Institution: University of Oxford

Unit of Assessment: 12 – Engineering

Title of case study: GDm-Health™: Gestational Diabetes management system

Period when the underpinning research was undertaken: Jan 2010 to Dec 2020

Details of staff conducting the underpinning research from the submitting unit:

Name(s):	Role(s) (e.g. job title):	Period(s) employed by submitting HEI:
Prof. Lionel Tarassenko	Professor of Electrical Engineering	1988 – present
Dr Carmelo Velardo	Post-Doctoral Research Assistant	2012 – 2018

Period when the claimed impact occurred: Jan 2015 to Dec 2020

Is this case study continued from a case study submitted in 2014? N

1. Summary of the impact (indicative maximum 100 words)

GDm-Health™ is a prescribed digital therapeutic to optimise the management of diabetes during pregnancy (gestational diabetes). GDm-Health™ is now deployed throughout the NHS in England (and one region of the US). It was designed in Prof. Tarassenko's research group, with extensive input from both patients and diabetes specialists, and licensed to Sensyne Health in 2017. The self-management enabled by the smartphone app and the real-time remote management enabled by the backend software algorithms deliver improved outcomes for both mother and baby, as evidenced in a clinical trial: reductions in preterm births with respect to usual care, from 12.7% to 5.0%, and in the number of caesarean deliveries, from 46.1% to 26.7%.

GDm-Health™ is listed on the NHS Digital Apps Library and is now operational in over 50 NHS Acute Trusts (November 2020). This represents more than half of the NHS Trusts in the UK which look after women with gestational diabetes. Almost 17,000 women in these Trusts have used GDm-Health™ (November 2020) and there are over 1,000 new users a month, with the Royal Surrey County Hospital reporting a 98% adoption rate by patients. According to NICE, the system saves the NHS, on average, GBP230 per patient by reducing the need for face-to-face appointments. Given estimates that 130,000 pregnant women have either pre-existing or gestational diabetes each year in the UK, the cost-saving potential to the NHS is GBP29,900,000 per year.

2. Underpinning research (indicative maximum 500 words)

Soon after Android/iOS smartphones and internet-enabled tablet computers first became available in 2008, Prof. Tarassenko was awarded a research grant from the Health Innovation Challenge Fund (a joint funding programme from the Wellcome Trust and Department of Health & Social Care) to undertake a programme of research which would lead to the design of a digital health system to support patients in the self-management of a chronic condition, which would exploit the new features of the technology. Patient focus groups, as well as clinical colleagues, were involved in the initial stages of the research. As a result of the feedback from the focus groups, the smartphone version of the digital health system was targeted at working age users, whilst elderly patients preferred the tablet computers.

The digital health system was designed with the following generic features:

- smart Bluetooth sensors for *reliable* physiological data collection;
- automatic transmission of the data to a secure backend server;
- patients given help to interpret their data;
- tailored *self-management* component;

- integration of the smartphone/tablet computer app into clinical pathways to facilitate remote management;
- prioritisation algorithms for the healthcare professionals remotely managing the patients.

Our generic digital health system went through the complete cycle of feasibility study, observational study and randomised controlled trial (RCT) for three different conditions: gestational diabetes, chronic obstructive pulmonary disease (COPD) and heart failure. This involved extensive collaboration with the Departments of Primary Care Health Sciences and of Women's and Reproductive Health. The generic features of the system were described in detail in a research paper, which used COPD as the exemplar. [**R1**] The diabetes-specific aspects of the system can be found in the following paper. [**R2**]

The gestational diabetes version of the system (GDm-Health™) was designed from 2010 onwards in Prof. Tarassenko's research group, with extensive input from both users and clinicians from the Nuffield Department of Women's & Reproductive Health (University of Oxford). It comprises a smartphone app, with a Bluetooth-enabled blood glucose meter, for the patient; and a secure website, with optimised data presentation and alerting algorithms for healthcare professionals. [**R2**] The app automatically transmits the blood glucose measurements to the website, along with annotations entered by the patient. In addition, the app provides personalised visual feedback on blood glucose control to the patient. The system has built-in capability for communication between healthcare professionals and the patient, using messaging to support the latter's self-management.

The GDm-Health™ system was refined using agile software development methodology through a process of beta testing with focus groups (2010-2011) [**R2**], followed by a phase of service development (2012-2013). [**R3**] The research helped create an important aspect of the system, which is the use of algorithms to prioritise patients for review by healthcare professionals. [**R2**] Improved outcomes were demonstrated at the end of a randomised clinical trial (2014-2016). [**R4**, **R5**] Following this, the system was exclusively commercialised to a healthcare technology company.

