Guidelines for treating risk factors need to include tools for shared decision-making

Fully informed decisions may need to overcome clinician over-optimism

John S Yudkin MD FRCP*

Emeritus Professor of Medicine, University College London

Division of Medicine, University College London, London, UK

Jayne Kavanagh MB ChB

Lead of the Medical Ethics and Law Unit and Principal Clinical Teaching Fellow, Academic Centre of Medical Education, UCL Medical School, Faculty of Medical Sciences, Royal Free Campus, University College London, London, UK

James P McCormack BSc (Pharm) Pharm D

Professor, Faculty of Pharmaceutical Sciences, The University of British Columbia, Vancouver, British Columbia, Canada

***Address for Correspondence:**

28, Huddleston Road,

London N7 0AG,

UK

Tel (+)44-207-607-3855

(+)44-7866-759270

Email j.yudkin@ucl.ac.uk

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The Clinical Problem

In a recently published case report, titled ‘The Tyranny of Guidelines,’ Sarosi recounts the story of an 86-year-old man living on his farm in Wisconsin and caring for his 92-year-old brother with early dementia (1). Six years earlier he had been started on an ACE inhibitor and metformin following a health check when he received his Medicaid card, with other oral agents subsequently added. But when his family practice was taken over by a large organisation, he was given a copy of the American Diabetes Association (ADA) guidelines, started on insulin in response to his HbA1c of 8.5%, and had his antihypertensive dose doubled because his blood pressure was 154/92. Three weeks later, he was admitted to hospital hypotensive and hypoglycaemic, with a hip fracture and a stroke. Both he and his brother subsequently needed residential care. The author pointed out the statement in the guidelines that ‘Older adults who are functional and cognitively intact and have significant life expectancy should receive diabetes care with goals similar to those developed for younger adults’ (2) – an HbA1c of 7% and a blood pressure of <140/90.

Are Guidelines Over-Prescriptive or do they Provide the Tools Needed for Patient-Centred Care?

The clinicians might claim they were only following guidelines. But when linked to quality measures and reimbursement, as happens for example in the US (3), and with the Quality and Outcomes Framework in the UK (4), guidelines can morph into orders. These guidelines suggest a target HbA1c below 8% and blood pressure of <140/90 in elderly patients unless their health status is ‘very complex/poor … (long-term care … end-stage chronic illnesses or moderate- to-severe cognitive impairment)’ with limited remaining life expectancy (2). And while the ADA and the European Association for the Study of Diabetes, recommend that ‘where possible, such decisions should be made with the patient, reflecting his or her preferences, needs and values’ (5), they provide no tools for quantifying the harm associated with a particular risk factor nor information comparing likely benefits and harms of treatments (6).

We argue that such tools, based on patient-relevant outcomes including gains in healthy life expectancy, are vitally needed – not just for shared decision-making, but also better to inform clinicians, guideline committees and comparative effectiveness agencies. In this man's case, an outcome model would have estimated that his treatment changes would have extended healthy life expectancy by no more than 5 weeks (7,8).

The National Institute for Health and Care Excellence (NICE) updated its guidelines for management of adults with type 2 diabetes in December 2015 (9). The targets for NICE are similar to, but in some cases even more aggressive than, the above mentioned guidelines. They recommend an HbA1c of 7% (or 6.5% if it can be achieved by a single drug which does not cause hypoglycaemia) and a blood pressure <140/80, although these targets might be relaxed in 'people who are older or frail … (or) with a reduced life expectancy.' NICE also states 'patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals.' But although the guidelines provide a useful decision aid for treatment *risks* by giving rates of adverse effects including hypoglycaemia, and examples of such frequencies as pictograms (eg 1 in 1000) (10), the only information on possible *benefits* is provided separately in the 'decision aid user guide for healthcare professionals,' and in the form of relative risk reductions (11). No information is provided to allow clinicians to quantify the risks associated with different levels of risk factors or their change, surely something which NICE or the ADA could have included, or commissioned, had it been considered important.

What Might The Patient Have Asked, and Been Told?

In the context of a patient resembling the one we have presented, let us speculate how such a conversation about his glycaemic control might go using the information in the NICE guideline (Table). With the information in the user guide, he would be told that getting his HbA1c down by 1% might reduce his risk of a non-fatal myocardial infarction by 13% (a relative benefit), but the healthcare professional could not have given any indication of the baseline

risk in the first place nor the possible gains in healthy life expectancy. He might be told, based on the guidelines, that it was important to improve his glucose control to prevent blindness or renal failure. However he would not have been told the evidence for this benefit is extrapolated from a 20%-25% reduction in surrogate endpoints (retinal photocoagulation and proteinuria changes) rather than there being virtually no evidence for glucose control actually reducing risks of blindness and ESRD (12). He would also not have been told his lifetime risks of these events are at most 1-2% (13). Fully informed decision-making needs fully informed clinicians as well as patients.

Table

Likely benefits from starting insulin in the patient described*

Glycated haemoglobin – reduction of 1%

Cardiovascular disease

Fatal – no impact

Non-fatal – RRR 13%

ARR 3.7% at 10 years

Blindness – RRR 25% (extracted from surrogate endpoints)

ARR 2.3% at 10 years

End Stage Renal Failure – RRR 25% (extracted from surrogate endpoints)

- ARR 0.03% at 10 years

Life expectancy gain – approximately 5 weeks

*The estimates are derived from the UKPDS-Outcomes Model 2 (ref 8)

Treating Risk Factors – For Individual or For Population Benefit?

