



Dr Justin Coleman



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Prof Mike Lean



## From the Editor's swag (The DiRECT trial & diabetes remission)

As a humble GP, if I wanted to catch a glimpse of one of the most important recent influencers of diabetes management

worldwide, I'd usually have to observe them from row 50 at an international conference.

Instead, last month I spent two weeks sleeping next to just such a bloke in a swag, on a camping tour of remote Aboriginal communities in the central Australian desert. Strange story.

Professor Mike Lean, Chair of Human Nutrition at Glasgow University, and former director of the Health Education Board of Scotland, shot to megastar prominence (at least in the world of diabetes management) in 2017 with the publication of his DiRECT trial.<sup>1</sup>

Even though the Diabetes Remission Clinical Trial struck me as ground-breaking at the time—it featured in my first ever DMJ editorial—the implications for primary health care have only increased since, with two-year follow up results remaining excellent, and governments of various countries sponsoring its rollout.

Before I recount how my GP band got to accompany Mike Lean's fiddle playing on stage at Uluru, let's recap on the trial findings.

Hundreds of ordinary citizens attending their general practice in Scotland and England were invited to undergo a tough, 3-month diet, with a view to significant weight loss in the 10-15kg range rather than

the usual 5kg or so on most diets. All had T2D diagnosed within the past 6 years, and average BMI 34 kg/m<sup>2</sup>.

The intensive weight loss was overseen not by outside experts, but by a nurse or dietitian already working at the local general practice, who had received 8 hours specific training; something very achievable and scalable in most countries, including Australia.

They used a commercial meal replacement, but any diet at around 850 calories per day will do the trick; a group in Nepal is about to roll it out using handful-measures of lentils and vegetables.

It is a difficult three months—participants can't eat normal meals with family—but as Mike pointed out during the talks he gave in Alice Springs, there are some cancers that don't shorten life span as much as diabetes does, yet most people are prepared to undergo three months of chemotherapy if it is likely to cause remission. And this diet sends T2D into remission.

All hypoglycaemic and antihypertensive medications were ceased on day one of the diet, and only reintroduced if clinically necessary – for most it wasn't. At one year (i.e. nine months after finishing the intensive diet) the majority still didn't need any diabetes medications; average 0.4 medications per person, compared to no reduction in the control group who received all the usual best-practice primary care but without the intensive diet support.

The results were stunning. Average weight loss was 10kg in the intervention arm versus 1kg in the control group ( $p < 0.0001$ ). A quarter (36 of 149) of those in the intervention group maintained at least

15kg of weight loss at 12 months compared to none (0 of 149) who received usual care.

Diabetes remission (defined as HbA1c  $< 6.5\%$  on no diabetes medication) was maintained at 12 months by 86% of those who lost at least 15kg and 57% of those who lost 10-15kg. Almost half (46%) of the entire population who agreed to try out the diet achieved remission; an extraordinarily high percentage when you consider the denominator includes all those who gave up on the diet and didn't lose weight—none of whom achieved diabetes remission.

The recently released 24-month data remains equally impressive.<sup>2</sup> A full 21 months after finishing the intensive diet (which was followed by less intensive structured support from the GP practice) two-thirds of those with  $\geq 10$ kg weight loss remained in diabetes remission, without any need to recommence hypoglycaemic medication. Compared to the control group, serious adverse events halved, triglycerides fell and quality of life improved.

In the control group—and remember, they still received the type of good diabetes care from GPs, dietitians and diabetes educators that we advocate for in this journal—only one in 30 achieved diabetes remission at 24 months. We have become so used to a T2D diagnosis being considered a one-way ticket that the very concept of remission still seems an anathema to many health professionals.

So, how did I come to be swagging it in the red dust of the outback for two weeks with the hottest name in diabetes management?

I'm a member of Australia's largest





(not necessarily best) GP band, and the 13 of us decided to tour Alice Springs and five remote Aboriginal communities, accompanying local bands on stage and sitting down to talk about ideas to tackle the scourge of obesity and T2D. Hearing that Prof Lean was an excellent fiddle player, our band front man Dr Sam Heard cold-called him in Scotland via email and was amazed when the adventurous Prof accepted his invitation.

My ostensible duty was to interview Prof Lean in recording studios by day and play piano by night, but what with kids, partners and a few academic hangers-on, my actual crucial role became loading and unloading 42 swags every day. It was one of the most

extraordinary fortnights of my life...but enough about me!

Have a read of the DiRECT trial at [www.directclinicaltrial.org.uk/](http://www.directclinicaltrial.org.uk/) and start thinking about how its lessons might translate into Australian general practice. It should be a game changer.

**Dr Justin Coleman**  
*Editor*

1. Lean M et al. Primary care-led weight management for remission of type 2 diabetes (DiRECT): an open-label, cluster-randomised trial. *Lancet*, Dec 2017.
2. Lean M et al. Durability of a primary care-led weight-management intervention for remission of type 2 diabetes: 2-year results of the DiRECT open-label, cluster-randomised trial. *Lancet Diabetes & Endocrinology*, Mar 2019

TOP LEFT: Rehearsing. Dr Justin Coleman - guitar, Dr Ingrid Wangel - violin, Professor Mike Lean - violin  
TOP MIDDLE: Working on the playlist.  
TOP RIGHT: The Cheeky Docs outback playlist finalised with help of a whiteboard  
BELOW: On with the show



## Diabetes inventor finally paid his dues

It's not often I read a court transcript, but a UK Supreme Court finding on 23 October<sup>3</sup> provides insight into a 1980s invention that has shaped how we measure blood glucose ever since.

Scientist Professor Ian Shanks has just been awarded £2 million compensation from multinational company Unilever, for whom he was working when he invented the electrochemical capillary fill device. His invention formed the basis for all the familiar 'finger prick' devices; most notably the ubiquitous BGL test strip.

Before the capillary fill technology, blood for chemical analysis involved millilitre quantities rather than the microlitre amounts used today—approximately 20 mcl at the time of Shank's invention, but around just 1 mcl now.

Although perhaps falling short of Fleming's penicillium mould 'eureka' moment, Shanks worked with the recently-invented liquid crystal displays (LCDs) and observed that any water touching the two plates of glass would be drawn by capillary reaction into the 10 micron gap between them.

In 1982 he visited diabetes researchers at Cranfield University, and learned about their new system for plating a micro-thin layer of an enzyme and electrodes, which could electrochemically estimate the glucose concentration of any liquid that touched the plate.

Experimenting with his daughter's microscope set, Shanks clamped two glass slides with bulldog clips and eventually drew up enough water to reach an area coated with the enzyme. From there, it was mainly a matter of modifying the design to be touched onto a drop of blood on a finger, and the rest is history.

That history was rewarded last month, ending a 13-year fierce legal battle. Although the patent for his invention was held by his employer Unilever, in 2006 Shanks applied for compensation based on a law that allows a 'fair share' to be paid for an invention that provides the employer with 'outstanding benefit'.

I'm no legal eagle, but something seems right about this win for the little guy.

3. United Kingdom Supreme Court. Shanks v Unilever Plc and others. Judgement given on 23 October 2019. Pdf available at <https://www.supremecourt.uk/cases/docs/uksc-2017-0032-judgment.pdf>