Further research, in a collaboration between Prof. Tarassenko and Prof. Clifton (Department of Engineering Science) and the company, has been carried out using the anonymised data of 15,000 patients to develop machine learning algorithms for the early identification of women requiring a switch to pharmacological treatment to manage their gestational diabetes. [**R6**]

3. References to the research (indicative maximum of six references)

[**R1**] Digital health system for personalised COPD long-term management. Velardo C, Shah SA, Gibson O, Clifford G, Heneghan C, Rutter H, Farmer A, Tarassenko L. *BMC medical informatics and decision making*. 2017 Dec;**17**(1):19-32 doi: 10.1186/s12911-017-0414-8. PMID: 28219430 (48 citations) (Journal article)
[**R2**] Development of a real-time smartphone solution for the management of women with or at high risk of gestational diabetes. Mackillop L, Loerup L, Bartlett K, Farmer A, Gibson OJ, Hirst JE, Kenworthy Y, Kevat DA, Levy JC, Tarassenko L. *J Diabetes Sci Technol*. 2014 Nov; **8**(6):1105-14. doi: 10.1177/1932296814542271. PMID: 25004915 (53 citations) (Journal article)
[**R3**] Acceptability and user satisfaction of a smartphone-based, interactive blood glucose management system in women with gestational diabetes mellitus. Hirst JE, Mackillop L, Loerup L, Kevat DA, Bartlett K, Gibson O, Kenworthy Y, Levy JC, Tarassenko L, Farmer A. *J Diabetes Sci Technol*. 2015 Jan;**9**(1):111-5. doi: 10.1177/1932296814556506. PMID: 25361643 (62 citations) (Journal article)
[**R4**] Trial protocol to compare the efficacy of a smartphone-based blood glucose management system with standard clinic care in the gestational diabetic population. Mackillop LH, Bartlett K, Birks J, Farmer AJ, Gibson OJ, Kevat DA, Kenworthy Y, Levy JC, Loerup L, Tarassenko L, Velardo C, Hirst JE. *BMJ Open*. 2016 Mar 17;**6**(3):e009702. doi: 10.1136/bmjopen-2015-009702. PMID: 26988348 (15 citations) (Journal article)
[**R5**] Comparing the Efficacy of a Mobile Phone-Based Blood Glucose Management System With Standard Clinic Care in Women With Gestational Diabetes: Randomized Controlled Trial.

Mackillop L, Hirst JE, Bartlett KJ, Birks JS, Clifton L, Farmer AJ, Gibson O, Kenworthy Y, Levy JC, Loerup L, Rivero-Arias O, Ming WK, Velardo C, Tarassenko L. *JMIR Mhealth Uhealth*. 2018 Mar 20; **6**(3):e71. doi: 10.2196/mhealth.9512. PMID: 29559428 (40 citations) (Journal article)
[**R6**] Towards a multivariate prediction model of pharmacological treatment for women with gestational diabetes mellitus. Velardo C, Clifton DA, Hamblin S, Khan R, Tarassenko L, Watkinson P, Mackillop L. (2020). submitted in June 2020 and accepted, subject to minor revisions, in September 2020. doi: 10.2196/21435 (Journal article – accepted manuscript)

Funding:
[**G1**] GBP100,000 per annum from the *Biomedical Informatics & Technology* theme of the NIHR-funded Oxford Biomedical Research Centre for five years (2012-2017)

4. Details of the impact (indicative maximum 750 words)

Gestational diabetes mellitus (GDM) affects 16-20% of all pregnancies in the UK annually with important implications for the health of the mother and baby. Women with GDM are predisposed to many co-morbidities including type 2 diabetes. Their babies are prone to adverse health outcomes including respiratory difficulties and metabolic complications in the neonatal period, and they carry a higher risk for future obesity and type 2 diabetes.

The system developed by Prof. Tarassenko and his research collaborators to support the management of GDM was licensed to Drayson Health (now Sensyne Health) in 2017. GDm-Health™ is an example of the development of self-management technology (smartphone app and website), with successful technology transfer, leading to improved patient outcomes and reductions in costs and time spent on administrative procedures for clinical staff. GDm-Health™ is now operational in over 50 NHS Acute Trusts (more than half of the NHS Trusts in the UK which look after women with gestational diabetes). [**S1**] As of August 2020, 16,955 women had used GDm-Health™ and there were over 1,000 new users each month. [**S2**]

Health Impact 1- Benefits for pregnant women
As evidenced in a Randomised Clinical Trial with 203 participants with GDM using the GDm-Health™ app (2018) [**S3**]:

- No significant difference in rate of change of blood glucose (–0.16 mmol/L in the intervention group and –0.14 mmol/L in the control group per 28 days) – i.e. blood glucose control was maintained despite reduction in the number of visits to hospital clinics.
- Significant improvement in compliance with self-monitoring (80% compared with 61%).
- Preterm birth was less common in the intervention group (5/101, 5.0% compared with 13/102, 12.7%; OR 0.36, 95% CI 0.12-1.01).
- There were fewer caesarean deliveries in the intervention group (27/101, 26.7% compared with 47/102, 46.1%, P = 0.005).

