CASE STUDY







Women's health

Camgenium is Supporting Antenatal Care with MedTech App Reassure Pregnancy.



Despite the immense advances in medical technology, women's health remains underserved. In particular, there is a clear gap in technology to support expectant mothers during pregnancy. Technology has the potential to reduce serious complications by monitoring maternal health, but is not widely used.



Camgenium, specialists in medical software development, recognised an opportunity to utilise technology to provide support during pregnancy to people at risk of pre-eclampsia. If pre-eclampsia is left undiagnosed it can result in serious harm to pregnant mothers and their unborn children.

Camgenium developed the Reassure Pregnancy app and website, empowering individuals in high-risk pregnancies to proactively monitor their symptoms and record them in a simple app. The information recorded in the app is shared in real time to the clinic dashboard, enabling clinicians to remotely monitor people throughout high-risk pregnancies. Reassure Pregnancy is certified as a class I medical device because it provides alerts if it detects changes that indicate that the mother's health may be deteriorating.

The Reassure Pregnancy app and website is currently in use at Milton Keynes University Hospital NHS Foundation Trust and University Hospitals Dorset – Poole. It was first introduced to Milton Keynes University Hospital in November 2018 and later to University Hospitals Dorset in April 2019. The Reassure app has been in daily use since its inception and has been used by over 1,000 women with high-risk pregnancies.



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The ability to remotely monitor the key indicators of pre-eclampsia gives pregnant people better control of their health. It also removes the burden of making multiple trips to the hospital. It frees up clinical time, often saving hundreds of pounds per pregnancy for the hospital. And, most importantly, for those individuals whose condition deteriorates, treatment and clinical supervision is provided faster, significantly improving outcomes for mothers and their babies.

Project background

Pre-eclampsia is a key risk for pregnant women and their babies. The early signs of pre-eclampsia, as outlined by the NHS, include high blood pressure and protein in urine. These are typically monitored during a pregnant person' routine antenatal appointments by measuring blood pressure and testing urine for the presence of proteins using a 'dipstick' test.

Individuals who are deemed high risk need to be monitored more frequently which involves multiple trips to the maternity clinic to record blood pressure and urine protein. This can be logistically difficult for someone who cannot travel conveniently to the clinic or who has other small children. These appointments also take significant clinical time in already stretched maternity departments.

During the Covid pandemic regular trips to the hospital posed an even greater risk for pregnant women potentially exposing them to the virus.

Camgenium recognised that blood pressure measurements, urine protein tests and accompanying symptom monitoring could be



safely undertaken at home, thus ensuring pregnant women didn't need to make unnecessary trips to the hospital. They could simply monitor their own health and that of their unborn child each day at home.

The solution

Reassure Pregnancy is a medical device grade app and clinical website developed by Camgenium that enables pregnant women to monitor symptoms of preeclampsia and take control of their own health and that of their unborn child.

The app and the clinical website have been built on Camgenium's flexible, no code, Xenplate software platform. This platform has prebuilt regulatory compliant modules. Camgenium is approved by the NHS to host websites on HSCN, the NHS private network. It is important to use HSCN for hosting the Reassure Pregnancy clinical website and clinician dashboard as it means that patient confidentiality is ensured by relying on existing NHS security systems.

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This eliminates the need for the burdensome level of secure access control that would be required were the system hosted on the internet. The patient apps connect to the clinical website via the internet, and Camgenium has NHS approved IT systems for linking applications on the internet to systems hosted on HSCN.

Medical device regulation applies to Reassure Pregnancy; it is a class I medical device because it provides alerts that patients and clinicians rely on to indicate that the mother and baby may be at risk. Camgenium is certified to ISO 13485, the international medical device standard, and is audited annually to this standard by BSI, the UK's National Standards Body, and gold-standard auditor. Camgenium has developed Reassure Pregnancy to meet UKCA standards.

Developing inclusive technology

User experience was a priority the development of the patient app, which was designed to have a simple and intuitive user interface. James Belcher, COO at Camgenium explains, "When we developed the Reassure Pregnancy app and website, we needed to ensure that pregnant women from all backgrounds could use the app with no or minimal training. We ensured that the app was available in multiple languages so that the user could select their preferred language. Inclusivity was an important design criterion for the Reassure Pregnancy app."

