CONCEPTT to care: the science of implementation in diabetes care

One of the frustrations one sees in diabetes care, in any sphere, is the patchy implementation of science. Science that has been carefully crafted, designed, been through trials—yet somehow fails to impact the lives of those who it is supposed to benefit. There are multiple reasons for this, and in no particular order, it can be due to financial constraints, clinical inertia, scarcity of knowledge, structural issues, leadership, or a mismatch between policy priorities and evidence base.

Yet, within the challenges that exist in any health system, there are examples where this trend has been reversed and adoption of science has occurred at a large scale, cutting across deprivation gaps, and most importantly showing results at a population level. To illustrate this, we discuss the CONCEPTT study[1] and its application in real-world continuous glucose monitoring (CGM) in pregnant women with type 1 diabetes within a setting of a tax-funded system, the National Health Service (NHS) in England.

Women with type 1 diabetes have poor pregnancy outcomes: half have preterm births and babies who are large for their gestational age, and half of the babies are admitted to neonatal care units.[2,3] Neonatal care units separate mothers and babies, with enduring consequences for maternal and infant wellbeing, bonding, and infant feeding (the emotional consequences for the baby are not inconsequential; sadly, these are strongly underestimated). The average neonatal care admission is 5 days, which is a huge emotional burden for families and a major cost for the NHS (£9500 per admission).[4] Maternal glucose is the major modifiable risk factor driving these complications. Across the NHS, antenatal clinics for patients at high-risk, delivered by multidisciplinary teams, work to optimise maternal glucose concentrations, minimising maternal and neonatal risks; yet there had been no improvement in maternal glucose or pregnancy outcomes in the past two decades.[2,3]

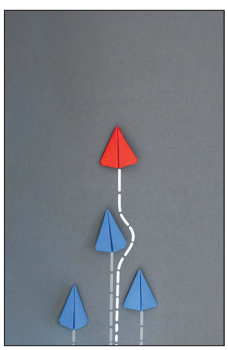
Some of the authors of this Comment carried out the CONCEPTT trial, showing that CGM improves maternal glucose concentrations and neonatal outcomes for pregnant women with type 1 diabetes.[1,5] CGM was not only clinically effective and cost-effective but cost-saving (saving £1571 per quality-adjusted life year gained) for the NHS.[4] Our ambition was to rapidly and uniformly translate these developments into NHS care, so that all pregnant women with type 1 diabetes across all antenatal clinics were offered CGM.

Working with policy makers, 2 years of ring-fenced funding was obtained from NHS England. We worked with regional diabetes and maternity networks, delivering interactive webinars, case-based learning sessions, and CGM implementation workshops to NHS clinical teams. We also developed a toolkit of educational support materials to enable safe and effective CGM use.[6] We co-designed these online and paper-based materials in partnership with women with diabetes and representatives from patient organisations.[6] We also modified ongoing data collection for the National Pregnancy in Diabetes Audit (NPID) to assess the effect of CGM on maternal glucose concentrations and neonatal outcomes.

The project commenced in March, 2020, with funding provided for nationwide CGM implementation from March, 2021 to March, 2023. We monitored for user uptake and potential inequalities based on ethnicity or social deprivation. Surveillance data showed that 98% of all pregnant women with type 1 diabetes were offered CGM, and no inequalities in providing access were detected.

Before implementation, NPID audit data showed no improvement in maternal glucose concentrations or neonatal outcomes for the previous 7 years.[3] Rates of preterm birth, large for gestational age birthweight, and neonatal care admissions were high and rising year-on-year (2014–20).[7] The 2023 NPID report indicates that there have been the first ever nationwide improvements in maternal glucose control from beginning to end of pregnancy and across all clinics.[7] Preterm births, large birthweight babies, and neonatal care admissions have also started to decline for the first time since NPID records began. Furthermore, rates of major congenital anomaly, stillbirth, and neonatal deaths in type 1 diabetes pregnancy are now reducing.[7]

Although the ring-fenced funding for CGM has now finished, we have taken steps to ensure the long-term



