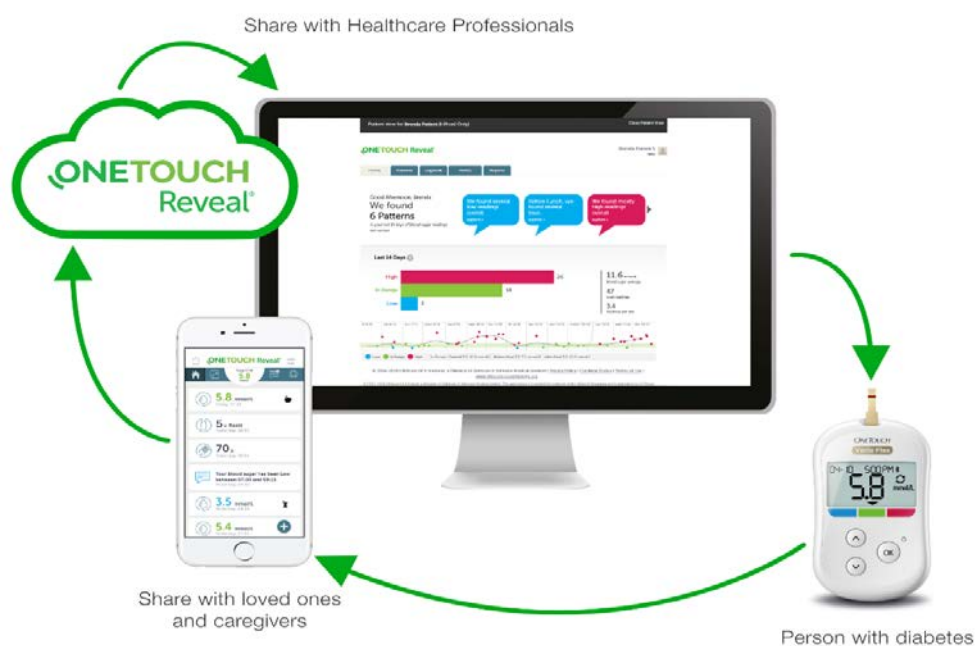


Innovative Medical Technology Overview

OneTouch digital system for diabetes management, remote real-time patient monitoring and remote consultations.



Key points

- The OneTouch digital system allows real-time sharing and monitoring of blood glucose data via a smartphone app and dedicated data cloud.
- The OneTouch digital system is the first third party real-time data sharing platform to be integrated into NHSScotland and its unique Application Programming Interface allows the NHSScotland to retain ownership of the data.
- One randomised controlled trial (RCT) and one single-arm trial found that the OneTouch digital system improved glycaemic control as measured by HbA1c. The results should be interpreted with caution due to a lack of statistical power and between group differences.
- Two pilot studies in NHSScotland proved the feasibility of using the OneTouch digital system in a clinical setting and led to a reduction in face to face appointments by use of remote consultations.

- The blood glucose testing strips used with the OneTouch digital system are cheaper than the strips used for other 'premium' blood glucose meters, based on 2019 Scottish Drug Tariff data. Although the OneTouch test strips are more expensive than those used with 'standard' blood glucose meters, one economic analysis illustrated that the additional test strip cost will be offset by longer-term savings generated from improved glycaemic control. There are number of potential limitations with this long-term analysis relating to quality of input data, and assumptions around market share and uptake.

The technology

The OneTouch digital system includes the following technologies: OneTouch Verio Flex™ blood glucose meter; OneTouch Reveal® smart app; OneTouch Reveal® cloud; OneTouch Reveal® web app; and the LifeScan Inc. Application Programming Interface.

After placing a droplet of blood on a disposable test strip, the OneTouch Verio Flex™ blood glucose meter produces a blood glucose reading which is then relayed via Bluetooth to the OneTouch Reveal® smartphone app. The OneTouch Reveal® smartphone app uploads the data to LifeScan's OneTouch Reveal® cloud and shares the data, via the OneTouch Reveal® web app, with their clinician and carers allowing them to track changes in glycaemic control and make contact with the patient if necessary.

