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ORIGINAL RESEARCH ARTICLE

Digital Versus Paper-Based Consent from the UK NHS Perspective: A Micro-costing Analysis

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Abstract

Background The paper-based consent pathway can be associated with missing information, error, and inadequate patient comprehension. Digital consent addresses some of these limitations. However, limited research has been conducted to understand relative costs and consequences associated with adopting digital consent pathways. The aim of this study was to compare the relative costs of digital consent pathways with paper-based consent pathways in UK National Health Service (NHS) clinical practice.

Method A micro-costing study was conducted from the UK NHS perspective. Multi-stakeholder involvement contributed to understanding how the paper-based consent pathway varies by department and hospital setting. Sensitivity analyses were conducted to identify the key cost drivers and scenario analyses explored the effect of consent timing and hospital digital readiness. Potential advantages and disadvantages of digital consent were also considered, such as possible impacts associated with consent-related litigation.

Results The cost per consent episode is approximately £0.90 more expensive when completed on paper. The ordering or printing of paper consent forms, and the transportation of forms to storage and back to clinic are process steps that would not be necessary with digital consent. Sensitivity and scenario analyses indicated consultation duration had the greatest impact on the relative costs of both pathways. Per litigation claim prevented, an average of £201,590 could be saved.

Conclusions Digital consent is potentially cost saving for the NHS. Consent for elective procedures is recommended in advance of the day of surgery, and digital consent used in this scenario demonstrated the greatest savings. Consultation duration was estimated to have the greatest impact on the relative costs of both pathways, which should be a focus of further investigation.

Key Points for Decision Makers

Changing the process of consenting from paper-based to digital has the potential to save costs to the NHS.

The time it takes for a consultant to gain consent has the largest impact on the overall costs of consent, therefore the potential for cost saving could be greater if digital consent can be completed more quickly than paper-based consent.

Further research needs to be done to determine the true consequences of potentially changing the method of consent.

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1 Introduction

The informed consent process requires that a clinician communicates relevant information about the condition and treatment options in a manner that is accessible and understood by the patient, and that the patient has sufficient time to consider their options. The Montgomery ruling brought significant attention to informed consent in the United Kingdom and beyond, whereby material risks specific to the patient need to be considered and discussed [1–3]. Informed consent is part of shared decision-making, a process in which clinician and patient together consider the benefits, risks and alternatives of the treatment to arrive at a decision encompassing what matters to the individual patient [4–6].

Consent pathways for procedures have largely remained a paper-based process, but there is evidence that this is prone to errors of omission, illegibility, lack of standardisation, using language not easily understood and forms not shared with patients [7–9]. Previous studies of pre-printed consent forms have suggested that litigation could be reduced by standardisation of risks. If risks are presented in a format that are more easily digested by patients, such as being absent of clinical jargon and avoiding the use of large amounts of handwritten text, this can prevent any issues with legibility and can reduce human error [10]. This is a key benefit of digital consent as the risks are also standardised and presented in text form, with some software enabling the consents forms to be displayed in different languages. The cost of litigation associated with inadequate informed consent has been increasing across multiple jurisdictions worldwide [11, 12]. Recent systematic reviews suggest that digital consent have no negative effect on patient understanding and may actually improve it, reduce anxiety and improve satisfaction [13, 14].

The introduction of digital consent into a healthcare setting requires changes to processes and ways of working [8]. Alongside the impact on the patient, it is important to consider wider potential consequences associated with a change in practice for obtaining consent including all healthcare workers involved in the consent process. Table 1 highlights the key advantages and potential disadvantages of using digital consent compared with paper consent. Importantly, the cost impact associated with switching to a digital consent pathway is not well understood. Therefore, the aim of this study was to estimate and compare the relative costs and discuss the potential benefits of digital consent pathways with paper-based consent pathways.

2 Methods

This study is a micro-costing study of the consent pathways when consent is obtained using paper or digital forms. A CHEERS Checklist has been completed and can be found in Supplementary Material Table 2.

2.1 Model Overview

The model consisted of two pathways, one for the digital consent pathway the other for paper consent pathway, using a decision tree structure. Figure 1 shows the paper consent pathway with five stages including printing, consent ahead of the day of surgery, storage before surgery, consent on the day of surgery and the pre op checklist. Figure 2 shows the digital consent pathway which only has three steps, consent ahead of the day of surgery, consent on the day of surgery and the pre op checklist. The process-steps in obtaining informed consent for surgical procedures were modelled in MS Excel®. The costs per consent episode attributed to each pathway were compared to identify a preferred consent pathway.

The model was based on the experience of the breast surgery department at Portsmouth Hospital National Health Service (NHS) Trust which acted as a representative surgical department with 110 consent procedures completed per month. Costs were provided in Great British Pounds (GBP).

Portsmouth Hospital NHS Trust were in the process of adopting the Concentric digital health system and therefore well placed to consider the process steps required in consent gained both using a paper-based or digital-based system. Interviews were conducted with clinicians (Senior nurses from breast, urology, ENT, colorectal, an orthopaedic plaster technician and breast clinicians—consultant, trainee and fellow) and non-clinicians (senior manager medical information/photography; breast services administrators, Waiting list co-ordinator, ENT outpatient supervisor, orthopaedic secretary, urology secretary, theatre admission administrators and a deputy coding manager), mean times were used to reach consensus. To better understand the paper-based and digital consent pathways by department and hospital setting, the elements of resource use, patient care, best practice and healthcare professional and patient preferences were discussed.

To apply the insight gained from the interview, a micro-costing study approach was adopted to measure healthcare costs from the UK NHS perspective and considered: staff time, and operational resources needed [15]. The assumptions around each task, its duration and the staff member completing each task are provided in Supplementary Table 1.