Sakchai Vongsasiripat/Getty Images

Lancet Diabetes Endocrinol 2024
Published Online
February 26, 2024
https://doi.org/10.1016/S2213-8587(24)00039-1

sustainability of nationwide CGM implementation. Together with NHS Maternity leads, we have developed a new Diabetes Element in the Saving Babies Lives Care Bundle,[8] with a focus on improving maternal glucose concentrations and neonatal outcomes through the use of CGM in pregnancy. This collaboration ensures that antenatal health-care teams are adequately trained to optimise CGM use and provides structural incentives for clinical teams to support pregnant women to achieve maternal glucose targets, with clear guidance for care escalation when glucose concentrations are above target.

We have taken time and care to engage health-care commissioners and policy makers; they supported the strategy of accelerated nationwide CGM implementation in type 1 diabetes pregnancy and leveraged the initial ring-fenced funding package. We established a Truman-style multidisciplinary working group whereby everyone (ie, patient organisations, commissioners, and clinicians), helped out and worked collaboratively to develop national implementation pathways, to coproduce and deliver educational support and training (eg, web-based resources, webinars, and lunchtime learning sessions), to regularly monitor CGM uptake and minimise regional health-care inequalities, and to robustly evaluate the real-world effect on pregnancy outcomes.

The fundamentals of the success boils down to a few key areas. First, the willingness of academics to work with policy makers from the very start of the process (including design and recruitment), as that helps to ensure a population is represented appropriately and learnings gained at an early stage (which further help in wider implementation), and an appreciation that research is only successful when it benefits lives at a wider scale—beyond the realms of the trial. Beyond that, such work is little beyond a footnote in the history of academia or a personal achievement in one's career. The existence of academia as a separate entity to policy is a barrier to the progress of research into lives and there needs to be appreciation by both parties of each other's worth, eventually all working together to benefit a wide population. From a policy perspective, there also needs to be understanding of the value academics bring to delivery through their understanding of the science. The engagement between academia and policy makers from the starting point of the CONCEPTT trial was a key component of its eventual success.

Next, we engaged at an early stage with organisations such as the UK National Institute for Health and Care Excellence (NICE) to ensure the fundamental question of whether the intervention is cost-effective was answered. This is important for discussions about investment in the NHS context, as it is a use of public taxpayers' money. Science alone is not enough—affordability is key and so is the industry's understanding of this, to avoid situations where the affordability to the individual or system dictates access. Including organisations that can analyse the cost-effectiveness and having discussions with industry figures on what adaptations to pricing structures or added value initiatives are present to make the investment affordable is crucial.

Making this programme a key plank of national policy occurred via the NHS Long Term Plan in 2019 while NICE was reviewing the data. This coordination helped to flag to systems the intent to deliver this programme if the cost-effectiveness was positive.

NICE updated their guidelines with a positive review in 2020 (NG3) and the roll-out began in 2021. A dedicated team (with datasets to track the offer of CGM in each region and the uptake by pregnant women) and the acceptance of CGM by pregnant women with type 1 diabetes were essential to the process. Patient engagement was done in collaboration with charities such as JDRF and Diabetes UK and through engagement on social media platforms and reaching out directly to individuals to explain the science.

The datasets also investigated social determinants of health (eg, deprivation and ethnicity) to ensure the uptake was equitable and unbiased. Data and tracking of the deprivation gap are crucial to improving equity and learning from the experience. Regular meetings between clinicians, local system leaders, and the national team were set up to ensure data were challenged and discussed. To help ensure the science in the original research study was replicated, national audits were done (involving data submission on uptake, demographics of patients, satisfaction levels, and relevant outcomes), which further reflected the real-world clinical benefit.

The key to implementation sits with understanding the innovation curve—and about strategies to tackle each of the steps. Too often, we divert our energy on the innovators and early adopters when, in reality, all they need is support for data collection or encouragement to develop innovative ways of delivery—their enthusiasm

is enough to drive progress. Datasets showing evidence and approval from national bodies, brings the majority of early stakeholders into the fold, whereas public data showing variation of uptake of relevant medication or technology tends to win over the majority of late stakeholders. For stakeholders who continue to not engage, one needs accountability, whether in the public domain (via media) or within organisations or via the voices of the patients, to ensure no one is left behind.