If the above data are extrapolated (an extrapolation made in Sensyne Health's Annual Report in August 2020), it can be estimated that, as a result of the use of GDm-Health™ from August 2018 to August 2020 [**S2**]:

- 2,096 caesarean sections have been prevented;
- 849 preterm births have been prevented;
- 1,765 (16%) of mothers have not transitioned to pharmacological treatment;
- 10,361 clinic visits have been saved.

Case study: **Better monitoring and fewer hospital visits for women who develop diabetes during pregnancy – Oxford Academic Health Science Network (AHSN)**
Between 2014 and 2017 the Oxford AHSN assisted in piloting GDm-Health™ across the Oxfordshire region and received feedback from 2,000 women. Feedback demonstrated improvements in reliability, convenience and efficiency. It showed better glucose control and a reduction in clinic visits by eligible women of approximately 25%, freeing up hospital capacity and improving efficiency. One unit estimated the time saving as an hour each day. Testimonials include:

"*It was handy to know that I was in constant touch with somebody and that I would get a message if there was something to worry about. We live about an hour away so having fewer appointments as a result of using this kit helped a lot*." [**S4**]
Gestational diabetes patient

"Feedback from women using GDm-Health has been very positive. They like to know that their condition is being monitored, and appreciate the immediate feedback when their condition requires intervention from a clinician. It is particularly beneficial to women whose first language is not English, or who struggle with literacy. Being able to use an app rather than a handwritten log book and emails suits the current pregnant population – the millennial, but is very easy for everyone to use." [**S5**]
"We would find it almost impossible to manage without the system now."[**S4**]
Former Diabetes Specialist Midwife, Royal Berkshire NHS Foundation Trust

Health Impact 2 - Benefits for clinical team managing the pregnant woman
As documented in independent evaluation at Royal Berkshire NHS Trust using GDm-Health™ over 4 months in 2016: [**S6**]

- 50% reduction in time spent by diabetes midwives on clerical and administrative tasks. Based on this evaluation, the Trust expected to save approximately 1 hour per day per clinic.
- Improved efficiency of the workflow by streamlining the process of communication between midwives and patients.
- Electronic capture of data in a single database enables detailed auditing of care and outcomes while supporting clinical governance. The annual diabetes in pregnancy audit now has a 1-day duration compared to 6 weeks without GDm-Health™, "…saving a considerable amount of time for the diabetes specialist midwife."
- 26% reduction in clinic visits by patients and "…associated reductions in travel costs and inconvenience, and greater control of their own care."
- The January 2020 Sensyne Health Interim report estimated time savings and reported 835 administrative hours saved and 10,361 clinic visits saved across 16 NHS Trusts using the software at the time. [**S7**]

Case study: **The Royal Surrey County Hospital delivers enhanced care to pregnant women with diabetes using remote monitoring and cloud technology** [**S8**]
The Royal Surrey County Hospital began using GDm-Health™ in April 2019. Within the first six months of using the system, the Trust achieved a high adoption of the technology among women, with 95% regularly recording blood glucose readings via the app. In April 2020, this number had increased to 98% as more women recognised the benefits of using remote monitoring. As a result of using GDm-Health™, the Trust has achieved:

- An 18% reduction in the number of appointments with midwives or diabetes specialist nurses.
- A 47% reduction in the number of appointments with diabetes specialist doctors.
- A 21% reduction in the average time to intervention. By identifying rising blood glucose levels more quickly and making earlier interventions, midwives at Royal Surrey are confident they are improving clinical care for both mother and child.
- The ability to conduct near real-time blood glucose readings providing clinicians with ongoing insight into patients' glycaemic control and contributing to service improvement, by allowing them to prioritise more urgent cases.
- Increased communication for mums-to-be with their clinician, with 100% of women using the GDm-Health™ app declaring that they are happy with the care provided by the Diabetes team.
- Reductions in administration. Prior to GDm-Health™ use, midwives spent a large portion of their day calling or emailing to collect readings, averaging 10 calls per day and 224 emails per month to/from expectant mothers. The app freed up time for clinicians to focus on patients in greatest need. In the four-month period following implementation, email traffic reduced by 54% and call volumes by 70%.

