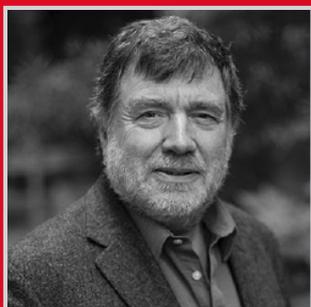


Interview



Professor Michael Barnes

CMO of Lyphe Group and Chair of The Medical Cannabis Clinicians Society (MCCS)
Director of Maple Tree Med Can Consultancy Ltd.,
Newcastle, UK

Q1 You started your career as a neurologist then specialised in neurorehabilitation. Where did your interest in medicinal cannabis stem from?

I became interested whilst working in multiple sclerosis clinics roughly 20 years ago. Some of my patients came to the clinic and told me that they were using cannabis for their pain and spasticity. I (informally) asked all those attending the clinic about their cannabis use, and about 50% said they were using cannabis. At about that time GW Pharmaceuticals (Cambridge, UK) also asked me to be involved in the development of Sativex®, the first cannabis medicine. Thus, my interest is long-standing.

Q2 As the founding Chair of The Medicinal Cannabis Clinicians Society (MCCS), could you tell us about your role and the society's aims?

I started the society as a 'home' for clinicians (not just medical doctors) to learn and share information about cannabis as a medicine. We put on a series of roadshows around the country, an annual conference, newsletters, and provide our members with updates on available products. We run a mentoring scheme to support doctors new to prescribing. Soon, we will have a

comprehensive database of published studies on efficacy and side effects for members to search. We now have around 100 members. It is run day-to-day by Hannah Deacon, the mother of Alfie Dingley who was the first child to obtain a license for cannabis, and our communications director, Kate Thorpe.

Q3 You were instrumental in securing the first prescription of medicinal cannabis in the UK. What were the biggest challenges involved in receiving approval for this?

It was quite a bit of work with the Home Office for over 3 months, but I have to say that they were very helpful and supportive. We were all working together to achieve something that had not been done before. In the end it was a 64-page, comprehensive document that covered the product we wanted to use and the clinical governance arrangements around that prescription. It was the catalyst that changed the law.

Q4 Specialist physicians have been able to officially prescribe medicinal cannabis in the UK since November 2018, yet only a handful of prescriptions have been issued. In your opinion, why do you believe this to be the case?

"We were all working together to achieve something that had not been done before"

Several reasons. First, lack of knowledge about the subject. Doctors have never been taught about cannabis and the endocannabinoid system. We need more training programmes, like the Academy of Medical Cannabis.¹ Second, guidelines for cannabis-based medicinal products by bodies such as the Royal College of Physicians (RCP) and the British Paediatric Neurology Association (BPNA), and more recently the National Institute for Health and Care Excellence (NICE), need to be significantly improved to be more informative and useful for clinicians. These are visibly anticannabis and try to push cannabis-based products down a pharmaceutical approval route, in which it doesn't fit. The MCCA have recently published more balanced guidelines.² Third, we do need more evidence of efficacy, but in my view there is sufficient evidence for many indications (especially pain, anxiety, sleep, spasticity, and epilepsy); however, clearly more evidence is needed. Let's prescribe the medicine (which is remarkably safe) and learn as we go. Finally, it is an unlicensed medicine and many medics are reluctant to prescribe for that reason, of which in my view they shouldn't be.

Q5 What lessons can countries where medicinal cannabis is not legalised learn from those where it is, in regard to both the establishment of legalisation and building of infrastructure into healthcare?

We must learn from countries that are further ahead, such as Canada, some states in the USA, and Germany. They have developed robust prescribing systems. We can certainly learn that we need a UK industry because at the moment it is all import and that causes supply delays and higher costs than are unnecessary. Many countries have developed an Office of Medicinal Cannabis to coordinate supply, approvals, prescribing, evidence, etc. That seems an excellent solution rather than relying on the pharmaceutical systems, which do not lend themselves to a plant product.