Other branded technologies are available, however LifeScan's OneTouch digital system is the only technology at present to be integrated into NHSScotland's healthcare system using a unique data sharing Application Programming Interface which allows the NHS to retain ownership of the data. An Application Programming Interface is programming code that governs access points to a server which holds a database. A website, in this case the OneTouch Reveal® web app, uses the Application Programming Interface to securely retrieve relevant information from the database.

The OneTouch technologies are manufactured by LifeScan Inc. and are CE marked. The OneTouch Reveal® cloud is hosted on the OneTouch Reveal® platform which is based in Sweden. It is Health Information Trust Alliance certified and is General Data Protection Regulation compliant. Data are only shared with clinicians or carers with the patient's consent and LifeScan Inc. do not retain ownership of any patient data.

The clinician only requires an internet connection and a web browser to use the OneTouch digital system. Additional digital infrastructure is not required.

Innovative aspect

LifeScan's OneTouch digital system is the only technology at present to be integrated into NHS Scotland's healthcare system using a unique data sharing Application Programming Interface which allows the NHS to retain ownership of the data.

Patient group

Patients with type 1 or type 2 diabetes who need to monitor their blood glucose levels.

Current practice: comparators and use in pathway of care

Self-monitoring of blood glucose is an important aspect of diabetes self-management. To achieve maximum benefits from self-monitoring, patients need to be able to review, understand, interpret and respond to the information obtained by self-monitoring devices. It should be noted that the general management of type 2 diabetes is focused on early intensive weight management with a goal of remission.

Blood glucose meters are self-monitoring devices that aim to improve glycaemic control by measuring blood glucose levels and facilitating improved understanding of blood glucose targets. Currently in NHSScotland, there is no way to share these data in real-time with clinicians. Instead reports are generated and shared with clinicians at a later date, which does not allow monitoring and communication between clinician and patient in real-time.

Product performance: published data

An RCT¹ and a single arm trial² investigated the effect of the OneTouch digital system on glycaemic control. Both studies included participants with type 1 or type 2 diabetes who were users of blood glucose meters in their diabetes management. The RCT was statistically powered at recruitment but due to drop outs the results were underpowered¹. The single arm trial was also underpowered². Trial length ranged from 12-24 weeks with no follow up. The lead authors for all the studies identified were employees of LifeScan Inc.

In the RCT¹, 137 participants were randomised to use either the OneTouch digital system or the OneTouch VerioFlex™ meter alone (no app or real-time feedback) for 24 weeks. If deemed clinically necessary from remote monitoring, participants in the digital system group were sent text messages every two weeks. This trial was conducted at five different sites in the United Kingdom (UK), two of which were in Scotland. Only data on completing participants were reported (n=128) and no details were provided of participants who dropped out. After 12 and 24 weeks, there were clinically and statistically significant improvements in glycaemic control (HbA1c levels), compared with baseline, in both the digital system (n=62; 0.78% and 0.67% reduction, respectively; $p<0.001$) and the meter only groups (n=66; 0.56% and 0.55% reduction, respectively; $p<0.001$). There was no statistically significant difference in HbA1c reduction between the two groups at either timepoint¹.

In the single arm study², participants (n=40) uploaded their blood glucose results from a OneTouch Verio (previous model to the VerioFlex™) to the OneTouch Reveal® web app for 12 weeks. This study was conducted in two NHSScotland clinics. After uploading data to the Reveal® web app it was then available to the participant's clinician. The clinician conducted a remote consultation with the participant at weeks 4 and 8. After 12 weeks, compared with baseline, the participants had a statistically and clinically significant improvement in glycaemic control: 0.4% reduction in HbA1c ($p<0.001$)².

