

Episode 5 Transcript

Topic: Clinical decision making: Evidence based, or Values based?

Hosted by: Leyla Noury

Guest: Professor Jonathan Michaels

This transcript has been edited for clarity

00:01

Welcome to 'Mason Institute Investigates,' a podcast series produced by the Mason Institute, funded by the Edinburgh Law School. In each episode we investigate current national and global issues involving ethics, law and policy in health, medicine, and the life sciences.

00:19 Leyla

Hello and welcome back to Mason Institute Investigates. I'm Leyla Noury and I'm joined by Professor Jonathan Michaels from the University of Sheffield, who will discuss with us his research on evidence-based practice and clinical decision making. Thank you very much for coming on to the podcast. Would you like to introduce yourself and maybe talk about what sparked your interest in your area of research?

00:43 Professor Michaels

Yes, certainly. I'm Jonathan Michaels. I trained as a vascular surgeon and it was at a time really of increasing emphasis on evidence-based medicine, and I became quite quickly interested in how evidence was gathered and how decisions are made. I was in clinical vascular surgery for about 30 years and then about 10 years ago I retired from that, but I've carried on doing some research and particularly relating to evidence-based healthcare and evaluating patients' preferences and what they find important about their healthcare. And also, through the work I was doing in decision theory and cost effectiveness analysis, I got involved with some of the work of NICE, the National Institute for Health and Care Excellence, and I was involved in the appraisals committee and the Guideline Development Committee. And for the past few years my interests have mainly been in policy and decision making, particularly the ethical aspects of it.

01:39 Leyla

So you're in quite a unique position. You have the experience of working at the frontline of the NHS, but you also have some knowledge of the ways the clinical guidelines are developed. So to start off, what is the role of NICE in clinical decision making?

01:54 Professor Michaels

NICE was originally set up in 1999, it was called the National Institute for Clinical Excellence originally, but now it's changed its name, it's the National Institute for Health and Care Excellence and they were tasked with producing national policy for evidence-based practice. When they were set up, it was a time of considerable media coverage about things like post code prescribing. There was a lot of new developments in healthcare and there'd been a lot of reorganization in the NHS, and we had GP fund holders and health authorities making different decisions about what treatments are going to be available and so there was a lot of publicity about people getting different availability of different treatments depending on where they lived. And so NICE was, I think, largely set up to try and produce some consistent evidence-based advice to the NHS about what treatments it should be funding. Over the years it's developed, and they've taken on a wider and wider remit. And they are now involved in guidance for social care and several different types of guidance that they produce. I think that, if you look at what it does, it produces quite a number of different sorts of guidance. The one that's probably the highest profile, the appraisals, the work of the appraisals committee, which often look at quite high-cost new developments and decide whether they should be funded by the NHS. It also produces much wider ranging guidelines that look at the whole areas of healthcare and it produces advice about new technologies and diagnostics and so on. Its underlying principles state that it makes its recommendations based on the best evidence that's available, but also an assessment of population benefits and value for money. And that's where you can get into some quite difficult decisions about what constitutes best value for money.

03:50 Leyla

And what sort of key issues stand out to you about the way NICE develops their advice?

03:56 Professor Michaels

I think NICE has a very difficult role. They've got several different things that they're trying to achieve. And they produce a lot of different kinds of guidance, and I think sometimes there's a concept that evidence-based health care is a sort of a scientific process where lots of experts get together and they review all the evidence, and out of that comes the decisions about what

we should be doing. And if you look at NICE guidance often, you know the guideline may have many thousands of pages of supporting documentation that's often quite technical. But at the end of the day, what those guidelines require is that you make value judgments, that there are a lot of value judgments involved in them, and that's often obscured by the very technical language, and so on. So, it looks like it's an expert decision about what we should be doing, whereas in fact hidden in there, there's often a lot of value judgements.

04:52 Leyla

So NICE has to assess what technologies and treatments are good value for money, and I suppose one way to analyse cost effectiveness is to use metrics such as QALY and EQ5D. Is that right?