Table 1 Potential advantages and potential disadvantages of digital consent

Potential advantages	Potential disadvantages
Patient perspective	Patient perspective
Shared decision-making	**Shared decision-making**
An increase from 28 to 72% of patients reporting gold-standard SDM [23]	Digital consent can potentially deter individuals who are not digital natives
Patient understanding may be improved with consent obtained digitally thanks to more space for lay descriptions and personalised content. In a systematic review of digital tools for obtaining informed consent, the outcome reported the most frequently was patient understanding. In studies with a focus on clinical/surgical procedures, the studies showed a generally positive effect on patient understanding and patient satisfaction but fewer studies showed a positive effect on patient anxiety [6, 13, 14]	Ready made templates can potentially encourage clinicians to avoid discussing consent with patients and utilise digital consent as an administrative tick-box
Digital consent platforms can signpost to other resources that the patients may find useful, such as NHS conditions pages	
Accessibility	**Accessibility**
Digital consent can be personalised to include content that is relevant to patients with disabilities and protected characteristics in accordance with human rights and equality legislation [28, 29]	Digital consent may potentially deter individuals who are not digital native and alienate patients with protected characteristics if not thoughtfully implemented
Digital consent platforms can incorporate functionality that allows reasonable adjustments to be made in the consent process for patients with disabilities and protected characteristics	
Digital consent platforms can signpost to other resources that the patients may find useful, such as NHS conditions pages	
Patient satisfaction	**Patient satisfaction**
Digital consent has been shown to improve patient satisfaction [13, 14]	Some patients may prefer to receive information on paper rather than digitally (however, digital information can be printed for these individuals)
Clinician perspective	Clinician perspective
Clinician satisfaction	**Clinician satisfaction**
Digital consent has been shown to improve clinician satisfaction [13, 14]	There may be some clinicians who are less comfortable with digital forms and therefore it may be difficult to promote engagement and reach the expected efficiency gains if, for example, the form needs to be printed for the patient
Forms are easy to access and remain legible/ are less subject to the pitfalls of carbon copies or photocopies	Network outage can seriously impact the functioning of digital consent
Digital consent platforms allow for dashboard analytics of patient and clinician usage and visibility of the consent forms within the EHR make auditing the consent process easier and more efficient	Digital consent requires hardware, so lack of availability to hardware would negatively impact the process
Institutional perspective	Institutional perspective
Efficiency	**Efficiency**
Reduction in lost forms which would save the time having to redo the consent on the day of surgery and/or prevent procedure cancellations [30]	The consenting process may initially take longer, particularly at the inception of digital consent, as the users learn to use the software
The impact on the patient and the costs to the NHS of a postponed procedure will be significant, particularly in specialties for which there are long waiting lists for procedures	Network outage can seriously impact the functioning of digital consent which can incur a significant financial loss to organisations
The consenting process is not slower and may be quicker using digital forms.	Uncertainty in the cost savings meaning the introduction of digital consent forms may be at an initial cost to the NHS Trusts
Potential of cost saving compared with paper consent forms	As digital consent is new, there may not be a budget line for it which may make the initial purchase difficult
Security	**Security**
Digital Forms are easy to access and remain legible and are not subject to the pitfalls of carbon copies or photocopies	Risk of cyber-attack or unethical hacking of resources resulting in loss of confidential data
Less likelihood of a digital form ending up in the wrong patients notes or being associated with human error of filing records	NHS trusts need to consider how well the digital consent systems conform to national guidance regarding data handling and security. NHS digital has a Cloud First Strategy. Digital consent solutions must be compliant with the annual Data Security and Protection Toolkit Assessment, maintain Cyber Essentials Plus certification and undertake annual external penetration testing
	Network outage can seriously impact the functioning of digital consent and contingency plans will need to be developed

Table 1 (continued)

Institutional perspective	Institutional perspective
Quality	
Easier to be compliant with best practice owing to more standardised elements of the process and less risk of omission of due to lack of standardisation [31]	
Avoidance of potential legal compliance issues related to the use of inadequate consent [1]	
Health service perspective	Health service perspective
Litigation	**Litigation**
Obtaining digital consent has the potential to prevent litigation owing to 'failure to warn'. If patients feel more engaged in the decision-making process, they may be able to understand the potential risks and benefits of the procedures and be able to make more informed choices [11]	Digital consent documentation without adequate discussion of consent with patients will not be legally valid. Therefore, digital consent can be used as a tool but should not replace the patient/clinician meaningful dialogue
If this occurs, not only is there the potential of significant cost savings (approximately £202,000 per claim) to the NHS but also prevention of the added administrative burden and stress to the PALs clinical teams involved in the complaint	
Environmental impact	**Environmental impact**
The carbon impact of the consent process is potentially significantly reduced as paper is removed and consent forms can be stored in net-zero cloud hosting	The environmental impact of training, network infrastructure, electricity consumption and hardware production has not been quantified and may be significant
Remote consent, possible via digital platforms, allows reduction of patient travel miles, enabling consultations to occur from the comfort of the patient's home	Significant efficiencies have been made in paper industry and printing to reduce environmental impact
May contribute to NHS net zero targets, and goals to move towards fully digital care record [32]	

NHS National Health Service, *PALS* patient advice and liaison service, *SDM* shared decision-making

