# Impact Assessment

## Concentric (Digital Consent) Deployment

### *within Oxford University Hospitals NHS Foundation Trust (OUH) and Buckinghamshire Healthcare NHS Trust (BHT)*


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# 1 Executive Summary

The implementation of Concentric Digital Consent at Oxford University Hospitals NHS Foundation Trust (OUH) and Buckinghamshire Healthcare NHS Trust (BHT) has demonstrated clear benefits in efficiency, patient experience, and cost-effectiveness, making a strong case for wider NHS adoption.

The analysis aimed to assess the preliminary impact of Concentric deployment at OUH and BHT by analysing the stakeholder (healthcare professional) experience and the broader economic impact of adopting the platform compared to the traditional paper-based consent system. A preliminary health economic analysis was conducted using 'real-world' data from the ophthalmology department at OUH. Additionally, a hypothetical health economic analysis was carried out for the obstetrics and gynaecology department at BHT, utilising data from existing literature. This report presents the findings of an impact assessment of the Concentric digital consent platform, conducted from September to November 2024.

**Key Findings:**

- **Operational Efficiency**: Digital consent reduced consent times by **7.14 minutes per episode** at OUH, improving clinic workflows and increasing patient throughput.
- **Financial Impact**: At OUH, there was projected **savings of £5.87 per episode, with total savings projected as £167,437 over three years** through reduced staff time, lower administrative costs, and elimination of missed consent forms.
- **Medicolegal Risk Reduction**: The platform reduces incomplete or lost consent forms, lowering exposure to costly litigation (estimated NHS-wide savings of £201,590 per prevented claim).
- **Patient-Centred Care**: Digital access to consent forms enhances shared decision-making and patient satisfaction, enabling patients to review and discuss treatment options at home.
- **Implementation Considerations**: The integration and training processes were largely successful. Minor challenges included Wi-Fi connectivity issues and user logout security risks on shared devices, both of which need ongoing IT support and best-practice adoption.

**Implications for Commissioners and Digital Leads:**

The results strongly support broader NHS adoption of digital consent, with a clear financial and operational case for scaling this model beyond the services and pathways assessed in OUH and BHT

- **Investment Justification**: Digital consent aligns with DHSC priorities to move from analogue to digital; to address the elective back-log and to create and improve workforce efficiency.
- **Scalability and ROI**: The system is cost-saving, clinically beneficial, and scalable across multiple specialties beyond ophthalmology and obstetrics & gynaecology.
- **Next Steps**: Future adoption strategies should focus on regional rollouts, embedding digital consent within EHR systems, and ensuring IT infrastructure readiness to maximise long-term benefits.

# 2 Introduction

Health Innovation Oxford & Thames Valley (HIOTV) supported Buckinghamshire, Oxfordshire and Berkshire West Integrated Care System (BOB ICS) in selecting technologies for the Health Technology Adoption and Accelerator Fund (HTAAF) funding application, which aims to support and speed up the adoption of innovations and technologies into clinical systems. HTAAF is an NHS England programme to support and accelerate the adoption of innovations and technology into clinical systems.

ICSs were invited to apply for up to £700,000 in funding for technologies from seven different categories focusing on national priorities. The BOB ICS was successful in securing funding for two technologies. Concentric was one of the innovations to receive support to accelerate its adoption at OUH and BHT in 2024 and 2025. The funding supports the renew/extend supplier contract and implementation support such as purchase of iPads.

The BOB ICS has commissioned HIOTV to support HTAAF Impact Assessment and Reporting. This involves two workstreams:

- Regional and National reporting to NHS England/BOB ICS on the benefits and outcomes of Concentric.
- An Impact Assessment, for which the deliverable is the following report.

## 2.1 Impact Assessment

Concentric provides digital consent for all treatment scenarios and is used in several NHS Trusts. This project focussed on deployment of the platform in selected services in OUH and BHT in 2024. The scope and objectives of the impact assessment were to measure the preliminary impact of Concentric deployment at OUH and BHT under HTAAF. Relevant data and information for preliminary health economic analysis were collected and processed by OUH, while BHT did not provide or process any data. Information provided by OUH and BHT informed pathway mapping activities, and an analysis plan was developed for the impact assessment.

**Stakeholder Engagement Study**

The objective was to conduct a stakeholder engagement study using semi-structured qualitative interviews to assess the impact of Concentric as a digital consent tool in the OUH pathway (ophthalmology) and BHT Pathway (obstetrics and gynaecology). HCPs using Concentric were included to understand their experience and acceptance of Concentric. The discussion guides used for the stakeholder engagement study can be found in Appendix 1- OUH Discussion Guide and Appendix 2- BHT Discussion Guide. The full stakeholder study report can be found in Appendix 3- Stakeholder Engagement Study. The findings are summarised in sections 5.1 and 5.2.

**Preliminary Health Economic Assessment**

A preliminary health economic analysis was planned with the intention of using relevant data provided by OUH and BHT to further understand the benefits and impact of Concentric on the respective Trusts. However, due to lack of data received from BHT for the preliminary analysis, a hypothetical analysis was completed instead. Using the provided data, a decision model was built for the preliminary analysis to assess the impact and potential cost benefit of Concentric in the OUH and BHT pathways. The ***preliminary*** health economic analysis report for OUH can be found in

Appendix 4- OUH Preliminary Health Economic Assessment. The ***hypothetical*** health economic analysis report for BHT can be found in Appendix 5- BHT Hypothetical Preliminary Health Economic Assessment. The findings are summarised in sections 5.4 and 5.5.

**Reporting and communication**

This final report for BOB ICS is provided on the effectiveness and impact of Concentric in OUH (ophthalmology) and BHT (obstetrics and gynaecology).

## 2.2 Concentric

Concentric is a digital consent platform, designed to replace traditional paper-based consent processes. Concentric has the capability to be tailored to all treatment scenarios. It is currently operational in several NHS Trusts (1).

The Concentric digital consent platform has previously undergone various health economic assessments to evaluate its effectiveness within the NHS. These assessments highlight key economic and operational benefits of transitioning from paper-based to digital consent processes. Prior studies have shown that the introduction of the Concentric digital consent platform to be either cost-neutral or cost-saving, with savings of approximately £0.81 to £1 per consent episode (2). While consultation times remain similar between digital and paper processes, administrative tasks are more efficient, allowing more time for shared decision-making. The platform also improves operational efficiency by reducing administrative burden, decreasing day-of-surgery delays and cancellations by 5-10%, and potentially increasing patient throughput (3). Additionally, Concentric enhances patient and clinician experience by improving shared decision-making and patient understanding, with studies reporting an increase in patients experiencing gold-standard decision-making from 28% to 72% (3). The platform also reduces medico-legal risks by improving documentation accuracy, mitigating errors that historically led to costly litigation. Furthermore, the digital transition supports sustainability goals by significantly reducing paper usage, lowering the environmental impact of healthcare organisations (4).

# 3 Pathway

Using information gathered from OUH and BHT, pre digital (paper) and digital (concentric) pathways were mapped for both Trusts. The pathway for the pre digital (paper) and digital consent pathway within the ophthalmology department at OUH was mapped using information gathered from OUH (Figure 1). Similarly, information from BHT was used to map the pre digital (paper) consent pathway for the obstetrics department (Figure 2), and gynaecology department (Figure 3).

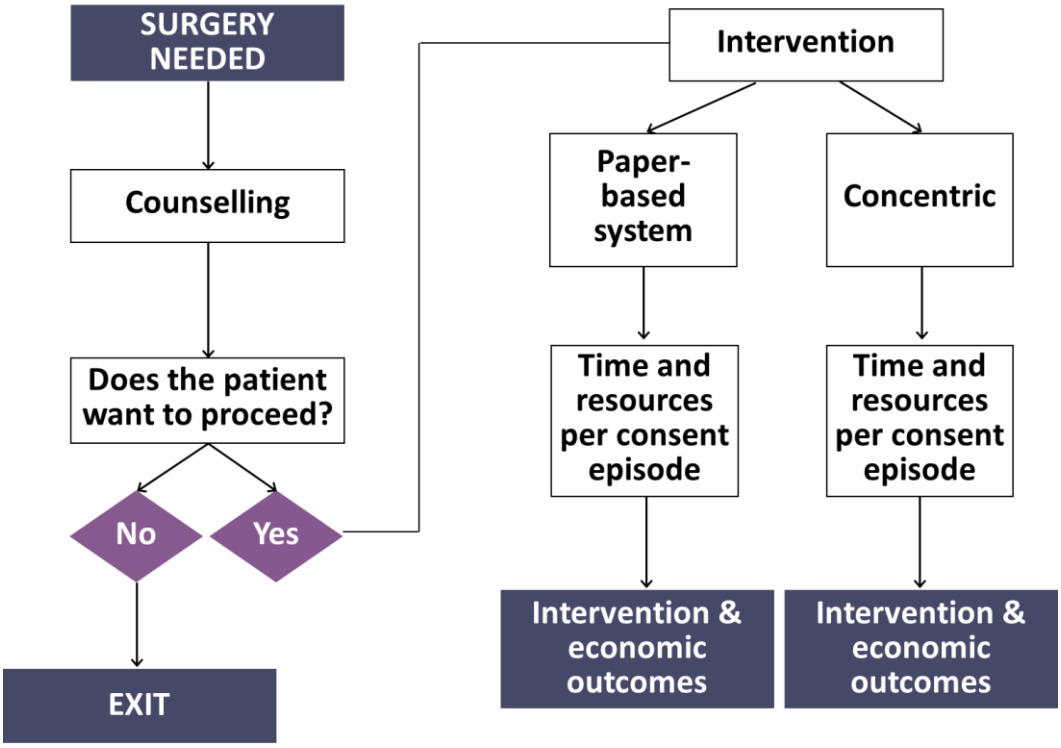


*Figure 1: Visual Representation of pre and post digital consent pathway within OUH ophthalmology department (information provided by OUH)*

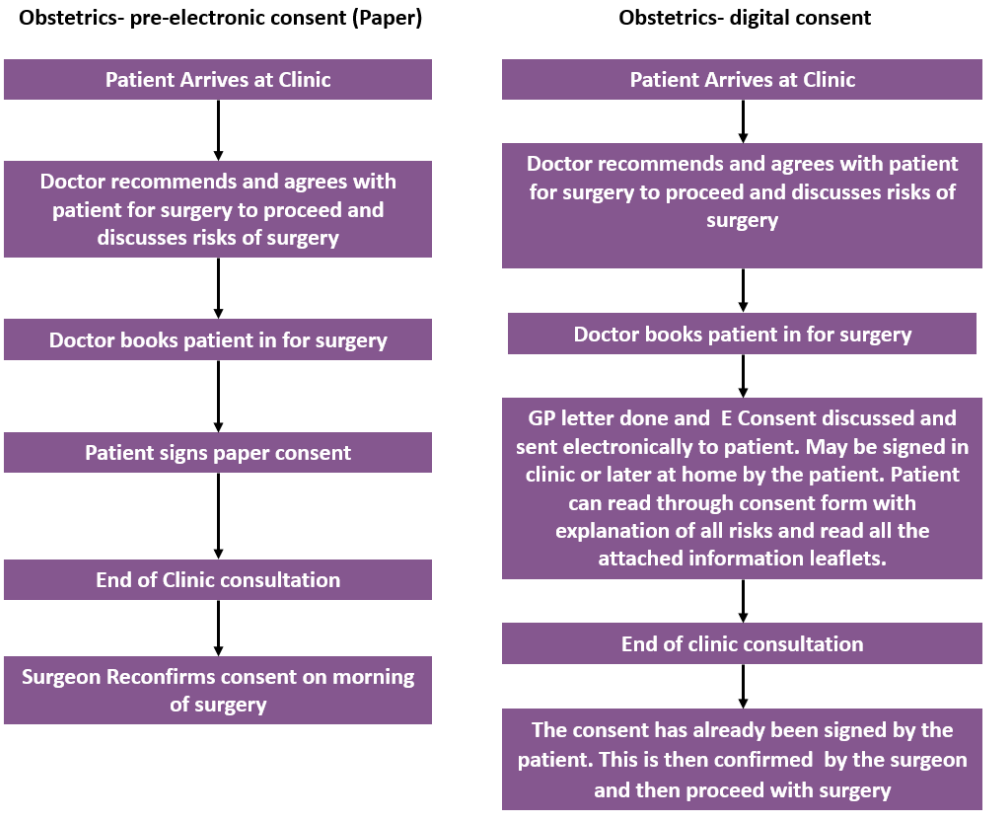


*Figure 2: Visual Representation of paper consent pathway (pre digital) and digital pathway in obstetrics (information provided by BHT)*

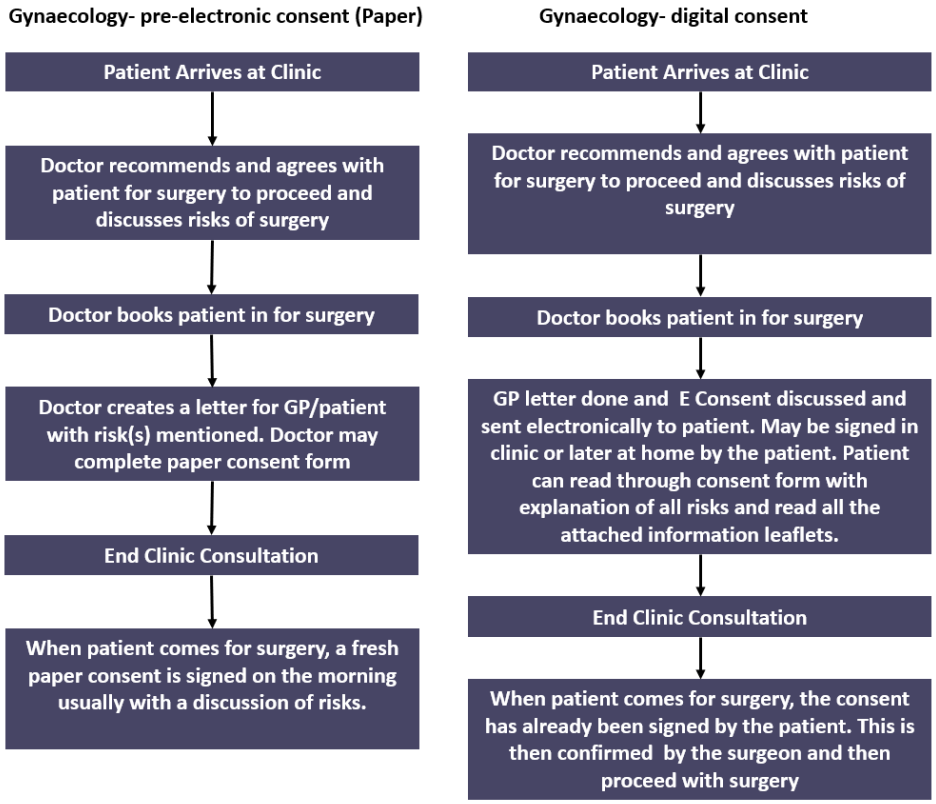


*Figure 3: Visual Representation of paper consent pathway (pre digital) and digital pathway within gynaecology (information provided by BHT)*

# 4 Methodology

The impact assessment consisted of four studies: OUH stakeholder engagement study, BHT stakeholder engagement study, OUH preliminary health economic analysis, BHT hypothetical preliminary health economic analysis.

## 4.1 Stakeholder Engagement Study Setting and Participants

Interviews with clinical staff from OUH and BHT took place between September and November 2024. At this time, all staff interviewed where familiar with Concentric, with digital consent embedded in the respective pathways. Stakeholders were asked 'introductory' questions followed by 'specific impact' questions to understand the impact of Concentric on the consenting process. The introductory questions explored familiarity and frequency of using the tool, including what features are most useful and ease of navigation. The specific impact questions covered aspects of clinical efficiency, integration, data reliability, consent related issues, shared decision making and patient satisfaction. Stakeholders were also asked to provide scores on five questions about the level of acceptance for Concentric as a digital consent tool (level of agreement). The discussion guides used for the stakeholder engagement study containing the questions for stakeholders can be found in Appendix 1- OUH Discussion Guide and Appendix 2- BHT Discussion Guide.

### 4.1.1 OUH

A focus Group was held at Oxford Eye Hospital (John Radcliffe, Oxford University Hospitals NHS Foundation Trust). The Focus group had 11 attendees from across the Ophthalmology department (pre assessment, surgery & theatres, outpatients). The roles of the Stakeholders included clinical lead, consultant nurse, consultant ophthalmologist, cataract surgeon, administrator, senior nurse, clinical fellow, specialist ophthalmic nurse.

### 4.1.2 BHT

Stakeholders from BHT consisted of clinical staff who are users of Concentric across the Obs and Gynae elective pathway. Job titles include day surgery sister, senior Sister, Gynaecological Lead, Obstetrics & Gynaecology Consultant and Lead Operating Department Practitioner (ODP). Due to time restraints and scheduling conflicts, a focus group was unable to take place. As an alternative, 1:1 sessions with stakeholders were held over Video conferencing software Microsoft Teams.

Following the interviews, the responses were transcribed and thematically analysed and reported in Appendix 3- Stakeholder Engagement Study.

## 4.2 OUH Preliminary Health Economic Analysis

The methodology employed in this preliminary health economic analysis involved conducting a literature review, structured data collection, and developing an early economic model to evaluate and compare the paper-based and Concentric consent systems.