05:05 Professor Michaels

Yes, that's right. If you're going to look at comparing value for money in a variety of different fields across healthcare, somehow you've got to make decisions comparing value for money if you're doing nursing care for advanced dementia or screening tests for cancer or fertility treatments, or if you get a new miracle cure for some fatal childhood illness. You've got to compare across those, and they're very different things and so somehow, you've got to combine things in a single metric. And that's where NICE uses quality adjusted life years, QALYs. So the quality adjusted life year is a measure that should take into account both how long people live and also the quality of that life. And in order to create that, you have to have some sort of measure of quality of life, so the one that they have favoured is something that's called the EQ5D. That's the EuroQol, that is a relatively simple measure that asks people questions like, in terms of mobility, is your mobility normal? Do you have any impairment of mobility or are you very disabled? And in terms of pain, do you suffer much pain and so on. And so it's actually got five different areas that it asks about. But they're quite abstract and it's quite simplified and there's a lot of argument about what it is that that actually gets at, and whether it misses out things that may be important to people.

06:26 Leyla

This sounds like a one size fits all approach to quantifying quality of life, and as you just mentioned, some measures are abstract. What are the problems with this? Does NICE attempt to account for different experiences of diseases in the population?

06:41 Professor Michaels

There's a very complex question about how we assess quality of life. I think these are relatively simplistic scales, but they are well validated and there are quite a few of them. It's not just the

EuroQol, there's a thing called the SF 36. There's a Nottingham Health Profile. So there are different health profiles, that give some measure of people's quality of life. There's really two stages to the process though, because of course, quality of life consists of many different competing things. You've got your mobility, pain, anxiety, and depression, how you function socially, all sorts of different dimensions of health. And in some way, you've got to put those together and what NICE does is to take what they call a societal view. There are two sides to the measurement of value. NICE in order to come up with a cost per QALY, which is what they use for their health economics assessment, you have to put the quality of life to a single measure, so that's called a utility. And in order to get the utility, what they do is they take values that are taken from the general public, a societal sample, to value different profiles of quality of life. And so the actual measures of quality of life come from patients with particular conditions, but then the values that are put on those different dimensions are given by a general public sample. And so that results in a measure that can be applied across the board to a variety of different conditions.

I think there's an issue here, which is that NICE is making guidance for the country, and so by its nature, it's got to make policy that is generalizable. Evidence-based medicine when it started out, I think, was thought of much more about getting the evidence about the best clinical effectiveness to inform individual clinical decisions. So, it was about clinicians and patients having the information available to decide what they wanted to do. On the other hand, if what you're going to do is make rationing decisions and so you've got to make a decision that's appropriate to everybody, then what you've got to do is to use some sort of average or generalizable values. And so the way that NICE achieves that is to get an average societal value for what people might think of as the quality of life associated, or the benefits associated with particular conditions. So there are two parts to evidence-based medicine. One is gathering the evidence about what the likely outcomes are of different treatments, and that's the sort of the statistical evidence that says, what's the probability that people are going to live a certain amount of time with a certain treatment, or that they're going to get certain complications, so all of that comes from the collection of the research evidence. But then you also need some evidence about what the population thinks is important because you're making decisions, fundamentally, you're making decisions about how to spend taxpayers money. And it's the population that are the taxpayers, and they have to decide what are the most important things in healthcare to spend the money on, so you've got those two sides of the decision.

09:58 Leyla

Yes, and something that I've read from your research is that the evidence on outcomes of different treatments is actually produced by the manufacturers who are supplying the treatment. This must be a conflict of interest because the evidence will have the manufacturer's own value judgements, and this likely manifests as bias, which I believe you have explored in your paper. Perhaps you'd like to expand on this?

