Bmj article on clinical practice guidelines:

# Making evidence based medicine work for individual patients

BMJ 2016; 353 doi: <http://dx.doi.org/10.1136/bmj.i2452> (Published 16 May 2016)Cite this as: BMJ 2016;353:i2452

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**Margaret McCartney and colleagues** argue that new models of evidence synthesis and shared decision making are needed to accelerate a move from guideline driven care to individualised care

A Google Scholar search using the term “evidence based medicine” identifies more than 1.8 million papers. Over more than two decades, evidence based medicine has rightfully become part of the fabric of modern clinical practice and has contributed to many advances in healthcare.

But many clinicians and patients have expressed dissatisfaction with the way evidence based medicine has been applied to individuals, especially in primary care.[**1**](http://www.bmj.com/content/353/bmj.i2452.full#ref-1) There is concern that guidelines intended to reduce variation and improve the quality of care have instead resulted in medicine becoming authoritarian and bureaucratic.[**2**](http://www.bmj.com/content/353/bmj.i2452.full#ref-2) Evidence generated from large populations has been distilled into large numbers of lengthy and technically complex guidelines. Guidelines in turn have been used to create financial incentive schemes such as the UK’s Quality and Outcomes Framework, whereby a substantial proportion of general practice income depends on achieving thresholds for drug therapy or surrogate outcomes in accordance with National Institute for Health and Care Excellence guidelines. Not only do these thresholds exceed the limits of the evidence for many people but they also encourage clinicians to ignore the need to elicit and respect the preferences and goals of patients.

## Guidelines and shared decision making

Guidelines grew out of a need to communicate best current evidence to clinicians, but their limitations are often not explicitly stated (box 1). For example, some guidelines on heart failure adopt an entirely disease oriented approach, ignoring patients’ views about the quality of their remaining life and the need to incorporate their goals in decision making.[**3**](http://www.bmj.com/content/353/bmj.i2452.full#ref-3) Depression guidelines often fail to acknowledge individual patient circumstances, especially how adverse life events or social support influences symptoms and responses to treatment.[**4**](http://www.bmj.com/content/353/bmj.i2452.full#ref-4)

#### Box 1: Problems with applying population based evidence to individuals

* Randomised trials often exclude patients with comorbidities
* Guidelines describe the evidence for single conditions; real patients often have several comorbidities
* Individual patients may have different values and preferences from their clinician and the people creating the evidence
* Guidelines may not cover aspects of care important to patients
* Guidelines may make recommendations, quite often based solely on expert opinion, when individual patients would make a different choice; this perpetuates the power imbalance between patients and clinicians
* Risks, benefits, and downsides of management options may be viewed differently at the level of the population than from the perspective of an individual
* Shared decision making is not clearly enabled in contemporary practice

Furthermore, most guidelines are written as though patients have only one condition, whereas multimorbidity is the norm.[**5**](http://www.bmj.com/content/353/bmj.i2452.full#ref-5) Conflict between the recommendations for different diseases risks drug-drug and drug-disease interactions and futile polypharmacy.[**6**](http://www.bmj.com/content/353/bmj.i2452.full#ref-6)

Finally, and most importantly, there is the danger of guideline recommendations being applied to people who do not place the same values on those recommendations as their clinician, or indeed those intended by the guideline creators. Evidence reviews by organisations such as National Voices have found that shared decision making engages people in their care and leads to decisions which patients find most appropriate to them.[**7**](http://www.bmj.com/content/353/bmj.i2452.full#ref-7) Surveys have shown that most patients wish either to share decision making with their clinicians or to take the decisions themselves.[**8**](http://www.bmj.com/content/353/bmj.i2452.full#ref-8) Guidelines should enable, not subvert, this process.

We therefore call for a transformation in the presentation and implementation of guidelines. Rather than relying on single disease focused guidelines that emphasise “best practice” for the population, we call for resources that will help doctors and patients to choose the evidence based interventions that fit with their values.

