Global considerations for informed consent with shared decision-making in the digital age

Edward Robert St John[1,2,3] Connor James Stewart Moore,[3] Raghu Ram Pillarisetti,[4] Erica Sarah Spatz[5]

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[1]Department of Breast Surgery, Portsmouth Hospitals University NHS Trust, Portsmouth, UK
[2]University of Portsmouth, Portsmouth, UK
[3]Concentric Health, Cardiff, UK
[4]KIMS-USHALAKSHMI Centre for Breast Diseases, Krishna Institute of Medical Sciences Secunderabad Hospital, Secunderabad, India
[5]Section of Cardiovascular Medicine, Yale School of Medicine, New Haven, Connecticut, USA

Correspondence to:
Mr Edward Robert St John, Department of Breast Surgery, Portsmouth Hospitals University NHS Trust, Portsmouth, UK; edward.stjohn@porthosp.nhs.uk

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Background

Shared decision-making (SDM) is increasingly recognised as fundamental to patient-centred care and enabling patients to make voluntary, informed decisions about their health.[1] SDM is the process whereby patients and clinicians come together to share their expertise. The patient acts as an expert of themselves, understanding their own preferences and their attitudes to risk. The clinician is an expert on the medical knowledge and scientific evidence. Together, treatment options should be explored, arriving at a treatment decision that is right for the patient and supported by the clinician. When dealing with invasive or high-risk procedures (eg, operations, chemotherapy, radiotherapy, immunotherapy), once the treatment decision has been made, the conversation turns to informed consent. This is the process of communicating and agreeing to the potential risks and benefits of the procedure, while acknowledging that there are alternative treatment options that have not been chosen. Though informed consent should be the culmination of SDM, alone it does not encapsulate the entire process. There is a distinction between decision-making and consent and this should ideally be accompanied by a period for reflection. Despite advances in SDM, the subsequent informed consent process has remained stagnant, often failing to meet ethical or legal standards of supporting meaningful patient autonomy.[2]

In reality, rapid surgical decisions may be required (e.g. emergency or cancer pathways), where time is a precious commodity to deliver optimal patient care. In these scenarios, it is common for discussions to move quickly from diagnosis to treatment options, to consent. However, scarcity of clinician time should not be an excuse for inadequate consent. Therefore, reimagining the consent process in the digital age by ensuring the benefits, risks and alternative treatment options are clearly and correctly presented as early as possible, has the ability of transforming this step from a ritualised gesture into a channel for improving health communication and incorporating the later principles of SDM.[3]

This article aims to educate about the variety of existing consent approaches, highlights legal and cultural complexities and describes emerging solutions to advance ethical, personalised consent in the digital age.

The global landscape of consent

Globally, consent laws and practices differ, shaped by differing legal standards, decision-making norms and bioethical perspectives.[4] Though the authors do not claim to know consent practice in every country and culture, many jurisdictions expect physicians to disclose information that a 'reasonable doctor' would provide, judging adequacy by professional custom.[5] However, in a number of jurisdictions, for instance, the UK and many states within the USA, a more patient-driven standard is applied, requiring doctors to disclose risks a reasonable patient would want to know.[1 2] The landmark UK Supreme Court ruling (Montgomery v Lanarkshire Health Board [2015] UKSC 11) requires doctors to disclose any 'Material Risks', interpreted broadly as a risk a reasonable patient would attach significance to. This means that even remote risks are relevant if they could impact the patient's decision-making.

