thus the report recommends that longer appointment times are prioritised for these patients in particular to establish a new system of care. The details of how that can be managed is clearly a challenge but could be provided in part through translational research, sharing successful practices that have been developed.

Conclusions

The 12 recommendations in the report are precise, with responsibilities and tasks assigned to particular institutions. Our hope is that this will encourage actual delivery of the resources and support that those working in primary care require in order to make the laudable ambitions of shared decision making a practical reality at last.

We know that doctors have always attempted to involve their patients in decisions where there is a genuine choice to be made, to keep abreast of the latest evidence on effectiveness, and to care for their patients with multimorbidity in a personalised way. Equally, we recognise that the ambitions of health professionals in primary care will continue to be constrained by workforce pressures, patient demand and the increased management required around polypharmacy and multimorbidity unless significant cultural and structural changes are made. We hope that this report stimulates exactly those sorts of changes.

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Box 1: The 12 recommendations in brief

Ensuring evidence is robust and relevant:

- 1) Patients, carers and the public should be more involved in the direction, delivery and dissemination of clinical research.
- 2) All those involved in clinical research and all healthcare professionals (at all career stages) should get a grounding in the research methods and statistics used to evaluate the benefits and harms of treatment options.
- 3) The importance of robust, reproducible and reliable research should be recognised and emphasised.
- 4) That new sources of evidence should be used to best advantage, with more emphasis on finding ways to extract and share useful data from every opportunity.

Ensuring evidence is trustworthy:

- 5) That research findings and data should be published in as open, balanced and full way as possible.
- 6) That any potential conflicts of interest are routinely declared and then managed in an open and transparent way
- 7) That academia-industry relationships are managed under a set of clear guidelines

Ensuring evidence is communicated and used effectively:

- 8) That patient information leaflets are improved to give a clear and balanced appraisal of the potential risks and benefits of treatment options
- 9) That NHS Choices becomes a central repository of clear, balanced and up to date evidence on healthcare options
- 10) That improved reporting of scientific evidence in the media is encouraged, with a role for academic establishments in ensuring their research is accurately reflected.
- 11) Increased support for shared decision-making, including adequate resourcing of primary care services and the provision of decision aids through NHS Choices
- 12) Continued dialogue and engagement with patients and the public to monitor the impact of these recommendations and ensure responsiveness to changing public needs in healthcare.

Box 2: A quick guide to communicating potential benefits and harms to patients

(based on the OPTION outline of shared decision making^{13, 14})

- 1) Let the patient know that there is a decision to be made about their treatment, with more than one option, and ask if they'd prefer to talk through the options with you or whether they'd prefer it in written form or as graphics (eg. on leaflets or website) to take away and read.
- 2) Ask the patient what is important to them, and their expectations and fears about the condition and the treatments. This will help you make sure you give them the information they most need, and reassure them where necessary.
- 3) Give the patient information about each option – including the option of no treatment – equally, with both the potential benefits and potential harms of each made clear:
 - a. Try to avoid percentages, instead using frequencies ('1 in...') as they are more easily and widely understood.
 - b. Never discuss 'relative risks' (eg. 'doubles the chance of...') without giving the absolute risks (eg. the risk is 'about 1 in 10,000'). Doubling the chances of a very rare event still leaves a very rare event!
 - c. When using frequencies, always keep the denominator the same (eg. '1 in 1000', '2 in 1000' and '4 in 1000' rather than '1 in 1000', '1 in 500' and '1 in 250') as they are much more easily compared.
 - d. 'Negative framing' and 'positive framing' (eg. 'the chances of you dying in the next 5 years are 5%' versus 'the chances of you being still alive in 5 years' time are 95%') can make a very big difference to people's perspectives. Try to use both (eg. 'on the one hand...but on the other hand you could see it as...') in order to help balance.
 - e. Being able to imagine an event makes it far more salient, so phrasing such as 'out of 100 patients like you taking this treatment, 5 are likely to suffer this complication' will make people much more aware and perhaps cautious of the complication than simply saying 'there is a 5 out of 100 chance of you having this complication'. Detailing what that complication will actually mean for their lives will make it even more vivid.
- 4) Try to give people a graphical representation of the choices they need to make, and the potential consequences of them. 'Decision trees' have proved very understandable to a large proportion of people (such as that used in the current NHS Breast Cancer screening leaflets, Fig 1). 'Icon arrays' to illustrate the numbers of people who are likely to be affected by something (either positive or negative) are also recommended (such as those used in the NICE decision aid for taking statins, Fig 1).
- 5) Check that the patient has understood the information, give them the chance to ask questions, and give them the option to make a decision, defer making a decision, or ask your advice on what decision to make – ensuring that it is clear whether that decision can be (or perhaps must be) reviewed at a later date.