The strategy thus needs to be multipronged from the very outset, bearing all that we have mentioned in mind.

A good example of such a strategy was mapped out from 2018 to 2023, which saw the adoption of Freestyle Libre in the NHS in England, in which the initial groups of the innovators and early adopters adopted within 6–12 months but the rest needed encouragement and strategies such as those mentioned previously to get to a universal uptake.

Implementation of research is possible beyond focused areas, such as in type 1 diabetes during pregnancy, as seen by the uptake of CGM across people with type 1 diabetes in the NHS. This programme has also created the foundations for the widest access to hybrid closed loop therapy globally via NICE, which further showcases success in one area cascading to bigger gains. This experience has the potential to be useful on a wider, global scale, where the challenges are the same, albeit with different funding models in place. Yet, as mentioned, barriers are not only financial and there are examples of how to overcome those other barriers, recognising the role of all collaborators in this process. With a truly collaborative team of dedicated clinicians, researchers, patients, and policy makers, bringing science into lives is possible.

EMS reports grants or contracts from Abbott Diabetes Care to their institution; honoraria from Abbott Diabetes Care and Ypsomed for giving lectures; support for travel expenses and registration fees of meetings from Ypsomed; and receipt of equipment from Abbott Diabetes Care to their insitution. HRM reports payment or honoraria from the UK & European Medtronic Advisory Board , Ypsomed UK Advisory Board, and the speaker bureaus of Medtronic, Roche, Sanofi-Aventis, Novo Nordisk, and Ypsomed; and support for travel expenses from Medtronic, Roche, Sanofi-Aventis, Novo Nordisk, and Ypsomed. KK and PK declare no competing interests.

*Eleanor M Scott, Helen R Murphy, Karen Kennedy, *Partha Kar*
drparthakar@gmail.com

Leeds Institute of Cardiovascular and Metabolic Medicine, University of Leeds, Leeds, UK (EMS); Norwich Medical School, University of East Anglia, Norwich, UK (HRM); Norfolk and Norwich University Hospitals NHS Foundation Trust, Norwich, UK (HRM); Diabetes Team, NHS England, Leeds, UK (KK); Portsmouth Hospitals University NHS Trust, NHS England, Portsmouth, UK (PK)

1 Feig DS, Donovan LE, Corcoy R, et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. *Lancet* 2017 ; **390:** 2347–59.
2 Murphy HR, Howgate C, O'Keefe J, et al. Characteristics and outcomes of pregnant women with type 1 and type 2 diabetes: national population based 5-year cohort study. *Lancet Diabetes Endocrinol* 2021; **9:** 153–64.
3 National Health Service England. National pregnancy in diabetes audit report 2020. 2021. https://digital.nhs.uk/data-and-information/publications/statistical/national-pregnancy-in-diabetes-audit/2019-and-2020 (accessed Nov 27, 2023).
4 Murphy HR, Feig DS, Sanchez JJ, de Portu S, Sale A. Modelling potential cost savings from use of real-time continuous glucose monitoring in pregnant women with type 1 diabetes. *Diabet Med* 2019; **36:** 1652–58.
5 Scott EM, Murphy HR, Kristensen KH, et al. Continuous glucose monitoring metrics and birth weight: informing management of type 1 diabetes throughout pregnancy. *Diabetes Care* 2022; **45:** 1724–34.
6 Diabetes Technology Network UK. The ABCD diabetes technology network https://abcd.care/abcd-diabetes-technology-network (accessed Nov 27, 2023).
7 National Health Service England. National pregnancy in diabetes audit 2021 and 2022. https://digital.nhs.uk/data-and-information/publications/statistical/national-pregnancy-in-diabetes-audit/2022/executive-summary (accessed Nov 27, 2023).
8 National Health Service England. Saving Babies' Lives version three: a care bundle for redycing perinatal mortality. 2023. https://www.england.nhs.uk/publication/saving-babies-lives-version-three/ (accessed Nov 27, 2023).