Timing of consent is important, with 'time for consideration' described by some regulators as an essential requirement to empower the patient and enable decision-making (eg, Decision Making and Consent, General Medical Council, UK). Importantly, this means having the consent discussion for an elective procedure in advance of the day of surgery, a practice which is still surprisingly uncommon around the world.[6] This has been backed up legally in the UK with the supreme court requiring 'adequate time and space' to be provided for a consent dialogue (Thefaut v Johnston [2017], EWHC 497 (QB)). However, standards may differ depending on the urgency of the surgery, with time for consideration expected for elective procedures but not necessarily required for more urgent procedures; for example, an emergency caesarean section, where oral consent may be acceptable. Cosmetic surgery is an example of a non-urgent, non-essential procedure, where many countries mandate stricter disclosure of risks personalised to the individual patient.[5]

The cost of litigation as a result of 'failure to warn' is increasing, particularly in western cultures.[7] In the USA and UK, patients typically bear the burden of demonstrating they suffered an injury due to inadequate risk disclosure. However, in Germany and France, the burden of proof falls on physicians to show they provided sufficient information.[5] Sweden, Finland and New Zealand are examples of countries who take a 'No-fault' approach to compensating for injury received while undergoing treatment. There is still the need

Table 1 Evidence-based rationale behind recommendations of steps to achieving patient-centred consent

Steps to patient-centred consent	Rationale
Standardise content	Standardised forms rationalise risk communication for procedures. Templates ensure patients receive consistent, comprehensive information.[13]
Discuss alternatives	SDM principles require that all reasonable options are discussed with patients before arriving at a treatment decision.[1]
Allow time	Absorbing new concepts requires reflection. Consent should ideally occur days to weeks before treatment. Time enhances information recall dramatically.[12]
Use multimedia	Videos and images boost patient understanding of complex interventions.[15]
Accommodate disabilities	Facilitate multisensory communication to overcome vision/hearing/cognitive limitations.[19]
Translate information	Important in regions with multiple languages and dialects (eg, India has 22 official dialects).
Employ user-centred design	Optimised design, such as simplified text and easily readable forms can overcome barriers to comprehension.[19]Important for communities with low health literacy.
Measure outcomes	Readily auditable forms allow for ongoing assessment of quality and adherence to local guidelines. Patient and clinician feedback allows for iterative improvements of digital consent.

SDM, shared decision-making.

to prove that injury has occurred, but no one individual or institution is at fault, and compensation is granted or denied based on eligibility rather than due to the negligence of the provider. Though this does not directly change the requirements of informed consent, it does shift the emphasis of blame away from the clinician with potential implications to the consent process. Interestingly, those countries that use this 'no-fault' approach, report a lower medical malpractice spend than those who do not.[8]

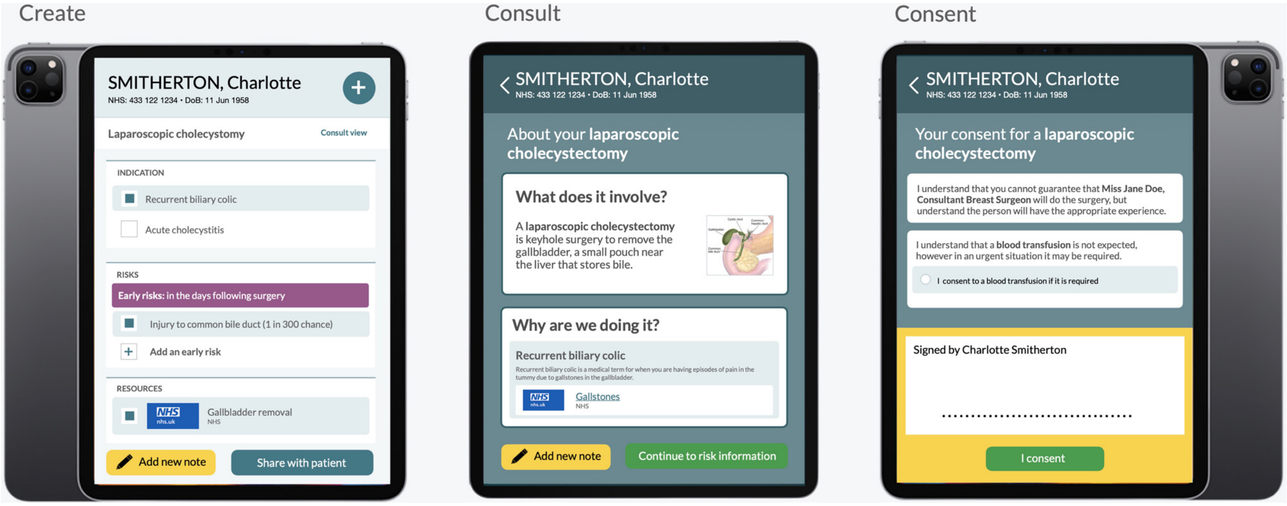
Beyond the legal system, cultural expectations vary. Greco-based bioethics emphasise individual autonomy, whereas some cultures prioritise physician authority[4] with many Asian and African countries favouring a more paternalistic model. In the paternalistic model,[9] healthcare professionals can obtain patients' signatures authorising consent to a procedure without substantive information exchange or counselling. Another divergence is the level of family involvement; for example, countries such as India and China,[5] where cultural norms often lead to treatment decisions being made collectively with relatives, rather than relying on individual autonomy.