### 4.2.1 Literature review

An extensive literature review was conducted to understand and identify the operational and economic factors influencing consent systems in healthcare. This review served as the foundation for identifying critical parameters, processes, and outcomes that influence the economic evaluation of the paper-based and digital consent systems. Key areas identified in the literature are:

1. Time required for clinical and administrative staff to perform consent-related tasks.
2. Frequency and consequences of documentation errors, including missed or incomplete forms.
3. Operational disruptions, such as surgery delays or cancellations caused by consent-related issues.
4. Legal and regulatory considerations, including compliance and medicolegal claims.
5. Environmental impact particularly the resource use associated with paper-based processes.

The review synthesised these insights to identify critical parameters influencing the consent process which should be considered in the preliminary economic analysis:

1. Time savings for staff across different roles and associated economic benefits.
2. Rates of missed or incomplete consent forms and associated operational and economic impact.
3. Frequency of day-of-surgery delays or cancellations and associated costs incurred.
4. Potential reduction in medicolegal claims and associated costs.

### 4.2.2 Data collection

Following the literature review, a structured data collection tool was developed to systematically gather the necessary data points for this preliminary health economic analysis. The data collection tool comprised 16 key questions aimed at collecting data on the initial implementation and ongoing costs associated with both the paper-based and digital consent systems, consent episode volume, and metrics related to efficiency and outcomes including staff time, rate of consent-related issues, operational efficiencies and delays, and medicolegal claims (Appendix 6- Preliminary HE data requirements). The document was shared with key stakeholders at OUH, including:

1. The digital project manager responsible for Concentric implementation and training in the Ophthalmology department.
2. A senior program manager from OUH.
3. A consultant ophthalmologist from the department.

While the analysis primarily relied on primary data provided by the OUH team, additional parameters, such as staff salaries and medicolegal claim costs, were sourced from peer-reviewed literature to ensure completeness of the data needed for the preliminary economic analysis.

Time horizon, perspective, and economic analysis:

Besides the per consent episode analysis, the analysis utilised two horizons- eight months and three years- based on the following rationale:

- **Per consent episode**: Provides a more detailed, micro-level comparison between the paper-based and digital systems, allowing for immediate impact assessment.
- **Eight-month time horizon**: Captures the current impact of implementing the Concentric system, as it has been in operation within the Ophthalmology department at OUH for this duration.
- **Three-year time horizon**: Representing the lifespan of two key resources required for implementation—specifically, the average three-year lifespan of iPads and the cost of staff training, aligned with the NHS retention rate over this period. This longer-term perspective allows for a more comprehensive evaluation of the system's economic benefits over time.

In accordance with National Institute for Health and Care Excellence (NICE) recommendations, a bottom-up NHS and Personal Social Service (PSS) cost perspective was adopted (5). This approach captures the costs incurred by the NHS as the provider of medical interventions requiring patient consent in England. Given the short time horizon of the analysis, no economic adjustments were made to account for inflation and discounting. The analysis was performed using Microsoft Excel version 2024.

Data used for the analysis:

The main categories of the primary and secondary data used for the analysis were:

1. Average number of consent episodes performed.
2. Implementation and ongoing resources and costs.
3. Efficiency and outcomes related data.

## 4.3 BHT Hypothetical Health Economic Analysis

### 4.3.1 Literature review

A literature review was conducted to understand and identify the operational and economic factors influencing consent systems in healthcare. This review served as the foundation for identifying critical parameters, processes, and outcomes that influence the economic evaluation of the paper-based and digital consent systems. Key areas identified in the literature are:

1. Time required for clinical and administrative staff to perform consent-related tasks.
2. Operational disruptions, such as surgery delays or cancellations caused by consent-related issues.
3. Legal and regulatory considerations, including medicolegal claims.

The review synthesised these insights to identify critical parameters influencing the consent process and should be considered in the preliminary economic analysis:

1. Time savings for staff across different roles and associated economic benefits.
2. Frequency of day-of-surgery delays or cancellations and associated costs incurred.
3. Potential reduction in medicolegal claims and associated costs.

### 4.3.2 Time horizon, perspective, and economic analysis

The analysis utilised two horizons- per consent episode and one-year time horizon - based on the following rationale:

- **Per consent episode**: Provides a more detailed, micro-level comparison between the paper-based and digital systems, allowing for immediate impact assessment.
- **One-year time horizon**: Captures the potential longer-term impact of implementing the Concentric system in the obstetrics and gynaecology department at BHT for this duration.

In accordance with the National Institute for Health and Care Excellence (NICE) recommendations, a bottom-up NHS and Personal Social Service (PSS) cost perspective was adopted (5). This approach captures the costs incurred by the NHS as the provider of medical interventions requiring patient consent in England. Given the short time horizon of the analysis, no economic adjustments were made to account for inflation and discounting. The analysis was performed using Microsoft Excel version 2024.

# 5 Results

The section below summarises the findings for the impact assessment studies. Full results can be found in Appendix 3- Stakeholder Engagement Study, Appendix 4- OUH Preliminary Health Economic Assessment and Appendix 5- BHT Hypothetical Preliminary Health Economic Assessment.

## 5.1 OUH Stakeholder Engagement results

### 5.1.1 Introductory questions

All stakeholders within the focus group were familiar with using Concentric. Stakeholders agreed that consenting electronically is valuable because it allows the information to be stored correctly. Stakeholders also felt that the ease of use and improved accessibility for patients allows the consenting process to be faster than paper-based consenting. Furthermore, all of the stakeholders felt that Concentric was easy to use and to navigate. The importance for the team to have adequate Wi-Fi and access to equipment (iPads, signature pads etc) was stressed.

### 5.1.2 Clinical efficiency

It was unanimously agreed by all stakeholders that Concentric has positively impacted efficiency of the consenting process within the Ophthalmology department. The most significant impact has been on time savings. A further efficiency is that the eye injection clinic are now able to offer and perform more appointments and injections because the contenting time has reduced from 10-15 minutes to three minutes. Stakeholders felt it was quick and simple to check a patients consent record on Concentric in comparison to the paper-based system. The stakeholders also felt that medicolegal and governance efficiencies have also been positively impacted

### 5.1.3 Integration

The clinical lead, digital project lead and digital project manager have been instrumental in facilitating the training and eventual adoption of Concentric. The department was kept fully informed via consistent communication of what the change will be and what to expect. Stakeholders commented that Concentric is easy and intuitive to us. They also credited the digital project manager for being engaged and available for any queries or questions they had on the tool- allowing staff to feel supported and really driving the change in process. One unforeseen infrastructure challenge faced by the digital project team was issues with Wi-Fi coverage and connectivity across the whole department. OUH IT support was required to boost Wi-Fi signal across the department and reconfigure iPad settings to operate at 5 hertz to avoid interference issues.

### 5.1.4 Data reliability

The stakeholders were in agreement that they find Concentric accurate at capturing consent data. There was also unanimous acceptance that all data is safe. Stakeholders have trust in OUH cybersecurity processes and policies. Further comments revealed the stakeholders thought the data in Concentric is no less vulnerable than any other data captured within the Trust.

### 5.1.5 Consent related issues

The stakeholders agreed that Concentric has reduced day-of-surgery cancellations and delays due to consent related issues. As Concentric allows patients to be consented quicker, the HCP is able to spend more time with the patient to discuss the risks and answer any questions the patient may

have. It was estimated the whole process takes significantly less time, only 30 minutes compared with around an hour when using paper consent. All risks for each procedure are already included in the Concentric form (eliminating the risk of omitting a particular clinical risk) and other staff members are able to clearly read the digital consent forms as opposed to occasionally needing clarity due to legibility of handwriting.

#### 5.1.6 Shared decision making & patient satisfaction.

There was resounding agreement that Concentric supports shared decision making and patient satisfaction within the Ophthalmology department. Stakeholders agree a significant benefit of digital consent is sharing the consent form via email with patients (or patients next of kin if requested) because the forms are easily retrievable and able to be discussed either at home with family or with the nursing staff/clinicians. Regarding patient satisfaction, the clinicians all agreed that patients had no issues with the use and understanding of the electronic consent.

## 5.2 BHT Stakeholder Engagement results

#### 5.2.1 Introductory questions

All stakeholders interviewed were familiar with using Concentric frequently. The frequency of use can be from four to eight patients a day. Stakeholders had positive feedback about the usefulness and ease of use of Concentric. Other stakeholders commented that the clarity and legibility of the digital consent form was particularly useful, with all of the stakeholders finding Concentric easy to navigate and use. The platform itself was deemed to be “very simple” and self-explanatory

#### 5.2.2 Clinical Efficiency

Stakeholders broadly agreed that there has been positive impact on clinical efficiency. One of the key benefits was the reduction in administrative time spent managing consent forms. Additionally, Concentric allows for quick amendments, reducing the time spent correcting errors or dealing with incomplete forms, which is common with paper documentation. Minor challenges were noted such as occasional discrepancies between the consent form on the system and the actual procedure to be performed, which can cause delays if not identified and corrected in time. However, stakeholders believe the system reduces the risk of errors, reduces the time spent searching for or correcting forms, and ensures that patients are informed of their procedure more effectively, allowing for a more streamlined and efficient clinical process.

#### 5.2.3 Integration

The training for the new electronic consent system was well received by all stakeholders and viewed as straightforward. The Concentric training is also now available as an online module for new trainees during their mandatory induction to the Trust. Wi-Fi connectivity (similar to those experienced at OUH) posed challenges, such as if the iPad loses connectivity resulting in delays with the consenting process or use of paper consent. However, these issues are being addressed with support from the Trust IT department. Overall, the adaptation to the system was smooth, with staff able to quickly integrate it into daily practice with ongoing support. Some Wi-Fi challenges were noted.

#### 5.2.4 Data reliability

The stakeholders agreed that the data within Concentric is reliable and had no concerns regarding the Concentric platform. A few points were raised on occasional issues that could be attributed to

human error rather than the platform, for example, making amendments (e.g. adding or deletions of procedures)

Regarding data access and security, there are concerns about the availability of sensitive patient information on shared devices, like iPads, particularly if users do not “log out” properly, potentially exposing patient data to unauthorised users. While some users are confident that data access is secure, they suggest improvements in how the system manages data to prevent displaying irrelevant or confidential patient information.

#### 5.2.5 Consent related issues

Stakeholders were unable to recall any cancellations or day of surgery delays due to digital consent errors as digital consent is embedded into the pathway and used consistently on a daily basis. Occasional isolated incidents where errors have been made were mentioned however they were attributed to human error as opposed to the digital platform itself.

#### 5.2.6 Shared decision making and patient satisfaction

The stakeholders agreed that digital consent supported shared decision making and patients were satisfied using and interacting with Concentric. Stakeholders particularly liked the ability to send the consent form and the relevant information to the patient after the first clinic appointment. Stakeholders feel that as a result the patient is more informed about their treatment. The stakeholders felt that Concentric has supported shared decision making in the pathway.

### 5.3 Level of agreement

Using a level of agreement tool, across both OUH and BHT, there is strong consistency in staff perceptions of Concentric, with high satisfaction levels reported at both sites (Figure 4). The tool has significantly improved the consenting process, with minimal concerns about the need for further enhancements or barriers to adoption. The platform's streamlined workflow has led to measurable time and cost savings, as well as improved operational efficiency.

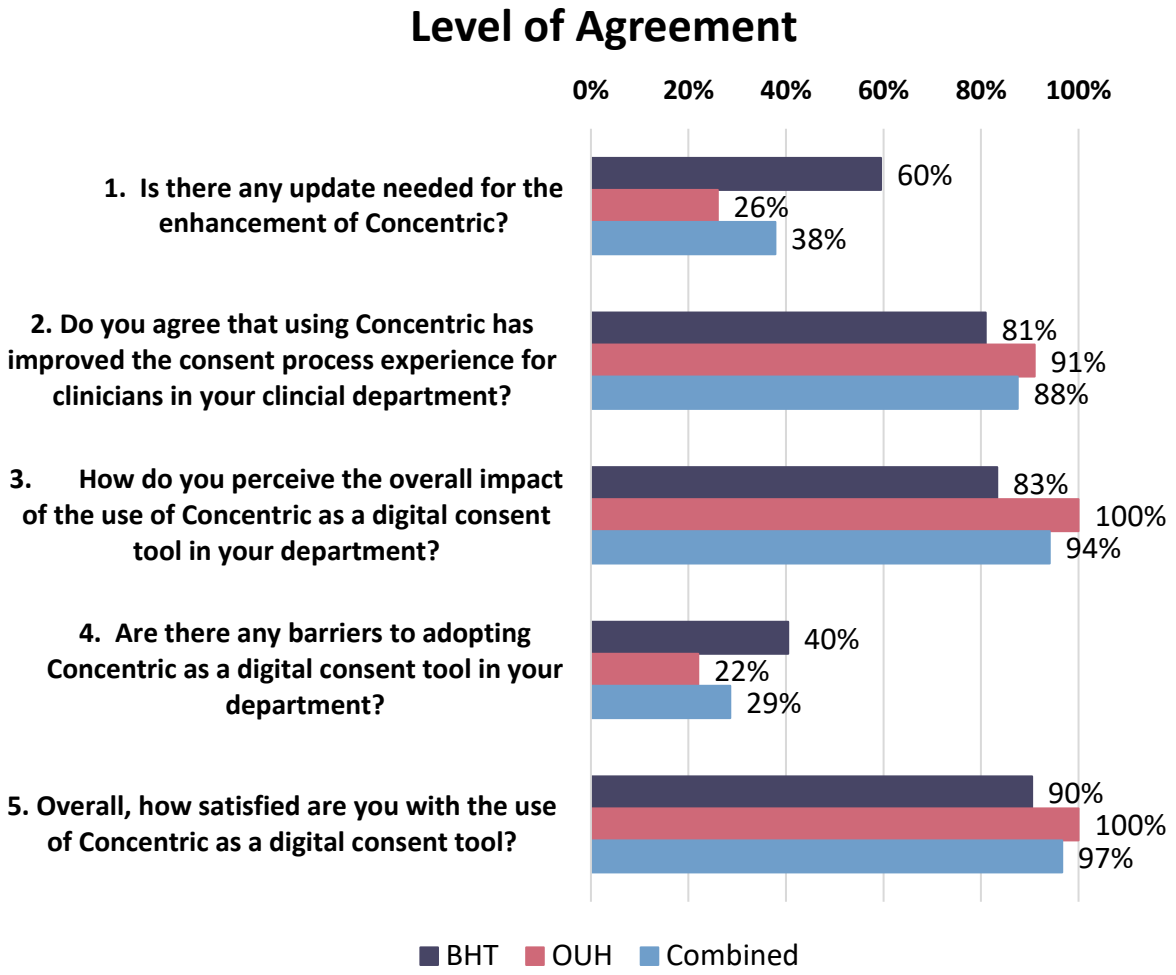


*Figure 4: Bar graph representing stakeholder level of satisfaction with use of concentric and a digital tool*

## 5.4 OUH Preliminary Health Economic Assessment Results

At OUH, the health economic analysis highlights substantial cost and efficiency benefits within the ophthalmology department, with the Concentric platform reducing staff workload, minimising risks of procedural delays, and offering long-term financial savings by mitigating medicolegal claims.

### 5.4.1 Key findings

Within the ophthalmology department:

- A reduction in consent times by 7.14 minutes per episode, resulting in savings of £5.87 per episode
- Total cost savings within the ophthalmology department of £37,209 over eight months, and £167,437 over three years
- The total costs incurred due to missed consent forms amounted to £3,222.49. When projected over 3 years, these costs increased to £14,501.19. In contrast, the Concentric digital system reported no instances of missed consent forms, eliminating these additional costs
- The projected costs of delays ranged from £125.51 for theatre-based delays to £241.23 for room injection treatment delays over the 8 months, and from £547.88 to £1,052.64 when projected over 3 years for each delay type respectively. No similar delays were reported with Concentric, demonstrating cost avoidance.

### 5.4.2 Data used for the analysis:

The main categories of the primary and secondary data used for the analysis were:

1. Average number of consent episodes performed.
2. Implementation and ongoing resources and costs.
3. Efficiency and outcomes related data.

The following sections describe these data points and outline the data incorporated in the preliminary health economic analysis.

### 5.4.3 Average number of consent episodes

The data on consent episodes for the Ophthalmology department at OUH were estimated based on departmental procedure volumes. For the paper-based system, no formal auditing of consent episodes was conducted before the implementation of Concentric. However, the team provided an estimation based on the department's average procedure volumes across different types of treatments.

It was inferred that the Ophthalmology department would have processed between 11,000 and 14,000 consents annually, translating to an estimated 917 to 1,167 consents per month. In contrast, for the Concentric digital system, data were collected over eight months following its implementation on 29 January 2024. This provided a more accurate measure of consent episodes processed through the new digital platform. Over this period, the system averaged 825 consents per month.

To facilitate the economic comparison between the two systems, this analysis assumes that the number of consent episodes in both systems was comparable and estimates 825 consents per month.

### 5.4.4 Implementation and ongoing resources and costs

The primary costs associated with the paper-based consent system included expenses for printing, storage, and disposal of physical consent forms, and staff costs related to time spent by clinical and administrative personnel on various tasks throughout the consent process. These tasks involved preparing, completing, and managing the paper consent forms, which required significant manual effort from staff.

In contrast, the Concentric digital system required initial investments in hardware, including the purchase of iPads, signature pads, and other associated accessories (See Appendix 7- Infrastructure costs). Additionally, there were software licensing fees to run the system. The annual licensing fee for unlimited episodes is £50,000, and OUH usually performs 340,000 consent episodes annually.