Box 3a: Questions for you as a patient:

Before seeing your doctor, patients and carers should ask themselves:

- **What health goals are most important to me?**
- **What are my expectations of treatment and which of the following questions will help me find out how this medicine can fulfil them?**

During your appointment you might want to ask your doctor:

Is this medicine right for me?

- What does this medicine do?
- How will this medicine improve my health?
- Are there other medicines that might be more helpful?
- What if I don't take this medicine?
- How certain are you that this treatment will work for me?

What are the potential benefits and risks of this medicine?

- What are the potential benefits of this medicine?
- What are the potential risks of this medicine?
- Are the potential benefits or potential risks higher for me? Is this a tried and tested medicine?

How will this medicine make me feel?

- How will this medicine affect my day-to-day life?
- Is this medicine going to improve the symptoms that concern me?
- What are the most common side effects? How severe are they? Are there likely to be any long-term side effects?
- Are there any issues with taking this medicine that my carer and/or family should be aware of?

How should I take this medicine?

- How should I take this medicine (e.g. how many times a day, with or without food, any food or drink to be avoided)?
- Can I take this medicine with my other medication?
- How long do I need to take this medicine for?
- When will it begin to have an effect?

Box 3b: Questions for you as a healthcare provider:

- What do I know about the patient's priorities, preferences and values? What health goal(s) is (are) most important to them?
- What is the likely prognosis (or baseline risk) without treatment?
- How much does / how likely is the treatment to modify outcomes which matter to the patient and over what time frame?
- Do I know how reliable this estimate is?
- What are the harms, treatment burden and other disadvantages of treatment?
- Does the likely balance of benefit and harm, in the light of the patient's own preferences, make this a worthwhile treatment option for this patient?
- Is this medicine necessary or are there alternative options that I should consider (e.g. other medicines or lifestyle changes)?
- How can I clearly deliver the information to the patient in a way that is most useful to them?

Fig 1: Ways of making numbers clearer

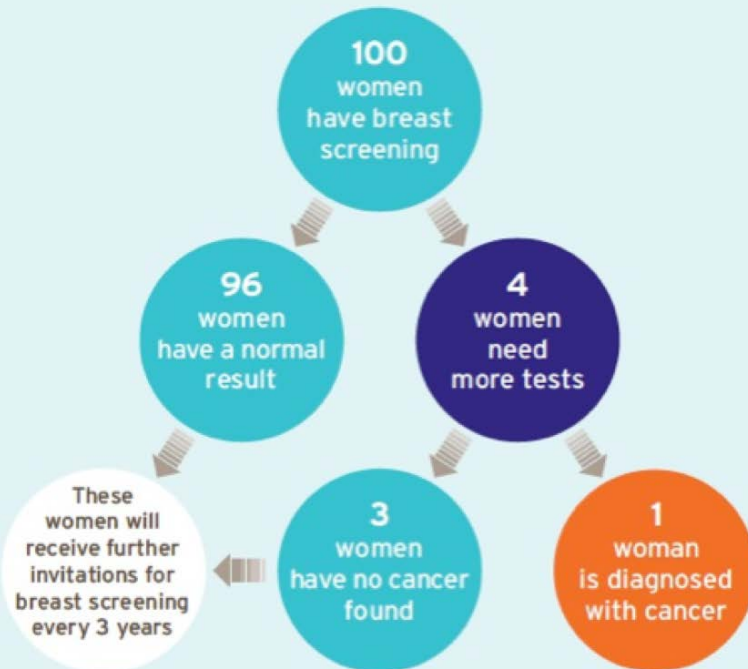
a) A 'facts box' – a concept originally designed and tested in the US¹³ (ref #3), and now being recommended worldwide as a clear way to present both potential harms and benefits in a balanced and clear way; b) A 'decision tree', as used in this case in the NHS breast cancer screening leaflets¹⁴, to help make the potential outcomes of different decisions clear; c) An 'icon array', here from the NICE decision aid for statins¹⁵, used to help make the probabilities of an outcome easily understood.