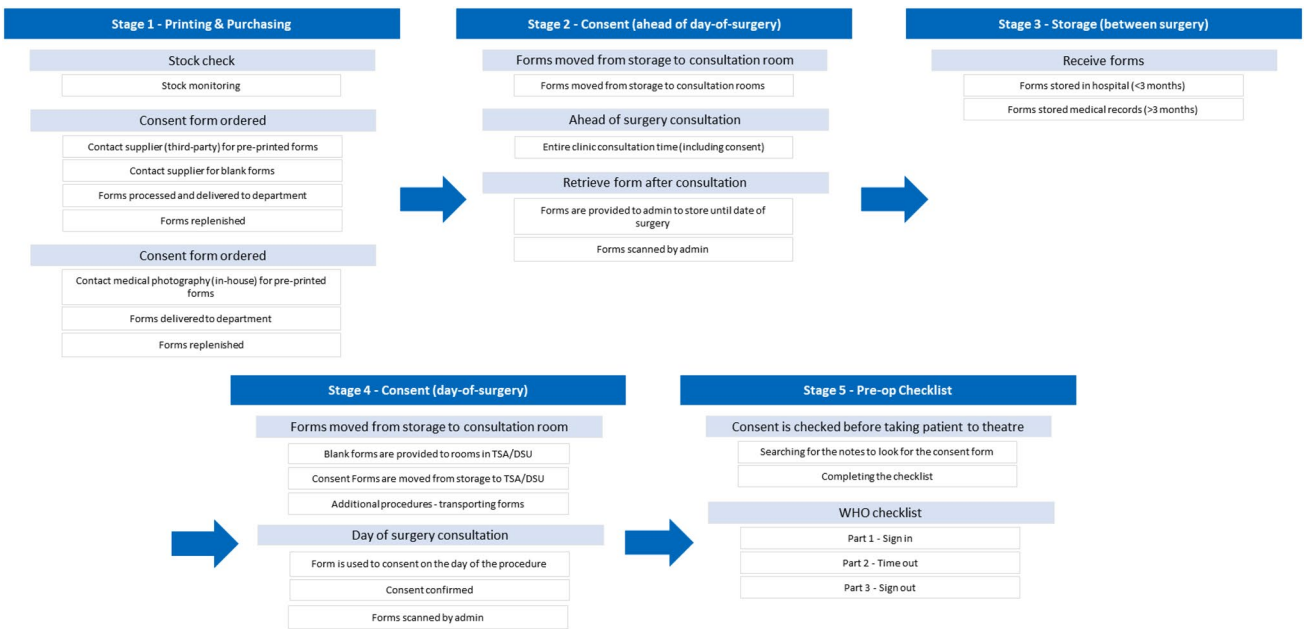

Fig. 1 Paper consent pathway. *TSA* theatre surgical admissions, *DSU* day surgery unit, *WHO* World Health Organization. This figure illustrates an example of the paper consent pathway separated into stages 1–5. It is important to note that parts of this pathway occur with each consent episode and other parts happen irregularly. In the base case the forms are not scanned by admin as this step depends on Trust policy for storing consent forms. The impact of forms being scanned into electronic health records is considered in a scenario analysis

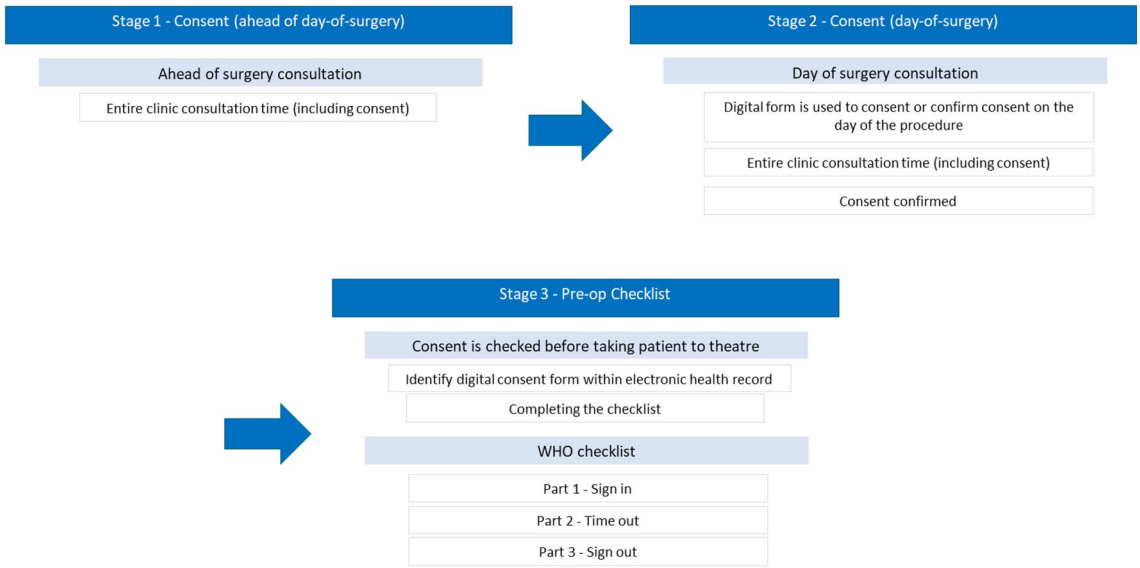

Fig. 2 Digital consent pathway. *WHO* World Health Organization. This figure illustrates an example of the digital consent pathway separated into stages 1–3. It is important to note that parts of this pathway occur with each consent episode and other parts happen irregularly

Sensitivity analysis was performed to identify cost drivers and scenario analyses explored consent timing, digital readiness and any scanning requirements. Discounting was not applied as the time horizon per consent episode was assumed to be less than 12 months.

2.2 Resource Utilization and Cost Data

2.2.1 Consent Procedure Pathway

The staff member responsible for the task, the duration of the task, and the frequency of the task (per week/month or per consent form) were deduced, through the interview process. UK-specific cost data were identified from the Personal Social Services Research Unit 2022/23 (PSSRU 2022/23) which include the cost to the NHS (including employer pension contributions and training costs) [15].

In the model, there were two types of paper consent forms that could be used: pre-printed (including pre-determined procedure specific risks and benefits) and blank template, both with different costs; the rates at which each of these were used would impact the cost of the pathway and was therefore also discussed in the interview process.

2.2.2 Consultation Time

A clinic consultation with the patient includes both a discussion about diagnosis, prognosis and the risks and benefits of all treatment options (including surgical, non-surgical and no treatment), and can also include the completion of the consent form. A surgical consultation costs the NHS approximately £141.00 per hour as identified in the PSSRU. Consultation times were determined by interrogation of allotted clinic times (the time scheduled for clinicians to see a patient) and comparisons between paper and digital pathways investigated with a time and motion study by determining the duration of consent, recorded by an independent observer (health care professional or researcher). The average clinic time allocated for explaining the diagnosis, treatment options, consenting and booking the patient for an operation was 25 min. Consent is then reconfirmed on the day of surgery, which involves a discussion between the surgeon and the patient to ensure understanding, and this process took approximately 5 min. However, significant variation exists owing to factors including the complexity of the diagnosis, a requirement for more investigations and patient preference to take more time to consider treatment options. The average consultation times used for consent in a cohort of patients undergoing breast surgery within the Portsmouth Hospitals University NHS Trust breast unit were found to be the same for both paper (6.9 min, $n = 12$) and digital consent (6.8 min, $n = 19$); therefore, the same times were used as inputs into the model for both pathways, thus not impacting the cost difference.

