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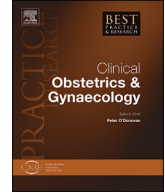
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Contents lists available at ScienceDirect

Best Practice & Research Clinical Obstetrics and Gynaecology

journal homepage: www.elsevier.com/locate/bpobgyn

COVID-19 in Women's health: Pre-operative gynaecological assessment and shared decision making

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A B S T R A C T

Keywords:

COVID-19 pandemic
Gynaecological services
Prioritisation
Consent
Pandemic response

The National Health Service (NHS) response to the coronavirus disease 2019 (COVID-19) pandemic brought about rapid and innovative changes to surgical care in gynaecology, shared decision making around operative procedures and pre-operative gynaecological pathways. Short-term changes are linked to the redeployment of resources away from elective gynaecology and long-term changes relate to accelerating the streamlining of treatments, telemedicine and education in patient self-management. The speed and recency of the response does not yet permit the creation of a large evidence base for effective and acceptable interventions, apart from anecdotal observations of 'what works well' good practice and guidance from the Royal Colleges and the National Institute for Health and Care Excellence (NICE).

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Introduction – UK background 2020

Little is published on how to best deliver pre-operative women's health care during the coronavirus disease 2019 (COVID-19) pandemic, which precludes a systematic review of evidence. There are no core outcome sets linked to pre-operative gynaecological assessment and shared decision making. This

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knowledge gap should be taken into account when planning future studies in this field. The current paper reflects the knowledge at the time of writing (January 2021).

The year 2020 has seen several lockdowns affecting the National Health Service (NHS) in England due to the worldwide COVID-19 pandemic. Especially during first lockdown, the NHS resources were largely diverted to care for COVID-19 patients and avoidance of nosocomial infection with considerable impact on benign routine surgical gynaecological care. The first lockdown saw a wide-ranging redeployment of anaesthetic staff from operating theatres to critical care, operating theatres used for care of COVID-19 patients and gynaecologists redeployed to obstetric services. Apart from redeployment, the workforce was also impacted by sickness from COVID-19, shielding and child care commitments. A reduction of elective activities protected patients from in-hospital viral transmission and associated post-operative pulmonary complications [1].

Following the temporary severe reduction or cessation of elective clinics and surgery during the first wave of the pandemic in spring 2020, there was a recommencement with national variations during the second wave, but as of January 2021, another reduction of elective services has happened.

Comparing figures provided by the NHS England with equivalent figures for the past two years, the British Medical Association (BMA) estimated that between April and June 2020, there were up to 1.5 million fewer general and acute admissions, up to 2.6 million fewer first general and acute outpatient attendances, around 280,000 fewer urgent cancer referrals, up to 25,900 fewer patients starting first cancer treatments following a decision to treat and up to 15,000 fewer patients starting first cancer treatments following an urgent general practitioner (GP) referral [2]. Modelling was performed to estimate cancellations of surgical procedures which showed that in the UK during the 12-week peak of major service disruption from COVID-19 in spring 2020, the cancellation rate for gynaecological cancer operations was estimated at 39.3% (from $n = 834,839$ to $n = 328,505$) and for benign gynaecology, 81.6% (from $n = 2,665,361$ to $n = 2,175,774$) [1].

Based on the average cost of £4000 per operation, it will cost more than £2 billion to clear the backlog of all surgeries cancelled in the UK [1]. Cancellations along patient pathways have led to a growing pool of patients being delayed on their patient journey, awaiting primary care appointments, secondary care referral or surgery. In the autumn of 2020, the NHS had undergone a phase marked by an attempt to catch up on previously cancelled surgery. Given the unpredictable future of the pandemic, and the impact of the faster-spreading COVID-19 variant B.1.1.7, intermediate and long-term planning is challenging. Even though the vaccination programme has been started, it will take time and resources for the NHS to get into a recovery phase and clear the backlog of gynaecological outpatient appointments and surgery. Moving back to the previous status quo may not be possible or desirable. Without doubt, some changes to the way, we deliver care will stay for good. In particular, the advance of practices in virtual medicine as a means to communicate with patients and health care professionals is likely to shape the face of medicine after the pandemic. Given the speed with which the adaptations were made and the absence of agreed core outcome sets, it is paramount that in the future, the service user's voice will be integrated, ensuring our novel ways of working are acceptable to service users moving forward, otherwise, the 'new normal' in clinical practice could widen existing inequalities in care.