## From tramlines to options

“Guidelines, not tramlines,” said David Haslam, chair of the National Institute for Health and Care Excellence (NICE), at its 2015 conference. To have impact, this principle must be echoed by other organisations, both professional and lay, and accompanied by actions. Guidelines are still required as collations of the best available evidence. But almost two thirds (62%) of research referenced in primary care guidelines is of uncertain relevance to primary care patients.[**9**](http://www.bmj.com/content/353/bmj.i2452.full#ref-9) Only 11% of American cardiology recommendations are based on high levels of evidence, with 48% based on the lowest level of evidence and expert opinion.[**10**](http://www.bmj.com/content/353/bmj.i2452.full#ref-10) Even if guideline recommendations are based on high quality evidence the trials usually exclude people who are frail or who have multiple comorbidities—those who are most likely to benefit from treatment but most susceptible to the potential harms.

Because of these limitations, guideline recommendations should indicate the quality of evidence on which they are based and include information about treatment effect size or probability of benefit, the characteristics of the patient group evidence is based on, and where uncertainty makes extrapolation difficult. Moreover, guideline producers need to resist the temptation to tell clinicians and patients what to do. Making recommendations for the population, often based on expert opinion, reinforces the power imbalance between professional expertise and the patient’s values and preferences.[**11**](http://www.bmj.com/content/353/bmj.i2452.full#ref-11)

Guidelines set out to collate evidence and make recommendations for optimised care, thereby reducing uncertainty, but this is a false idol. Guidelines should admit uncertainty, especially the many uncertainties inherent in comorbidity, and make stochastic uncertainty explicit. It is not possible to predict what will happen to an individual, and the perspectives are quite different for populations and individuals. Small absolute benefits from an intervention for an individual may aggregate to a large benefit for the population if the prevalence of the condition is reasonably high and potential uptake of treatment—for example, use of folic acid to prevent congenital abnormalities. For harms of treatment, there may be a small absolute individual risk of a serious side effect. The impact of the side effect at the level of the population may be high if the treatment is used widely, and may be considered important enough to withdraw the treatment from general use. This removes a potentially valuable treatment option for someone who has perhaps found the treatment highly effective and has a very low absolute risk of being harmed.

## Supporting shared decision making

Resolving such uncertainties with a definitive decision for all is sometimes appropriate, but the more informed the public become, the less tenable is the paternalistic approach—especially for serious illness, frailty, long term conditions, and primary prevention. We need resources that encourage conversations between the clinician and patient that include, “What are the options?” ”What matters to you?” and “What are your hopes and priorities for the future?”[**12**](http://www.bmj.com/content/353/bmj.i2452.full#ref-12)

Currently, it is difficult to personalise recommendations from guidelines, even for those skilled in evidence based medicine. A detailed search of hundreds of pages of statistical tabulation is often needed to find the data required to inform a decision and translate it into easily understandable terms.[**13**](http://www.bmj.com/content/353/bmj.i2452.full#ref-13) Key data for individuals may be buried in technical appendices, which may even be unpublished.

There is also a massive and confusing duplication of effort in guideline production. For example, the International Guideline Library identifies 57 hypertension guidelines published in the past 10 years. Methodological developments have concentrated on producing guidelines, but we now need to focus on efficient and effective updating and simplification of existing guidelines.

In contrast, the creation of usable tools to share decisions with patients is patchy and uncoordinated, despite robust international quality standards.[**14**](http://www.bmj.com/content/353/bmj.i2452.full#ref-14) These standards include visual representations of benefits and risks of the main treatment options and presentation of data in absolute not relative terms, in natural frequencies, and as numbers needed to treat and harm (NNT, NNH).