10:25 Professor Michaels

If we think about the research studies that go into the evidence, then a large amount of the research that's carried out, I think it's about two-thirds in this country, is actually funded by industry, and so the industry funds research in order to show that their products work. I mean, there wouldn't be much point in them doing research that didn't show benefit in their products. And so, research is often geared in order to try and do that. Now, sometimes that means that they plan their trials, plan comparators that are more likely to show that their treatments are better. They may exclude patients from trials who are not likely to benefit so much. So it's often the case that elderly patients or patients with other illnesses are excluded from trials. So often the trials are quite selective in who they include. And the way that they measure the outcomes is often quite selective. Things like quality of life, are often not in trials, or if they are in trials, they may not be reported when it comes to the publications. So there may be a lot of biases in the evidence that's actually available to people when they make these decisions, and then the actual process that's gone through in order to make the decision, involves the stakeholders that are involved in that particular technology. It involves the industry. Often there are patient representatives or patient representative groups, and the clinicians who are interested in that particular technology. And all those people, are the people that are in the room when the decision is made. But what's not talked about is the people who are not in the room, the people whose technologies may be displaced because the health service has a limited budget. So if something is spent on a new, expensive technology, it's not available for other purposes.

12:14 Leyla

In one of your articles, you address epistemic injustices and evidence-based medicine. What are the ways that these injustices happen in the development of clinical guidelines?

12:26 Professor Michaels

When Fricker talked about epistemic injustices, what she was talking about is people being wronged in their capacity to contribute to knowledge, and people can contribute to knowledge in lots of different ways. They have unique knowledge about their own illnesses, and they can contribute through participating in research and often research has some biases inherent in it, in that people from certain groups are excluded, particularly elderly groups or those with comorbidities and so on, may be excluded from the research process, and that may bias the results of the research. And also, when it comes to the decision-making process, as I was saying before, the people in the room making the decision are often those with an interest in the particular subject being discussed, clearly they'll be the people who are experts or have a personal interest in the subject matter that's being discussed by the committee at the time. But there'll be no one in the room that's there to represent the people who may be on the other side of things, and may have their services displaced by the funding that's required for the new technology. And NICE uses a variety of different value elements that they may take into account in order to increase the value that's attributable to a particular technology and no one knows whether those value elements apply equally to the technology that might be displaced, because there's no direct linkage between the things that we spend our money on and the things that we stop spending our money on in order to pay for it.

14:00 Leyla

So what are the implications for resource allocation in the NHS if NICE approves an expensive treatment? Does NICE even have a threshold?

14:08 Professor Michaels

The underlying principle is that NICE is making a decision about value for money because the NHS has a limited budget and therefore if we spend money in one area then it's not available somewhere else. The trouble is that we don't know for sure what's going to be displaced. So if money is spent on a new technology, we don't know where they're going to get that money from. And NICE has, since they started, actually, they've had this threshold of £20,000 per quality adjusted life year that, if anything, is probably a bit high. There's a little bit of research been done, that's tried to look at what's actually displaced from the healthcare, from the NHS, when new technologies are funded, and that suggests that probably we're losing more than a QALY for each £20,000 that NICE spends. But what NICE has also done is it's said that for under certain circumstances, they will increase that threshold, so they'll pay more than that, where there are other considerations. And that's where we start to think about: what other things may be of value and one of the first things was cancer. The cancer treatments were

given priority some years ago for what they called 'end-of-life' treatment. So, if people were nearing the end of their life due to cancer, and there was a cancer drug, they increased the threshold for that to £50,000 rather than the £20,000, that was previously the standard. And there's been a lot of discussion about that, about why it is that cancer, just as a particular group of diagnoses, should take priority over other things. And more recently they introduced a new route for what they call 'highly specialised technologies', and these are things that often treat rare conditions, that are serious conditions and for which there are new treatments coming out of that are very expensive. And in those cases they've been pushing up that threshold to £100,000 or even £200,000 per QALY in effect, and what it means is that they're displacing much larger amounts of health benefit elsewhere in the service.

There were questions about what it is that that we should be putting extra value on. Is rarity on its own or new innovative drugs? Are they something we should be funding extra? Is that what's in agreement with societies' views or not? And the difficulty is that I think that, particularly with the highly specialised technologies, because they're often for rare, very rare conditions, there are very identifiable people who appear in the media with serious conditions, and therefore get a lot of sympathy. And it creates a huge pressure to fund those things. Whereas the invisible people whose resources are being taken away are not seen in the media and we don't even know who they are. We don't, you know, we don't know, what's being missed.