Pre-COVID-19 shared decision making, consent and pre-assessment

Management decisions in benign gynaecology are driven by patient preference, since medical treatments or 'watch and wait' rarely lead to life-threatening complications. Treatment is aimed at improving the quality of a patient's life. Exceptions are gynaecological cancers, early pregnancy complications and menstrual disorders leading to haemorrhagic shock or ureteric endometriosis leading to renal impairment. In any case, the decision for surgery has to be reached in a joint, non-paternalistic consultation or a series of discussions, incorporating the process of informed consent and the philosophy of patient centred care [3].

Gynaecological oncology services during the COVID-19 pandemic

The continued provision of gynaecological cancer services needed novel delivery, minimising patients' exposure to COVID, operating in COVID-19 clean sites and maximising non-surgical options.

Gynaecological oncology procedures can be split into diagnostic and surgical management. For diagnostics, outpatient procedures were the first choice. During the pandemic, oncological clinics – including one-stop clinics, colposcopy, rapid access clinics, vulval clinics – have been maximised to ensure biopsies could be obtained for endometrial, cervical and vulval lesions. Diagnostic procedures required under general anaesthetic have been performed in the Independent Sector (IS) after both patient and staff swabbing for COVID-19 and an initial pre-operative isolation period for the patient of 14 days, later reduced to 3 days [4].

If a cancer is confirmed, the patient is discussed at the network multidisciplinary team (MDT) meeting, comprising surgeons, radiologists, pathologists, oncologists and specialist nurses, and an individualised treatment plan made. To aid in this decision making, Table 1 is used. This was initially created by the NHS England as a guide for systemic cancer treatment, i.e. chemotherapy, but was modified by the British Association of Surgical Oncology (BASO) to aid decision making for operations:

The majority of gynaecological oncology operations fall into priority 1 or 2. If a patient was considered to have a low or very low chance of success (priority level 3–4), careful decision making between the MDT and the patient is required. For priority levels 5–6, including non-resectable sites of disease, surgery is not indicated.

The timing of surgery is to follow the NHS England recommendations for surgical prioritisation, Table 2 has been modified by the BASO for cancer operations:

As for benign conditions, priority 1 operations – life, limb or organ-saving operations – take place in the acute hospitals, priority 2 is to be performed urgently within a COVID-19 clean site – following the NICE COVID-19 isolation rules. Priority 3 was originally planned to be performed in the recovery phase. As the pandemic has lasted longer than originally thought in March 2020, these cases have

Table 1
Prioritising patients for systemic anti-cancer treatment.

Priority level	Categorisation based on treatment intent and Risk: Benefit ratio of treatment
1	<ul style="list-style-type: none"> • Curative treatment with a high (>50%) chance of success • Adjuvant (or neo) therapy which adds at least 50% chance of cure to surgery or radiotherapy alone or treatment given at relapse
2	<ul style="list-style-type: none"> • Curative treatment with an intermediate (20%–50%) chance of success • Adjuvant (or neoadjuvant) therapy which adds 20–50% chance of cure to surgery or radiotherapy alone or treatment given at relapse
3	<ul style="list-style-type: none"> • Curative therapy of a low chance (10–20%) of success • Adjuvant (or neo) therapy which adds 10–20% chance of cure to surgery or radiotherapy alone or treatment given at relapse
4	<ul style="list-style-type: none"> • Non-curative therapy with a high (>50%) chance of >1 year of life extension • Curative therapy with a very low (0–10%) chance of success. • Adjuvant (or neo) therapy which adds a less than 10% chance of cure to surgery or radiotherapy alone or treatment given at relapse
5	<ul style="list-style-type: none"> • Non-curative therapy with an intermediate (15–50%) chance of >1 year life extension. • Non-curative therapy with a high (>50%) chance of palliation/temporary tumour control, but < 1 year of life extension.
6	<ul style="list-style-type: none"> • Non-curative therapy with an intermediate (15–50%) chance of palliation or temporary tumour control and <1 year of life extension.