2.2.3 Fixed Costs of Digital Consent Pathway

The cost of change management will depend on the level of digital infrastructure already in use, and staff training already completed within the hospital settings. In the base case, we assume the equipment required for digital consent is present and already regularly used in clinics and the long-term

costs attributed to the initial setup would be minimal or that consent can be performed through personal devices. Therefore, only ongoing fixed costs of digital consent, such as the licensing fee for use of the digital consent software (Concentric Health Ltd, Cardiff, UK) and any updates that may be required over time were obtained. Scenario analysis was performed where the cost of implementation was considered based on the digital maturity of the hospital.

2.2.4 Litigation

A reduction in consent form error and unintentional omission of core risks could be a key benefit to digital consent. To determine the current scope and cost to the NHS of using paper consent processes, a freedom of information (FOI) request was made to NHS Resolution to establish the number of claims and the damages paid for claims where the primary cause is 'Fail to warn-informed consent' [11]. The freedom of information request was made in August 2022 being fulfilled in September 2022. It covered all of England's 'failure to warn-informed consent' claims that were closed in an 11-year period between 2011 and 2022. These data on total value and number of 'informed consent' claims were used to estimate an average cost per claim of £201,590. The impact on litigation is not included within the micro-costing study but forms part of the CCA.

2.3 Base Case Assumptions

The parameter and cost inputs included in the model base case are described in Table 2, respectively. Guidance from the Royal College of Surgeons states that consent

Table 2 Cost inputs

	Base case inputs	Paper consent		Digital consent	
		Time (minutes per form) or number of forms	Cost per form	Time (minutes per form) or number of forms	Cost per form
Staff costs (unit costs per hour)					
Consultant surgical	£141.00[a]	32	£75.20	32	£75.20
Staff nurse, midwife (entry level), theatre nurse	£48.00[a]	1	£0.80	1	£0.80
CSWN	£40.00[a]	0.02	£0.012	0	£0.00
CSWN higher level, nurse associate practitioner acute	£40.00[a]	6	£4.00	6	£4.00
Porter	£11.48[b]	1.48	£0.28	0	£0.00
Medical secretary/personal assistant	£11.48[b]	0.02	£0.00	0	£0.00
Receptionist	£11.48[b]	0.99	£0.19	0	£0.00
HCA	£11.48[b]	7.16	£1.37	0	£0.00
External provider of consent forms (per form)					
Ordered forms (external)—pre-printed	£0.46 (GAMMA, $\alpha = 25$, $\beta = 0.02$)	88 forms			
Ordered forms (external)—blank template	£0.22 (GAMMA, $\alpha = 25$, $\beta = 0.01$)	22 forms			
% pre-printed forms	80% (BETA, $\alpha = 4$, $\beta = 1.05$))		£0.418		£0.00
Software license and maintenance (per form)					
Software maintenance					£0.29 (GAMMA, $\alpha = 25$, $\beta = 0.40$)
Digital consent software license					£1.08 (GAMMA, $\alpha = 25$, $\beta = 0.40$)
Total costs per form					
		Paper consent	£82.27	Digital consent	£81.37

CSWN clinical support worker nursing, *FY* foundation year, *HCA* Healthcare assistant

[a]PSSRU (2023)

[b]NHS band two with 2+ years' experience based on 37.5-h week

should be obtained in advance of surgery to 'ensure that the patient has sufficient time and information to make an informed decision' [16]. In the base case, all patients provided consent prior to the day of surgery and consent was confirmed on the day of surgery. An equal clinical consultation duration (including consent) of 25 min and reconfirmation of consent on the day of surgery taking 5 min was assumed for both pathways.

The extent to which hospitals use electronic healthcare records (EHR), tablets and mobile devices varies across healthcare providers. In the base case, it is assumed that the digital consent software is accessed through devices which already exist within the hospital (or via the user's mobile phone) and therefore there are no additional fixed costs related to the purchase of hardware. The digital consent web-application works via an internet connection (Ethernet, WiFi, mobile data) on computers, tablets and smartphone devices with all mainstream browsers supported. The costs of using the software and any maintenance costs are included in the licence costs. The digital consent provider acts as a data processor for the Trust and therefore the Trust has control and ownership of the consent content. Scenario analysis estimates the impact of additional fixed costs of hardware based on the level of hospital digital maturity.

All resource use parameters used in the base case were based on observations and estimations of the breast surgery department at Portsmouth Hospital NHS Trust. In the base case, 80% of the consent forms were pre-printed and 20% were blank templates, examples of both are in the supplementary materials. The costs of ordering and moving forms to and from storage are process steps that are not necessary with digital consent. An example of the digital consent framework is also in the supplementary material. Some completed consent forms are placed in storage for more than 3 months whilst the patient waited for an operation, and we determined this occurred in approximately 10% of consent episodes. In a centre with 110 consented procedures per month (Portsmouth Hospital NHS Trust breast surgery department), we identified a paper consent form would have to be collected from storage by a porter every other day.

The costs of retrieving paper health records from archives (including a paper consent form) were restricted to costs of the staff transporting the health records to and from the medical records storage facility within the hospital. This was estimated to take approximately 15 min per day. This does not however consider the transportation of records to an external storage venue which would take significantly longer (or require vehicle transport from the archived records team). There were no assumed costs for storage, nor costs borne by medical records staff who would file the paper consent form, and therefore these costs may be under-estimated.

2.4 Sensitivity Analysis

One-way sensitivity analysis (OWSA) was performed by varying parameter estimates by 20% to identify those parameters which had the greatest influence on the total cost difference. In the absence of published estimates 20% variation was chosen to provide adequate variation to estimate the most influential parameters. Probabilistic sensitivity analysis (PSA) was also conducted (10,000 simulations) to explore overall uncertainty in the estimated costs. Gamma distributions were applied for cost and resource use parameters. For the proportion variables, a beta distribution was applied. NHS hourly rates were not varied in PSA as these are not subject to change; however, the time each healthcare staff member spends on each task was varied in the PSA.