Economic Impact 1 – GDm-Health™ adoption has resulted in cost savings across the NHS

- GDm-Health™ has rapidly gained adoption in the NHS. It is now operational in over 50 NHS Acute Trusts (more than 50% of the NHS Trusts in the UK which look after women with gestational diabetes). 16,955 women have used GDm-Health™ (figure updated in November 2020 [**S1**]) and there are over 1,000 new users a month. [**S2**]
- Based on the costs of standard care **[S6]**, using GDm HealthTM would save approximately GBP230 per patient by reducing the need for additional appointments (60% saving over the standard care per-patient costs).
- The 2019 *Topol Review: Preparing the healthcare workforce to deliver the digital future: An independent report on behalf of the Secretary of State for Health and Social Care* examined the health economics evidence for GDm-Health™. The review estimated that there were approximately 80,000 women with GDM in the UK (an underestimate, as the latest estimate is 130,000 – see International Diabetes Federation: Diabetes Atlas 2019). Users of the GDm-Health™ app require up to 2 fewer clinic visits on average during their pregnancy. Equating (for 80,000 women) to a maximum of 160,000 outpatient appointments annually, the equivalent of 40,000 hours of outpatient clinic time annually. [**S9**]
- GDm-Health™ saw its first clinical use in the US in an evaluation which started March 2020 and finished 24th December 2020. In 2019 Sensyne a contract was signed with US healthcare provider Jefferson Health to pilot GDm-Health™ in its hospitals. Jefferson Health is one of the largest healthcare providers in Pennsylvania and New Jersey and the fastest growing health system in the US. Philadelphia-based Jefferson Health manages 14 hospitals with 2,800 beds, 6,000 physicians and 7,000 nursing staff. Sensyne Health and Jefferson Health's collaboration provides a platform to build a US sales model for GDm-Health™. [**S2, S10**]
- The GDm-Health™ app and Sensyne Health have won numerous prizes: Winner of the 2014 Quality in Care Diabetes *Best Digital Initiative* award, 'Highly commended' in the '*Team Work*' category University of Oxford Innovation Awards 2018, and the 2020 HSJ Award in '*Medtech, Device or Hardware Innovation*' category, the HSJ awards are recognized as the top awards in the UK for new healthcare developments. [**S11**]

5. Sources to corroborate the impact (indicative maximum of 10 references)

[**S1**] Sensyne Health Interim Results Report Jan 2021 (reporting until Nov 2020) evidencing the total number of NHS Acute Trusts using GDm-Health™ (2020) pg6-7
[**S2**] Sensyne Health Annual Report Aug 2020 evidencing the total benefits to patients (pg16), staff (pg17), and operational statistics (pg8) (2020)
[**S3**] The published results of a clinical trial, evidencing the benefits to pregnant women: Mackillop L, et al., "Comparing the Efficacy of a Mobile Phone-Based Blood Glucose Management System With Standard Clinic Care in Women With Gestational Diabetes: Randomized Controlled Trial", *JMIR Mhealth Uhealth*. 2018 Mar 20;6(3):e71. doi: 10.2196/mhealth.9512. PMID: 29559428
[**S4**] Oxford Academic Health Science Network (AHSN) case study evidencing positive results in a pilot on 2,000 women from 2014 to 2017 in the Oxford AHSN region (2017)
[**S5**] Sensyne Health case study of Royal Berkshire NHS Trust's use of GDm-Health™ (2018)
[**S6**] NICE Medtech innovation briefing evidencing the benefits to clinical staff caring for pregnant women and the cost benefits of implementing GDm-Health™ (2017) pg10 for time and efficiency for diabetes midwives, pg9 for cost savings
[**S7**] Sensyne Health Interim Results Report Jan 2020 evidencing the total benefits to patients and clinical staff up to Jan 2020 (2020) pp14-19
[**S8**] Sensyne Health case study of The Royal Surrey County Hospital evidencing time saved by clinicians through use of GDm-Health™ (2020)
[**S9**] Evidence of the predicted savings owing to GDm-Health™: The Topol Review: Preparing the healthcare workforce to deliver the digital future: an independent report on behalf of the Secretary of State for Health and Social Care (2019) pg63
[**S10**] Sensyne Health press releases detailing initial 12-month collaboration between Sensyne Health and US healthcare provider Jefferson Health (January 2019) and that the company had launched GDm-Health™ in the US (December 2020).
[**S11**] Awards won by the GDm-Health™ app **a**) 2014 Quality in Care Diabetes, **b**) University of Oxford Innovation Awards 2018 **c**) 2020 HSJ Award