Table 2
Categorising patients for surgical cancer treatment.

Priority level	Categorisation
1a	Emergency – operation needed within 24 h to save life. This should be undertaken on the acute site, as currently.
1b	Urgent – operation needed with 72 h. This should be undertaken on the acute site, as currently.
2	Elective surgery with the expectation of cure, prioritized to: Surgery within 4 weeks to save life or prevent progression of disease beyond operability. This should be prioritized within a clean site
3	Elective surgery can be delayed for 10–12 weeks with no predicted negative outcome. This should be prioritized for recovery phase, depending on length of pandemic.

required careful re-prioritisation and monitoring. After 3 months, many priority 3 cases have become priority 2.

Informed, freely given consent is a process that should be incorporated into the decision making from the start and should not just represent a paper exercise of signing a consent form. Women should be made aware that they can withdraw consent at any stage. In the modern NHS, efficiencies such as placing patients directly onto waiting lists and admitting patients to hospital on the day of operation require careful attention to the organisation of consent. 'If written consent is obtained immediately before the operation, it is vital to ensure that the patient has been offered the opportunity to further discuss any intervention in a clinic visit or a visit to a pre-operative assessment unit/use information packs with a copy of the appropriate consent form' [5]. Generally, after a decision has been reached jointly, surgery is scheduled and patients are placed on waiting lists. Even prior to the pandemic, UK surgical waiting lists have been long in international comparison, for instance, for hysterectomies [6], and susceptible to winter flu pressure with associated adverse impact on patients [7].

Pre-assessment prior to the pandemic

The process of pre-operative evaluation is essential in assessing the medical condition of patients, evaluating their overall health status, determining and optimising risk factors, and relaying information with the overall aim to improve perioperative outcomes, patient and physician safety and satisfaction [8].

Patients booked for a gynaecology procedure requiring anaesthesia or sedation attend a face-to-face pre-operative assessment clinic. Depending on specific institution models, this may be a formally booked or a walk-in appointment.

Given the protocolised nature of pre-operative assessment clinics, in most hospitals, these are nurse-led or nurse-delivered services. This physical in-person appointment allows baseline observations to be recorded, as well as a focussed history (including medical, surgical, anaesthesia and social history), medication review and an assessment of functional capacity. Physical examination is usually limited to an airway examination, however, observing a patient mobilise and sit at rest provides valuable, and generally reassuring non-verbal information for the assessor. Further tests can be ordered, usually laboratory blood tests (commonly a full blood count, group and save and iron studies in gynaecology) and routine methicillin-resistant *Staphylococcus aureus* (MRSA) swabs. Additionally, bedside investigations such as a baseline electrocardiogram can be undertaken if indicated [9]. At this point, referrals to other specialties may be considered for optimisation or to an anaesthetist directly if there are any concerns. Finally, during these appointments, information is passed directly to the woman (both verbal and written), including the type of anaesthesia to expect, specific medications to take or omit in the lead up to surgery, and fasting guidance for food and clear fluids [10].

In the presence of significant medical co-morbidities or medical complexity, an American Society of Anaesthesiologists Physical Status Classification System (ASA) [11] score of more than 3, or when the gynaecological procedure is classed as major, then the woman may be selected for a clinician pre-assessment, by a senior anaesthetist, and this typically allows for a more detailed medical assessment, and estimation of risk scores for perioperative complications [10].