Q6 The main indication for medicinal cannabis use has been for multiple sclerosis and severe epilepsy. What data are there for its use in other neurological diseases?

The best evidence is for pain; there is no doubt about that. Cannabis also has opioid sparing effects, which is very helpful in these days of opioid over-prescribing. There is also good evidence for its use for anxiety and sleep disorders.

Q7 What qualifies a patient to become a recipient of medicinal cannabis? And what aspects of a patient's health should be taken into consideration when making the decision?

A specialist doctor can prescribe cannabis for any condition (preferably within their own area of expertise, of course). The patient needs to have tried all reasonable licensed alternatives in my view, and then if they haven't worked sufficiently or are limited by side effects, then cannabis could be tried for those indications with a good evidence base. Like any other medicine, the doctor needs to take into account the condition of the patient and there are some contraindications, such as a history or family history of psychosis, some cardiac rhythm problems, and a few other relative contraindications. Other concomitant medication needs to be borne in mind as well. A low cannabidiol (CBD) compound is best at first, and then a slow titration of tetrahydrocannabinol (THC) as needed.

Q8 What are the biggest risks associated with the prescription of medicinal cannabis for a patient with a neurological disease?

There are few risks. As above, a history of psychosis or of some cardiac dysrhythmias needs to be taken into account, and concomitant drugs need consideration. A careful cannabis physician will always 'start low and go slow' with dosing, trying a high-CBD/low-THC product first before a gradual titration upwards of dose and product type.

Q9 Products only containing CBD have gained the most traction on the road to approval, but there is now a movement from the medical community to include low levels of THC alongside CBD in products. Are there benefits of including both CBD and THC in a formula, and if so, what are they?



"The law has been changed and now we need less restrictions from the medical hierarchy and better guidelines"

CBD should usually be tried first. Some epilepsies and pain conditions will benefit from addition of some THC and indeed some pain problems need relatively high THC. There seems to be benefit in many symptoms for CBD and THC in combination. There is also some evidence that isolates, for example pure CBD, are less efficacious than a 'full extract' product that contains other minor cannabinoids and terpenes; this is the entourage effect. More research is needed, but that seems to be the pattern.

Clinical trials establishing the safety and efficacy of a drug are essential for the approval by the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA). How does the current clinical infrastructure pose as a challenge for medicinal cannabis clinical research?

Many medical authorities are assuming that cannabis can follow the classic pharmaceutical route. The plant, which has 113 cannabinoids and over 100 terpenes and flavonoids, simply does not fit the standard 'single molecule' pharmaceutical assessment process. We need a system of approval and appraisal of a botanical product. It can go through trials like any other medicine, but let's not be obsessed with the

double-blind placebo-controlled model. Other forms of evidence need to be taken into account, for example good quality observational trials and N-of-1 trials.

What are the next steps for securing access to those in need of medicinal cannabis?

We urgently need NHS prescriptions. These are legal through specialist doctors. The law has been changed and now we need less restrictions from the medical hierarchy and better guidelines. There are doctors interested in this medicine and see its value. Let them prescribe and let us learn as we go. After all, many people who would benefit from cannabis are being affected by intractable pain and resistant epilepsy, for example. It is immoral to deny them a medicine that may be useful and is remarkably safe if prescribed by a knowledgeable doctor.

References

1. The Academy of Medicinal Cannabis (TAOMC). Available at: <https://taomc.org/en/>. Last accessed: 17 April 2020.
2. Medical Cannabis Clinicians Society (MCCS). Recommendations and Guidance on Medical Cannabis under Prescription. 2020. Available at: <https://www.ukmccs.org/wp-content/uploads/2020/03/Recommendations-and-Guidance-on-Medical-Cannabis-under-Prescription-2nd-Edition-2020.pdf>. Last accessed: 17 April 2020.