2.5 Scenario Analysis

2.5.1 Consent Timing

To explore the cost impact of consent timing, a scenario of on the day consent was conducted, although this does not fulfil the General Medical Council (UK) requirements of allowing patients time to consider treatment options, on-the-day consent is commonplace in the NHS [4]. The total consultation time (prior and on the day of surgery) was assumed to be the same (30 min) as in the prior consent base case; however, the distribution was different: 20 min for the initial consultation prior to the day of surgery and 10 min for the on the day consultation, which includes obtaining consent. In this scenario 80% of the consent forms used were blank and 20% were pre-printed forms based on estimates of current practice from the interviews where it was stated that mostly blank forms rather than pre-printed forms are used for consent obtained on the day of surgery.

2.5.2 Digital Maturity

To explore the cost impact of digital maturity, changes to the consent process and the hardware required were explored. In each scenario, the cost of digital consent software licensing was included (£1.08 per consent episode) [17]. Some digital consent platforms do not require any additional hardware as they can be accessed via mobile devices, others may need a separate device, or the preference of the user may warrant the purchase of hardware, such as electronic tablets or signature trackpads. As such, scenarios considered cost impacts for hardware to obtain digital consent. The expected lifetime of the hardware, and the resale value were used to calculate the depreciation value. On the basis of a department

performing 110 consented procedures a month, three scenarios were explored that included:

1. A semi-digitally mature hospital department where only one tablet was needed.
2. An immature hospital department where four trackpads and one tablet were needed.
3. A digitally naive hospital department where six track pads and two tablets were required.

2.5.3 Scanning

Some hospital departments have digital aspects to the recording of healthcare episodes and managing patient notes. Therefore, three additional scenarios were explored:

1. A paper consent form completed prior to the day of surgery and was immediately scanned into the EHR for use on the day of surgery.
2. A paper consent form was completed and stored until the day of surgery when it was used to confirm the consent and after the surgical procedure the paper consent form was scanned into the EHR.
3. Paper-based consent was obtained and documented on the day of surgery, it was scanned into the EHR after the surgical procedure was completed.

To ensure the project was patient focussed, we worked with the Patient-Public Involvement (PPI) group at Portsmouth Hospitals University NHS Trust and set up a regular focus group for impact assessment. During study design and implementation, we offered a stabilising, reflective space for development and critique. This study aligns with the PPI group's vision of improving the quality and accessibility of consent for healthcare treatments.

3 Results

In the base case, as described in Table 2, the paper-based consent pathways and the digital consent pathways were associated with an estimated cost of £82.27 and £81.37 per consent episode, respectively.

When only the process elements of the pathway are considered (excluding the digital consent software license fee and the software maintenance), the paper-based consent pathway costs approximately £2.27 more than the digital consent pathway. Consequently, a digital consent product would need to cost less than £2.27 per consent episode to be cheaper than existing paper-based consent workflows.

When we include the cost of a digital consent software license fee and the software maintenance the paper-based pathway is still marginally more expensive than the digital consent pathway (£0.90 per consent episode).

If digital consent contributed to preventing litigation claims where the primary cause was directly related to patient consent, then savings to the NHS could be substantial. On the basis of data collected between 2011/12 and 2021/2022, per litigation claim prevented, an average of £201,590 savings was estimated.

As illustrated in Fig. 3, OWSA demonstrated that any aspect of the pathway that changes the total amount of consultation time needed to obtain consent would have a significant impact on the total costs of obtaining consent. If digital consent was found to save consultation time, each minute would add £2.35 in savings. PSA also demonstrated significant uncertainty in potential savings associated with the digital consent pathway as demonstrated in Fig. 1 of the supplementary materials (the mean of the PSA estimates that paper-based consent pathway costs £0.58 more than the digital consent pathways).

Table 3 provides an overview of scenario analysis findings. Day of surgery consent indicated that the cost per consent episode becomes marginally more expensive (£0.90) when completed digitally than remaining completely paper-based, because archival costs are negated.

Digital maturity scenarios are based on consent being obtained prior to the day of surgery for all patients. Savings were identified for digitally mature hospital departments to digitally naïve hospital departments, from £0.90 to £0.72 per consent episode, respectively. The cost of additional hardware reduces this saving but as the hardware can be used for several years over many consent episodes, and for other purposes, the additional costs per consent episode resulted in the digital consent pathway being less expensive than the paper-based consent pathway.

When the paper consent form is scanned immediately after the clinical consultation prior to the day of surgery, the cost difference reduces to £0.24 (in favour of digital), as the costs of transporting paper records from storage would be removed. When the paper consent form was completed prior to the day of surgery, stored until the day of surgery when it was used in the reconfirmation of consent and after the surgical procedure the paper consent form was scanned into EHR, the cost difference increases to £1.28 as the costs of scanning would be in addition to the other elements of the process pathway. When consent is obtained on the day of surgery and the paper consent form is scanned after the surgical procedure, the costs increase for the paper-based on the day consent pathway resulting in a difference of £0.47.