How the COVID-19 pandemic is impacting decision making, access to surgery and pre-assessment

There is considerable national variation on the impact of gynaecological surgery, depending on the region, hospital trust and unit and the local rate of COVID-19 infection. Some tertiary centres are dedicated to COVID-19 care and thus routine care is continuing at a reduced level, other hospitals operate a satellite system where COVID-19 patients are looked after in district hospitals and elective surgery can proceed largely uninterrupted.

Initial gains made in informing the public about the ordeal and suffering of endometriosis patients (12, 2020 #14) from delayed access to diagnosis and effective treatment [13,14] are being thwarted by the impact of COVID-19 on patient pathways. Given growing waiting lists, there is concern that women with pre-malignancies, malignancies, and also symptomatic benign conditions may be suffering deterioration on waiting lists leading to a progression of their disease process.

In a small questionnaire-based study, women (N = 20) experiencing postponement of their fibroid surgery were contacted on the waiting list by phone for physical and emotional assessment (using the screening questionnaire for disaster mental health, screening for posttraumatic stress and depression). Both physical and mental symptoms deteriorated, 60% reported subjective increase in fibroid size, 75% were severely affected according to post-traumatic stress disorder scores and 75% were likely to develop depression [15]. Even when surgery is not postponed, women suffer high levels of psychological stress, with fear of having endometriosis-related problems during the pandemic period described in a study from Turkey [16]. This calls for compassionate care for women already on the waiting list. Severe pain leading to deterioration in mental health can be a mitigating factor for bringing a patient in for surgery during the pandemic.

'Novel ways of responding to challenges'

In June 2020, the Department of Health and Social Care stated 'whilst routine hospital treatments were suspended to provide capacity to treat COVID-19 patients, we are now working closely with the National Health Service and other partners to restart these in a safe way. Guidance has already been issued on this, and approaches are being tailored at local level according to local capacity and local demand, with the most urgent services being restarted first. Guidance also outlines that contracted independent sector hospital and diagnostic capacity should also be used in the restarting of routine elective procedures' [17].

Restructuring of services

In an attempt to clear the current backlog, the private sector and the NHS trusts have increased surgical capacity. Some trusts have pooled their patients to even out capacity, or teams follow their patients in order to operate in neighbouring hospitals within the trust or the private sector. Health care professionals may have to travel to different sites and work with unfamiliar teams and in unusual settings. Whether pre-assessment and clinical tests are done in the home unit or the outsourced unit (group and save bloods are required locally) standard operating procedures (SOPs), good communication channels, good quality communication and teamwork are paramount, in particular, WHO checklists and operating team briefings [18].

There is an emerging role for dedicated managers, schedulers, nurse practitioners to work cross-site and manage such logistically complex theatre lists, including MDT surgery (endometriosis, oncology). Pre-operative MDT discussions, undertaken virtually, can help identify the right setting for a patient and plan complex surgery. Written SOPs are valuable reference points in this context.

Hospitals have introduced a traffic light system according to the level of COVID-19 safety, necessitating different degrees of pre-operative COVID-19 testing and self-isolation. Pre-assessment arrangements may vary depending where patients are operated. Again, clear guidance for health care professionals and patients is paramount.

In addition, administrators and schedulers may face a bottleneck of pre-assessment slots given the sudden increase in surgical capacity after the 'first wave'. It is the responsibility of consultants and managers to plan surgical lists carefully and as early as possible, to give patients ample time to self-isolate and for routine COVID-19 antigen testing. Moreover, there may be a need to pre-assess and isolate a pool of women, since some women may not pass pre-assessment due to having COVID-19 or anaemia, to avoid the precious resource of a theatre list going fallow.

Hospital restructuring is demanding a high degree of flexibility of staff, such as working in unfamiliar surroundings and with unacquainted teams. Making adaptations to working during the pandemic can increase the risk of workforce burnout [16]. Early recognition of signs of psychological distress, setting up adequate support services and long-term aftercare for the NHS health care workers are of paramount importance [19]. Furthermore, training of gynaecology junior doctors may be affected due to redeployment, shielding, sickness and a reduction in planned operating procedures.

