

Virtual consent for virtual patients: benefits of implementation in a peri- and post-COVID-19 era

The COVID-19 pandemic has caused major disruptions to the healthcare system, including increased reliance on virtual services, particularly clinic appointments. This leads to difficulty in obtaining informed consent; the vast majority of patients now need to be consented on the day of the procedure. To reduce problems with this process, the practice of obtaining electronic consent may be the correct way forward.

Subhabrata Mukherjee¹

Asif Raza^{1,2,3}

Author details can be found at the end of this article

Correspondence to:

Subhabrata Mukherjee;
smsubhabrata@gmail.com

The COVID-19 pandemic has caused major disruptions in the provision of healthcare for patients. A significant change includes the increased reliance on virtual services, particularly clinic appointments (Gilbert et al, 2020).

For patients who have to undergo an investigation or procedure, an important part of a clinic visit is the discussion regarding this and obtaining informed consent from the patient. The General Medical Council (2008) states that consent can be implied, given orally for simpler procedures or written for more complex interventions. The Royal College of Surgeons of England (2018) recommends that written consent, signed by the patient, should be obtained at the clinic visit. The same consent form can be used on the day of surgery, as long as a significant period of time has not elapsed between the two events. A specific time period has not been defined by the Royal College of Surgeons. The clinician would normally be expected to make a judgment regarding an appropriate time period based on factors such as the patient's cognitive status and ability to retain and understand the information provided by the clinician. However, the COVID-19 pandemic has led to most preoperative clinic visits now being virtual, taking place by telephone or video consultation, and thus a written consent form cannot be obtained before the procedure or investigation. The pandemic has also caused substantial delays in planned procedures and therefore, on the day of the procedure, patients may have forgotten the information provided to them at the clinic they attended before the pandemic started.

Challenges in obtaining informed consent

The process of obtaining informed consent in this situation poses considerable challenges to both the patient and doctor. From a patient's perspective, they may have forgotten the initial discussion that they had about their procedure during the previous clinic and therefore may feel that they are signing a consent form on the day of surgery without all the knowledge and understanding they need to make an informed decision. From a doctor's perspective, they may be under time pressure to obtain consent in order to maintain effective theatre use and minimise on-the-day cancellations.

Additionally, incomplete manually filled consent forms may contain illegible writing, use abbreviations or omit vital information such as patient details, hospital numbers, important benefits, complications and alternative treatments. Chong et al (2018) performed an audit of 4805 procedure consent forms over a 1-year period. They found that every month, 15% of consent forms were invalid as they were not completed correctly. This failure in the consent process may lead to medicolegal problems and subsequent litigation.

A study involving a freedom of information request on litigation claims against the NHS around consent found that, between 2015 and 2019, there were 2300 cases relating to a failure in the informed consent process (Wald et al, 2020). Litigation costs rose year by year, with a fourfold increase over the 4-year period, and in 2019 reached £62 million. The authors claim that the Montgomery ruling has made it easier for lawyers to pursue claims. The Montgomery ruling states that while taking consent for a procedure, the doctor should make the patient aware of the possible 'material risks', which a reasonable person in the patient's position

How to cite this article:

Mukherjee S, Raza A. Virtual consent for virtual patients: benefits of implementation in a peri- and post-COVID-19 era. *Br J Hosp Med.* 2020. <https://doi.org/10.12968/hmed.2020.0368>

would like to take into account before making a decision (Chan et al, 2017). Therefore, it is vital that enough time is given to both the doctor and patient to discuss not only the benefits but also the risks and alternatives to the procedure or test being recommended.

Electronic consent

In order to reduce the incidence of problems around obtaining manual consent, the use of electronic consent is increasing. Electronic consent has been used for research participants (NHS Health Research Authority, 2018) and is now being adopted by some NHS trusts for treatment (Meek, 2015).

There are several benefits of electronic consent. First, using a standard electronic consent form with check boxes and the option of customisation will ensure all important points listed on the form are discussed. Second, consent forms are easily accessible by patients, allowing them sufficient time to understand and further investigate their options before signing it. Third, the data recorded by electronic consent forms can be audited more easily and therefore help identify errors in completed forms. Finally, electronic alerts can be sent to the medical team if the period of time that has elapsed is thought to be too long and the patient needs to give consent again before the procedure. However, obtaining consent electronically may be more difficult or inappropriate in those lacking capacity or those with hearing or visual impairment.

Electronic consent can be structured as general consent (opt in), general denial (opt out), general consent with specific denials, and general denial with specific consents. If a patient portal is used, it should include interactive multimedia tools to make it easier for patients to understand procedures and should be produced in multiple languages. With the use of teleclinic technologies, translators can more easily join a video consultation, allowing a more detailed and accurate discussion around investigations, treatment and consent.