17:02 Leyla

Now as I understand it, NICE is also responsible for social care guidance. You have mentioned in one of your papers that because there is hardly any ring fencing in expenditure, basic care processes would have to compete directly with health outcomes. Why is this an issue?

17:17 Professor Michaels

I think there are various different things. One of the things I've said in the past is that we tend to value those things that we can measure rather than thinking about how we might measure those things that we value. And so there are some things that if you think about healthcare research, there are some things that are very easy to measure or relatively easy to measure. So the things like blood tests and you know you can easily measure peoples cancer markers in their blood. Or you can get objective measures. You measure their blood pressure, or you can measure how far somebody can walk on a treadmill at a certain speed, and those are things that's quite easy to measure, so they're often the things that are chosen for clinical trials. But of course, patients aren't really interested in what their serum rhubarb is or what their bone density is; what they're interested in is how those things affect them. And even

things like walking on a treadmill, of course everyone's interested in how far they can walk, but how far you can walk may mean very different things to different people. You know if you're a postal worker or a keen runner, then it may make a lot of difference to you, whereas if you're retired and have a fairly sedentary lifestyle, walking the same distance may not be so important. So these things are all relative and some things are much more difficult to measure. Things like quality of life as we were saying, it is more difficult. It's multidimensional and different people will have different views about which aspects are important. But then there are some things that we probably don't measure at all. We, you know, people find things are important in their healthcare. People talk about compassion. They talk about dignity, respect, things like continuity of care. There are lots of things within our healthcare that we actually think are valuable, and yet we don't have any measures for them. And I think it's those things that tend to get displaced because they're not measured. And so there was that statement from someone in one of the documents from NICE a while ago that said that people find things important, compassion and dignity were important things that cost nothing, and that's not the case. They do cost. You have to have enough staff. You have to have enough beds and those are all resources that are quite expensive, so you know the 18-hour ambulance waits that we're seeing outside hospitals, the people being treated in a corridor in an accident & emergency department because there's no bed for them in the hospital. Those are all things that, with appropriate resources, could be improved. And if those resources are being spent on very high-cost new technologies, then they're not available for those sort of purposes, and so it may well be those sort of things that get pushed out by the new technologies.

19:50 Leyla

What is the next step to correcting or shifting the discourse towards a healthcare system that is more receptive to disinvestment decisions and the caring needs of the patient population?

20:02 Professor Michaels

The first thing is that there needs to be really public debate about what it is that we want from our healthcare system. There have been a lot of publications largely coming from experts in health economics and other fields, looking at various value frameworks that look at what we should put value on, and NICE itself has had some discussions in the past about whether it puts extra value on things like burden of illness. So, whether we give extra value to conditions that are more severe over and above the QALY benefits. And these things, there are a lot of difficulties in deciding exactly what it is that we value in healthcare. And I think that the things that I was talking about, things like compassion and dignity and respect and autonomy are all

important to patients and yet they don't seem to have figured much in the discussions about how we value outcomes and how we put value on what the health care system spends its money on. So I think that's the first thing is sort of to increase the public debate about what it is that we want our health service to achieve. And there are some very specific things about how we deal with representing people that are not currently represented in the system. That one of the suggestions is that NICE should be looking not just at investment decisions, but at the disinvestments. It should be putting equal weight on how we save money in an evidence-based way as it does on how we spend money. And that's difficult I think, because often disinvestment decisions aren't made on a whole technology; they're made on the basis of savings and costs in staffing or bed numbers or something like reducing a service. And so it's not so easy to do a cost effectiveness analysis on what happens if you reduce the staffing levels on a ward or close some of the beds.

I think that there should be much more independence in the system. The idea that the industry who have a vested interest in having their drugs approved are the people who write the reports about whether their drugs are cost effective or not, seems to me to create an immediate conflict and the original route that NICE had was to have independent academic groups writing the reports, and there needs to be some way of having someone in the room who will represent other people's interests. Not just the interests of the people who are promoting a particular technology.