Triaging and surgical decision making

Careful consideration should be given when planning the management of gynaecological conditions. Factors to consider are the acceptability and prognosis of non-surgical versus surgical management options, and possible deterioration in case of delayed surgery. Focus group discussions with endometriosis patients as part of a recent study by the authors (ref. as next one) have highlighted the general omission of alternatives to surgery such as hormonal treatment, self-management options and physiotherapy, and an honest discussion of surgical prognosis. Models to predict pain relief after surgery are under development [20].

Self-management strategies may be useful for some women: Leonardi et al. present a resource for women living with endometriosis during the pandemic and signpost to evidence-based problem-focussed strategies (e.g. education about endometriosis, managing work and study, exercise, social activities) and emotion-focussed strategies (relaxation and mindfulness, acceptance and commitment therapy, adopting a positive attitude) at times when surgery may be not available [21]. Although it is tempting to signpost patients to smartphone applications, for instance for pain management, these apps are not acceptable to everyone, even 'digital natives' [22].

Co-morbidities, especially risk factors for COVID-19 infection should be factored into the equation. Modifiable risk factors, such as smoking and obesity, must be addressed. If the risk benefit balance is unfavourable, surgery should be avoided/postponed.

Individual COVID-19 risk assessment is paramount: falling ill with COVID-19 in the peri-operative period increases 30-day mortality (Fig. 1). Increasing surgical complexity and increasing age confer an increase in risk. For high-risk individuals, elective surgery may be better delayed until after the pandemic.

Once placed on the list, women will have to be informed about the likely waiting time and given points of contact when required, and if feasible, follow-up appointments to monitor wellbeing whilst on a waiting list. A face-to-face appointment is required for operative planning, when assessing the surgical route or extent of disease.

In the UK, consultants are obliged to review their prioritisation of their patients regularly. The Federation of Surgical Speciality Association (FSSA) [23] states 'It is essential that all patients listed in

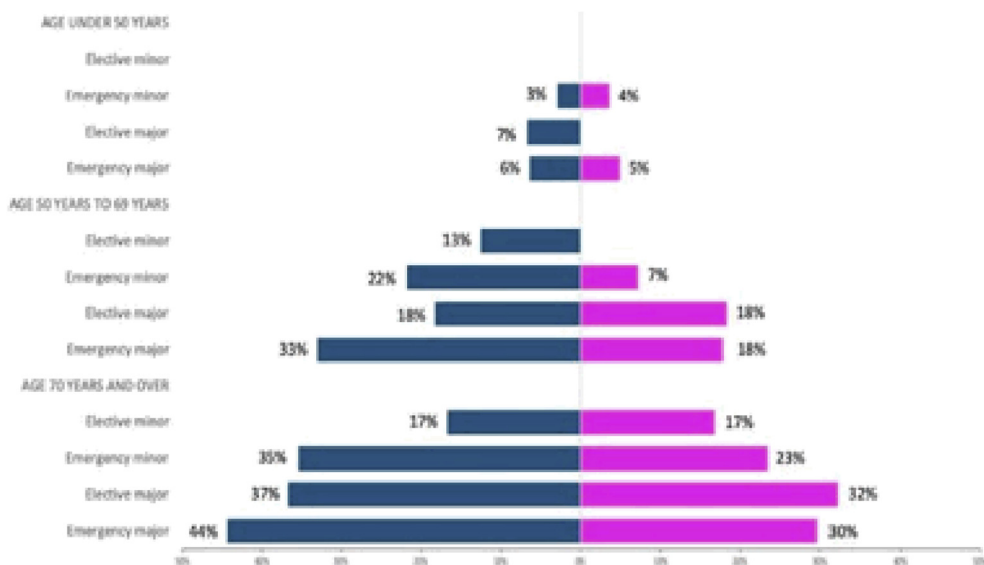


Fig. 1. Thirty-day mortality rates of men (blue) and women (pink) who had a peri-operative SARS-CoV-2 infection, by age [34].