Training costs were considered for both systems. Each staff member received a minimum of 10 minutes of training for the paper-based system and approximately 12 minutes of face-to-face training for the Concentric system. A total of 363 staff members were trained in both systems, including ophthalmologists, nurses, administrators, and other clinical and support staff. The trainer costs ranged from £23.60 to £98.39 per hour, depending on the trainer's staff category.

Lastly, the time spent by clinical and administrative staff on various stages of the consent process for both systems was accounted for. This includes the total time spent by different staff categories performing these tasks, as outlined in Table 1.

*Table 1: Time Spent by Clinical and Administrative Staff on Various Stages of the Consent Process for Paper-Based and Concentric Digital Systems*

| **Paper-Based System** | | **Concentric** | |
|---|---|---|---|
| *Function- task* | *Average time (Minutes)* | *Function- task* | *Average time (Minutes)* |
| **Clinical staff (Band 6,7, or 8 nurses and a consultant)** | | **Clinical staff (Band 6,7, or 8 nurses and a consultant)** | |
| Time to find, assemble (labels), and complete the form | 2.63 | Time to log in to Concentric and locate MRN | 0.37 |
| Time to fill out the paper consent form | 1.25 | Time to fill out the digital consent form | 0.61 |
| Time to explain the consent | 10 | Time to explain the consent | 10 |
| Time to capture the signature | 0.36 | Time to capture the signature | 0.32 |
| Extra time to finish the consent form | 0.25 | Extra time to finish the consent form | 0.18 |
| **Administrative staff (Band 3&4)** | | **Administrative staff (Band 3&4)** | |
| Time to scan and store the form | 1.5 | N/A | 0 |

| | | | |
|---|---|---|---|
| Time to locate the form in Medisoft | 2 | Time to locate the form in Medisoft | 0.37 |
| Time to dispose of the form in confidential waste | 1 | N/A | 0 |
| **Total time per consent episode** | **18.99** | **Total time per consent episode** | **11.85** |

To assess the costs incurred from staff time, the NHS Terms and Conditions of Service (Agenda for Change) pay rates for 2024-2025 were used to calculate the hourly rate for each staff category involved in the consenting process (6).

For comparison, the minimum and maximum cost per consent episode were calculated based on the following staff categories:

- **The minimum staff cost scenario** assumes that the consenting task is performed by a nurse, with the hourly rates for Band 6, 7, and 8 nurses used for the calculation. The average hourly rate for these bands was £25.07, corresponding to an average per-minute cost of £0.42 Table 2).
- **The maximum staff cost scenario** assumes that the consenting task is performed by a consultant. The consultant hourly rate used for this calculation was £98.39, based on the data provided by the OUH team, translating to £1.64 per minute.

*Table 2: The hourly rates and per-minute costs for Band 6, 7, and 8 nurses based on the NHS Terms and Conditions of Service pay scales.*

| **Clinical Staff (Band 6-8 Nurses) Cost Breakdown** | **Average Annual Salary** | **Hourly Rate** | **Per-Minute Rate** |
|---|---|---|---|
| Band 6 | £40,568.33 | £20.80 | £0.35 |
| Band 7 | £49,161.00 | £25.21 | £0.42 |
| Band 8 | £56,904.33 | £29.18 | £0.49 |
| **Average cost** | | **£25.07** | **£0.42** |

In addition to the clinical staff, administrative staff (Band 3 and 4) are responsible for tasks such as scanning, storing, and managing consent forms. Their costs are outlined in Table 3 below.

*Table 3: Cost breakdown for administrative staff (Band 3-4)*

| Administrative Staff (Band 3-4) Cost Breakdown | Average Annual Salary | Hourly Rate | Per-Minute Rate |
|---|---|---|---|
| Band 3 | £24,872.50 | £12.76 | £0.21 |
| Band 4 | £27,822.00 | £14.27 | £0.24 |
| **Average cost** | | **£13.51** | **£0.23** |

### 5.4.5 Efficiency and outcomes-related data

The analysis considered several key efficiency and outcome metrics to compare the paper-based and Concentric digital consent systems as summarised in Table 4.

*Table 4: Efficiency and outcome metrics for paper-based and Concentric digital consent systems*

| Efficiency and Outcomes Parameter | Paper-Based Consent System | Concentric |
|---|---|---|
| Staff time | 18.99 minutes | 11.85 minutes |
| Day of treatment cancellation | N/A | N/A |
| Day of treatment delays | 4 incidences in three months | N/A |
| Rate of missed consent forms | 1.95% | N/A |
| Rate of medicolegal claims | 2% | N/A |

1. **Staff time savings**

As shown in Table 2, the staff time at each stage of the consent process was significantly reduced with the Concentric digital system. On average, the paper-based system requires 18.99 minutes per consent episode, while Concentric reduced this to 11.85 minutes.

2. **Missed consent forms**

The paper-based system had a 1.95% rate of missed consent forms, based on an audit conducted by the department. A missed consent form typically requires a patient to be re-consented, resulting in delays and inefficiencies in patient care. The Concentric system, however, did not report any cases of missed forms.

3. **Day of treatment delays and cancellations**

Neither system reported day-of-treatment cancellations. However, for the paper-based system, there were four incidences of treatment delays over three months. These delays were variable depending on the type of procedure. For example, theatre delays were estimated to be 15 minutes on average, involving multiple staff categories. On the other hand, room injection treatment delays were estimated to last 45 minutes, primarily involving nursing staff. The Concentric system did not report any treatment delays in the analysed period.

**4. Medicolegal claims**

The paper-based consenting system reported a 2% rate of medicolegal claims. The cost of these claims was estimated at £25,000, based on data retrieved from the literature (7) (8).

These costs include both the damages awarded to claimants and the legal fees incurred during the claim process. No cases of medicolegal claims associated with consent-related issues were reported with the use of Concentric.

### 5.4.6 OUH Preliminary Health Economic Results

### 5.4.7 Initial and ongoing cost comparison

The analysis results indicated significant cost differences between the paper-based and the Concentric digital consent systems, with the former incurring higher implementation and ongoing costs to Concentric (Table 5). The cost per consent episode was £19.54 in Concentric compared to £25.18 with the main driver of difference being the staff costs.

Over 8 months and with 825 consent episodes performed monthly, the paper-based system cost £166,159, while the Concentric system cost less at £128,950, resulting in a savings of £37,209. Similarly, over 3 years, the paper-based system's total cost was £747,717, compared to £580,280 for the Concentric system. This demonstrates a long-term cost reduction of £167,437 with the digital system.

*Table 5: Summary of costs for paper-based and concentric consent systems across different time horizons*

| **Paper-Based System** | | **Concentric System** | | **Cost Difference** |
|---|---|---|---|---|
| *Item* | *Cost per Consent Episode* | *Item* | *Cost per Consent Episode* | |
| Paper | £0.15 | Technological infrastructure | £0.33 | |
| Pencils and labels unit | £0.25 | Training cost | £0.15 | |
| Disposal costs | £0.01 | Concentric license cost | £0.147 | |
| Staff time (Max cost scenario) | £24.78 | Staff time (Max cost scenario) | £18.9 | |
| ***Cost per consent episode*** | **£25.18** | ***Cost per consent episode*** | **£19.54** | **£ 5.64** |
| ***Cost over 8 months period*** | **£166,159** | ***Cost over 8 months period*** | **£128,950** | **£ 37,209** |
| ***Cost over 3 years*** | **£747,717** | ***Cost over 3 years*** | **£580,280** | **£ 167,437** |

### 5.4.8 Efficiency and outcomes comparison

#### *5.4.8.1 Staff time saving*

The analysis of time and associated costs for consent episodes in paper-based and Concentric systems reveals notable differences in staff time savings with Concentric resulting in significant cost savings (Table 6 and Table 7). Specifically, the total time per consent episode decreased from 18.99 minutes with the paper-based system to 11.85 minutes with Concentric, representing a reduction of 7.14 minutes per consent, representing a reduction of 7.14 minutes per episode. This time savings primarily stems from differences in tasks such as locating patient information, filling out forms, and processing administrative steps.

In terms of cost and based on the minimum and maximum cost scenarios, the total cost per consent episode for clinical and administrative staff combined was estimated to range from £7.07 to £24.77 in the paper-based system and from £4.88 to £18.91 in Concentric. The cost savings per episode ranged between £2.33 (minimum) and £5.87 (maximum) (

Table *8*).

*Table 6: Staff time and cost analysis for consent processes in the paper-based system*

| Function-task | Average Time | Min Cost | Max Cost |
|---|---|---|---|
| **Clinical staff** | | | |
| Time to find, assemble (labels), and complete the form | 2.63 | 1.1 | 4.31 |
| Time to fill out the paper consent form | 1.25 | 0.5 | 2.1 |
| Time to explain the consent | 10 | 4.2 | 16.4 |
| Time to capture the signature | 0.36 | 0.15 | 0.59 |
| Extra time to finish the consent form | 0.25 | 0.11 | 0.41 |
| **Administrative Staff** | | | |
| Time to scan and store the form | 1.5 | 0.34 | 0.34 |
| Time to locate the form in Medisoft | 2 | 0.45 | 0.45 |
| Time to dispose of the form in confidential waste | 1 | 0.23 | 0.23 |
| **Total time per consent episode** | **18.99** | **£7.07** | **£24.77** |

*Table 7:Staff Time and Cost Analysis for Consent Processes in the Concentric Digital System*

| Function-task | Average Time | Min Cost | Max Cost |
|---|---|---|---|
| **Clinical staff** | | | |
| Time to log in to Concentric and locate MRN | 0.37 | 0.16 | 0.61 |
| Time to fill out the paper consent form | 0.61 | 0.26 | 1 |

| | | | |
|---|---|---|---|
| Time to explain the consent | 10 | 4.2 | 16.4 |
| Time to capture the signature | 0.32 | 0.13 | 0.53 |
| Extra time to finish the consent form | 0.18 | 0.08 | 0.3 |
| **Administrative Staff** | | | |
| Time to scan and store the form | 0 | 0 | 0 |
| Time to locate the form in Medisoft | 0.37 | 0.083 | 0.083 |
| Time to dispose of the form in confidential waste | 0 | 0 | 0 |
| **Total time per consent episode** | **11.85** | **£4.9** | **£18.9** |

*Table 8: Cost comparison of staff time per consent episode: paper-based vs. Concentric system*

| System | Average Time | Minimum Cost Scenario | Maximum Cost Scenario |
|---|---|---|---|
| Paper-based consent system (A) | 18.99 | £7.07 | £24.77 |
| Concentric (B) | 11.85 | £4.9 | £18.9 |
| **Difference (A-B)** | **7.14** | **£2.33** | **£5.87** |

#### *5.4.8.2 Missed consent forms*

The analysis of missed consent forms in the paper-based system indicates significant inefficiencies. For every 825 consents processed, an average of 16 forms were missed, necessitating re-consenting. The cost of re-consenting per form was estimated at £25.18, adopting the maximum cost scenario.

Over 8 months, the total costs incurred due to missed consent forms amounted to £3,222.49. When projected over 3 years, these costs increased to £14,501.19. In contrast, the Concentric digital system reported no instances of missed consent forms, eliminating these additional costs (Table 9).

*Table 9: Projected costs of missed consent forms in the paper-based system*

| Time Horizon | Number of Missed Consent forms | Total Costs Incurred |
|---|---|---|
| **8 months** | 128 | **£3,222.49** |
| **3 years** | 576 | **£14,501.19** |

#### *5.4.8.3 Day of treatment delays*

The analysis of the day-of-treatment delays revealed significant operational inefficiencies in the paper-based consent system compared to the Concentric digital system. Over 3 months, four incidents of delays were recorded with the paper-based system while no similar delays were

reported with Concentric. These delays were categorised into two types: theatre-based delays and room injection treatment delays.

Theatre-based delays, lasting an average of 15 minutes and involving various staff members, incurred an average cost of £11.41 per incident. Room injection treatment delays, ranging from 45 to 60 minutes, had a higher average cost of £21.93 per incident (Table 10).

Extrapolating these figures for 8 months and 3 years, the projected costs of delays ranged from £125.51 for theatre-based delays to £241.23 for room injection treatment delays over the 8 months, and from £547.88 to £1,052.64 when projected over 3 years for each delay type respectively.

*Table 10: Cost estimation of day-of-treatment delays in the paper-based consent system*

| Delay Type | Duration (mins) | Cost per Incidence | Cost Over 8 Months | Cost Over 3 Years |
|---|---|---|---|---|
| Theatre based | 15 | £11.41 | **£125.51** | **£547.88** |
| Room injection treatment | 45-60 | £21.93 | **£241.23** | **£1,052.64** |

#### *5.4.8.4 Medicolegal claims*

The analysis of potential medicolegal claims in the paper-based consent system revealed significant financial implications. Based on the assumption that 2% of monthly performed consents result in medicolegal issues and assigning a cost of £25000 per delay based on the literature as described above, the findings are as follows (Table 11):

*Table 11: Projected costs of medicolegal claims in the paper-based consent system*

| Time Horizon | Number of Claims | Total Costs Incurred |
|---|---|---|
| 8 months | 132 | **£3,300,000** |
| 3 years | 594 | **£14,850,000** |

In contrast, the Concentric digital consent system's improved documentation and completeness significantly reduced the risk of such claims to zero. The elimination of missed or incomplete forms (reported as 100% completeness with Concentric compared to 93% with paper-based systems) suggests a substantial reduction in potential medicolegal risks and associated costs with the Concentric digital consent system.

## 5.5 BHT Hypothetical Health Economic Analysis Results

### 5.5.1 Key Findings

The hypothetical analysis indicates significant potential cost savings within the obstetrics and gynaecology department, including:

- Potential process cost savings of £370.98 per month and £4,455 annually.
- Potential staff cost savings of £5,381.50 per month and £64,625 annually.
- A potential reduction in day-of-treatment cancellations by £6,064 per month, leading to annual savings of approximately £72,764.
- The digital consent system could significantly reduce medicolegal claims.
    - In the lower-cost scenario, this could save the department an estimated £171,875 per month and £2,062,500 per year.
    - In a higher-cost scenario, where each claim is valued at £220,487, the potential savings rise to £1,515,848 per month and £18,190,177 per year.

### 5.5.2 Literature review results

Based on published literature, the obstetrics and gynaecology department at BHT performs a total of 5500 deliveries annually (9). This is the equivalent of 458 deliveries monthly. Caesarean sections (CSs) represent around 27.2% of all deliveries performed (An equivalent of 125 caesarean sections per month).

In addition to the monthly and annual number of consent episodes performed, the literature review additionally identified the following data points relevant to the preliminary hypothetical health economic analysis:

1. **Process cost savings:** The estimated cost savings using Concentric is £0.81 per consent episode) (2) . The cost difference is mainly due to savings on paper consent handling such as storage, uploading, and other paper-related tasks.
2. **Staff cost savings:** A study concluded that with each minute saved from consultation time due to the introduction of the digital content system, £2.35 would be added to the cost savings (10). Additionally, a study at Nottingham University Hospitals NHS Trust found that clinicians reported saving 5 to 10 minutes per consent form by not having to handwrite information when using digital consent tools (11).
3. **Day of treatment cancellation or delays:** Cancellation rates for elective surgeries in NHS hospitals generally range from 10-14% (12). The most common reasons for these cancellations include lack of theatre time (59.7%), medical reasons (10.8%), patient no-shows (16.2%), changes in the surgical plan (5.4%), administrative reasons (3.7%), and miscellaneous reasons (4.2%) (13). This analysis assumes that the administrative (3.7%) and miscellaneous (4.2%) reasons are considered to be related to consent issues, making up 7.9% of all cancellations.

Based on published studies, the introduction of Concentric results in a 5-10% reduction in day-of-treatment cancellations (14).

The NHS experiences significant costs due to last-minute cancellations of elective surgeries, which are estimated to amount to £400 million annually (12). The average cost per cancellation is reported to be approximately £5,177**.** This figure is derived by dividing the total annual cost of cancellations (£400 million) by the reported 77,266 cancelled operations per year in the NHS.

4. **Medicolegal claims:** Introducing digital consent reduces "failure to warn" risk by 50% (2). Between 2005 and 2019, the NHS settled over 2,300 claims related to failure to inform patients, with a total value approaching £400 million. This indicates an average of approximately 165 such claims per year (15). The reported cost per medical claim varies significantly from thousands and millions in the literature, the analysis adopted the lower range of such claims with a value of £25,000 per claim (7) and a higher-cost scenario based on 2013-2018 data, which showed an average claim cost of £220,487 per case. The higher-cost scenario was derived from a total of 1,025 claims over a five-year period (2013-2018), costing £226 million, leading to an estimated £220,487 per claim (16).

### 5.5.3 Outcomes measured

This section presents the results of the cost savings analysis derived from the literature findings. Hypothetical economic analysis was conducted to estimate potential cost savings in four key areas: *process cost savings, staff cost savings, reduction in day-of-treatment cancellations, and reduction in medicolegal claims*. Each outcome is discussed and presented in a separate table.

**Process cost savings**

The analysis concluded that introducing digital consent results in a monthly cost saving of £370.98 and an annual cost saving of £4,455.00. These savings are attributed to reduced costs in paper consent handling, storage, and uploading.

Table 12 provides a detailed description of the process cost savings, calculated using the number of monthly and annual consent episodes and the per-episode saving of £0.81.

