Evaluation of a remote consent implementation project using the NASSS Framework

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Background

- Traditional processes of obtaining paper consent for medical procedures can be time-consuming and stressful for patients and lead to operational impacts, such as theatre delays or cancellations through lost forms.
- Digital transformation is a science that involves a consideration of the interplay of many factors – broadly between people, the technology, organisations, and the macroenvironment. There remains a high risk of failure in digital transformation efforts across industries (1).

Methods

- We sought to evaluate a pilot initiative to introduce remote consenting to Moorfields Eye Hospital using the NASSS (Nonadoption, Abandonment, and Challenges to Scale-Up, Spread, and Sustainability) framework, a widely used framework designed to help evaluate the likelihood of new technology adoption and scaling.

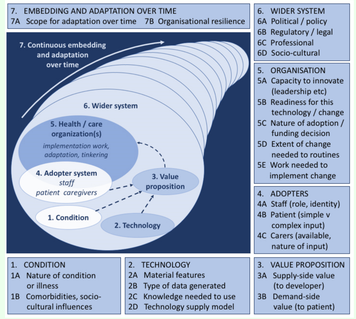


Figure 1. The NASSS Framework (1).

- A mixed methodology approach was used. Quantitative analysis included evaluating:
  - Clinic efficiency using a time and motion study.
  - Sustainability by extrapolating travel savings from patient surveys and publicly published CO_2 emissions data.
  - Digital exclusion by auditing baseline characteristics amongst patients who did and did not sign remote consent forms.
- Qualitative analysis included thematic analysis of observational notes taken during meetings, patient and clinician surveys.

Results

Table 1. A Summary of Identified Strengths, Barriers and Complexity for Each NASSS Domain

Domain	Strengths	Barriers	Complexity
Domain 1: The Condition	Well characterised, understood and predictable conditions/ procedures.	Still no easy solution to overcoming language barriers to efficiently and reliably consent (same process as traditional consent).	Simple
Domain 2: The Technology	Reported ease of use amongst clinicians and patients. Able to use the technology 'off the shelf'. Minimal training required to use the platform.	Some customisation required to convert existing consent forms into standard platform format.	Simple
Domain 3: The Value Proposition	Supply-side monetary, learning and future marketing benefits. Demand-side efficiency, operational and sustainability gains. Demand-side improvements in acceptability and safety for patients.	All demonstrated benefits are based on estimates and projects, in the absence of a formal economic or sustainability analysis.	Complicated
Domain 4: The Adopter System	Good levels of satisfaction amongst staff and patients.	Concerns about digital exclusion partly borne out by the data. Interdependent technologies (such as signature pads and print functions) are potential points of failure.	Complex
Domain 5: The Organisation	Good managerial relations, including involving the Trust Consent Lead, multiple service directors, Chief Clinical Information Officer and Trust Executive Board. Remote consent fits into existing team routines and care pathways.	Single organisation but with 2 different electronic health records – making the process of integration more cumbersome. Some work may be needed to train and engage staff.	Complicated
Domain 6: The Wider Context	Recent case law and GMC guidance aligns with the principles of remote consent (3-5). Aligns with NHS Long Term goals to facilitate more remote pathways for healthcare (6-7). Aligns with NHS Net Zero sustainability goals (8).	Societal perspectives of trust in healthcare technology may still exist.	Simple
Domain 7: Adaptation Over Time	Evidence of effective co-design during the pilot period. Strong Trust focus on change management, supported by Department of Digital Medicine. Expanding Clinical Safety Team critical to identifying, evaluating and managing risks Benefit from the lessons from previous and concurrent use of Concentric at other large Ophthalmic units.	Multiple competing priorities for staff time and resources, typical for an NHS Trust.	Simple

Table 2. Relative risk (RR), Confidence Intervals (CI) and p-values of signing the remote consent form for age > 75y, visual acuity (VA) 0.3 LogMAR or worse, and ethnicity.

Risk factor	RR	CI	p-value	N
Age > 75	1.85	1.42-2.40	<0.001	288
VA 0.3 LogMAR or worse in better seeing eye	1.56	0.99-2.44	0.05	129
White ethnicity	1.14	0.62-2.08	0.68	90
Non-white ethnicity	0.88	0.48-1.61	0.67	90

Age was a statistically significant risk factor for patients not signing the remote consent form. Visual acuity 0.3 LogMAR or worse, white and non-white ethnicities were not. Further evaluation is needed as the sample size was powered at $\alpha = 0.05$ and $\beta = 0.2$ to detect RR ≥ 1.85 for VA 0.3 LogMAR or worse, and ≥1.8 for minority ethnicity.

Figure 2. Proportion of patients seen remotely prior to day of surgery and estimated travel savings.

63% of patients who were sent a remote consent form were seen virtually, and 98% of those patients did not require face-to-face appointments until the day of surgery, resulting in significant travel savings in cost, time, and indirect carbon emissions. The estimated average patient commute was a 7.5-mile, 45-minute journey at £7 cost and carbon emission of 0.89 KgCO2e. F2F = "Face-to-face appointment".

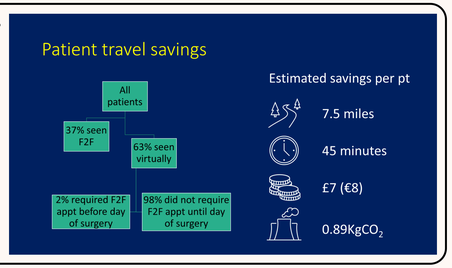


Table 3. Select patient feedback after using remote consent.

Many patients perceived the remote consent process easy to follow. Some reported needing family members' assistance. Some patients alluded to age or visual impairment as potential barriers to technology use. Themes for improvement include providing more information (by text messages and in letters) and more language options. Language was also theme amongst the 25 patients who did not sign the consent form prior to the day of surgery. In this subgroup, 20% did not have a device to sign on at home, and 60% did not receive the consent form.

Positive:	Areas for improvement:
• *"Easy to sign on the phone and receive information."* • *"It was very clear and easy to follow instructions whilst doing it."* • *"Keep up the good work."* • *"Once clicked on the link was relatively easy to follow the steps."* • *"By providing a telephone number is of great value to your clients."* • *"Family member assisted at home to help sign the platform."* • *"Digital world is not for everyone. Rest is all good."*	• *"More language options"* • *"For Senior CITIZEN who are not up to date with new technology at the moment, some will never be."* • *"He forgot to bring his glasses therefore found it quite difficult. Better have someone to help."* • *"Add more information to patient letters."* • *"Send text message reminders"* • *"Communicate a prewarning to expect the text message or email."*

Time and Motion Study

A time and motion study was performed evaluating 75 patients' flow during a one-week "cataract drive". This showed that surgeons explained the risks and benefits of surgery in 92 seconds on average, and patients signed the consent form in 58 seconds with remote consent.

Conclusions

- Evaluating this pilot using the NASSS framework has helped identify potential sources of difficulty as the Trust seeks to maximise the chance of successful implementation during the post-pilot deployment and scaling phase.
- Key success factors include facilitating remote care pathways with associated patient travel and CO_2 emissions savings. The remote consent platform was well received by most patients and clinicians, easy to use, and clinically efficient.
- Salient focus areas for implementation and scaling are overcoming language barriers, improving patients' access to data and technology, and ensuring benefits for diverse patient subgroups, such as older patients.
- Efforts to overcome these barriers include offering digital skills workshops, data and device loans, and pilot initiatives for multilingual and multimedia patient information (e.g., video).

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