Product performance: local data and ongoing projects

Two local studies were identified. These were the NHS Clyde-Cloud study carried out in NHS Greater Glasgow & Clyde and a virtual gestational diabetes clinic study carried out in NHS Lothian.

The NHS Clyde-Cloud was a pilot project to demonstrate that data could be sourced from a third party device and transferred into the NHS with the NHS retaining ownership of the data. This was done using the OneTouch digital system in people with type 1 diabetes, aged 16-25 years (n=20), in Glasgow. The pilot ran for 5 months in 2017. Once it was demonstrated that data could be sourced from a third party while the NHS retained ownership, the project was stopped. The trial manager reported that access to real-time data enabled them, on two occasions, to avoid hypoglycaemic events by intervening in a timely manner. (K Robertson, Consultant Paediatrician and Clinical Lead in Children's Diabetes Services, NHS Greater Glasgow & Clyde. Personal Communication, 30 Sept 2019).

A pilot study in NHS Lothian³ provided virtual clinics for patients with gestational diabetes in order to reduce the number of face to face appointments and by proxy the number of missed face to face appointments. The intervention included use of the OneTouch digital system for remote assessment of blood glucose data plus consultations by either email or phone depending on need. At the end of the pilot, there was a reduction of approximately 32 face to face appointments per week and high levels of satisfaction from both patients and clinicians.

Unpublished and ongoing studies

One unpublished RCT⁴, based in the United States, was identified (NCT03556605, n=100). This RCT was a parallel arm, open-label, partial crossover trial investigating the clinical value and user acceptance of the OneTouch digital system compared with blood glucose monitoring without connection to a mobile diabetes app. This trial was due to finish in September 2019 but has not yet been published.

Safety

The OneTouch VerioFlex™ meter is CE marked. Clinical evidence on the safety of the technologies was limited to the RCT¹ reported above. A total of 60 adverse events and 10 serious adverse events occurred over the 24-week study period, none of these were related to use of the OneTouch devices.

Economic and cost considerations

The OneTouch digital system technologies (OneTouch VerioFlex™ meters, Reveal® smart and web apps and Application Programming Interface) are available free of charge to NHSScotland. The only consumable cost is test strips at £15.12 per 50 strips. This makes the OneTouch test strips the cheapest option for 'premium' meters with additional technology in NHSScotland (£15.12–£16.30). Cost of test strips for 'standard' meters in NHSScotland ranges from £8.74–£9.99. A list of standard and premium meters in use in NHSScotland and their associated cost

are provided in Table 1. The manufacturer reports that premium meters make up 43.7% of blood glucose meters prescribed by NHSScotland.

Two budget impact models for NHSScotland were provided by the manufacturer. The budget impact was calculated on the following conversion rates from current meters to the OneTouch digital system over a 5-year period: 10%, 25%, 50%, 75% and 100%. The first model focused on savings made on test strips (Table 2) while the second included potential savings based on reductions in long-term diabetes complications over a 25-year period (Table 3). The second model assumed 100% compliance after conversion and a sustained 0.67% reduction in HbA1c. It is this assumed improvement in glycaemic control that leads to a reduction in diabetes complications.

Table 1 List of standard and premium meters, cost of test strips and market share as per 2018

Standard			Premium		
Name	Cost 50 strips (£)	Market share^	Name	Cost 50 strips (£)	Market share^
Glucorx®	9.95	11.1	Ascensia Contour Next Link®	15.16	12.7
Nipro	8.99	9.8	Accu-Chek Aviva®	16.21	12.1
Accu-Chek Mobile®	9.99	8.4	Freestyle Optium®	16.30	8.7
Glucomen Areo®	9.95	5.7	OneTouch Verio®	15.12	3.2
Accu-Chek Performa®	7.50	4.4	OneTouch Vita®*	-	0.0
Ascensia Contour®	9.99	4.2	Other		7.0
OneTouch Select Plus®	9.99	1.9			
OneTouch Ultra®*	-	1.5			
Wavesense Jazz®	8.74	0.1			
Other		9.1			

Test strip costs sourced from Drug Tariff Scotland December 2019⁵

^Market share according to LifeScan in 2018.