any category are regularly, clinically reviewed to ensure their condition is not changing and in need of re-prioritising'. The regularity with which patients are reprioritised is up to the service, however, a decision to screen the patients on waiting lists every 3 months makes clinical sense as this is the point at which P3 patients should have had their treatment. The assessment comprises the degree of urgency of the procedure P1 < 3 days, P2 < 1 months, P3 within 3 months and P4 > 4 months. The FSSA is taking into account mitigating factors – such as pain – and collating co-morbidities and risk factors for COVID-19 (such as age >60, pregnant >28 weeks, being from a Black, Asian/minority ethnic group, male gender, body mass index >40, underlying health conditions such as asthma or diabetes). The currently used four-tier system (P1–4) is not specific to gynaecology, nonetheless, there is published guidance from the Royal College of Obstetricians and Gynaecologists [24].

A novel surgical prioritisation tool specific to gynaecology has been hospital-validated in the United States of America. The new tool, Gynaecologic Medically Necessary Time-Sensitive (Gyn-MeNTS), includes co-morbidities that predispose to COVID-19. Gyn-MeNTS was tested against a simpler tool based on clinical urgency, the modified Elective Surgery Acuity Scale (mESAS). Despite finding overall high interrater reproducibility in the Gyn-MeNTS scoring system for all three pairs of scorers ($\kappa > 0.80$, $P < 0.001$), it did not discriminate the most urgent cases as determined by either the mESAS system or surgeons' subjective judgement well. The authors believe that the tools capture distinct issues related to urgency and see a future in combining both tools to achieve an optimal system for rating surgical urgency objectively [25].

In addition to mandatory prioritisation, the NHS England published a framework for the validation of surgical waiting. The aim of this tool is to reassure patients on waiting lists that they have not been forgotten, establish the patient's wishes regarding treatment, good communication with the patient and GP and produce a validated waiting list.

The steps are as follows: 1. Technical validation – ensure the waiting list is accurate and up to date; 2. Patient discussion – patients are contacted by a locally determined competent team, to establish their wishes; 3 – Remote clinical consultation and communication to GP (the tool contains a guide for administrative validation including outcomes, a shared decision-making tool that might be used if the patient requests a clinical review, and prehabilitation options should surgery go ahead.

The focus on patient discussion is labour-intensive and will have to be shared between doctors and senior nurses. Locally, trusts might choose to post standard letters rather than scheduling consultation for the majority of patients. Additional resources, time and staffing will be required.

The novel concept of prehabilitation describes patient education about self-management approaches that can reduce both the risk of surgery and adverse outcome from a COVID-19 infection. Measures can include weight loss, physical activity, improving mental health, optimising diabetes and hypertension, and smoking cessation. The Centre for Perioperative Care and the Royal College of Anaesthetists have produced useful patient guidance [26]. Due to an extended time spent on waiting lists, some women may require re-imaging, tests and a re-visiting of the indication for surgery.

Consent

Consent is a common weak spot for litigation and often not well done in clinical practice [27]. Novel ways of conveying the information required to facilitate informed consent, such as videos and smartphone applications are now required more than ever. The General Medical Council (GMC) has updated a user-friendly simple guide on patient-centred obtaining of consent, taking into account the present challenges for the UK's health services and patient care by the pandemic and new or different ways of working [28]. A lawyer's synopsis of consent in the post COVID-19 era is outlined on the British Orthopaedic Association's website [29].

When carrying out informed consent, it has to be taken into account that 'postoperative pulmonary complications occur in half of patients with perioperative COVID-19 infection and are associated with high mortality' [30]. In gynaecology, the 30-day mortality of COVID-19-positive women was reported as 4.8%. The authors recommend that consideration should be given to postponing non-urgent procedures and promoting non-operative treatment to delay or avoid the need for surgery.

Modifications to pre-operative assessment

As with most medical pathways, the process for pre-operative assessment for elective gynaecology procedures has markedly changed, to facilitate safe, effective and efficient surgery during the COVID-19 pandemic.