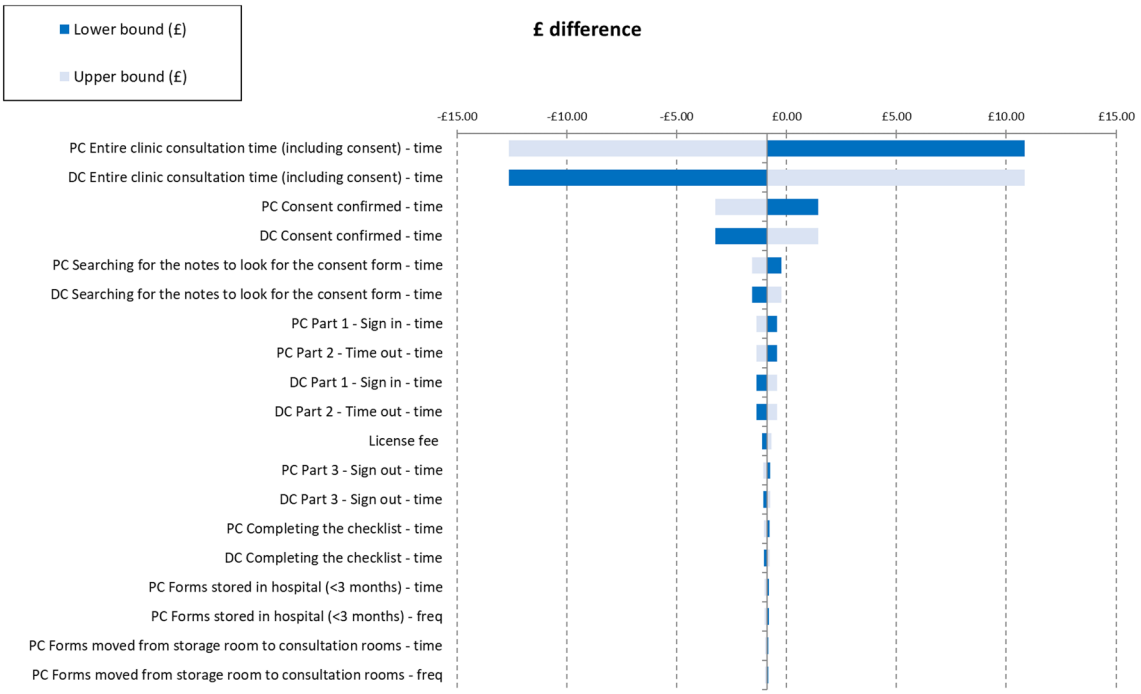

Fig. 3 One-way sensitivity analysis results for total cost of alternative consent pathways. *DC* digital consent, *PC* paper-based consent**.** Relevant model parameters were varied by 20% to characterize uncertainty and examine the potential impact on total cost of alternative consent pathways

Table 3 Scenario analyses findings

Pathway	Total costs per consent episode (total costs without consultation time)		
	Paper consent	Digital consent	Costs difference
Consent scenarios			
All consent prior	£82.27 (£11.77)	£81.37 (£10.87)	− £0.90
All consent on the day of surgery	£80.52 (£10.02)	£81.37 (£10.87)	£0.85
Digital readiness scenarios			
Semi-digitally mature	£82.27 (£11.77)	£81.40 (£10.90)	− £ 0.87
Digitally immature	£82.27 (£11.77)	£81.49 (£10.99)	− £ 0.79
Digitally naïve	£82.27 (£11.77)	£81.56 (£11.06)	− £0.72
Scanning scenarios			
Scan immediately—consented prior	£81.61 (£11.11)	£81.37 (£10.87)	− £ 0.24
Scan after procedure—consented prior	£82.65 (£12.15)	£81.37 (£10.87)	− £ 1.28
Scan after procedure—consented on the day	£80.91 (£10.41)	£81.37 (£10.87)	− £ 0.47

The total cost of consultation time is 30 min of consultant surgical time in all scenarios and both pathways are equivalent to £70.50. This excludes the 2 min to complete the WHO checklist which is not affected by the mode of consent delivery. All consent prior: consent is obtained from all patients in the initial consultation prior to the day of surgery. All consent on the day of surgery: consent is obtained from all patients on the day of surgery. Semi-digitally mature: one electronic tablet purchased. Digitally immature: four trackpads and one electronic tablet purchased. Digitally naïve: six trackpads and two electronic tablets purchased. Scan immediately—consented prior: consent form scanned on the day of initial consultation. Scan after procedure—consented prior: consent form not scanned until after the procedure. Scan after procedure—consented on the day: consent form not scanned until after the procedure

4 Discussion

Healthcare across the world is undergoing digital transformation, which involves integration of digital technologies in all aspects of healthcare. The World Health Organisation promotes implementation of digital technologies by healthcare providers to empower patients and achieve health for all [18]. By 2023, the NHS long-term plan aimed for all secondary healthcare providers to transition to digital records [19]. As services become digital, digital consent is therefore likely to become more widely adopted [20]. The digital consent pathway presents a streamlined consent pathway which could offer cost savings. The paper-based consent pathway poses a significant cost to hospitals when considering costs associated with purchasing, printing, storing, and transport [21]. There are other potential savings which could occur if the frequency of consent-related litigation were to reduce [22].

Potential cost savings associated with the digital consent pathway were mostly impacted by the time the consultant spends obtaining consent for the procedure, with digital maturity and the use of scanning of paper consent also important. The acceptability of the change in process and user experience of any digital consent tool for healthcare professionals and patients are important considerations [8]. Alternative digital consent software providers are likely to have different pricing and maintenance costs and as such, costs per consent episode may therefore vary by provider.

Digital consent has the potential to reduce errors and the risk of lost forms which could result in treatment delays and negatively impact patient experience [8, 23–25]. Digital consent may reduce barriers to care by improving access in the consent process by providing the option to adjust font size, including simplified language and signposting external resources [10]. These benefit suggest that digital consent may be able to reduce the number of failure to warn-informed consent claims which could in turn reduce litigation costs. Concerns about digital security can be mitigated by incorporating digital consent systems that conform to Trust, national and international guidance on data handling and data safety.

Accessibility is important, with concerns often raised about the risk of digital exclusion [26], however the digital consent tool is designed to be used by a clinician with a patient, therefore patients do not require their own hardware but will be provided this within the hospital (as is also the case with pen and paper in hospital). The patient does not need to have access to the internet at home and can be provided with a printed copy of their consent on paper, though the large majority of patients choose to receive a digital copy. The digital consent web-application provides additional accessibility benefits compared with paper [27], such as the ability to change colours, contrast levels, fonts, the ability to zoom and read aloud features for the hard of sight or hearing and text that is as simple as possible to understand. In addition, the digital consent forms are designed to be able to be easily translated into > 100 languages using browser translation tools.