***Table 12:*** *Process Cost Savings from the Implementation of Digital Consent*

| Parameter | Monthly (£) | Annual (£) |
|---|---|---|
| Consent episodes | 458 | 5500 |
| Cost savings per consent episode | 0.81 | 0.81 |
| **Total savings** | **£370.98** | **£4,455** |

**Staff cost savings:**

The analysis concluded that digital consent leads to monthly staff cost savings of £5,381.50 and annual savings of £64,625.00. These savings arise from an average time saving of 5 minutes per consent episode and a value of £2.35 per minute saved, as supported by literature findings.

Table 13 outlines the staff cost savings, reflecting the calculation steps involving the number of consent episodes, time savings, and cost per minute saved.

***Table 13:*** *Staff Cost Savings from Time Efficiencies in Digital Consent*

| Parameter | Monthly (£) | Annual (£) |
|---|---|---|
| Consent episodes | 458 | 5500 |
| Minutes saved per consent episode | 5 | 5 |
| Cost saving per minute (£) | 2.35 | 2.35 |
| **Total savings** | **£5,381.5** | **£64,625** |

**Savings on the day of treatment cancellation or delays**

The analysis concluded that implementing a digital consent system could lead to significant cost savings by reducing day-of-treatment cancellations associated with consent issues. Given that 125 caesarean sections are performed per month, an estimated 1.185 procedures are cancelled monthly, totalling 14.22 cancellations per year for consent issues. With a reported cost of £5,177 per cancellation, adopting a digital consent system could result in a saving of £6,064 per month and approximately £72,764 per year (Table 14).

***Table 14:*** *Cost Savings from Reduction in Day-of-Treatment Cancellations Due to Consent Issues*

| Parameter | Monthly (£) | Annually (£) |
|---|---|---|
| Total caesarean sections | 125 | 1500 |
| Current cancellation rate (%) | 12 | 12 |
| Number of cancellations | 15 | 180 |
| Percentage of cancellations due to consent issues (%) | 7.9 | 7.9 |
| Cancellation due to consent issues | 1.185 | 14.22 |
| Cost per cancellation (£) | 5,117 | 5,117 |
| **Total savings from consent-related cancellations** | **£6,064** | **£72,764** |

**Savings on medicolegal claims**

The analysis considered two medicolegal cost scenarios: a lower-cost scenario estimating claims at £25,000 per case, and a higher-cost scenario based on 2013-2018 data, which showed a significantly higher claim cost of £220,487 per case. A 50% reduction in claims, as anticipated with digital consent implementation, would result in annual savings of £2,062,500 in the lower-cost scenario and £18,190,177 in the higher-cost scenario (Table 15).

***Table 15:*** *Cost Savings from Reduction in Medicolegal Claims Due to Digital Consent*

| Parameter | Lower Cost Scenario (£) | Higher Cost Scenario (£) |
|---|---|---|
| Total claims (monthly) | 13.75 | 13.75 |
| Total claims (annually) | 165 | 165 |
| Reduction in claims (%) | 50 | 50 |
| Avoided claims (monthly) | 6.875 | 6.875 |
| Avoided claims (annually) | 82.5 | 82.5 |
| Cost per claim (£) | 25000 | 220,487 |
| **Total savings (monthly)** | **£171,875** | **£1,515,848** |
| **Total savings (annually)** | **£2,062,500** | **£18,190,177** |

# 6 Discussion

The implementation of Concentric across OUH (Ophthalmology) and BHT (obstetrics & Gynaecology) has delivered measurable efficiency gains, enhanced data integrity, and improved patient engagement. However, beyond these immediate benefits, there are deeper implications that warrant exploration, both for the sustainability of digital consent within these Trusts and for wider adoption across the region.

**Efficiency Gains and Operational Impact**

Stakeholders from both Trusts agreed that Concentric has improved the speed and accuracy of the consenting process compared to paper forms, with significant time savings noted across departments. Digital consenting has also facilitated quicker amendments and reduced errors, further streamlining workflows.

The ability to reduce consent episode times by an average of 7.14 minutes at OUH represents a significant shift in clinical workflow efficiency. In ophthalmology, where time-sensitive procedures such as eye injections previously took 10-15 minutes per patient, the new digital consent system has condensed this to just three minutes, enabling an increase in throughput. This efficiency directly benefits patients through shorter wait times and increased appointment availability, while staff report a streamlined process that reduces cognitive and administrative burdens.

At OUH, there were no reported instances of 'day-of treatment delay', 'day of treatment cancellation' or 'missed consent forms' were reported whilst using Concentric. At BHT In terms of day-of-treatment cancellations, it was estimated that 1.185 cancellations per month and 14.22 per year were due to consent-related issues. With a cost of £5,177 per cancellation, introducing the digital consent system could result in a monthly cost savings of £6,064 and annual savings of approximately £72,764. This aligns with existing research highlighting the operational efficiencies of digital consent systems (3). Additionally, at BHT further projected process cost savings were identified, with the digital system potentially reducing expenses by £370.98 per month and £4,455 per year due to lower costs associated with paper handling, storage, and document uploading. The reduction in consent-related issues not only offers financial benefits, but stakeholders also feel increased confidence in the consenting process due to the reduced risk of errors. The potential resulting impact on patient safety could be further explored in future adoptions.

**Medicolegal and Clinical Governance: Reducing Risk and Cost**

One of the most compelling findings is the projected reduction in medicolegal claims. Every year 12,000 medicolegal claims are brought against the NHS in England at a cost of £8 billion: 6.7% of the NHS England budget (17). Documentation accuracy is a critical concern, therefore the platform's ability to eliminate missed or incomplete forms represents a significant shift in risk management. The system ensures that documentation is secure, legible, and accessible, reducing the likelihood of disputes and litigation. However, there were some concerns about data security from stakeholders, particularly regarding shared devices and staff logging out. Although attributed to human and not system error the process must be proactively managed to ensure patient confidentiality and compliance with regulatory standards.

At BHT, the hypothetical health economic analysis projected annual savings exceeding £2 million in medicolegal claims alone, the implications are striking. The obstetrics and gynaecology teams could see fewer consent-related surgical cancellations, which currently cost the Trust significant sums per

year. If these projections hold, digital consent could serve as a strategic tool for cost containment and workforce optimisation, not just for BHT but for other Trusts in the region considering similar adoption.

For OUH and BHT, this has direct operational and reputational implications. A reduction in claims would not only improve financial stability but also enhance already the strong clinician confidence in the consenting process. A recent study by Houten et al. further supports these findings. Their micro-costing analysis comparing digital and paper-based consent pathways in the NHS found that digital consent is cost-saving for the NHS with £201,590 saved per litigation claims prevented and with the digital tool streamlining the workflow process (10). This aligns with our analysis and suggests that the Concentric platform could provide substantial financial benefits when implemented at scale across healthcare organisations.

**Shared Decision-Making and Patient Engagement**

The ability to send consent forms electronically to patients allowed for better communication, enabling patients to review their information at home or with family members before the procedure, supporting shared decision making and informed consent. This is particularly impactful for vulnerable populations, such as patients with visual impairments or language barriers, where accessibility is crucial.

It is essential to understand long-term patient outcomes and the impact of digital consent potentially improving comprehension, adherence to pre- and post-procedure guidelines, and clinical results. Future evaluations should explore this link and incorporate patient-reported experience measures (PREMs) to assess whether patients feel more involved in their care decisions.

**Implementation, Scalability and Lessons for Wider Regional Adoption**

The success of Concentric at OUH and BHT provides valuable insights that can inform wider regional adoption. Stakeholders appreciated the intuitive design of the platform, making the learning curve minimal. However, both sites faced some challenges related to Wi-Fi connectivity, which occasionally affected the use of iPads, causing delays or reverting staff back to paper forms. These infrastructure issues were addressed by IT support teams, who improved signal strength and optimised iPad settings. Despite these occasional challenges, the overall integration process was seen as a success, with strong departmental engagement ensuring the continued use and adoption of Concentric. Other services and trusts within the BOB ICS footprint and beyond could benefit from this model, though several factors must be considered:

- **Infrastructure Readiness:** Both OUH and BHT encountered Wi-Fi connectivity issues that temporarily disrupted digital consent usage. A regional rollout would require upfront investment in IT infrastructure and IT support to ensure seamless adoption.
- **Interoperability with Electronic Health Records (EHRs):** Digital consent must integrate smoothly with existing EHR systems to avoid duplication of work. The experiences of OUH and BHT should inform best practices for integration.
- **Change Management and Workforce Buy-in:** The successful engagement of clinical and digital champions at OUH played a critical role in driving adoption. Scaling digital consent will require similar engagement strategies tailored to the needs and workflows of different clinical specialties.

**Environmental and Sustainability Considerations**

While not a primary focus of the health economic analysis, a move away from paper-based consent aligns with NHS Net Zero goals (18). The environmental footprint of printing, storing, and disposing of paper consent forms is not trivial, particularly in high-volume departments like ophthalmology and obstetrics. Future analyses should quantify the sustainability benefits of digital consent and consider how these align with NHS's Net Zero goals

**Implications of Digital Consent Systems for OUH, BHT, and Nationally**

The findings from OUH and BHT present a strong case for permanent adoption and further scaling of digital consent beyond the initial pathways. For the region, the findings serve as a blueprint for future digital transformation efforts. If digital consent can be successfully embedded in high-volume, high-risk specialties like ophthalmology and obstetrics, there is every reason to explore its applicability in other clinical areas such as surgery, oncology, and emergency care.

The real opportunity lies in taking these lessons beyond individual services, pathways and Trusts and embedding digital consent into regional strategies for modernising patient pathways. The benefits are clear: reduced administrative burden, greater patient engagement, lower legal risk, and a more efficient NHS. The implementation and resulting success of concentric alights heavily with the NHS 10-year plan, specifically the shift from 'analogue to digital' (19). The findings presented also support an overarching NHS objective to drive efficiency and productivity within the system. The next step is ensuring that these insights drive policy and investment decisions at scale.

# 7 Conclusion

The implementation of Concentric at OUH and BHT has demonstrated a positive impact on operational efficiencies, data integrity, and patient engagement. The platform has effectively streamlined workflows, reduced consenting times, and enabled more accurate documentation. These improvements have resulted in considerable cost savings, including reductions in consent-related cancellations and operational expenses associated with paper handling. Additionally, the system's ability to mitigate medicolegal risks is significant, with projected savings in claims costs providing substantial value to the NHS. These outcomes are in direct alignment with the NHS's 10-year plan, which aims to transition from analogue to digital systems while enhancing overall efficiency within the healthcare sector.

The success of Concentric serves as a valuable blueprint for scaling digital consent across other services and Trusts within the region. For wider adoption, however, key considerations such as infrastructure readiness, system interoperability, and change management will be essential. Addressing challenges, including Wi-Fi connectivity issues and ensuring smooth integration with existing Electronic Health Records (EHRs), will be pivotal for future implementation. Furthermore, the environmental benefits of reducing paper usage align with the NHS's Net Zero goals, further reinforcing the case for digital consent. Ultimately, the insights gained from OUH and BHT should guide regional strategies for digital transformation, contributing to improved patient pathways and a more efficient NHS.

# 8 Recommendations

**Recommendations**

- **Clinical and Digital Champions**: Clinical and digital champions within each department are critical for fostering engagement, encouraging training, and ensuring the sustained adoption and advocacy of Concentric across teams.
- **Proactive Communication**: Clear, proactive communication regarding process changes, implementation timelines, and expected outcomes is essential for building departmental understanding and securing buy-in for Concentric adoption.
- **Infrastructure Challenges**: Addressing infrastructure challenges, particularly Wi-Fi connectivity issues, is vital to ensure seamless integration and full adoption of Concentric across departments.
- **Further Impact Monitoring**: Continue with a structured evaluation framework including:
    - A 12–24 month real-world data collection plan at BHT to validate cost savings.
    - A roadmap for Trust wide and /or regional adoption within BOB ICS based on lessons learned from OUH and BHT.
    - Incorporate Net Zero and PREM considerations.

**Future Recommendations**

To ensure the continued success and full adoption of Concentric, future research should focus on:

- **Long-term Impact**: Evaluating the long-term effects of digital consent on clinical outcomes, patient satisfaction, and operational efficiency.
- **Technical Improvements**: Addressing technical challenges such as Wi-Fi connectivity and device login issues to minimise disruptions.
- **Data Security**: Enhancing data security measures to protect patient information, especially on shared devices.

**Broader Implications**

The adoption of digital consent platforms like Concentric represents a significant step forward in advancing digital health initiatives. By improving efficiency, reducing costs, and enhancing patient care, these platforms contribute to the broader goals of healthcare innovation and sustainability.

**Stakeholder Feedback**

Stakeholders have voiced strong support for Concentric, highlighting its positive impact on clinical workflows and patient engagement. Concentric has improved the consent process, making it faster and more reliable. Patient satisfaction has reportedly increased due to the platform's clarity and ease of use, which has enhanced their overall experience.

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Appendix 1- OUH Discussion Guide

**Discussion Guide**

# Stakeholder Engagement Study: Assessing the impact of Concentric as a digital consent tool

## Background

Health Innovation Oxford & Thames Valley (the Oxford HIN) is one of 15 Health Innovation Networks commissioned by NHS England and the UK Office for Life Sciences. Established in 2013, Oxford HIN (formerly Oxford AHSN), represents the innovation arm of the NHS and is strategically positioned at the intersection of healthcare and life sciences, playing a critical role in driving the adoption of effective innovations within the NHS. The Oxford HIN has a proven track record of supporting ideas, products, and services to fully realise their potential, thus ensuring that impactful innovations reach patients and healthcare providers. Additionally, the Oxford HINs actively stimulate economic growth in the life sciences sector, fostering an environment where innovative solutions can thrive and contribute to the overall advancement of healthcare.

The Oxford HIN serves 3.3 million people in Berkshire, Buckinghamshire, Milton Keynes, and Oxfordshire. In partnership with Buckinghamshire, Oxfordshire, and Berkshire West Integrated Care System, Oxford HIN is conducting a stakeholder engagement study focused on assessing Concentrics impact in the Ophthalmology department at Oxford University Hospitals NHS Foundation Trust (OUH).

## Aim and Objectives

Concentric provides digital consent for all treatment scenarios and is currently used in several NHS Trusts, including OUH. The objective of this study is to conduct a stakeholder engagement using semi-structured qualitative interviews to assess the impact of Concentric as a digital consent tool in the Ophthalmology department at OUH. Clinicians and staff from OUH using Concentric will be interviewed to understand their experience and acceptance of Concentric in the clinical pathway.

## Introductory Questions

1. How familiar are you with Concentric as a digital consent tool?
2. How often do you use Concentric?

   *Follow-up:* Can you quantify this, i.e. An average per day or month?
3. What features of the digital tool do you find most useful?
4. How easy is it to navigate and use Concentric?

   *Prompt:* Do you face any specific challenges or difficulties while using Concentric?

## Specific Impact Assessment Questions

1. In your opinion, has Concentric impacted your efficiency in obtaining and managing patient consent in the Ophthalmology department?
2. In your opinion, has Concentric affected the time spent on each consenting episode in the ophthalmology department?

   *Prompt:* Has there been a change in the timing of certain processes? i.e., the Time spent on each consent episode, the time spent on consent preparation, the time spent accessing and managing consent information, the time spent scanning forms onto the EHR, etc.
3. How easy was integrating Concentric into the Ophthalmology department workflow? Specifically:
   I. How much time was required for the training to use Concentric effectively?
   II. Did the integration of Concentric require any significant changes to the existing process/ infrastructure? Please specify.
4. In your opinion, how reliable do you find Concentric in terms of capturing accurate consent information? Specifically:
   I. Have you encountered any issues with the accuracy of the data collected?
   II. How has Concentric affected the rate of consent-related errors and incomplete or missed forms at the department?
5. Do you have any data privacy concerns regarding the data collected through Concentric?
6. Has the use of Concentric impacted the number of day-of-surgery cancellations or delays due to consent-related issues in the Ophthalmology department?
7. In your opinion, do you feel that Concentric adequately explains the consent process and supports shared decision-making in the ophthalmology department?
8. Has the use of Concentric affected patient satisfaction in the Ophthalmology department?

**Role & Department:**

## Future Improvements & Overall Impression

1. Is there any update needed for the enhancement of Concentric?
   *Prompt:* Are there any additional features you want to see in future updates?

| Not likely | | | | | | Extremely likely |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

2. Do you agree that using Concentric has improved the consent process experience for clinicians in the Ophthalmology department?

| Strongly Disagree | | | | | | Strongly Agree |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

3. How do you perceive the overall impact of the use of Concentric as a digital consent tool in the Ophthalmology department?

| Very negative | | | | | | Very positive |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

4. Are there any barriers to adopting Concentric as a digital consent tool in the Ophthalmology department?

| Not likely | | | | | | Extremely likely |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 8 |

5. Overall, how satisfied are you with the use of Concentric as a digital consent tool in the Ophthalmology department?

| Not satisfied | | | | | | Very satisfied |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

# Appendix 2- BHT Discussion Guide

## Discussion Guide

## Stakeholder Engagement Study: Assessing the impact of Concentric as a digital consent tool

### Background

Health Innovation Oxford & Thames Valley (the Oxford HIN) is one of 15 Health Innovation Networks commissioned by NHS England and the UK Office for Life Sciences. Established in 2013, Oxford HIN (formerly Oxford AHSN), represents the innovation arm of the NHS and is strategically positioned at the intersection of healthcare and life sciences, playing a critical role in driving the adoption of effective innovations within the NHS. The Oxford HIN has a proven track record of supporting ideas, products, and services to fully realise their potential, thus ensuring that impactful innovations reach patients and healthcare providers. Additionally, the Oxford HINs actively stimulate economic growth in the life sciences sector, fostering an environment where innovative solutions can thrive and contribute to the overall advancement of healthcare.