Communication in real-world consent conversations is frequently inadequate and prone to error.[10] Common deficiencies include a lack of detail about risks, benefits, and alternatives, use of complex medical jargon, and failure to ensure patient comprehension.[10] This disconnect between robust legal standards and suboptimal clinical practices highlights how changing laws is insufficient without also addressing systemic and cultural barriers that perpetuate physician-centric consent processes over meaningful SDM and informed consent.

Realising patient-centred consent

Well-executed consent is associated with better healthcare experiences.[11] However, consent frequently remains centred around obtaining a signature rather than facilitating patient understanding. Clinicians face time pressures, information recall overload and difficulty conveying complex options.[1] Patients struggle to comprehend concepts such as risks or alternatives.[12] Consent conversations often occur in stressful environments and unsurprisingly, patients routinely emerge with limited understanding of what they have agreed to.[1 12]

The implications of inadequate consent span from mental distress to physical harm.[11] Deficiencies in consent conversations have sparked malpractice litigation worldwide.[2 13] Patients who feel uninformed about options may experience regret after surgery or loss of trust in the medical system. Missed opportunities for SDM and misaligned expectations frequently culminate in poorer clinical outcomes, psychological impacts and increased healthcare



SMITHERTON, Charlotte
NHS: 433 122 1234 • DoB: 11 Jun 1958

Laparoscopic cholecystomy

INDICATION
■ Recurrent biliary colic
☐ Acute cholecystitis

RISKS
Early risks: in the days following surgery
■ Injury to common bile duct (1 in 300 chance)
+ Add an early risk

RESOURCES
■ Gallbladder removal
NHS

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About your **laparoscopic cholecystectomy**

What does it involve?

A **laparoscopic cholecystectomy** is keyhole surgery to remove the gallbladder, a small pouch near the liver that stores bile.

Why are we doing it?

Recurrent biliary colic

Recurrent biliary colic is a medical term for when you are having episodes of pain in the tummy due to gallstones in the gallbladder.

Gallstones
NHS

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Your consent for a **laparoscopic cholecystectomy**

I understand that you cannot guarantee that **Miss Jane Doe, Consultant Breast Surgeon** will do the surgery, but understand the person will have the appropriate experience.

I understand that a **blood transfusion** is not expected, however in an urgent situation it may be required.

○ I consent to a blood transfusion if it is required

Signed by Charlotte Smitherton

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Figure 1 Example of a fully digital consent workflow. Create: A digital consent form is customised from a procedure specific database. Consult: Information is shared with the patient and is accessible during and outside of a consultation. Consent: Typically, patients can consent using an electronic signature, with the form integrated into the electronic healthcare record. Figure reproduced by permission of Concentric Health, Cardiff, UK.