This study presents the first comprehensive cost analysis of the potential benefits and costs of a digital consent pathway compared with paper-based pathways. The micro-costing approach adopted presents a precise assessment of the economic impact for a specific department associated with alternative pathways. Although the costs were estimated from a UK NHS perspective, there are many aspects to the process steps in gaining consent that are common across healthcare systems worldwide. Sensitivity analyses enabled the drivers of cost impacts to be explored and the uncertainty in the estimates to be assessed. Scenario analyses highlighted aspects that may be structurally different between trusts, such as their level of digital provision and infrastructure already in place.

In the UK, most of the consent is currently obtained on the day of surgery, however, this is not best practice and does not fulfil GMC requirements [4, 22]. We therefore chose to demonstrate the paper-based consent pathway using a department (breast surgery) that already practices consent within clinic prior to the day of surgery using paper consent forms in the base case. Consent will be reconfirmed with the patient on the day of surgery on the basis of the initial documentation, and this has been included within the costing based on an estimate provided in the interviews of a 5 min consultation. If consent was obtained using a digital-based system prior to surgery then there should not be a need for paper consent forms for reconfirmation, just access to the original consent form. If consent has not been obtained in advance, then a digital consent system can be used on the day of surgery.

Limitations of this study include that the consent pathway was only analysed until the point of surgery. In addition, costs of information leaflets were not included within the current analysis, and it is anticipated that this inclusion would increase the paper-pathway costs (as digital versions can be made available). Scenario analysis included costs of scanning paper consent into an EHR; however, if not scanned then archiving paper consent forms after surgery would also incur costs. As these costs were not included in this study the potential savings of digital consent may be under-estimated. In hospital trusts that still use paper notes, the notes may need to be moved regardless of whether there is a paper-based consent form contained within the notes. If this is the case the costs of the paper pathway may have been overestimated in this study. Owing to the investment in hardware and initial changes

to processes in trusts that are less digitally mature, the cost savings of digital consent become more relevant the more digitally mature (and less reliant on paper) the hospital is in the short-term. This study was also limited by the availability of data for staff time required to perform specific aspects of both pathways. In practice, the informed consent discussion permeates through a consultation and therefore it was too difficult to determine the exact time spent specifically performing consent in each consultation, therefore, overall clinic time was used. The data came from a single site (Portsmouth Hospital NHS Trust); although broadly representative of surgical consent procedures within the NHS, there may be variation in practice among different surgical departments and hospitals across the country. The experience of digital consent systems was limited to a single system, the Concentric digital health system. However, this system is representative of digital consent systems and the pathway changes that occur as a result of the movement from paper-based consent to digital consent will occur regardless of the digital-consent system employed within the Hospital Trust. The variation in parameters used in the sensitivity analyses were based on broad assumptions and may not reflect the true uncertainty in parameter estimates.

Examining other costs and benefits of digital consent allowed a broader perspective than simply the cost to the hospital to be considered; however, additional evidence on the patient and healthcare professional opinion of digital health systems within the NHS setting would supplement this work.

Digital consent has the potential to introduce an alternative way of obtaining consent and streamline the pathway without increasing costs to the hospital. Clinic consultation duration was estimated to have the greatest impact on the relative costs of both pathways and as such further research is required to explore the assumption of equivalence, evaluate possible impacts on consent-related litigation, and other possible impacts associated with digital consent, such as improvements in the quality of consent and decision-making. A budget impact analysis could be conducted to consider the national and international impact of using digital consent systems. A meaningful dialogue between the patient and clinician is critical for obtaining high quality consent. Therefore, digital consent solutions should act as a tool to facilitate the consent process but should not replace this interaction.

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Declarations

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Ethics approval Ethics approval was not deemed necessary because the study involved anonymous data from patient records only. The study did not involve human experiments or use of human tissue. Using the United Kingdom nationally available HRA research toolkit (https://www.hra-decisiontools.org.uk/ethics), this study was not deemed to require IRAS ethics. This quality improvement study underwent institutional approval by the Portsmouth Hospitals University NHS Trust: Audit QIP ID 5309. Stakeholders participated voluntarily in this study. The methods applied in this study were carried out in accordance with the UK General Data Protection Regulations (UK GDPR) and National Health Service (NHS) Health Research Authority's (HRA's) operational guidance on the implementation of GDPR for health and social care research.

Data availability Additional data are available on request to the corresponding author.

Consent to participate Not applicable.

Consent for publication (from patients/participants) Not applicable.

Code availability Model is available on request to the corresponding author.

Author contributions M.I.H., C.L., A.C., S.T., C.R. and E.S.J. carried out data collection, parameter estimation, supporting model curation; R.H., A.M. and N.A. created the model and implemented the parameter estimations into the model; R.H., M.I.H., A.M., N.A., C.L., A.C., S.T., C.R. and E.S.J. wrote and reviewed the manuscript.