An electronic consent form can be generated at the time of the remote consultation with the patient. The patient is sent a secure electronic link or text message to their phone, which opens up a secure link. The patient clicks on the link, which opens up an electronic consent form on their phone or other electronic device. The patient can sign the form electronically with a digital signature. Once completed, it automatically returns electronically to a secure hospital server via an encrypted transfer. The electronic consent form is subsequently sent back to the patient administration system or electronic patient record by an outbound health level seven medical document management message and is available for the doctor to review before the procedure or investigation. Patients can also keep a portable data format (PDF) copy of the consent on their phone or computer, or print out a copy for their records. Data security can be enhanced by various processes, such as blockchain-based hashing and time stamping. This allows better data security by extraction of a cryptographic identifier. The General Data Protection Regulations, which are part of the Data Protection Act 2018, should be followed with respect to maintaining the privacy of the individual as well as security of the individual's data, including the electronic consent form.

Abujarad et al (2018) developed a web-based mobile health application to enhance patients' understanding and engagement while making informed decisions. They designed a patient-centred tool that comprises virtual coaching with text-to-speech automated translation, interactive graphics, videos, animations and presentations. The informed consent process is also completed electronically.

Another way to obtain consent electronically during a virtual consultation could be by recording the conversation with the patient's permission. The confirmation of consent would be kept in the patient's record. Recording an audio or video file as evidence of the consent discussion would have the advantage of keeping a record not only for the patient but also one that other healthcare staff could access if necessary. Potential drawbacks of recording consent in this manner could be less engagement by clinicians for fear of litigation if their consent had not been adequate. However, if the consent procedure is performed in a standardised manner, using standardised consent forms pre-populated with all necessary information, the risk of litigation will be minimised.

Development and implementation of a safe and efficient electronic consent process needs investment of time and resources. In addition, involvement of the regulatory authorities such as the General Medical Council, the Medicines and Healthcare products Regulatory

Key points

- The COVID-19 pandemic has caused increased reliance on virtual clinic appointments; obtaining written consent for a procedure or investigation is not presently possible from a preoperative telephone or video consultation.
- The pandemic has caused substantial delays to planned procedures; therefore, on the day of the procedure, patients may have forgotten the information provided to them at their previous face-to-face clinic visit.
- The majority of patients now need to give consent on the day of the procedure, which not only may reduce theatre utilisation time and consequently lead to on-the-day cancellations, but can also increase the risk of subsequent litigation as paper consent forms filled under time pressures may omit vital information.
- Obtaining electronic consent at the virtual preoperative clinic may reduce the incidence of problems around obtaining manual consent on the day of the procedure.
- Electronic consent can be provided from a virtual clinic and the patient can have a copy of the consent form to consider well in advance of the procedure. Using an electronic consent form prepopulated with all the necessary information will lessen the risk of potential harm to the patient and therefore lessen medicolegal litigation.

Agency and the medical defence bodies is necessary. However, it is likely that virtual consent will become increasingly necessary and perhaps the standard way of obtaining informed consent in the future, in an ever-increasing virtually delivered healthcare system.

Author details

¹Department of Urology, Northwick Park Hospital, London North West University Healthcare NHS Trust, UK

²Department of Medicine, Plymouth University Peninsula School of Medicine, Plymouth, UK

³Medical School, Imperial College London, London, UK

References

- Abujarad F, Alfano S, Bright TJ et al. Building an informed consent tool starting with the patient: the patient-centered virtual multimedia interactive informed consent (VIC). *AMIA Annu Symp Proc.* 2018;2017:374–383
- Chan SW, Tulloch E, Cooper ES et al. Montgomery and informed consent: where are we now? *BMJ.* 2017;357:j2224. <https://doi.org/10.1136/bmj.j2224>
- Chong W, Fong ACY, Yeo YL et al. Reducing the number of invalid surgical consents in the day surgery unit. *BMJ Open Qual.* 2018;7(1):e000167. <https://doi.org/10.1136/bmjopen-2017-000167>
- General Medical Council. Consent: patients and doctors making decisions together. 2008. <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/consent> (accessed 7 July 2020)
- Gilbert AW, Billany JCT, Adam R et al. Rapid implementation of virtual clinics due to COVID-19: report and early evaluation of a quality improvement initiative. *BMJ Open Qual.* 2020;9(2):e000985. <https://doi.org/10.1136/bmjopen-2020-000985>
- Meek T. Worcestershire markets eConsent tool. 2015. <https://www.digitalhealth.net/2015/06/worcestershire-markets-econsent-tool/> (accessed 7 July 2020)
- NHS Health Research Authority. HRA and MHRA publish joint statement on seeking and documenting consent using electronic methods (eConsent). 2018. <https://www.hra.nhs.uk/about-us/news-updates/hra-and-mhra-publish-joint-statement-seeking-and-documenting-consent-using-electronic-methods-econsent/> (accessed 7 July 2020)
- Royal College of Surgeons of England. Consent: supported decision-making. 2018. 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 (accessed 7 July 2020)
- Wald DS, Bestwick JP, Kelly P. The effect of the Montgomery judgment on settled claims against the National Health Service due to failure to inform before giving consent to treatment. *QJM.* 2020;hcaa082. <https://doi.org/10.1093/qjmed/hcaa082>