Table 2 Opportunities of digital consent and evidence-based rationale

Digital opportunities	Rationale
Time for consideration	Patients can review information before or after appointments (including remotely), when less pressured.
Standardisation	Digital templates integrate animation and standard text to avoid oversights and ensure readability.[12 20]
Documentation	By retaining accessible records, digital consent may help address challenges with fragmented documentation across disconnected hospital systems.
Environmental	Decreasing paper usage and allowing remote consent opportunities decreases carbon impact.
Equity and accessibility	Well-designed technology can bridge access barriers related to disability, language or health literacy.
Streamlining	Paperless and remote workflows improve efficiency, allow easy sharing with family and friends and electronic signatures can simplify operational workflows.[10]
Monitoring and outcome collection	Digital systems collect data to identify improvements.

cost.[7 12 13] SDM should enable and enhance the informed consent process, with clinicians eliciting preferences and guiding deliberation. To achieve this, there is evidence that the steps outlined in table 1 can help healthcare systems achieve patient-centred consent.

Modernising consent in a digital age

Paper problems

Presently, paper-based consent forms have well-documented limitations in meeting the above patient-centred standards. Use of paper leads to increased form errors, incomplete documentation and lost or misplaced forms.[10 13 14] Paper cannot synthesise information at scale or capture the nuances of the full patient–provider conversation.

Digital opportunities

Digital consent tools offer the potential to facilitate high-quality consent aligned with patients' needs and preferences and can enable detailed assessment of consent processes and quality (figure 1). Online applications enable convenient access to multimedia materials and efficient translation[15] with multimedia tools demonstrated to have a higher impact than videos only.[16] Digitally supported SDM embeds consent within collaborative decision-making, creating meaningful interactions.[3] Recent systematic reviews have concluded that digital technologies for informed consent decreased error rates[13] and had a positive effect on early comprehension, without any negative effect on satisfaction, anxiety[17] or consent outcomes.[16] This suggests potential benefits may be realised by using digital consent without causing detriment. The opportunities provided by digital consent are described in table 2.

Digital risks

While digital applications enable more personalised interactive consent (eg, with the combined use of text, audio and visual formats), digital divides persist with varying personal preferences for paper or digital processes and with resource disparities excluding marginalised groups from digital access. Digital literacy also varies demographically and geographically. If not thoughtfully designed with inclusivity in mind, digital consent could inadequately serve populations lacking technology proficiency, including elderly and disabled patients. Hospitals lacking electronic infrastructure may not be able to effectively implement digital consent without broader system-wide digitisation. However, perhaps digital access is less of a barrier than often perceived with the global exponential growth in smartphone usage, for example, the Cisco Annual Internet Report (2018–2023) demonstrates that over 70% of the global population will have mobile connectivity by 2023.

Digital technologies have been associated both positively by supporting and negatively by interfering with patient–clinician interactions.[18] A significant risk to digitisation of the consent process is that the 'meaningful dialogue' between the doctor and the patient is inappropriately replaced with an interaction with the digital tool alone. Currently, digital consent providers endeavour to emphasise the importance of maintaining the clinical conversation, and therefore, digital consent acts as a synergistic tool rather than a replacement of the consent process. While asynchronous and/or remote digital consent allows for operational efficiency and more time for reflection, some patients may prefer in-person conversations for complex decisions.

Learning points and take-home message

Ultimately, patients worldwide deserve consent processes that facilitate their understanding and empower them to select the treatment that is right for them. Time for consideration is crucial and we strongly encourage consent discussions to be performed in advance of the day of surgery, where appropriate, to allow adequate time for reflection. As emerging technologies reshape healthcare communication, we have an unprecedented opportunity to redefine consent as a mechanism for advancing patient autonomy globally. This requires reconciling legal norms, decision-making values and practical realities across diverse societies. Consent laws warrant modernising to emphasise SDM ethics over formalised disclosures. Patients' values should steer information exchange, clinicians need support and incentives to prioritise understanding, and healthcare systems must implement structural changes to enable the compassionate informed conversations at the core of SDM. Regardless of location, culture and technological readiness, it is the communication between the doctor and the patient which is paramount for high-quality SDM and informed consent, therefore, digitisation must enhance rather than replace this process.

X Edward Robert St John @ercstjohn and Raghu Ram Pillarisetti @RRPillarisetti

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ORCID iD
Edward Robert St John http://orcid.org/0000-0002-7306-6954

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