References

1. Chan SW, Tulloch E, Cooper ES, Smith A, Wojcik W, Norman JE. Montgomery and informed consent: where are we now? BMJ. 2017;12(357): j2224.
2. Court TS. Montgomery (Appellant) v Lanarkshire Health Board (Respondent) (Scotland)—The Supreme Court [Internet]. [cited 2023 Oct 27]. Available from: https://www.supremecourt.uk/cases/uksc-2013-0136.html.
3. McKinnon C, Loughran D, Finn R, Coxwell-Matthewman M, Jeyaretna DS, Williams AP. Surgical consent practice in the UK following the Montgomery ruling: a national cross-sectional questionnaire study. Int J Surg Lond Engl. 2018;55:66–72.
4. General Medical Council. Guidance on professional standards and ethics for doctors: decision making and consent [Internet]. 2020 [cited 2023 Apr 11]. Available from: https://www.gmc-uk.org/-/media/documents/gmc-guidance-for-doctors---decision-making-and-consent-english_pdf84191055.pdf.
5. Spatz ES, Krumholz HM, Moulton BW. The new era of informed consent: getting to a reasonable-patient standard through shared decision making. JAMA. 2016;315(19):2063–4.
6. St John ER, Ezzat A, Holford N, Rizki H, Hogben K, Leff DR. Digital consent to improve patient perception of shared decision-making: comparative study between paper and digital consent processes in patients undergoing breast surgery. Br J Surg. 2022;109(11):1172–3.
7. Reeves JJ, Mekeel KL, Waterman RS, Rhodes LR, Clay BJ, Clary BM, et al. Association of electronic surgical consent forms with entry error rates. JAMA Surg. 2020;155(8):777–8.
8. St John ER, Bakri AC, Johanson E, Loughran D, Scott A, Chen ST, et al. Assessment of the introduction of semi-digital consent into surgical practice. Br J Surg. 2021;108(4):342–5.
9. Oshima Lee E, Emanuel EJ. Shared decision making to improve care and reduce costs. N Engl J Med. 2013;368(1):6–8.
10. Owen D, Aresti N, Mulligan A, Kosuge D. Customizable pre-printed consent forms: a solution in light of the Montgomery ruling. Br J Hosp Med Lond Engl 2005. 2018;79(2):97–101.
11. Ainsworth N, Hussain MI, Houten R, Martin AP, Toh S, Rao C, et al. Informed consent failures: National Health Service Resolution data. Br J Surg. 2023;110(8):993–5.
12. Klemann D, Mertens H, van Merode F. Trends and developments in medical liability claims in The Netherlands. Healthcare. 2022;10(10):1929.
13. Kiernan A, Fahey B, Guraya SS, Boland F, Moneley D, Doyle F, et al. Digital technology in informed consent for surgery: systematic review. BJS Open. 2023;7(1):zrac159.
14. Gesualdo F, Daverio M, Palazzani L, Dimitriou D, Diez-Domingo J, Fons-Martinez J, et al. Digital tools in the informed consent process: a systematic review. BMC Med Ethics. 2021;22(1):18.
15. Personal Social Services Research Unit (PSSRU). 2024. [cited 2024 Jul 17]. Unit costs database of health and social care professionals 2022/23. Available from: https://doi.org/10.22024/UniKent/01.02.105685.
16. sitecore\ddean@rcseng.ac.uk. Royal College of Surgeons. [cited 2023 Oct 27]. 3.5.1 Consent. Available from: https://www.rcseng.ac.uk/standards-and-research/gsp/domain-3/3-5-1-consent/.
17. G-Cloud 13-CCS [Internet]. [cited 2023 Oct 27]. Available from: https://www.crowncommercial.gov.uk/agreements/RM1557.13.
18. 9789240020924-eng.pdf [Internet]. [cited 2023 Oct 27]. Available from: https://iris.who.int/bitstream/handle/10665/344249/9789240020924-eng.pdf?isAllowed=y&sequence=1.
19. NHS Long Term Plan [Internet]. [cited 2023 Oct 27]. Available from: https://www.longtermplan.nhs.uk/.
20. Parsons SL, Daliya P, Evans P, Lobo DN. Digital informed consent: modernising information sharing in surgery to empower patients. World J Surg. 2023;47(3):649–57.
21. Fukuda H, Imanaka Y, Kobuse H, Hayashida K, Murakami G. The subjective incremental cost of informed consent and documentation in hospital care: a multicentre questionnaire survey in Japan. J Eval Clin Pract. 2009;15(2):234–41.
22. Getting It Right First Time (GIRFT) & NHS Resolution. Learning from litigation claims [Internet]. 2021 [cited 2023 Jun 14]. Available from: https://www.gettingitrightfirsttime.co.uk/wp-content/uploads/2021/05/Best-practice-in-claims-learning-FINAL.pdf.
23. Dyke R, St-John E, Shah H, Walker J, Loughran D, Anakwe R, et al. Comparing shared decision making using a paper and digital consent process. A multi-site, single centre study in a trauma and orthopaedic department. Surg J R Coll Surg Edinb Irel. 2023;21(4):235–41.
24. St John ER, Scott AJ, Irvine TE, Pakzad F, Leff DR, Layer GT. Completion of hand-written surgical consent forms is frequently suboptimal and could be improved by using electronically generated, procedure-specific forms. Surgeon. 2017;15(4):190–5.
25. Chhin V, Jerry R, Terry M, Sophie F. Leveraging the benefits of mobile technology to improve the efficacy of the consent-to-treatment process. J Med Imaging Radiat Sci. 2016;47(1):S2.
26. Age UK. 2023. *Offline and Overlooked*. Retrieved from [Age UK website]. https://www.ageuk.org.uk/globalassets/age-uk/documents/reports-and-publications/reports-and-briefings/offline-and-overlooked-report.pdf.
27. Concentric Health. (2021). Accessibility statement. Retrieved from. Retrieved from [Concentric Health website]. https://concentric.health/standards-policies/accessibility-statement/.
28. United Kingdom Government. Human Rights Act 1998 [Internet]. 1998 [cited 2023 Jul 17]. Available from: https://www.legislation.gov.uk/ukpga/1998/42#:~:text=1998CHAPTER42,Rights%3Bandforconnectedpurposes.
29. United Kingdom Government. Equality act 2010 [Internet]. 2010. Available from: https://www.legislation.gov.uk/ukpga/2010/15/contents.
30. Missing consent forms in the preoperative area: a single-center assessment of the scope of the problem and its downstream effects | Medical Education and Training | JAMA Surgery | JAMA Network [Internet]. [cited 2023 Oct 27]. Available from: https://jamanetwork.com/journals/jamasurgery/fullarticle/1710508.
31. CONSENT: SUPPORTED DECISION-MAKING a guide to good practice [Internet]. The Royal College of Surgeons of England; [cited 2023 Oct 27]. Available from: https://www.rcseng.ac.uk/-/media/files/rcs/standards-and-research/standards-and-policy/good-practice-guides/new-docs-may-2019/rcs-_consent-supported-decision-making.pdf.
32. Delivering a 'Net Zero' National Health Service [Internet]. [cited 2023 Oct 29]. Available from: https://www.england.nhs.uk/greenernhs/wp-content/uploads/sites/51/2022/07/B1728-delivering-a-net-zero-nhs-july-2022.pdf.

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