The Oxford HIN serves 3.3 million people in Berkshire, Buckinghamshire, Milton Keynes, and Oxfordshire. In partnership with Buckinghamshire, Oxfordshire, and Berkshire West Integrated Care System, Oxford HIN is conducting a stakeholder engagement study focused on assessing Concentrics impact in the Obstetrics & gynaecology department at Buckinghamshire Healthcare Trust (BHT).

### Aim and Objectives

Concentric provides digital consent for all treatment scenarios and is currently used in several NHS Trusts, including BHT. The objective of this study is to conduct a stakeholder engagement using semi-structured qualitative interviews to assess the impact of Concentric as a digital consent tool in the Obstetrics & gynaecology department at BHT. Clinicians and staff from BHT using Concentric will be interviewed to understand their experience and acceptance of Concentric in the clinical pathway.

### Introductory Questions

2. How familiar are you with Concentric as a digital consent tool?
3. How often do you use Concentric?

   *Follow-up:* Can you quantify this, i.e. An average per day or month?

5. What features of the digital tool do you find most useful?
6. How easy is it to navigate and use Concentric?

   *Prompt:* Do you face any specific challenges or difficulties while using Concentric?

## Specific Impact Assessment Questions

9. In your opinion, has Concentric impacted your efficiency in obtaining and managing patient consent in the Obs & Gynae department?

10. In your opinion, has Concentric affected the time spent on each consenting episode in the Obs & Gynae department?

    *Prompt:* Has there been a change in the timing of certain processes? i.e., the Time spent on each consent episode, the time spent on consent preparation, the time spent accessing and managing consent information, the time spent scanning forms onto the EHR, etc.

    - Time spent discussing and explaining risks during the initial clinic consultation
    - Time spent preparing and sending the consent form to the patient
    - Time spent by patients reviewing and signing the consent form
    - Time spent on the day of surgery to confirm consent
    - Time saved on administrative tasks like scanning paper forms into the Electronic Health Record (EHR)

11. How easy was integrating Concentric into the Obs & Gynae department workflow? Specifically:
    III. How much time was required for the training to use Concentric effectively?
    IV. Did the integration of Concentric require any significant changes to the existing process/ infrastructure? Please specify.

12. In your opinion, how reliable do you find Concentric in terms of capturing accurate consent information? Specifically:
    I. Have you encountered any issues with the accuracy of the data collected?
    II. How has Concentric affected the rate of consent-related errors and incomplete or missed forms at the department?

13. Do you have any data privacy concerns regarding the data collected through Concentric?

14. Has the use of Concentric impacted the number of day-of-surgery cancellations or delays due to consent-related issues in the Obs & Gynae department?

15. In your opinion, do you feel that Concentric adequately explains the consent process and supports shared decision-making in the Obs & Gynae department?

16. Has the use of Concentric affected patient satisfaction in the Obs & Gynae department?

**Role & Department:**

## Future Improvements & Overall Impression

6. Is there any update needed for the enhancement of Concentric?
   *Prompt:* Are there any additional features you want to see in future updates?

| Not likely | | | | | | Extremely likely |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 9 |

7. Do you agree that using Concentric has improved the consent process experience for clinicians in the Obs & Gynae department?

| Strongly Disagree | | | | | | Strongly Agree |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

8. How do you perceive the overall impact of the use of Concentric as a digital consent tool in the Obs & Gynae department?

| Very negative | | | | | | Very positive |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 8 |

9. Are there any barriers to adopting Concentric as a digital consent tool in the Obs & Gynae department?

| Not likely | | | | | | Extremely likely |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

10. Overall, how satisfied are you with the use of Concentric as a digital consent tool in the Obs & Gynae department?

| Not satisfied | | | | | | Very satisfied |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |

# Appendix 3- Stakeholder Engagement Study

## 1 Stakeholder Engagement Study Setting and Participants

Interviews with clinical staff from OUH and BHT took place between September and November 2024. At this time, all staff interviewed where familiar with Concentric with digital consent embedded in the respective pathways.

### 1.1 OUH

Focus Group at Oxford Eye Hospital (John Radcliffe, Oxford University Hospitals NHS Foundation Trust). The Focus group had 11 attendees from across the Ophthalmology department (pre assessment, surgery & theatres, outpatients). The roles of the Stakeholders included clinical lead, consultant nurse, consultant ophthalmologist, cataract surgeon, administrator, senior nurse, clinical fellow, specialist ophthalmic nurse.

### 1.2 BHT

Stakeholders from BHT consisted of clinical staff who are users of Concentric across the Obs and Gynae elective pathway. Job titles include day surgery sister, senior Sister, Gynaecological Lead, Obstetrics & Gynaecology Consultant and Lead Operating Department Practitioner (ODP). Due to time restraints and scheduling conflicts, a focus group was unable to take place. As an alternative, 1:1 sessions with stakeholders were held over Video conferencing software Microsoft Teams.

### 1.3 OUH Stakeholder Engagement Results

During the stakeholder engagement study, participants were questioned to understand the impact of Concentric using the discussion guide (Appendix 1- OUH Discussion Guide).

#### 1.3.1 Introductory Questions

All stakeholders within the focus group were familiar with using Concentric. The tool went live in the ophthalmology department across two weeks in January 2023 and is fully embedded into the pathway. Paediatric ophthalmology was delayed due to being under a separate directorate. All stakeholders are trained and using the tool on a regular basis. Within the ophthalmology department around 400 consent episodes per month are taken, eliminating the need for paper consent in the past two months.

The use of Concentric varies between the ophthalmology specialties and individual roles for the HCPs. The only role with no direct experience of Concentric was the administrator. The nurses explained that in clinic they may see up to seven or eight patients a day, and these will all require consent. The pre assessment unit typically undertakes a high volume of consent with seven to eight patients a day per nurse working in clinic at that time.

> *"I'm involved in that clinic almost every day, and depending on how many patients I see, then I do the consenting, and it's, it's a breath of fresh air for us"*
>
> *Specialist Ophthalmology Nurse Practitioner*

When discussing the benefits of Concentric, stakeholders all agreed that consenting electronically is valuable because it allows the information to be stored correctly and in one place. Stakeholders also felt that the ease of use and improved accessibility for patients allows the consenting process to be faster than paper-based consenting. Furthermore, all of the stakeholders felt that Concentric was easy to use and to navigate. The nurses felt confident in using Concentric as the platform has "logical steps" which they felt reduced the risk of error.

One challenge the team have faced is that within Oxford Eye Hospital (OEH) there is a private contractor (Provider) operating which are yet to switch to digital consent. The private contractor still operates a paper-based consent system, so for some nurses and staff there is potential that they are using both paper and digital, dependant on the patient. Additionally, the importance for the team to have adequate Wi-Fi and access to equipment (iPad, signature pads etc) was stressed. Another challenge mentioned was that the new consent forms did not include a question relating to pregnancy. To rectify this the form required audit and quality assurance, however, it was regarded as a beneficial exercise as it ensured compliance and review of processes that may not have been fully reviewed recently.

*"It's also very intuitive isn't it?"*

*Consultant Ophthalmologist*

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*"I quite enjoy consenting... Because it is easy."*

*Nurse Consultant*

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### 1.3.2 Specific Impact Assessment Questions

#### *1.3.2.1 Clinical Efficiency*

It was unanimously agreed by all stakeholders that Concentric has positively impacted efficiency of the consenting process within the Ophthalmology department. The most significant impact has been on time savings, with notable other efficiencies captured including an increase in the number of appointments, medicolegal, clinical governance and net zero.

There has been a significant reduction in the time spent on consenting episodes within the ophthalmology department. Creating the digital consent within the department now takes on average 19 seconds per form (between 17-20 seconds). This is in contrast to the previous process of the paper consent form. The pilot study showed the paper consent process took just under five minutes. However, it was found that it could take up to 20 minutes it total due to activities such as identifying the right form, finding the right form in the cupboard or at other locations within the department, writing down the name of the procedure, writing down any complications/ adverse events, writing down other procedures and finding the correct stickers. . Further administrative resource would also be needed to scan in the forms and upload them to the EPR. An audit found the worst-case scenario of time taken to complete a paper consent was between 14 and 20 minutes

A further efficiency is that HCPs in the eye injection clinic are now able to offer and perform more appointments and injections because the injection time has dropped from 10-15 minutes to three minutes due to the reduction in consenting time. Stakeholders explained that consent must be checked for every injection, for the correct drug in the correct eye. Prior to digital consent, checking this information required looking at the patient summary and reviewing all the uploaded PDF files which could take longer than 10 minutes or may have information missing due to being incorrectly scanned. Currently, due to Concentric this process takes a fraction of the time, estimated at 30 seconds. The injection clinic is now able to accommodate extra patients from the emergency department or urgent cases and perform the intervention same day. Patients find having same day treatment hugely beneficial.

Stakeholders situated in the minor operations department see patients once every three or four months, however the patients only need consenting once per year. A nurse commented it was quick and simple to check a patients consent record on Concentric in comparison to the paper-based system which required looking through a patient's history and corresponding documents which have been scanned in to determine whether the consent is still valid.

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*"So now, with the consent you can just click, and you know that it's there, the correct track, the correct eye, and it's super-fast."*

*Medical Fellow*

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Efficiencies in Medicolegal matters were also noted by the stakeholders. As the forms are now digital and stored electronically, they are always available and retrievable at any moment should any issues arise. Similarly, clinical governance has been positively impacted by the introduction of Concentric. Previously the scanning of paper consent forms had the potential to compromise the completeness of the form if they were not scanned adequately and were missing the name of the patient, procedure or signature.

Net zero contributions were also acknowledged by stakeholders, specifically the reduction in usage of paper (printing and re printing the paper consent form, of which many were customised) was perceived as a waste of time and cost by the nurses.

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*"Since you can drop the injection time per patient from 10 or 15 minutes to three. This means that you can do way more injections, and you can offer more early treatment to way more patients, and we're a clinic that injections clearly have been overbooked, and now we're able to offer more injections or more appointments for patients in the clinic."*

*Medical Fellow*

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*"The digital consent has really worked well, and I think it's because we do a standard sort of operation- cataract surgery. These are all on the same page. So, it's much easier than writing it down individually."*

*Consultant Ophthalmologist*

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*"If they were here three months ago, and then we don't know when was the last time they signed a consent form, you have to go through the records, you know, and find out the recent consent form. It's easier to go straight to Concentric".*

*Nurse Practitioner*

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#### *1.3.2.2 Integration*

The ophthalmology team are fully trained, and the tool has been fully integrated into the department. To achieve this the clinical lead, digital project lead and digital project manager have been instrumental in facilitating the training and eventual adoption of Concentric. The clinical champions/ core advocates were also supported by a lead in the nursing staff, a lead in the administration staff, and a lead also in nursing, allied health professionals, and two trainees. The department was also kept fully informed via consistent communication of what the change will be and what to expect.

The clinical lead explained that training was provided to everyone (~188 staff) and took a period of 2 weeks to complete. There was a phased training schedule, starting with pre-admission, to cataract surgery, then to all procedures & theatres then finally outpatients. The digital project manager engaged with each staff member individually to give the training which took ~10 mins per person. Re-training was also offered to staff when needed, and continually retrained until the whole department had moved to digital consent. Stakeholders commented that because Concentric is so easy and intuitive to use they had no problems in learning how to use it. They also credited the digital project manager for being engaged and available for any queries or questions they had on the tool- allowing staff to feel supported and really driving the change in process. Additionally, all stakeholders were in agreement that Concentric fitted seamlessly into the ophthalmology pathway.

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*"I mean, it took like, less than two minutes to show me how to do it. So, it was very fast and very intuitive. Just know which button to press, then you're there. And I don't think it's difficult at all"*

*Ophthalmology Consultant*

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*"The key to success is communication"*

*Ophthalmology Consultant*

The implementation of Concentric had minimal barriers to adoption. The training and utilisation of the technology was quickly adopted by the ophthalmology staff. One unforeseen infrastructure challenge faced by the digital project team was issues with Wi-Fi coverage and connectivity across the whole department. Not until installation of the devices (iPad/ signature pads) onto the Wi-Fi network was it discovered there was too much interference, resulting in the devices losing connection. This was impactful on the consenting process because when connection drops, the consenting process had to begin again or written on paper. OUH IT support was required to boost Wi-Fi signal across the department and reconfigure iPad settings to operate at 5 hertz to avoid interference issues. Signature pads are also used and are more cost effective than an iPad. Patients also had familiarity with using signature pads, comparing it to 'signing for a parcel.'

*"This project has made it very clear that we have to have good Wi Fi coverage"*

*Ophthalmology Consultant*

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*"So, when you hand that signature pad to the patients, "oh am I signing a parcel?" So, they're quite used to it"*

*Specialist Ophthalmologist nurse*

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#### *1.3.2.3 Data Reliability*

The stakeholders were in agreement that they find Concentric "100%" accurate at capturing consent data. The nurses found it incredibly helpful that the risks for procedures are included in the consent form so there was no chance of anything being missed.

Members of the ophthalmology department mapped the information needed for Concentric from the ophthalmology EPR (Medisoft) to ensure all data transfer was complete. They also worked with Concentric to design bespoke forms to ensure they were appropriate for the department.

*"With the papers, where you have to write additional risk by hand, there will be some chance that you miss something, but everything [on Concentric] is there. There is no way you can miss something"*

*Medical Fellow*

There was also unanimous acceptance that all data is safe. Stakeholders have trust in OUH cybersecurity processes and policies. Further comments revealed the stakeholders thought the data in Concentric is no less vulnerable than any other data captured within the Trust. Elaborating on this theme, stakeholders made the comparison to paper consent being far more vulnerable as paper can be easily "taken," whereas within Concentric the consent can only be accessed by authorised users.

A point was also raised regarding cost reduction as the consent papers no longer need to be shredded and appropriately disposed of due to their confidential nature.

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*"It is secured, and it is controlled where it goes. It's only people that do have access to the systems can access it."*

*Ophthalmology Nurse*

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#### *1.3.2.4 Consent Related Issues*

The stakeholders agreed that Concentric has reduced day-of-surgery cancellations and delays due to consent related issues. One of the theatre nurses explained that as Concentric allows patients to be consented quicker, the surgeon is able to spend more time with the patient to discuss the risks and answer any questions the patient may have. It was estimated the whole process takes significantly less time, only 30 minutes compared with around an hour when using paper consent. Stakeholders also confirmed that delays have also been reduced due to the electronic nature of the consent forms being uniform and standardised. All risks for each procedure are already inputted (eliminating the risk of omitting a particular clinical risk) and other staff members are able to clearly read the digital consent forms as opposed to occasionally needing clarity due to legibility of handwriting.

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*"Instead of the surgeon needing an hour to go and consent them, takes half an hour maximum, and that includes signing their operation side and all the other questions"*

*Ophthalmology Nurse*

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*"If it says the "right eye"- that means it's the right eye, because everybody can read it. So that is something that I think we will see the impact in reduce of faults, as there is no misunderstanding."*

*Ophthalmology Nurse*

#### *1.3.2.5 Shared decision making & patient satisfaction.*

There was resounding agreement that Concentric supports shared decision making and patient satisfaction within the OEH. Stakeholders were forthcoming with their thoughts an opinions on how well Concentric supports shared decision making by providing accessibility to patients, providing more time for clinicians and nurses to discuss risks or questions with the patients and allowing a higher throughput of patients.

Stakeholders agree a significant benefit of digital consent is sharing the consent form via email with patients (or patients next of kin if requested) because the forms are easily retrievable and able to be discussed either at home with family or with the nursing staff/clinicians.

*"When you're writing down in your own writing [paper consent], they might not understand what it was, and then it requires another phone call, which you have to answer so it takes some more time, but if they have the [digital] copy which is very legible, they can read it, and they can understand it."*

*Ophthalmology Nurse*

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*"It's very objective and reproducible in the sense that is there electronically. And at the time I finished consenting, they get it there, and they're either on their phone or their email, so they've got it there. We got the record there, so I think it is working really well"*

*Pre-Operative Nurse Consultant*

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Regarding patient satisfaction, the clinicians all agreed that patients had no issues with the use and understanding of the electronic consent. Various stakeholders commented on the improvement in accessibility for their patients. The ophthalmology patient population includes patients who may have poor vision or may be more physically incapacitated due to age. The nurses felt Concentric is much easier to read for the patients as it is black on white, as opposed to the pink paper forms prior which caused some difficulty for some patients. The font is legible, and the font size can be changed to accommodate the patients' needs. Additionally, for patients signing the consent form with a pen may at times be difficult, however now they are able to sign with their fingertip, or on a signature pad which many patients find much easier.

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*"It's so good they can use a fingertip to sign it, and if they're really struggling in very odd situation you can give them a little hand that you can write as well. Overall, got really positive feedback from all patients".*

*Consultant Ophthalmologist*

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*"So, for example, if you have an iPad, they put on a lap, whereas the consent form was almost spilling off the sides, not getting completed properly or legibly."*

*Consultant Ophthalmologist*

*"It's electronic. So patient confidence in a service that looks as if it's sort of cutting edge, we obviously are, but, you know, it gives them that confidence that we know we're talking about, we've got the technology, because that counts for an awful lot. So, I think it's impressive for patients."*

*Nurse Consultant*

## 1.4 BHT Stakeholder Engagement Study Results

### 1.4.1 Introductory Questions

Within the obstetrics & gynaecology department all stakeholders interviewed for the study were familiar with using Concentric frequently (over a year, for every patient). For Gynae patients the frequency of use can be from four to eight patients a day. Stakeholders had positive feedback about the usefulness and ease of use of Concentric.

