Transcript of the talk given by Dr Julian Treadwell to the '*How can we all best use evidence to judge the potential benefits and harms of medicines?*' Oversight Group on 20 January 2016

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"The public debate about overmedicalisation is often very polarized and of poor quality, so I'd like to offer a hopefully more reasoned view of the issue.

It might be helpful to start with a bit about myself and why I've ended up sitting here today – it has relevance to the question in hand.

I graduated in the early 90s as evidence based medicine (EBM) was taking off and was in a generation of GPs who had a fair bit of teaching in critical appraisal. I continued in clinical practice, enthusiastically running a cardiovascular prevention clinic and working in a practice leading the charge in diabetes care in our local area. Over the last decade however, consideration of evidence gradually gave way to simply following guidelines and hitting targets, and most of us now feel that overtreatment is a significant problem (with some variety in how we understand and express this concern).

3 years ago I became very interested in the 'Preventing Overdiagnosis' and TMM[1] movements and within this have spent a lot of time looking at the evidence behind the guidelines and I have to say was quite shocked at what I found.

I'm Vice Chair of a Standing Group on Overdiagnosis at the Royal College of General Practitioners (chaired by Dr Margaret McCartney) and we have 200+ strong network of GPs interested in this along with some secondary care doctors, academics and international colleagues. In the last couple of years I've had a number of meetings at NICE and spoken at their last two conferences on evidence and guidelines and there are ongoing plans to continue these conversations. I've also done a lot of speaking to GPs about this area and have gathered a very good sense of how the profession is feeling.

I've been sitting on the *'Methods of evaluating evidence'* stream which has been looking very thoroughly at quantitative questions we ask when judging the value of medicines. This helps us answer questions like 'do statins have side effects' , 'do statins reduce mortality in a primary prevention context' or 'do antiviral drugs prevent mortality from 'flu?'

But what I'd like to raise today is another aspect of the question *'How does society use evidence to judge the risk and benefits of medicines?'* which is more to do with the values we place upon these risks and benefits.

I'll start with a slightly provocative proposal that, currently, the value judgments about whether a treatment is a 'good idea' or not, is made at some distance from the person destined to take the treatment – in the ivory towers of the evidence and guideline producers. These judgments may be very obvious where there is clear evidence of great benefit, but can also be made on the basis of statistically significant evidence of pretty small clinical effects (which a specialist may value) or on extrapolations of evidence involving a leap of faith.

[1] The BMJ's *'Too much medicine campaign'*. http://www.bmj.com/specialties/too-much-medicine

These decisions are then translated into binary guideline recommendations (do, do not do) without quantification of effect size, discussion of uncertainties or expression of nuance. A particular problem is that of external validity – the evidence is derived from populations unlike general practice's multi-morbid, older caseload.

Front line clinicians end up receiving black and white messages, usually with an exhortion to 'do more'.

To take statins as an example; although the new guideline, if read in full, was in fact very good and stated that statins should only be an offer, after lifestyle recommendations, the headline messages were very different. At the launch, NICE's headline was that if the 4.5million new people eligible took treatment, then we might prevent 28,000 heart attacks, 16,000 strokes and 8,000 deaths over three years. There was no mention of the 4,448,000 patients who would take statins for no benefit over this timeframe. The overwhelming message received was that NICE was telling everyone they should have statins and that GPs should be responsible for making this happen, hence the furor.

This article in the BMJ caught my attention last month: *'Five in six women reject drugs that could reduce their risk of breast cancer.*' A study had shown that outside of clinical trials only 9% of high risk women accepted prophylactic tamoxifen. Even in the trials the uptake was only 25%. Comments from one author and another commentator were: 'It's crucial to find out why so many chose not to take the drugs' and 'We need to find out more about how women at higher risk of breast cancer make decisions about the different ways they can reduce the risk of developing the disease to make sure that they have the information they need to make the choice that is right for them'.

Behind these comments you can hear mystified frustration – clearly these women are making the 'wrong' choice and we need to do something to persuade them otherwise. It's likely however, that they did have the 'information they need' and made a rational decision based on a NNT5y of about 100 to prevent a case of breast cancer versus 40% rates of hot flushes, 25% rates of fatigue and 10% vaginal symptoms. The 'experts' have different values to the patients.

In this case, the women are bound to have been given information about potential benefit – but all too often, long term treatments are given without this quality information because it is so hard to access for doctors and patients.

Multi-morbidity is now the norm and it's very common for someone elderly with the usual cluster of non–communicable diseases to be taking (recommended by guidelines):
3 blood pressure drugs, a statin, 2 or 3 glucose lowering drugs, aspirin or an anticoagulant, a proton pump inhibitor (PPI), a painkiller or two and a psychotropic medication of some kind. In this scenario, we all feel that this is usually wrong, that harms are likely to outweigh benefits, but we are being told that the evidence tells us this is what we 'should' be doing.

The evidence around harms is usually observational or absent. How do we judge which treatments to hold back, in discussion with our patient?

Just over a year ago, I spoke for the motion in a debate at a GP conference *'GPs are over treating our older patients'*. 90% agreed before the debate and I think I clocked up another 5% by the end.

What are the solutions?

Principally, it is around better communication of the evidence to front line clinicians and patients. I understand I'll be speaking to the Communications group later in the year and can go into detail there, but the basics will be around principles such as using absolute risk reduction (ARR) not relative risk reduction (RRR), numbers needed to treat (NNT), clarity about population applicability, honesty about uncertainties in the evidence, and when evidence is direct and clear and when recommendations are opinion based.

The Shared Decision Making movement has a lot to offer and the production of patient decision aids goes a long way to solving these problems.

Front line clinicians also need better, user friendly evidence tools built into guidelines and clinical systems to help make person-centered decisions.

Fundamentally though, we need a change in how medical evidence is presented to the public and professionals. Simplicity and striking headlines have pushed out clarity and honesty. This will require experts to relinquish a degree of control and move away from telling us all what to do and towards providing us with usable presentations of the evidence base in order that patients can make their own decisions in partnership with their doctors."