a)

| Influenza Vaccination in the Elderly Numbers for adults aged 60 years and older observed for 1 year. | | |
|---|---|--|
| The influenza vaccination may prevent adults aged 60 years and older from getting influenza. The protective effect varies from year to year. Flush, hardening or pain sensitivity due to the vaccination around the injection site are possible. | | |
| Benefits | 1.000 elderly with a placebo vaccination* | 1.000 elderly with influenza vaccination |
| How many elderly suffered from confirmed influenza? | 42-128 | 17-45 |
| How many elderly suffered from an influenza-like-illness? | 39-98 | 21-84 |
| How many elderly died (all cause mortality)? | 1-22 | 5-14 |
| Harms | | |
| How many elderly suffered from soreness of the arm muscle or pain sensitivity? | 37 | 132 |
| How many elderly suffered from flush, hardening or pain sensitivity around the injection site? | 9 | 71 |
| *People received a placebo-injection, e.g. saline solution, instead of the influenza vaccine. | | |
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| Last update: April 2016 | | |

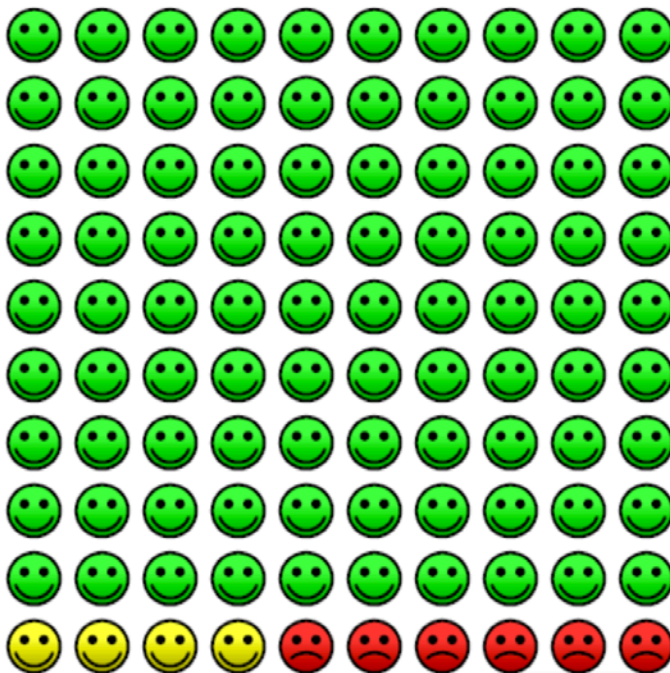
b)

What happens to 100 women
each time they have breast screening



c)

Cardiovascular risk 10% over 10 years: taking atorvastatin



If all 100 people take atorvastatin for 10 years, over that time on average:

- 4 people will be saved from developing CHD or having a stroke (the yellow faces)
- 90 people will not develop CHD or have a stroke, but would not have done anyway (the green faces)
- 6 people will still develop CHD or have a stroke (the red faces).