*"We've been using it for quite a while now, one or two years. So, it's part of our day to day lives, not just in gynae, but across all specialties now"*

*Senior Sister*

The most useful features identified by participants related to both the patients and the healthcare professionals. A stakeholder commented that the ability to send the information and consent details to the patient with the information leaflets, so the patient is able to fully read and understand the procedure in their own time, with "no pressure" was extremely useful. Other stakeholders commented the clarity and legibility of the digital consent form was particularly useful as the information on the form is now completely legible whereas previously there may have been clarifications made on a person's handwriting. All of the stakeholders found Concentric easy to navigate and use. The platform itself was deemed to be "very simple" and self-explanatory.

*"It's actually quite clear and concise, so you can actually you know exactly what they're consented for"*

*Lead ODP*

*"It's very easy. It's very user friendly"*

*Obstetrics & Gynaecology Consultant*

Two challenges of using the platform were mentioned. The first is if there are any issues with the Wi-Fi. Although accepted as an IT/ infrastructure issue, if the iPad loses connectivity this may cause delays with the consenting process or cause the consent to be taken on paper instead. The second

challenge described by two stakeholders was related to making amendments (e.g. adding or deletions of procedures) was the layout and design of consent forms. Occasionally, due to the how amendments are made (free text) or if they are consented for additional procedures (e.g catheterisation) it can sometimes be difficult for staff to find the changes on the form, and the amendments do not show on the platform in chronological order. Although the most recent form will be shown at the top of the page, human error can lead to selecting the wrong form for review. A suggestion made to rectify this would be to remove the prior consents from the "front sheet" which eliminates the possibility of opening up a consent form that is not up to date.

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*"If there was anything that I personally would like to see changed, it would be that once the old consents, the procedure, those dates have gone, that they're actually off of that front sheet, because then you don't have any ability to open old consents. We've had an incident where an old consent has been used to check in a patient, and we've gone into theatre realise it's the wrong one"*

*Lead ODP*

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### 1.4.2 Specific Impact Assessment Questions

#### *1.4.2.1 Clinical Efficiency*

All of the staff involved with obstetrics & gynaecology care use Concentric and broadly agreed that there has been positive impact on clinical efficiency. One of the key benefits was the reduction in administrative time spent managing consent forms. With digital consent, staff can access the consent form directly on iPads, eliminating the need to search for or handle paper documents. This immediate access streamlines the process, as staff can easily verify signatures and review consent details before the patient arrives in theatre. Additionally, Concentric allows for quick amendments, reducing the time spent correcting errors or dealing with incomplete forms, which is common with paper documentation. The stakeholders were unable to quantify any specific time saved in performing these activities but felt that it was faster. Overall, the system reduces the need for follow-up, enhances accuracy, and accelerates the consenting process, contributing to smoother workflow and less time spent on administrative tasks.

However, some stakeholders also noted minor challenges that could impact efficiency. While digital consent reduces issues such as lost paperwork, there are occasional discrepancies between the consent form on the system and the actual procedure to be performed, which can cause delays if not identified and corrected in time. There is also the added step of logging into devices which can still introduce a small delay. Despite these challenges, stakeholders agreed that digital consent has improved clinical efficiency compared to paper forms. The system reduces the risk of errors, reduces the time spent searching for or correcting forms, and ensures that patients are informed of their procedure more effectively, allowing for a more streamlined and efficient clinical process.

*"I don't think, personally, I would say that it has impacted too much on efficiency. I would say it's more efficient from a good consenting point of view."*

*Consultant*

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*"You can make amendments quite easily on the iPad, rather than trying to find another form or scribble down the side of a consent form"*

*Lead ODP*

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*"I think it has saved a lot more time for me having to dig around in the patient's notes or pre op to try and find it."*

*Lead ODP*

#### *1.4.2.2 Integration*

The training for the new electronic consent system was well received by all stakeholders and viewed as straightforward. Staff attended group training sessions, with one-on-one sessions available for those who needed additional support or were not able to attend the group training. The system was easy to navigate for most users, particularly for those involved in checking consents, although some members of staff initially hesitated due to concerns about using personal devices. To address this, only Trust iPads would be used. The Concentric training is also now available as an online module for new trainees during their mandatory induction to the Trust. While Wi-Fi connectivity posed challenges, these were being addressed, and the overall adaptation to the system was smooth, with staff able to quickly integrate it into daily practice with ongoing support.

*"Training was quite simple, very straightforward"*

*Lead ODP*

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*"The Wi-Fi is the big issue- but they're working on that at the moment so it's a work in progress. Our iPads came in time, so there so we never had any struggle to use to use Concentric on the Trust iPads"*

*Lead ODP*

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*"I think there was a whole team which was devoted to helping Concentric get launched"*

*Consultant*

#### *1.4.2.3 Data Reliability*

The stakeholders agreed that the data within Concentric is reliable and had no concerns regarding the Concentric platform. A few points were raised on occasional issues that could be attributed to human error rather than the platform. One issue is the potential for healthcare professionals to inadvertently rely on outdated consent forms, especially when procedures are similar but not identical. This can lead to confusion if the wrong consent form is mistakenly used, even if it appears "green" and current.

Additionally, there have also been instances where consent forms need to be confirmed or re-signed on the day of surgery, but this process is not always followed, causing discrepancies between the consent date and the actual procedure date. A proposed solution is to visually differentiate between active and outdated consents (e.g., grey-out old forms) to improve safety and reduce the chance of errors.

Regarding data access and security, there are concerns about the availability of sensitive patient information on shared devices, like iPads, particularly if users do not “log out” properly, potentially exposing patient data to unauthorised users. Concentric does have safeguards, such as unique authentication codes and two-factor login, but issues still arise when users leave consent data open or fail to log out. Additionally, some users report unnecessary patient consent data from previous days being displayed, which poses privacy concerns. While some users are confident that data access is secure, they suggest improvements in how the system manages data to prevent displaying irrelevant or confidential patient information.

*“It doesn't necessarily always get captured within the platform, or maybe it's just our Surgeons that don't write it down, which is completely possible”*

*Senior Sister*

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*“I just think the main common error, if it is an error, is people looking at the consent thinking it is the up to date one, when really it's an old one, especially when they're having a very similar procedure”*

*Lead ODP*

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*“I’m not concerned about any data issues”*

*Lead ODP*

#### *1.4.2.4 Consent related issues*

The majority of stakeholders have no concerns with consent related errors. They are unable to recall any cancellations or day of surgery delays due to digital consent errors. Furthermore, as digital consent is embedded into the pathway and used consistently on a daily basis it has not led to consent related errors. A couple of stakeholders mentioned occasional isolated incidents where errors have been made but attributed to human error as opposed to the digital platform itself.

*"No cancelations, which I would say are purely to do with Concentric per se, it may be consent related from a more generic point of view, where this was not really discussed with them in clinic."*

*Consultant*

---

*"I think we had a slight delay when we were trying to look at consent forms, when someone signs on behalf of a patient…. I think there was a point where there was no option for someone to sign on their behalf."*

*Lead ODP*

---

#### *1.4.2.5 Shared Decision Making & Patient Satisfaction*

The stakeholders agreed that digital consent supported shared decision making and patients were satisfied using and interacting with Concentric. Stakeholders particularly liked the ability to send the consent form and the relevant information to the patient after the first clinic appointment (and before the scheduled surgery) which gave patients time to read about and understand their procedure. If the patients have further followed up questions they are able to ask the relevant healthcare professional before the procedure. Stakeholders feel that as a result the patient is more informed about their treatment. The stakeholders felt that Concentric has supported shared decision making in the pathway.

*"They [the patient] will read through everything once again [at home via email]. And if they're happy to proceed, they will go ahead and sign it. So that means that you've done one round in the clinic then they get home and read. So, I actually find that really reliable from a proper consent point of view."*

*Consultant*

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*"Personally, I think there is a lot of information on there [Concentric], but I think, as with everything, it's the explanation from your surgeon at the meetings that that they will remember more than the words they're reading on the paper. So, I think it's a collaboration, isn't it?"*

*Lead ODP*

---

*"I think it's pretty good from a patient satisfaction point"*

*Consultant*

---

*"No one's complained"*

*“I think so,  they're [the patients] all very super impressed "Oh, this is so fancy".”*

*Consultant*

## 1.5 Level Of Agreement

In this section, stakeholders were asked to provide scores on five questions about the level of acceptance for Concentric as a digital consent tool. They were asked to score the statements/questions from 1 (strongly disagree) to 7 (strongly agree). A bar chart of the results is shown in Figure 5, below.

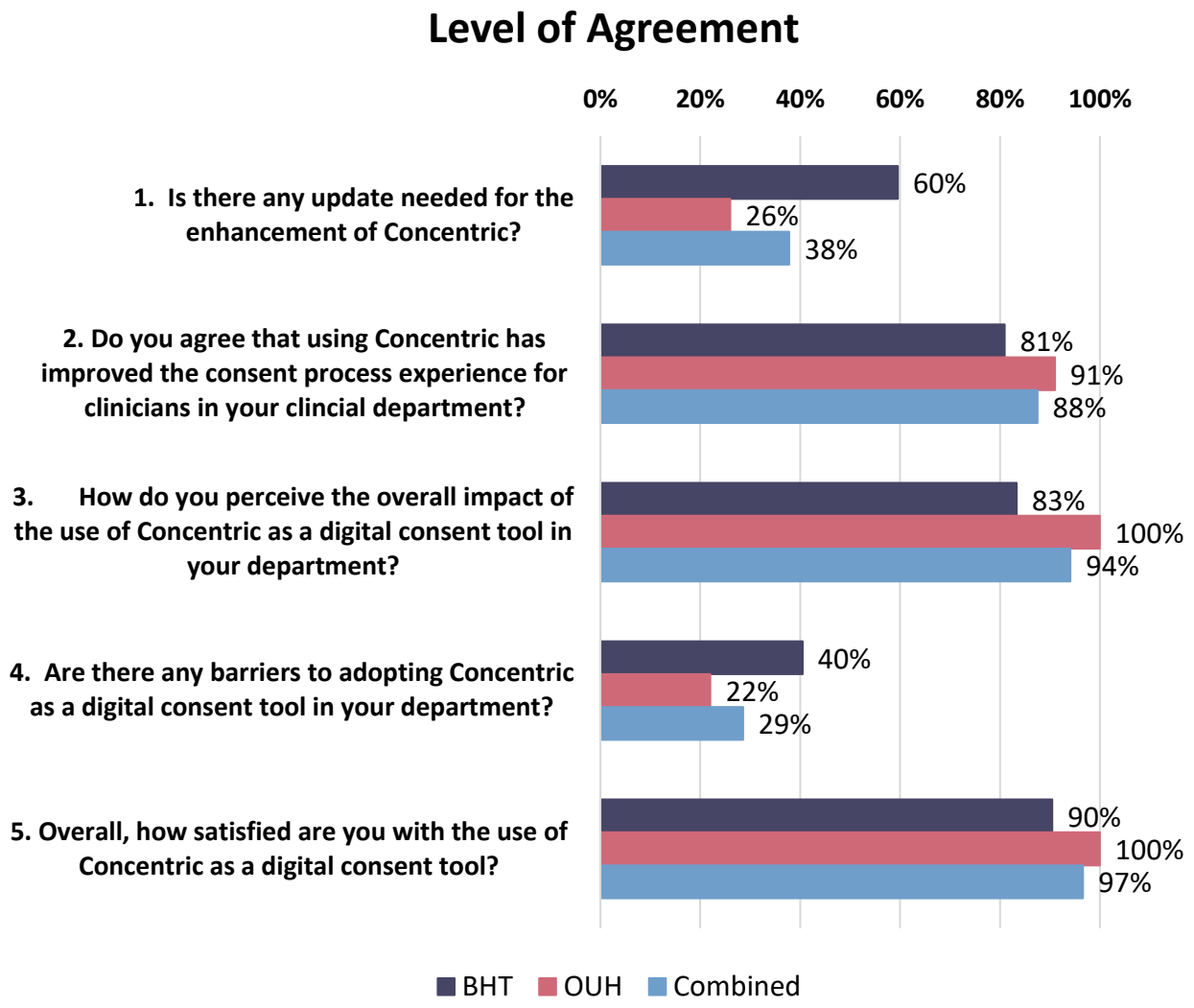


*Figure 5: Bar Chart representing the level of agreement from stakeholders*

The results highlight a strong consistency between the OUH and BHT sites regarding staff perceptions of Concentric. Overall, there is a high level of satisfaction with the tool at both sites, demonstrating its positive reception among stakeholders. Additionally, stakeholders noted an improvement in the consenting process, further reflecting the tool's effectiveness. There was minimal agreement regarding the need for enhancements or barriers to adoption, which further highlights the acceptance of Concentric.

# Appendix 4- OUH Preliminary Health Economic Assessment

## 1 Introduction to the preliminary health economic analysis

As part of the impact assessment, a preliminary health economic analysis was conducted to evaluate the economic implications of implementing the Concentric digital consent platform in the Ophthalmology department at Oxford University Hospitals NHS Foundation Trust (OUH). The analysis compares the newly implemented digital system with the department's prior paper-based consenting system.

The preliminary economic analysis includes a comprehensive cost comparison of the implementation and ongoing resources required for both systems, alongside an evaluation of efficiencies gained and their associated economic outcomes. The findings aim to inform the ophthalmology department and broader stakeholders about the financial and operational implications of adopting a digital consent platform compared to the paper-based consent system.

### 1.1 Preliminary health economic analysis objectives

The preliminary health economic study aimed to assess the economic impact of incorporating Concentric into the Ophthalmology department's workflow at OUH. The specific objectives were to:

1. **Cost comparison:** Evaluate the initial implementation and ongoing costs of the paper-based system and Concentric.
2. **Efficiency analysis:** Estimate staff time savings, operational efficiency improvements, and the associated financial implications.
3. **Outcome-related costs:** Compare costs incurred due to missed consent forms, surgery delays or cancellations, and medicolegal claims.

Comparators:

Both systems follow similar stages in the consent process: preparation, explanation, confirmation, and documentation (See Figure 6).

Paper-based consent system:

The paper-based system involved manual preparation, printing, signing, and storing of physical paper forms. These were later scanned and uploaded to the Electronic Patient Record (EPR) system. Administrative staff were responsible for storage and disposal, while clinical staff handled patient preparation and consent collection.

Concentric digital consent platform:

Introduced as a pilot in January 2024, Concentric uses electronic forms accessed via iPads and signature pads. The system integrates with the EPR, streamlining electronic storage. Implementation involved existing clinical and administrative staff, supplemented by support from digital and IT teams.

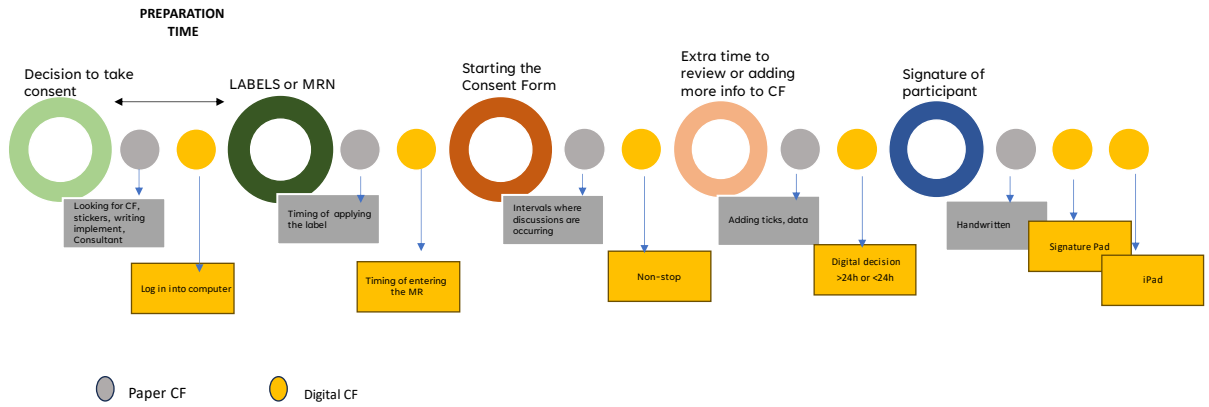


*Figure 6: Comparative Workflow of Paper-Based and Concentric Digital Consent Systems in the Ophthalmology department at OUH as provided by the OUH team*

## 1.2 OUH Methodology

The methodology employed in this preliminary health economic analysis involved conducting a literature review, structured data collection, and developing an early economic model to evaluate and compare the paper-based and Concentric consent systems.

Literature review:

An extensive literature review was conducted to understand and identify the operational and economic factors influencing consent systems in healthcare. This review served as the foundation for identifying critical parameters, processes, and outcomes that influence the economic evaluation of the paper-based and digital consent systems. Key areas identified in the literature are:

6. Time required for clinical and administrative staff to perform consent-related tasks.
7. Frequency and consequences of documentation errors, including missed or incomplete forms.
8. Operational disruptions, such as surgery delays or cancellations caused by consent-related issues.
9. Legal and regulatory considerations, including compliance and medicolegal claims.
10. Environmental impact particularly the resource use associated with paper-based processes.