In the UK some NHS shared decision aids[**15**](http://www.bmj.com/content/353/bmj.i2452.full#ref-15) were produced, but they were not commissioned in tandem with NICE guidelines and are not widely used. NICE produced two pilot patient decision aids for preventing stroke in atrial fibrillation[**16**](http://www.bmj.com/content/353/bmj.i2452.full#ref-16) and lipid modification to reduce cardiovascular risk,**[17](http://www.bmj.com/content/353/bmj.i2452.full%22%20%5Cl%20%22ref-17)** but there is no published strategy to progress this work.

Elsewhere, the Alberta cardiovascular risk reduction guideline for primary care is two pages long, offers lifestyle and drug options without judging which is best for an individual, and has links to attractive risk calculators that show visually and with NNTs that, for example, the reduction in risk from adopting a Mediterranean diet may be as great for some patients as taking a high intensity statin (figs 1 and 2[⇓](http://www.bmj.com/content/353/bmj.i2452.full#F1 F2)).[**18**](http://www.bmj.com/content/353/bmj.i2452.full#ref-18) The Option Grid project (<http://optiongrid.org/>), originally based in the UK but now based at Dartmouth College in the US, produces straightforward, readily understood, simple decision aids for primary care.



**Fig 1** Benefits of adopting a Mediterranean diet for primary prevention of cardiovascular disease (www.topalbertadoctors.org)[**18**](http://www.bmj.com/content/353/bmj.i2452.full#ref-18)



**Fig 2** Benefits of using a high intensity statin for primary prevention of cardiovascular disease ([www.topalbertadoctors.org](http://www.topalbertadoctors.org/))**[18](http://www.bmj.com/content/353/bmj.i2452.full%22%20%5Cl%20%22ref-18)**

Usable decision aids should now be seen as one of the most important end products for evidence based medicine. They should include formats suitable for people with learning disabilities, poor literacy, or without internet access, and be available in multiple languages. We urgently need to move away from resource consuming duplication of effort by different guideline producers in different countries, towards a global coordinated system of shared knowledge production focused on individual decision making The internet makes this highly possible if the will to do so is present.

## Clinicians need help to share decisions

The paternalistic model of “doctor knows best” is, we believe, fading, but it is less clear how to embed the primacy of the patient as key decision maker consistently into routine clinical practice. This requires a shift in role and consultation style for many healthcare professionals. Some patients will be keen to make all possible decisions about their care; others may prefer recommendations from healthcare professionals. Both extremes have to be accommodated. Choice is often not discrete, may not seem logical, and may be influenced by changing circumstances and therefore change over time.

Doctors serve as an interpreter and guardian at the interface between illness and disease, and as a witness to the illness experience. Much of the switching of roles within a single consultation happens effortlessly, even unconsciously.[**19**](http://www.bmj.com/content/353/bmj.i2452.full#ref-19) The complexity of how decisions are made needs to be better recognised and, indeed, encouraged as good practice.

Healthcare professionals who have grown used to “one size fits all” outcome targets (such as being penalised for failing to reach flu vaccination targets) may feel uncomfortable when patients make decisions different from their advice or national guidance,[**20**](http://www.bmj.com/content/353/bmj.i2452.full#ref-20) and feel responsible if subsequently “things go wrong.” Yet autonomy is key.

The deep change in the culture of healthcare that we advocate will require a long process of facilitation through formal and informal education, in which technical decision support plays a key part. Health professionals will need new measures of quality, especially in the communication of risk, benefit, harm, downsides of medicalisation, and uncertainty. At the same time, public understanding of these issues needs to be supported.

Pay for performance systems are part of the problem. They do not encourage shared decision making because doctors are penalised if they do not comply with guidance. Such schemes should take into account what choices are acceptable to patients, what trade-offs are acceptable, and what factors such as more time or better information would facilitate more options.

We believe that GPs should not be paid according to how many patients comply with guideline recommendations. Instead, they should be encouraged to make decisions according to the evidence and patient preference (box 2). When decisions differ from guidance these could be noted in the medical records using codes such as patient choice, shared decision, or discussed and decided rather than marked as exceptions.[**21**](http://www.bmj.com/content/353/bmj.i2452.full#ref-21)

#### Box 2: Suggested actions to improve evidence informed, individualised decision making

• Care should take place within a partnership where the patient as a whole matters more than their individual conditions

• The limitations of the evidence should be explicitly stated. Can guidelines safely be applied to people with frailty or who are very old? Are women and people from ethnic minorities adequately represented in the underlying trials?