*OneTouch Ultra and Vita are no longer available in NHSScotland. They have been included in this table as they were part of the 2018 market share budget impact model.

Model 1 – comparison of test strip costs

The savings generated are dependent on the magnitude of conversion from existing meter to the OneTouch digital system. Savings are also dependent on conversions being from a ‘premium’ meter which has additional technology due to the high cost of test strips. If there was a conversion from a standard meter to the OneTouch digital system this would be cost incurring. The data in Table 2 only describes conversion from ‘premium’ meters to the OneTouch digital system.

Model 2 – as model 1 but includes long term treatment costs

The assumed savings generated through improvements in glycaemic control and long term conditions were also dependent on magnitude of conversion from existing meters to the OneTouch digital system (Table 3). All scenarios are costing saving in the long term. These savings should be treated with caution as the assumed 0.67% reduction in HbA1c was based on a within group and non-powered result¹ and assumes a sustained reduction over 25 years while the 0.67% reduction was measured after 24 weeks with no follow up.

Table 2 Cumulative savings made on test strips in Scotland

Percentage converted to OneTouch over 5 years*	Cumulative savings^				
	Year 1	Year 2	Year 3	Year 4	Year 5
10	£7,897	£23,691	£47,381	£78,969	£118,454
25	£19,742	£59,227	£118,454	£197,423	£296,134
50	£39,485	£118,454	£236,907	£394,845	£592,268
75	£59,227	£177,680	£355,361	£592,268	£888,402
100	£78,969	£236,907	£473,815	£789,691	£1,184,536

*Conversion rate per year is assumed to be linear.

^Based on a typical T1DM and insulin dependent T2DM patient using 4.2 and 2.1 strips per day respectively

Table 3 Cumulative savings made in reduction of long term conditions

Percentage converted to OneTouch	Cumulative savings*				
	Year 5	Year 10	Year 15	Year 20	Year 25
10	£1,626,176	£6,248,676	£13,715,485	£22,164,399	£27,156,940
25	£4,065,440	£15,621,691	£34,288,711	£55,410,998	£67,892,349
50	£8,130,880	£31,243,382	£68,577,423	£110,821,996	£135,784,698
75	£12,196,320	£46,865,073	£102,866,134	£166,232,993	£203,677,046
100	£16,261,760	£62,486,764	£137,154,846	£221,643,991	£271,569,395

*Assumes 100% compliance and sustained reduction of HbA1c of 0.67%

In addition to the two budget impact models, LifeScan funded an economic analysis of cost savings of using the OneTouch digital system in five European countries⁶. This analysis was based on the results from the RCT which examined the effect of the OneTouch digital system². The authors applied an HbA1c reduction of 0.66% of all people with diabetes who were insulin dependent and a separate analysis of a 0.92% reduction in all people with type 2 diabetes who were insulin dependent. The savings generated were based on a decrease in long term conditions and either a decrease in five or 10 percent of severe hypoglycaemic events. The per annum savings for all people with diabetes in the UK were the equivalent of £4.8 million and £9.3 million respectively. The per annum savings for all people with type 2 diabetes in the UK were £2.8 million and £5.1 million, respectively. These results should also be treated with caution as they are again based on the same within group and underpowered results. It should also be noted that the five and 10 percent reductions in hypoglycaemic events were arbitrary values not based on clinical evidence. Lastly, the model was based on an assumed 100% uptake and compliance which is unlikely to be achievable.

Patient and clinician experience and other considerations

The studies identified^{1, 2} also examined user experience of the technologies. Overall, patient-reported experience of the OneTouch digital system were mainly positive. Patients reported that: they felt the digital system allowed them to be connected to their clinician in a “seamless” manner¹; they wished they had been given the OneTouch digital system at the start of their diagnosis; and the app allowed them to make progress with their diabetes management². A survey of clinicians with experience of the OneTouch digital system provided positive comments stating it would help patients remain engaged with their condition and help manage their blood glucose between appointments⁷.