The review synthesised these insights to identify critical parameters influencing and should be considered in the preliminary economic analysis:

5. Time savings for staff across different roles and associated economic benefits.
6. Rates of missed or incomplete consent forms and associated operational and economic impact.
7. Frequency of day-of-surgery delays or cancellations and associated costs incurred.
8. Potential reduction in medicolegal claims and associated costs.

These findings informed the selection of parameters for data collection and the construction of the preliminary health economic analysis.

**Data collection:**

Following the literature review, a structured data collection tool was developed to systematically gather the necessary data points for this preliminary health economic analysis. The data collection tool comprised 16 key questions aimed at collecting data on the initial implementation and ongoing costs associated with both the paper-based and digital consent systems, consent episode volume, and metrics related to efficiency and outcomes including staff time, rate of consent-related issues, operational efficiencies and delays, and medicolegal claims (Appendix 6- Preliminary HE data requirements). The document was shared with key stakeholders at OUH, including:

4. The digital project manager responsible for Concentric implementation and training in the Ophthalmology department.
5. A senior program manager from OUH.
6. A consultant ophthalmologist from the department.

While the analysis primarily relied on primary data provided by the OUH team, additional parameters, such as staff salaries and medicolegal claim costs, were sourced from peer-reviewed literature to ensure completeness of the data needed for the preliminary economic analysis.

Time horizon, perspective, and economic analysis:

Besides the per consent episode analysis, the analysis utilised two horizons—eight months and three years—based on the following rationale:

- **Per consent episode**: Provides a more detailed, micro-level comparison between the paper-based and digital systems, allowing for immediate impact assessment.
- **Eight-month time horizon**: Captures the current impact of implementing the Concentric system, as it has been in operation within the Ophthalmology department at OUH for this duration.
- **Three-year time horizon**: Representing the lifespan of two key resources required for implementation—specifically, the average three-year lifespan of iPads and the cost of staff training, aligned with the NHS retention rate over this period. This longer-term perspective allows for a more comprehensive evaluation of the system's economic benefits over time.

In accordance with National Institute for Health and Care Excellence (NICE) recommendations, a bottom-up NHS and Personal Social Service (PSS) cost perspective was adopted (5). This approach captures the costs incurred by the NHS as the provider of medical interventions requiring patient consent in England. Given the short time horizon of the analysis, no economic adjustments were made to account for inflation and discounting. The analysis was performed using Microsoft Excel version 2024.

Data used for the analysis:

The main categories of the primary and secondary data used for the analysis were:

4. Average number of consent episodes performed.
5. Implementation and ongoing resources and costs.

6. Efficiency and outcomes related data.

The following sections describe these data points and outline the data incorporated in the preliminary health economic analysis.

### 1.2.1 Average number of consent episodes

The data on consent episodes for the Ophthalmology department at OUH were estimated based on departmental procedure volumes. For the paper-based system, no formal auditing of consent episodes was conducted before the implementation of Concentric. However, the team provided an estimation based on the department's average procedure volumes across different types of treatments.

It was inferred that the Ophthalmology department would have processed between 11,000 and 14,000 consents annually, translating to an estimated 917 to 1,167 consents per month. In contrast, for the Concentric digital system, data were collected over eight months following its implementation on 29 January 2024. This provided a more accurate measure of consent episodes processed through the new digital platform. Over this period, the system averaged 825 consents per month.

To facilitate the economic comparison between the two systems, this analysis assumes that the number of consent episodes in both systems was comparable and estimates 825 consents per month.

### 1.2.2 Implementation and ongoing resources and costs

The primary costs associated with the paper-based consent system included expenses for printing, storage, and disposal of physical consent forms, and staff costs related to time spent by clinical and administrative personnel on various tasks throughout the consent process. These tasks involved preparing, completing, and managing the paper consent forms, which required significant manual effort from staff.

In contrast, the Concentric digital system required initial investments in hardware, including the purchase of iPads, signature pads, and other associated accessories (See Appendix 7- Infrastructure costs). Additionally, there were software licensing fees to run the system. The annual licensing fee for unlimited episodes is £50,000, and OUH usually performs 340,000 consent episodes annually.

Training costs were considered for both systems. Each staff member received a minimum of 10 minutes of training for the paper-based system and approximately 12 minutes of face-to-face training for the Concentric system. A total of 363 staff members were trained in both systems, including ophthalmologists, nurses, administrators, and other clinical and support staff. The trainer costs ranged from £23.60 to £98.39 per hour, depending on the trainer's staff category.

Lastly, the time spent by clinical and administrative staff on various stages of the consent process for both systems was accounted for. This includes the total time spent by different staff categories performing these tasks, as outlined in Table 16.

*Table 16: Time Spent by Clinical and Administrative Staff on Various Stages of the Consent Process for Paper-Based and Concentric Digital Systems*

| **Paper-Based System** | | **Concentric** | |
|---|---|---|---|
| *Function- task* | *Average time (Minutes)* | *Function- task* | *Average time (Minutes)* |
| **Clinical staff (Band 6,7, or 8 nurses and a consultant)** | | **Clinical staff (Band 6,7, or 8 nurses and a consultant)** | |
| Time to find, assemble (labels), and complete the form | 2.63 | Time to log in to Concentric and locate MRN | 0.37 |
| Time to fill out the paper consent form | 1.25 | Time to fill out the digital consent form | 0.61 |
| Time to explain the consent | 10 | Time to explain the consent | 10 |
| Time to capture the signature | 0.36 | Time to capture the signature | 0.32 |
| Extra time to finish the consent form | 0.25 | Extra time to finish the consent form | 0.18 |
| **Administrative staff (Band 3&4)** | | **Administrative staff (Band 3&4)** | |
| Time to scan and store the form | 1.5 | N/A | 0 |
| Time to locate the form in Medisoft | 2 | Time to locate the form in Medisoft | 0.37 |
| Time to dispose of the form in confidential waste | 1 | N/A | 0 |
| **Total time per consent episode** | **18.99** | **Total time per consent episode** | **11.85** |

To assess the costs incurred from staff time, the NHS Terms and Conditions of Service (Agenda for Change) pay rates for 2024-2025 were used to calculate the hourly rate for each staff category involved in the consenting process (6).

For comparison, the minimum and maximum cost per consent episode were calculated based on the following staff categories:

- **The minimum staff cost scenario** assumes that the consenting task is performed by a nurse, with the hourly rates for Band 6, 7, and 8 nurses used for the calculation. The average hourly rate for these bands was £25.07, corresponding to an average per-minute cost of £0.42 (Table 17).
- **The maximum staff cost scenario** assumes that the consenting task is performed by a consultant. The consultant hourly rate used for this calculation was £98.39, based on the data provided by the OUH team, translating to £1.64 per minute.

*Table 17: The hourly rates and per-minute costs for Band 6, 7, and 8 nurses based on the NHS Terms and Conditions of Service pay scales.*

| Clinical Staff (Band 6-8 Nurses) Cost Breakdown | Average Annual Salary | Hourly Rate | Per-Minute Rate |
|---|---|---|---|
| Band 6 | £40,568.33 | £20.80 | £0.35 |
| Band 7 | £49,161.00 | £25.21 | £0.42 |
| Band 8 | £56,904.33 | £29.18 | £0.49 |
| **Average cost** | | **£25.07** | **£0.42** |

In addition to the clinical staff, administrative staff (Band 3 and 4) are responsible for tasks such as scanning, storing, and managing consent forms. Their costs are outlined in Table 18 below.

*Table 18: Cost breakdown for administrative staff (Band 3-4)*

| Administrative Staff (Band 3-4) Cost Breakdown | Average Annual Salary | Hourly Rate | Per-Minute Rate |
|---|---|---|---|
| Band 3 | £24,872.50 | £12.76 | £0.21 |
| Band 4 | £27,822.00 | £14.27 | £0.24 |
| **Average cost** | | **£13.51** | **£0.23** |

### 1.2.3 Efficiency and outcomes-related data

The analysis considered several key efficiency and outcome metrics to compare the paper-based and Concentric digital consent systems as summarised in Table 19.

*Table 19: Efficiency and outcome metrics for paper-based and Concentric digital consent systems*

| Efficiency and Outcomes Parameter | Paper-Based Consent System | Concentric |
|---|---|---|
| Staff time | 18.99 minutes | 11.85 minutes |
| Day of treatment cancellation | N/A | N/A |
| Day of treatment delays | 4 incidences in three months | N/A |
| Rate of missed consent forms | 1.95% | N/A |
| Rate of medicolegal claims | 2% | N/A |

5. **Staff time savings**

As shown in Table 16, the staff time at each stage of the consent process was significantly reduced with the Concentric digital system. On average, the paper-based system requires 18.99 minutes per consent episode, while Concentric reduced this to 11.85 minutes.

6. **Missed consent forms**

The paper-based system had a 1.95% rate of missed consent forms, based on an audit conducted by the department. A missed consent form typically requires a patient to be re-consented, resulting in delays and inefficiencies in patient care. The Concentric system, however, did not report any cases of missed forms.

7. **Day of treatment delays and cancellations**

Neither system reported day-of-treatment cancellations. However, for the paper-based system, there were four incidences of treatment delays over three months. These delays were variable depending on the type of procedure. For example, theatre delays were estimated to be 15 minutes on average, involving multiple staff categories. On the other hand, room injection treatment delays were estimated to last 45 minutes, primarily involving nursing staff. The Concentric system did not report any treatment delays in the analysed period.

8. **Medicolegal claims**

The paper-based consenting system reported a 2% rate of medicolegal claims. The cost of these claims was estimated at £25,000, based on data retrieved from the literature (7) (8).

These costs include both the damages awarded to claimants and the legal fees incurred during the claim process. No cases of medicolegal claims associated with consent-related issues were reported with the use of Concentric.

### 1.2.4 OUH Preliminary Health Economic Results

#### *1.2.4.1 Initial and ongoing cost comparison*

The analysis results indicated significant cost differences between the paper-based and the Concentric digital consent systems, with the former incurring higher implementation and ongoing costs to Concentric (Table 20). The cost per consent episode was £19.54 in Concentric compared to £25.18 with the main driver of difference being the staff costs.

Over 8 months and with 825 consent episodes performed monthly, the paper-based system cost £166,159, while the Concentric system cost less at £128,950, resulting in a savings of £37,209. Similarly, over 3 years, the paper-based system's total cost was £747,717, compared to £580,280 for the Concentric system. This demonstrates a long-term cost reduction of £167,437 with the digital system.

*Table 20: Summary of costs for paper-based and concentric consent systems across different time horizons*

| **Paper-Based System** | | **Concentric System** | | **Cost Difference** |
|---|---|---|---|---|
| *Item* | *Cost per Consent Episode* | *Item* | *Cost per Consent Episode* | |
| Paper | £0.15 | Technological infrastructure | £0.33 | |
| Pencils and labels unit | £0.25 | Training cost | £0.15 | |
| Disposal costs | £0.01 | Concentric license cost | £0.147 | |
| Staff time (Max cost scenario) | £24.78 | Staff time (Max cost scenario) | £18.9 | |
| ***Cost per consent episode*** | **£25.18** | ***Cost per consent episode*** | **£19.54** | **£ 5.64** |
| ***Cost over 8 months period*** | **£166,159** | ***Cost over 8 months period*** | **£128,950** | **£ 37,209** |
| ***Cost over 3 years*** | **£747,717** | ***Cost over 3 years*** | **£580,280** | **£ 167,437** |

### 1.2.5 Efficiency and outcomes comparison

#### *1.2.5.1 Staff time saving*

The analysis of time and associated costs for consent episodes in paper-based and Concentric systems reveals notable differences in staff time savings with Concentric resulting in significant cost savings (Table 21 and Table 22). Specifically, the total time per consent episode decreased from 18.99 minutes with the paper-based system to 11.85 minutes with Concentric, representing a reduction of 7.14 minutes per consent, representing a reduction of 7.14 minutes per episode. This time savings primarily stems from differences in tasks such as locating patient information, filling out forms, and processing administrative steps.

In terms of cost and based on the minimum and maximum cost scenarios, the total cost per consent episode for clinical and administrative staff combined was estimated to range from £7.07 to £24.77 in the paper-based system and from £4.88 to £18.91 in Concentric. The cost savings per episode ranged between £2.33 (minimum) and £5.87 (maximum) (Table 23).

*Table 21: Staff time and cost analysis for consent processes in the paper-based system*

| Function-task | Average Time | Min Cost | Max Cost |
|---|---|---|---|
| **Clinical staff** | | | |
| Time to find, assemble (labels), and complete the form | 2.63 | 1.1 | 4.31 |
| Time to fill out the paper consent form | 1.25 | 0.5 | 2.1 |
| Time to explain the consent | 10 | 4.2 | 16.4 |
| Time to capture the signature | 0.36 | 0.15 | 0.59 |
| Extra time to finish the consent form | 0.25 | 0.11 | 0.41 |
| **Administrative Staff** | | | |
| Time to scan and store the form | 1.5 | 0.34 | 0.34 |
| Time to locate the form in Medisoft | 2 | 0.45 | 0.45 |
| Time to dispose of the form in confidential waste | 1 | 0.23 | 0.23 |
| **Total time per consent episode** | **£18.99** | **£7.07** | **£24.77** |

*Table 22:Staff Time and Cost Analysis for Consent Processes in the Concentric Digital System*

| Function-task | Average Time | Min Cost | Max Cost |
|---|---|---|---|
| **Clinical staff** | | | |
| Time to log in to Concentric and locate MRN | 0.37 | 0.16 | 0.61 |
| Time to fill out the paper consent form | 0.61 | 0.26 | 1 |
| Time to explain the consent | 10 | 4.2 | 16.4 |
| Time to capture the signature | 0.32 | 0.13 | 0.53 |
| Extra time to finish the consent form | 0.18 | 0.08 | 0.3 |
| **Administrative Staff** | | | |
| Time to scan and store the form | 0 | 0 | 0 |
| Time to locate the form in Medisoft | 0.37 | 0.083 | 0.083 |
| Time to dispose of the form in confidential waste | 0 | 0 | 0 |
| **Total time per consent episode** | **£11.85** | **£4.9** | **£18.9** |

*Table 23: Cost comparison of staff time per consent episode: paper-based vs. Concentric system*

| System | Average Time | Minimum Cost Scenario | Maximum Cost Scenario |
|---|---|---|---|
| Paper-based consent system (A) | 18.99 | £7.07 | £24.77 |
| Concentric (B) | 11.85 | £4.9 | £18.9 |
| **Difference (A-B)** | **7.14** | **£2.33** | **£5.87** |

#### *1.2.5.2 Missed consent forms*

The analysis of missed consent forms in the paper-based system indicates significant inefficiencies. For every 825 consents processed, an average of 16 forms were missed, necessitating re-consenting. The cost of re-consenting per form was estimated at £25.18, adopting the maximum cost scenario.

Over 8 months, the total costs incurred due to missed consent forms amounted to £3,222.49. When projected over 3 years, these costs increased to £14,501.19. In contrast, the Concentric digital system reported no instances of missed consent forms, eliminating these additional costs (Table 24).

*Table 24: Projected costs of missed consent forms in the paper-based system*

| Time Horizon | Number of Missed Consent forms | Total Costs Incurred |
|---|---|---|
| **8 months** | 128 | **£3,222.49** |
| **3 years** | 576 | **£14,501.19** |

#### *1.2.5.3 Day of treatment delays*

The analysis of the day-of-treatment delays revealed significant operational inefficiencies in the paper-based consent system compared to the Concentric digital system. Over 3 months, four incidents of delays were recorded with the paper-based system while no similar delays were reported with Concentric. These delays were categorised into two types: theatre-based delays and room injection treatment delays.

Theatre-based delays, lasting an average of 15 minutes and involving various staff members, incurred an average cost of £11.41 per incident. Room injection treatment delays, ranging from 45 to 60 minutes, had a higher average cost of £21.93 per incident (Table 25).

Extrapolating these figures for 8 months and 3 years, the projected costs of delays ranged from £125.51 for theatre-based delays to £241.23 for room injection treatment delays over the 8 months, and from £547.88 to £1,052.64 when projected over 3 years for each delay type respectively.

*Table 25: Cost estimation of day-of-treatment delays in the paper-based consent system*

| Delay Type | Duration (mins) | Cost per Incidence | Cost Over 8 Months | Cost Over 3 Years |
|---|---|---|---|---|
| Theatre based | 15 | £11.41 | **£125.51** | **£547.88** |
| Room injection treatment | 45-60 | £21.93 | **£241.23** | **£1,052.64** |

#### *1.2.5.4 Medicolegal claims*

The analysis of potential medicolegal claims in the paper-based consent system revealed significant financial implications. Based on the assumption that 2% of monthly performed consents result in medicolegal issues and assigning a cost of £25000 per delay based on the literature as described above, the findings are as follows (Table 26):

*Table 26: Projected costs of medicolegal claims in the paper-based consent system*

| Time Horizon | Number of Claims | Total Costs Incurred |
|---|---|---|
| 8 months | 132 | **£3,300,000** |
| 3 years | 594 | **£14,850,000** |

In contrast, the Concentric digital consent system's improved documentation and completeness significantly reduced the risk of such claims to zero. The elimination of missed or incomplete forms (reported as 100% completeness with Concentric compared to 93% with paper-based systems) suggests a substantial reduction in potential medicolegal risks and associated costs with the Concentric digital consent system.

## 1.3 Discussion

This preliminary health economic analysis highlights the substantial cost and efficiency benefits of implementing the Concentric digital consent platform compared to the traditional paper-based system. The findings demonstrate significant efficiencies and cost savings with the Concentric platform, highlighting its value as a solution for consent management. Key advantages include reduced staff workload, minimised risks of procedural delays, and potential long-term financial benefits from reduced medicolegal claims.