Another possibility would be to have a ring-fenced budget that could be used for service developments. That way you could have a budget where new developments that were costly, didn't compete directly with existing services, and that's something that's been tried by NICE in the past. They took over the management of the Cancer Drugs Fund and created a system with a ring fence budget for that. And they've recently introduced a similar thing for what they called the Innovative Medicines Fund.

So, there is a precedent for this. Of course, it doesn't mean that we shouldn't be looking for savings from disinvesting in treatments that aren't cost effective or looking for economies elsewhere. But if those are identified through evidence-based processes, then any money or savings could be added to the budget for new service developments. And it gets away from this idea that some areas are subject to disinvestment without any real consideration of the cost effectiveness of what's being lost.

23:29 Leyla

And what is NICE doing to encourage or promote public debate?

23:34 Professor Michaels

So NICE has actually been very good at consultation. It consults very widely on all the guidance that it produces and when it comes to the changes in their processes and their methods, they also consult on those documents. But the problem is, it's very difficult through those processes to get the views of a good cross section of the general public. Academic groups will often respond and industry obviously has staff with the skills and the resources to be able to respond to any consultation. But most of the general public won't even be aware that there's a consultation going on, or that it might have some effect on the availability of their health services. And so there needs to be some other process to be more proactive in involving the public.

Soon after NICE started, they set up a thing called the Citizens Council and that got together a wide sample of the public that came together for quite intensive sessions to debate difficult social or ethical issues relating to NICE's work. And they produced some very good documents around that. There was a very good document about social value judgements that's now been superseded by NICE's set of principles.

But the Citizens Council, I think, last met in about 2015 and hasn't met since. NICE has now replaced that with a new system that it calls NICE Listens. And last year, I think they got together a series of workshops with the general public to look at issues around addressing health inequalities. So I think we need to wait and see how that process turns out, but there really needs to be some way of getting the public involved in what are often value based and ethical decisions that NICE needs to take.

25:17 Leyla

Are there any other aspects of NICE's role in clinical decision making that you're interested in examining in the future?

25:25 Professor Michaels

I'm interested in the way that policy is not only made, but how it's implemented. And I think that one of the things that I've been looking at recently is why it is actually so often that NICE guidance is not followed. When you look at a lot of the NICE guidance what you find is that there's still huge variation in practice, and that it hasn't greatly influenced or hasn't influenced practice in the way that might have been expected. And I think part of that is this sort of distrust of NICE guidance because it's seen as a rationing body by many. And so many people see it as having made decisions, not on the basis of what's most effective or best for individual patients, but what's the best way to contain resources.

26:10 Leyla

One final question, before we bring this episode to a close, why should there be greater awareness or more discussion about evidence-based medicine and clinical decision?

26:21 Professor Michaels

I think that one of the problems is that things are often presented in a very black and white way, whereas in fact, these are very difficult questions and complex issues and there are a lot of trade-offs to be made. Fundamentally, if you're a patient, you want to get the best possible treatment for you or for your family. On the other hand, NICE has a duty to try and make the best use of what are limited NHS resources. So there are a variety of things that it needs to take into account and some of these things compete. There have to be trade-offs between the libertarian values of allowing people autonomy and to make their own choices about their health care; the utilitarian views that we need to get the best possible value for the resources that are available, and on the other hand, there's also the egalitarian view that we need to make sure that resources are distributed fairly and try and address inequalities in health. And these different values may compete. If we give people freedoms to determine their own health care, then those with the greatest resources may be most able to access better health care and those who are elderly or have comorbidities may have less capacity to benefit from treatment. So, from a utilitarian point of view, we may get less total benefit from addressing inequalities. Ultimately, these things are often competing and there needs to be open discussion about which values take priority in different circumstances.

27:57 Leyla

I think that's a good place to end this episode. Thank you very much Professor, for taking the time to discuss your research in clinical decision making and evidence-based practice.

28:05 Professor Michaels

Thanks very much.

28:09

Thank you for listening to today's podcast. We hope that you enjoyed it. For further information, check out the links in the show notes of this episode. Stay tuned for the next episode where I share the best parts of the podcast series called Just Emergencies. See you next time!