The app and website have been provided free of charge for use at Milton Keynes University Hospital NHS Foundation Trust and University Hospitals Dorset in Poole.



When a pregnant individual receiving treatment at one of these hospitals has symptoms that indicate a high risk of preeclampsia they are registered and onboarded onto the app. They will also be provided with a blood pressure monitor and urine dipstick tests to identify abnormal levels of protein in their urine. With these, the individual is able to record daily blood pressure readings, urine protein results in the app.

The Reassure Pregnancy app also allows users to record if other common symptoms of pre-eclampsia are present: headaches, blurred vision, stomach pain and changes to the baby's movements. These symptoms can also be easily recorded within the app and the results sent in real time to the back-end website at the hospital. Again, if any of these symptoms are present, the system will alert the medical professionals in charge of the individuals care who will take action if any of the symptoms recorded in the app pose a serious risk to the pregnant woman or baby.



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Dr Philip Gaffney, CEO at Camgenium stated, "Our focus is to use technology to improve patient outcomes and enhance efficiencies in patient care. The Reassure Pregnancy app enables pregnant women to take control of their health and the health of their unborn child to proactively monitor symptoms which could lead to pre-eclampsia."

In summary

is clear that Camgenium's Reassure Pregnancy app is a potential lifeline for highrisk mothers and their unborn children throughout pregnancy. The app not only reduces the number of antenatal appointments needed; it can also indicate early signs of pre-eclampsia which might otherwise have been missed. The successful and prolonged use of this medical device in the maternity clinics at both Milton Keynes University Hospital NHS Foundation Trust and Hospitals University Dorset in demonstrates the important role technology can play in improving the health outcomes for pregnant women and their unborn children and also in increasing clinical efficiency and effectiveness.

Camgenium is redefining antenatal care through technology and the company will introduce Reassure Pregnancy to further NHS hospital trusts in the coming months.

Technology walkthrough



The app has been designed to be intuitive and simple to use.

The first screen a new user sees is the Home screen. To start recording blood pressure or urine protein, the user simply touches the buttons on the screen and the app will open the appropriate page in the app.

The icons at the bottom of the screen are present on all screens and provide a menu that allows the user to navigate back to the home page, view previously recorded data, access help information and frequency asked questions (FAQs), view any alerts that have been issued and send and receive messages to and from the clinician team.



This screen, the Blood Pressure screen, allows users to enter blood pressure readings they have made and record the time and date. This means that earlier such recordinas. as those made the previous day by a GP, may be added to the patient's record.

This screen also allows the user to enter information about other symptoms that may indicate pre-eclampsia.



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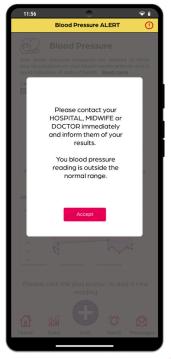
These symptoms are: headaches, blurred vision, abdominal pain and a reduction in the baby's movements, all of which can prove significant.



Once the symptoms have been entered into the app the results will be displayed on this screen which allows the mother to see how blood pressure has changed over time.

If the data recorded indicate a problem, an alert will be issued.

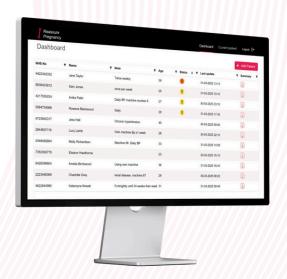
The patient's alert appears as an onscreen pop-up, which the individual must accept to acknowledge that medical attention is required.



The patient alert addresses the risk that the clinic may not be notified of the problem if there is a connectivity issue. The alert instructs the individual to contact a clinician.



The urine protein section of the app gives the individual an easy way to enter the result of each dipstick test. If the results are normal alerts will not be displayed. However, abnormal readings will be flagged to clinicians and to patients just like any abnormal blood pressure reading.



The clinical dashboard provides clinicians with a view of all of their patients who are using the system. For each it shows their latest results and whether an alert has been issued, but not yet acted on. This allows the team to focus on the patients who are in need of care.

To discover more speak to one of our experts.