It should be noted that users of the technology will need to be capable of self-monitoring their blood glucose and have a smartphone or tablet with access to the internet and that the clinicians will also need access to the internet.

Conclusions

The OneTouch digital system is the only real-time diabetes monitoring system to be integrated into NHSScotland. This has been facilitated by a custom built Application Programming Interface that allows NHSScotland to retain ownership of the data. Access to real-time data through the OneTouch digital system supports remote consultations and has the potential to reduce the number of face to face consultations for some patients, and as a result reduce the associated time and cost of delivering the service.

From the available evidence the OneTouch digital system may have a positive and clinically meaningful effect on glycaemic control in people with diabetes who need to monitor their blood glucose. It is not clear if these HbA1c reductions are simply due to changing to the meter or the whole OneTouch digital system. In addition, the interpretation of these results is limited by a lack of statistical power, lack of between group results and relatively short trial length. Fully powered RCTs would strengthen the evidence base.

If the OneTouch digital system were implemented across NHSScotland it would be cost saving, in terms of consumables, but only when replacing other premium blood glucose meters. Costs may be avoided by the NHS by a reduction in hypoglycaemic events and long term complications. These analyses should be treated with caution as they are based on underpowered, within group results from a short-term trial.

References

1. Grady M, Katz LB, Cameron H, Levy BL. Diabetes App-Related Text Messages From Health Care Professionals in Conjunction With a New Wireless Glucose Meter With a Color Range Indicator Improves Glycemic Control in Patients With Type 1 and Type 2 Diabetes: Randomized Controlled Trial. *JMIR diabetes*. 2017;2(2):e19. Epub 2017/08/07.
2. Grady M, Cameron H, Levy BL, Katz LB. Remote Health Consultations Supported by a Diabetes Management Web Application with a New Glucose Meter Demonstrates Improved Glycemic Control. *Journal of diabetes science and technology*. 2016;10(3):737-43.
3. Zammit N. Piloting a nurse-led virtual clinic in the diabetes antenatal service. *Healthcare Improvement Scotland*, [Unpublished] 2019.
4. ClinicalTrials.gov. Tu Salud (Your Health) Randomized Control Study in Patients With Diabetes Using a Mobile App. 2019 [cited 2019 Mar 07]; Available from: <https://clinicaltrials.gov/ct2/show/NCT03556605>.
5. Information Services Division NNSS. Scottish Drug Tariff Part 9, Chemical Reagents. 2019 [cited 2019 Dec 02]; Available from: <https://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Scottish-Drug-Tariff/Docs/December%202019/2019-12-SDT-PART%209.pdf>.
6. Fritzen K, Basinska K, Rubio-Almanza M, Nicolucci A, Kennon B, Verges B, *et al*. Pan-European Economic Analysis to Identify Cost Savings for the Health Care Systems as a Result of Integrating Glucose Monitoring Based Telemedical Approaches Into Diabetes Management. *J Diabetes Sci Technol*. 2019:1932296819835172. Epub 2019/03/29.

7. Katz LB, Grady M, Stewart L, Cameron H. Patient and healthcare professional satisfaction with a new, high accuracy blood glucose meter with color range indicator and wireless connectivity. Expert review of medical devices. 2016;13(7):619-26.

What is an Innovative Medical Technology Overview (IMTO)

An IMTO is a high-level, light-touch summary of the evidence surrounding an innovative technology. An IMTO seeks to offer an early indication of the strengths and weaknesses of the technology, with a view to contributing to local decision-making by NHS health professionals, managers and procurement colleagues.

IMTOs are not peer reviewed and do not contain recommendations. IMTOs should be considered alongside existing guidance applicable to NHSScotland.

All new and innovative technologies need to have been registered on the NHSScotland Health Innovation Assessment Portal (HIAP).