LETTER TO THE EDITOR

The challenge of multidisciplinary research: improving diabetic pregnancy together

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Voormolen *et al.*[1] describe the challenges for multidisciplinary research in diabetic pregnancy, referring to the reluctance of many specialists to participate in the Dutch national GlucoMOMS study. The arguments provided by the authors make it seem as if Dutch endocrinologists oppose the principle of evidence-based medicine. Instead of providing the real, i.e. scientific and potentially ethical, reasons for the relatively low national enthusiasm of referring diabetes type 1 (DM1) patients for inclusion in the GlucoMOMS trial, they state that 'doctors prefer offering their patients (un-evaluated) treatment options to offering nothing or even worse: the unpopular truth of we don't know what's the best thing to do'.

The GlucoMOMS study compares masked continuous glucose monitoring (CGM) during one week per month in type 1 (DM1), type 2 (DM2) and insulin-requiring gestational diabetes versus self-measured blood glucose (SMBG) monitoring. For adult (non-pregnant) DM1 patients, ample evidence exists showing that the use of real-time (RT)-CGM is better than frequent SMBG only when the device is used more than 60-75% of the time.[2] A study which *intermittently* (25% of the time) applies *masked* CGM in pregnant DM1 patients cannot be regarded as the evaluation of a major step forward, and will not by any means contribute to gathering adequate evidence for the use of state-of-the-art RT-CGM in pregnancy. Indeed, after the GlucoMOMS study was granted, many endocrinologists suggested that the researchers update the study protocol and add a prolonged RT-CGM intervention in pregnant DM1, but to no avail.

Improving pregnancy outcomes for DM1 requires a near-normal preconceptional HbA1c and maintaining near-normoglycaemia during pregnancy and delivery. However, it takes much effort to reach this goal without frequent severe and non-severe hypoglycaemias. Currently, RT-CGM-guided pump therapy is the best technical option in non-pregnant DM1 patients.[4] One does not have to be 'a believer' to hypothesise that this may also pertain to *pregnant* DM1 patients.

For adequate self-management, i.e. the mainstay of diabetes treatment already preconceptionally, masked CGM can be used as an educational tool if the treatment goal is not achieved by conventional methods, including frequent SMBG and diary use. Pregnancy, however, especially in the first 16 weeks, is associated with blood glucose fluctuations that are difficult to control and can lead to severe hypoglycaemia. Pregnant DM1 women, by feeling the responsibility of adequate glucose control for pregnancy outcome, may become insecure and vulnerable. The RT-CGM device, which helps them to stay in control and warns them in case of hyperglycaemia or hypoglycaemia, is an important supportive tool.

To further inform Voormolen *et al.*, already in 2010 the expert group of the Dutch Diabetes Federation strongly advised the Healthcare Insurance Board (CVZ) only to reimburse RT-CGM for several indications awaiting the results of national data collection on outcome. Therefore, within a collaborative national initiative, also supported by The Netherlands Organisation for Health Research and Development (ZonMw), together with the Dutch Diabetes Patient Organisation, endocrinologists are currently collecting data in all patients using RT-CGM with many eligible centres (>50) already participating (www.stichtingbidon.nl).[4]

We agree with the authors' remark stating that, '..... millions if not billions of euros are spent on ineffective and therefore by definition useless treatments', and we are assured that they will concur with the fact that even greater budgets are spent on poorly designed and therefore a priori non-conclusive studies that advance neither clinical science nor care.[5]

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