The Concentric platform’s streamlined workflow notably with a reduction in the average time required for consent episodes by approximately 7.14 minutes. This improvement translates to significant cost savings in both clinical and administrative staff time, emphasising the tool's potential to enhance operational efficiency. Additionally, the elimination of missed consent forms underlines the system’s reliability and its potential to reduce procedural delays and administrative work.

A recent study by Houten et al. further supports these findings. Their micro-costing analysis comparing digital and paper-based consent pathways in the NHS found that digital consent is cost-saving for the NHS with £201,590 saved per litigation claims prevented and with the digital tool streamlining the workflow process (10). This aligns with our analysis and suggests that the

Concentric platform could provide substantial financial benefits when implemented at scale across healthcare organisations.

Additionally, a comprehensive scoping review by Chimonas et al. examined 25 articles on electronic consent in clinical care, published between 2005 and 20222. The review revealed consistent findings around improved efficiency and data integrity with e-consent systems. The synthesis showed that e-consent was generally preferred by users and led to improved data completeness, legibility, and accuracy compared to paper-based processes (20). These findings further reinforce the potential benefits of implementing digital consent platforms like Concentric.

A particularly compelling finding is the projected reduction in costs associated with medicolegal claims. With incomplete or missing consent forms being a major contributor to such claims, the Concentric system's improved documentation accuracy offers a proactive solution to mitigating this financial and reputational burden for healthcare providers. Every year 12,000 medicolegal claims are brought against the NHS in England at a cost of £8 billion—6.7% of the NHS England budget (17).

Although the analysis did not fully explore the environmental impact of transitioning to a digital-based system, the reduced reliance on paper and associated resources aligns with broader sustainability goals in healthcare.

This analysis has its limitations. The reliance on estimated and retrospective data, especially for the paper-based system, introduces potential biases in the cost and time comparisons. Additionally, the relatively short duration of analysis for the Concentric system limits the ability to capture long-term outcomes. Future studies should consider a broader and longer-term evaluation to corroborate these findings and explore additional metrics such as clinical outcomes.

## 1.4 Conclusion

In conclusion, the adoption of the Concentric digital consent platform offers transformative benefits. These include enhanced efficiency through streamlined consent processes, significantly lower operational costs by reducing the need for paper and administrative tasks, and a reduced risk of medicolegal claims due to improved accuracy and documentation.

Specifically, the analysis revealed a cost saving of £37,209 over eight months and £167,437 over three years compared to the paper-based system. Staff time savings were notable, with an average reduction of 7.14 minutes per consent episode, translating to reduced costs of up to £5.87 per episode. Furthermore, the elimination of missed consent forms and treatment delays contributed to operational improvements and avoided additional costs.

The findings from this analysis strongly support the broader implementation of the Concentric platform across various clinical settings and shows its alignment with the NHS goals for innovation, sustainability, and improved patient care.

# Appendix 5- BHT Hypothetical Preliminary Health Economic Assessment

## 1 Introduction to the hypothetical preliminary health economic analysis

As part of the impact assessment, a hypothetical preliminary health economic analysis was conducted to evaluate the economic implications of implementing the Concentric digital consent platform in the Obstetrics and Gynaecology department at Buckinghamshire Healthcare NHS Trust (BHT). The analysis compares the newly implemented digital system with the department's prior paper-based consenting system.

Due to the lack of data, this preliminary health economic analysis adopted a hypothetical approach relying mainly on published secondary data from the literature. The findings aim to inform the stakeholders at BHT and wider stakeholders about the financial implications of adopting a digital consent platform compared to the paper-based consenting system.

### 1.1.1 Literature review

A literature review was conducted to understand and identify the operational and economic factors influencing consent systems in healthcare. This review served as the foundation for identifying critical parameters, processes, and outcomes that influence the economic evaluation of the paper-based and digital consent systems. Key areas identified in the literature are:

4. Time required for clinical and administrative staff to perform consent-related tasks.
5. Operational disruptions, such as surgery delays or cancellations caused by consent-related issues.
6. Legal and regulatory considerations, including medicolegal claims.

The review synthesised these insights to identify critical parameters influencing and should be considered in the preliminary economic analysis:

4. Time savings for staff across different roles and associated economic benefits.
5. Frequency of day-of-surgery delays or cancellations and associated costs incurred.
6. Potential reduction in medicolegal claims and associated costs.

These findings informed the selection of parameters for data collection and the construction of the preliminary health economic analysis.

### 1.1.2 Time horizon, perspective, and economic analysis

The analysis utilised two horizons—per consent episode and one-year time horizon—based on the following rationale:

- **Per consent episode**: Provides a more detailed, micro-level comparison between the paper-based and digital systems, allowing for immediate impact assessment.
- **One-year time horizon**: Captures the potential longer-term impact of implementing the Concentric system in the obstetrics and gynaecology department at BHT for this duration.

In accordance with the National Institute for Health and Care Excellence (NICE) recommendations, a bottom-up NHS and Personal Social Service (PSS) cost perspective was adopted (5). This approach captures the costs incurred by the NHS as the provider of medical interventions requiring patient consent in England. Given the short time horizon of the analysis, no economic adjustments were made to account for inflation and discounting. The analysis was performed using Microsoft Excel version 2024.

## 1.2 BHT Hypothetical Preliminary Health Economic Results

### 1.2.1 Literature review results

Based on published literature, the obstetrics and gynaecology department at BHT performs a total of 5500 deliveries annually (9). This is the equivalent of 458 deliveries monthly. Caesarean sections (CSs) represent around 27.2% of all deliveries performed (An equivalent of 125 caesarean sections per month).

In addition to the monthly and annual number of consent episodes performed, the literature review additionally identified the following data points relevant to the preliminary hypothetical health economic analysis:

5. **Process cost savings:** The estimated cost savings using Concentric is £0.81 per consent episode) (2) . The cost difference is mainly due to savings on paper consent handling such as storage, uploading, and other paper-related tasks.
6. **Staff cost savings:** A study concluded that with each minute saved from consultation time due to the introduction of the digital content system, £2.35 would be added to the cost savings (10). Additionally, a study at Nottingham University Hospitals NHS Trust found that clinicians reported saving 5 to 10 minutes per consent form by not having to handwrite information when using digital consent tools (11).
7. **Day of treatment cancellation or delays:** Cancellation rates for elective surgeries in NHS hospitals generally range from 10-14% (12). The most common reasons for these cancellations include lack of theatre time (59.7%), medical reasons (10.8%), patient no-shows (16.2%), changes in the surgical plan (5.4%), administrative reasons (3.7%), and miscellaneous reasons (4.2%) (13). This analysis assumes that the administrative (3.7%) and miscellaneous (4.2%) reasons are considered to be related to consent issues, making up 7.9% of all cancellations.

Based on published studies, the introduction of Concentric results in a 5-10% reduction in day-of-treatment cancellations (14).

The NHS experiences significant costs due to last-minute cancellations of elective surgeries, which are estimated to amount to £400 million annually (12). The average cost per cancellation is reported to be approximately £5,177**.** This figure is derived by dividing the total annual cost of cancellations (£400 million) by the reported 77,266 cancelled operations per year in the NHS.

8. **Medicolegal claims:** Introducing digital consent reduces “failure to warn” risk by 50% (2). Between 2005 and 2019, the NHS settled over 2,300 claims related to failure to inform patients, with a total value approaching £400 million. This indicates an average of approximately 165 such claims per year (15). The reported cost per medical claim varies

significantly from thousands and millions in the literature, the analysis adopted the lower range of such claims with a value of £25,000 per claim (7) and a higher-cost scenario based on 2013-2018 data, which showed an average claim cost of £220,487 per case. The higher-cost scenario was derived from a total of 1,025 claims over a five-year period (2013-2018), costing £226 million, leading to an estimated £220,487 per claim (16).

### 1.2.2 Outcomes measured

This section presents the results of the cost savings analysis derived from the literature findings. Hypothetical economic analysis was conducted to estimate potential cost savings in four key areas: *process cost savings, staff cost savings, reduction in day-of-treatment cancellations, and reduction in medicolegal claims*. Each outcome is discussed and presented in a separate table.

**Process cost savings**

The analysis concluded that introducing digital consent results in a monthly cost saving of £370.98 and an annual cost saving of £4,455.00. These savings are attributed to reduced costs in paper consent handling, storage, and uploading.

Table 27 provides a detailed description of the process cost savings, calculated using the number of monthly and annual consent episodes and the per-episode saving of £0.81.

***Table 27:*** *Process Cost Savings from the Implementation of Digital Consent*

| Parameter | Monthly (£) | Annual (£) |
|---|---|---|
| Consent episodes | 458 | 5500 |
| Cost savings per consent episode | 0.81 | 0.81 |
| **Total savings** | **£370.98** | **£4,455** |

**Staff cost savings:**

The analysis concluded that digital consent leads to monthly staff cost savings of £5,381.50 and annual savings of £64,625.00. These savings arise from an average time saving of 5 minutes per consent episode and a value of £2.35 per minute saved, as supported by literature findings.

Table 28 outlines the staff cost savings, reflecting the calculation steps involving the number of consent episodes, time savings, and cost per minute saved.

***Table 28:*** *Staff Cost Savings from Time Efficiencies in Digital Consent*

| Parameter | Monthly (£) | Annual (£) |
|---|---|---|
| Consent episodes | 458 | 5500 |
| Minutes saved per consent episode | 5 | 5 |
| Cost saving per minute (£) | 2.35 | 2.35 |
| **Total savings** | **£5,381.5** | **£64,625** |

**Savings on the day of treatment cancellation or delays**

The analysis concluded that implementing a digital consent system could lead to significant cost savings by reducing day-of-treatment cancellations associated with consent issues. Given that 125 caesarean sections are performed per month, an estimated 1.185 procedures are cancelled monthly, totalling 14.22 cancellations per year for consent issues. With a reported cost of £5,177 per cancellation, adopting a digital consent system could result in a saving of £6,064 per month and approximately £72,764 per year (Table 29).

***Table 29:*** *Cost Savings from Reduction in Day-of-Treatment Cancellations Due to Consent Issues*

| Parameter | Monthly (£) | Annually (£) |
|---|---|---|
| Total caesarean sections | 125 | 1500 |
| Current cancellation rate (%) | 12 | 12 |
| Number of cancellations | 15 | 180 |
| Percentage of cancellations due to consent issues (%) | 7.9 | 7.9 |
| Cancellation due to consent issues | 1.185 | 14.22 |
| Cost per cancellation (£) | 5,117 | 5,117 |
| **Total savings from consent-related cancellations** | **£6,064** | **£72,764** |

**Savings on medicolegal claims**

The analysis considered two medicolegal cost scenarios: a **lower-cost scenario** estimating claims at **£25,000 per case**, and a **higher-cost scenario** based on 2013-2018 data, which showed a significantly higher claim cost of **£220,487 per case**. A 50% reduction in claims, as anticipated with digital consent implementation, would result in annual savings of **£2,062,500** in the lower-cost scenario and **£18,190,177** in the higher-cost scenario (Table 30).

***Table 30:*** *Cost Savings from Reduction in Medicolegal Claims Due to Digital Consent*

| Parameter | Lower Cost Scenario (£) | Higher Cost Scenario (£) |
|---|---|---|
| Total claims (monthly) | 13.75 | 13.75 |
| Total claims (annually) | 165 | 165 |
| Reduction in claims (%) | 50 | 50 |
| Avoided claims (monthly) | 6.875 | 6.875 |
| Avoided claims (annually) | 82.5 | 82.5 |
| Cost per claim (£) | 25000 | 220,487 |
| **Total savings (monthly)** | **£171,875** | **£1,515,848** |
| **Total savings (annually)** | **£2,062,500** | **£18,190,177** |

### 1.2.3 Discussion

This preliminary health economic analysis aimed to evaluate the potential cost savings associated with the implementation of the Concentric digital consent tool in the Obstetrics and Gynaecology Department at Buckinghamshire Healthcare NHS Trust (BHT). The findings suggest that the digital consent platform could yield substantial financial benefits compared to the traditional paper-based system, particularly with regard to process cost savings, staff cost savings, day-of-treatment cancellations, and medicolegal claims.

Process cost savings were identified, with the digital system reducing expenses by £370.98 per month and £4,455 per year. These savings result from lower costs associated with paper handling, storage, and document uploading. This aligns with existing research highlighting the operational efficiencies of digital consent systems (3). Secondly, the digital consent system resulted in significant staff cost savings. By saving an average of 5 minutes per consent episode, the department could achieve monthly savings of £5,381.50 and annual savings of £64,625.

In terms of day-of-treatment cancellations, the report estimated that 1.185 cancellations per month and 14.22 per year were due to consent-related issues. With a cost of £5,177 per cancellation, introducing the digital consent system could result in a monthly cost savings of £6,064 and annual savings of approximately £72,764.

The digital consent system could significantly reduce medicolegal claims. In the lower-cost scenario, this could save the department an estimated £171,875 per month and £2,062,500 per year. However, in a higher-cost scenario, where each claim is valued at £220,487, the potential savings rise to £1,515,848 per month and £18,190,177 per year. By lowering the risk of "failure to warn" claims by 50%, the Concentric tool helps mitigate medicolegal risks, potentially leading to substantial cost savings for the NHS Trust.

These findings underscore the potential financial advantages of adopting digital consent, particularly in reducing administrative costs, improving efficiency, minimising surgical cancellations, and mitigating medicolegal risks.

Despite the positive findings, the analysis has several limitations. It relies primarily on secondary data from the literature, which may not fully reflect the specific conditions and practices at BHT, potentially leading to discrepancies in the results. The impact of digital consent may vary depending on factors like the department's size, technology infrastructure, and the procedures being performed. Additionally, the cancellation costs used in the analysis were based on a general NHS estimate, which may not align with actual costs at BHT. Finally, the analysis covered a relatively short

time frame, which may not capture long-term effects such as changes in adoption rates, technological advancements, and the future expansion of digital systems.

### 1.2.4 Conclusion

This preliminary health economic analysis supports the adoption of the Concentric digital consent tool in the Obstetrics and Gynaecology Department at BHT. The findings suggest that implementing digital consent could result in significant cost savings, particularly through reduced administrative costs, staff time savings, fewer cancellations, and lower medicolegal claims. These results are consistent with existing literature, which shows that digital consent systems can enhance operational efficiency, generate financial savings, and improve legal compliance. Further research using real-world data from BHT is necessary to validate these findings and refine the analysis for more accurate predictions of cost savings and operational impacts over the long term. Nevertheless, the preliminary findings suggest that Concentric Digital Consent is a promising tool that could enhance efficiency and reduce costs in the NHS, benefiting both healthcare providers and patients.

# Appendix 6- Preliminary HE data requirements

## HTAAF Preliminary Economic Analysis Data Requirements

**Integration and Implementation**

1. What is the average number of surgical consent episodes performed in the ophthalmology department per month/year before and after implementing Concentric?
2. What is the cost per consent episode in the ophthalmology department for: a. The paper-based system b. The Concentric system
3. For Concentric, does the cost per consent episode include health workforce training costs? If not, what are these additional costs?
4. Regarding staff training in the ophthalmology department: a. How much time was required for staff training on the paper-based system? b. How much time was required for staff training on Concentric? c. Who was the instructor for the train-the-trainer sessions on Concentric and their band level?
5. Technological readiness: a. What level of technological readiness was required in the ophthalmology department to implement Concentric? b. Were there any significant changes in the technological infrastructure when transitioning from the paper-based system to Concentric? c. If yes, what were these changes, and how much did they cost?
6. What were the costs associated with the paper-based consent in the ophthalmology department, specifically: a. Paper printing & b. Storage
7. For both systems, which staff categories are involved in the consenting process in the department?

**Efficiency and Outcomes:**

8. What's the average consent process duration for both the Concentric and paper-based systems in the ophthalmology department?
9. For both the paper-based system and Concentric, what is the time spent on the consent process by: a. Administrative staff b. Clinicians/ surgeons c. Nurses across the following stages of the consent process: a. Preparation time b. During consenting c. Post-consent
10. For both the paper-based system and Concentric, what are the rates of: a. Day-of-treatment delays b. Surgeries cancellations (not same day) c. Same-day cancellations d. Surgery waiting times related to consent issues in the ophthalmology department?
11. What is the rate of medico-legal claims related to consent issues for both the paper-based system and Concentric in the ophthalmology department?
12. What is the rate of incomplete consent forms in both the paper-based system and Concentric in the ophthalmology department?
13. What is the rate of missed consent forms in both the paper-based system and Concentric in the ophthalmology department?
14. What is the incidence of wrong-site surgeries and procedural errors related to consent issues in both the paper-based system and Concentric in the ophthalmology department?
15. What were the types and frequency of errors in the paper-based system in the ophthalmology department?
16. What types and frequency of technical errors have been reported with Concentric in the ophthalmology department?

# Appendix 7- Infrastructure costs

**Detailed costs of technological infrastructure for Concentric digital consent system**

| Item | Cost |
|---|---|
| iPad 64G | £340.00 |
| Stylus pens | £0.65 |
| Otter box iPad Case | £20.35 |
| iPad Charger/Lead - iPad Charger Plug | £20.05 |
| iPad Charger/Lead - iPad Charger Lead | £18.51 |
| Wacom Signature Pads | £168.05 |
| Tough Pak iPad Cases | £124.00 |