• Key evidence from guideline writers should be summarised using visual representations of benefits and risks, or numbers needed to treat and harm

• Guidelines should be written assuming that patients will wish to make choices and give information in a way that highlights what choices fit better with different preferences (eg, fewer blood tests, less medication, preference to avoid face-to-face psychological therapy)

• Patient decision aids should be published in tandem with guidelines, but better research is required into how to provide information about choices that is easily and quickly understood

• Short pressurised consultations may not be the best place for making choices

• Chronic disease management “courses” sharing current practice should be developed by patients and professionals and then evaluated

• Clinicians and patients should be encouraged to make decisions according to both the evidence and patient preference

• The negative effect of guidelines on the quality of care for individuals requires evaluation. Guidelines should be created for and evaluated in real world conditions

## A way forward

We know that decision making by individuals can vary, change, and is often dependent on contexts and influences beyond the consultation. We do not expect that more patient decision aids, clearer guidelines, and opportunities to practice real world patient centred consultations will make decisions perfect, but for some people they will make them better.

We cannot easily resolve the difficulties of creating capacity and time for patient centred, shared decision making. The narrative of the past decade has been of industrial medicine, treating all patients with the same intervention without explicit concern for their preferences. Artificial metrics of access have been prioritised over kindness and continuity of care even though we know that continuity of care is valued by people with chronic illnesses[**22**](http://www.bmj.com/content/353/bmj.i2452.full#ref-22) and is associated with lower costs and reduced hospital admissions.[**23**](http://www.bmj.com/content/353/bmj.i2452.full#ref-23) Good care involves a partnership between patients and health professionals where people matter more than their separate health conditions. The pursuit of higher quality healthcare must involve bifocal vision: a relentless drive to improve evidence based, system-wide, patient oriented outcomes combined with a firm commitment to patient centredness grounded in diversity and individuality. This requires a revolution not only within research, guidelines, and education, but also in work structures and contracts. But if we are serious about individualised, patient centred care, we need nothing less.

## Footnotes

* Contributors and sources: This essay is the product of a discussion on the RCGP Overdiagnosis Group email group. Other members of the writing group are Kashif Bhatti, Ahmed Rashid, Duncan Shrewsbury, Helen Macdonald, Greg Irving, Jessica Watson, and Jeremy Taylor. MMcM, in correspondence with group members, developed the idea and all members of the writing group contributed to the development of key themes for the paper. MMcM wrote the first draft of the paper based on an initial framework written by NM and refined it with important intellectual contributions from GI, JW, HM, AR, and JTa. MMcM and NM produced the final draft, All authors provided feedback on early drafts, redrafted in response to reviewers comments, and approved the final manuscript.
* Competing interests: We have read and understood BMJ policy on declaration of interests and declare the following interests: MMcM is a GP partner, receives income from two relevant books, The BMJ , the BBC, and lay press for writing and broadcasting, and is chair of the RCGP standing group on overdiagnosis; JTr is a salaried GP, vice-chair of the RCGP standing group on overdiagnosis, and an editorial board member of Drug and Therapeutics Bulletin; RL is a part-time consultant to the Yale Open Data Access project, which receives funding from Johnson and Johnson to develop methods to promote clinical trial data sharing; the project has also received funding in the past from Medtronic. JTa is chief executive of National Voices and chair of the Five Year Forward View People and Communities Board; AR was seconded to NICE from September 2014 to August 2015 as a clinical fellow; JW’s salary is part funded by the National Institute for Health Research; GI is also part funded by the NIHR and he sits on a NICE medical technology advisory committee.
* Provenance and peer review: Not commissioned; externally peer reviewed.

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