Absolute risk reductions and numbers needed to treat are now more widely disseminated, but the fact is that when translated into gains in healthy life expectancy these are, at best, moderate (14). Moreover, in a person with a 10

year cardiovascular risk of 40%, 9 out of 10 people started on a statin (relative risk reduction ~25%, but, in this patient, absolute risk reduction of 10%) will not derive a clinical benefit over that timespan. In people at much lower risk, or in those treated with less effective strategies (like glucose lowering) (15), the interventions might be considered more for the benefit of public health – reducing population disease incidence - rather than anything an individual might deem as worthwhile. This is something of which many clinicians are unaware when they write prescriptions (14,16,17). In one study, physicians presented with 3 'grey cases' grossly overestimated the probable benefits of intensifying glucose control (median around 7 years versus around 5 weeks from an outcomes model) and blood pressure lowering (~7 years versus ~10 weeks) (14). This over-optimism underlies the need for better tools to estimate likely harms, benefits and risks. Such tools might also inform the NICE guideline development group as to what are the likely additional benefits from reducing target HbA1c to 6.5% (8,18).

Shared Decision-Making Needs Time, Plus Tools, to Allow Patients to Make Informed choices

In its professional guidance, the UK's General Medical Council (GMC) advises doctors that their role is to outline the benefits, risks and burdens of a treatment or procedure in clear and understandable fashion, but it is the patient who weighs up the information, together with other relevant issues, and makes the decision (19). A recent UK Supreme Court judgment concerning the information provided to a woman with diabetes about the benefits and risks of a caesarean section for her and her fetus, has now configured legal obligations with ethical guidance (20). The Montgomery judgment highlighted the importance of shared decision-making that is properly informed; this may be interpreted as establishing a new legal requirement that information about the potential harms and benefits of a proposed course of action should be communicated accurately (21).

In the context of treating risk factors, two other considerations often apply – the patient is typically asymptomatic, and the treatment has

the potential of being life-long. Individuals respond very differently in their aversion to taking regular medication (22, 23) so guidelines need to facilitate choices that are consistent with that person's priorities (24). While many patients will still demur to their clinician in decisions about such treatment, it is surely incumbent upon guideline developers to include, or at least provide some directions to, appropriately developed and properly tested (24) shared decision-making tools that could be used (Box). If guideline writers decide that existing tools need further work, we suggest it is incumbent upon them at least to provide some ballpark figures that clinicians can use. Moreover, because people respond in a variety of ways to different formats for explaining benefits (25), such tools and figures need similarly to show estimates of benefit in a variety of formats -absolute risk reductions (ARR), numbers needed to treat (NNT), and gains in healthy life expectancy (8,14,25,26). Furthermore, the multiplicity of complications of diabetes, which benefit to different degrees from improved glycaemic control, makes for problems in expressing benefit as ARR or NNT (15). Because of this, a model-derived summary measure, such as gains in healthy life years, may be more relevant when it comes to intensive glucose lowering (8).

The impact of glucose lowering in people with type 2 diabetes on such summary measures is likely quantified in weeks or months (8,14), rather than years. This should also influence the agenda of cost-effectiveness agencies, which explicitly accept this concept in cancer treatments but perhaps not for diabetes. Such summary measures might permit a more patient specific assessment of the value of glucose lowering medication. Token statements such as 'patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals' do not make for patient-centered guidelines. If guideline writers with all their expertise and resources can't come up with specific tools or approaches, it is improbable that individual users will be able to fill in the knowledge translation blanks left by these guidelines.

BOX

Estimating benefits of interventions for cardiovascular risk factor lowering

A variety of tools have been developed to inform the shared decision-making process, using a variety of prediction models and interfaces, and ranking different treatments or estimating their benefits with different measures. Their use is summarised in ref 27.

- The Absolute CVD Risk/Benefit Calculator (http://chd.bestsciencemedicine.com/calc2.html).
- Mayo Clinic Heart Disease Risk Calculator (http://www.mayoclinic.org/diseases-conditions/heart-disease/in-depth/heart-disease-risk/itt-20084942)
- Mayo Clinic Diabetes Decision Aid (https://diabetesdecisionaid.mayoclinic.org/index.php/site/compare?PHPSESSID=k3sgf2rju1t2bpo8738bf95354 and ref 27).
- Healthy Living for People with Diabetes web-based self-management programme (ref 25).
- United Kingdom Prospective Diabetes Study – Outcomes Model 1 and 2 (refs 7,26).
- London School of Economics Statin Ranking Tool* (http://www.lse.ac.uk/IPA/ResearchAndEngagement/ProjectArchive/VisualisingData/StatinRankingTool.aspx).

***** While this is not a diabetes decision aid, it shows how it is possible to integrate comparative treatment rankings from network meta-analysis with patient preferences in decision-making**.**

Contributor and Sources

JSY conceived the concepts of individual versus public health benefit. JK introduced the discussion of the relevance of the recent Supreme Court judgment. The three authors have discussed several previous drafts of the manuscript. JSY is a physician with an interest in diabetes, who has conducted research over the last 25 years on the benefits and hazards of risk factor reduction and in particular on the problems of a 'glucocentric' approach to type 2 diabetes. More recently he has explored the potential benefits and hazards of over-medicalisation in regard to intensive treatment of diabetes and 'prediabetes.' JK is a medical ethicist and a physician working in the field of sexual health. She is a Principal Clinical Teaching Fellow and lead for Medical Ethics and Law at UCL Medical School. JM is a pharmacist with an interest in outcomes-based research and in communication for shared decision-making.

Conflicts of Interest

The authors declare no conflicts of interest.

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