The notion of a telehealth pre-operative assessment, although envisaged before the pandemic [31,32], has become a reality with rapid initiation and implementation. Anecdotally, considerable success has been described, however, real data on the effectiveness of telemedicine for pre-operative assessment are lacking [33].

Telehealth in the context of pre-operative assessment is largely undertaken with pre-booked clinics, by nurses and anaesthetists depending on the complexity of the pre-operative assessment. Remote assessments may highlight particularly high-risk patients or difficulties in telehealth assessment (e.g. patient cognitive or hearing issues) and consequently indicate the need for a face-to-face assessment.

Most telehealth pre-operative assessments are undertaken using telephone consultations. The video conference function to allow women and clinic staff to visualise each other in a consult setting has several logistical barriers, including patient resources (e.g. hardware technology, data or broadband connection), hospital resources (noise-less environments, webcams, microphones/head-sets) and secure network connections and platforms. Consequently, limitations of virtual assessments primarily include not being able to physically see a patient which can provide important bedside information on overall physical health, as well as allow wider discussions and input from patient relatives, which is especially important for higher risk women or higher risk surgeries or a combination of both.

Additional limitations of a remote assessment at this point in the pathway include the inability to perform a complete assessment – laboratory blood tests and simple bedside tests such as an electrocardiogram – in the same appointment. Furthermore, passing on of written information, such as patient information literature (fasting times, anaesthesia technique and expectations) is not possible. Therefore, these steps to complete the pathway are typically undertaken at a subsequent single hospital attendance to limit multiple hospital visits: an ‘obs and swabs’ (observations and swabs) appointment, 72 h prior to the date of the surgery, which is mandatory for routine COVID-19 antigen testing. Limitations of undertaking these steps at such short notice prior to the surgery date include inadequate time to action any abnormal results (e.g. blood test parameters or knowledge of undiagnosed hypertension) and may result in on-the-day cancellations or the decision to proceed with surgery with less than ideal optimisation.

Conclusions

The COVID-19 pandemic has impacted the way clinicians consult with patients and reach joint decisions about surgery with them, patients' clinical pathways, and the time they spend on waiting lists. The negative impact on patients and staff, such as indirect COVID-19 morbidity and mortality, upstaging of disease and psychological sequelae, is starting to emerge.

Born out of the experience of the pandemic, novel ways of working have found their way into clinical practice rapidly. As examples, the notion of prehabilitation, the large-scale realisation of virtual appointments and a new emphasis on self-management of gynaecological conditions have been accelerated by the pandemic.

Decision making has been affected by COVID-19 in multiple ways, including rationing of theatre space requiring additional prioritisation not previously used outside the emergency setting. Patient choice and engagement have been central at all points, with many requesting that their procedure be postponed or even cancelled due to COVID-19. Others, after careful consent and counselling, have wished to proceed with their operation. Working closely with patients, exploring all treatment options and keeping them informed throughout the pandemic ensures a better experience for these patients during a difficult time where medical provisions are limited.

Practice points

- The process for pre-operative assessment for elective gynaecology procedures has markedly changed, during the coronavirus disease 2019 (COVID-19) pandemic.
- Women need to be carefully consented, given the increased risk of post-operative mortality following COVID-19 infection.
- As the pandemic has lasted longer than originally expected, many cases have become of increased priority, therefore, careful regular re-prioritisation and monitoring of women is important.
- Virtual assessments have become necessary to avoid patients coming to the hospital.
- There are several limitations of virtual assessments, such as excluding women who cannot verbalise their complaints well which results poorer quality of care for them.

Research agenda

- Research is required into the acceptability and effectiveness of these novel ways of working.
- Remote measures have not been evaluated with clinicians and service users.
- The voices of service users are taken into account, in particular, those of seldom heard and disadvantaged women, so as not to increase inequalities.

Declaration of competing interest

None of the authors declare conflicts of interest.

Acknowledgments

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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