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The impact of coronavirus disease 2019 on genitourinary and prostate cancer care and clinical trials: A qualitative exploration of the Australian and New Zealand experience

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Abstract

Purpose: This qualitative study aimed to understand the impact of the coronavirus disease 2019 pandemic from March to November 2020 on healthcare delivery and clinical trials for genitourinary (GU) cancers in Australia.

Methods: Annually a pre-conference workshop is hosted by the Australian New Zealand Urogenital and Prostate Cancer Trials Group for supportive care health professionals. In November 2020, those that selected to attend were invited to participate in a focus group. Workshop and focus group discussions were recorded and transcripts were analyzed thematically.

Results: Seventy-two individuals involved in GU cancer care and clinical trials took part. Participants described negative changes to GU cancer care and clinical trials from the pandemic due to reduced clinical services and increased wait times. Trial recruitment was paused temporarily during lockdowns, and standard treatment protocols were used to limit hospital visits. Trial process changes included electronic capture of informed consent, home delivery of oral medications, and delegations of assessments. These changes increased administrative activity for clinical trial teams and Human Research Ethics Committees. A transition to telehealth enabled continuity of service delivery and trials but reduced the opportunity for face-to-face patient consultations with increasing concern about the failure to detect supportive care needs.

Conclusion: The pandemic has prompted a critical review of service delivery and clinical trials for people with GU cancers.

KEYWORDS
Australia and New Zealand, clinical trials, COVID-19, genitourinary cancers, prostate cancer, qualitative research

1 | INTRODUCTION

The severe acute respiratory syndrome coronavirus 2 virus of coronavirus disease 2019 (COVID-19) continues to spread globally at a significant pace. The unprecedented burden of the pandemic on health systems worldwide has important implications for cancer care and for the conduct of cancer clinical trials. The pandemic response continues to necessitate rapid development, dissemination, and ongoing implementation of health regulations and protocols.[1,2] Such protocols continue to incorporate strategies such as social distancing, use of personal protective equipment, protection of vulnerable communities, quarantine requirements, and rapid adoption of telehealth.[3]

Australia and New Zealand have experienced lower infection transmission rates of COVID-19 compared with other countries but have implemented some of the longest and most stringent lockdown protocols.[4] Globally, the priority for inpatient oncology units has been and continues to be, to prepare for and adapt to shortages in staff, beds, and other healthcare resources due to surges of patients with COVID-19 requiring acute care and intensive care unit beds. Despite many hospitals having dedicated cancer care facilities, large outbreaks have required the reallocation of units, hospital wards, or entire systems to care for patients during outbreaks. The impact of changes on people affected by cancer, and the healthcare professionals managing their care, has yet to be fully understood.[5] Early reports suggest that the effects have already been profound, with implications for care into the future.[6,7]

The opportunity for rapid health system innovation during the pandemic has been embraced by healthcare leaders.[8] However, little remains reported about the experiences of frontline nurses, allied health professionals, and clinical trial professionals who have adapted to rapidly changing protocols for clinical service delivery and clinical research while continuing to meet the complex needs of people with cancer.[9]

The Australian New Zealand Urogenital and Prostate (ANZUP) Cancer Trials Group[1] is an internationally recognized collaborative cancer trials group that undertakes clinical trials in genitourinary (GU) cancer. Annually, the membership meets and discusses issues that impact those diagnosed with GU cancers, and at its November 2020 annual meeting, a workshop to explore the impact of the COVID-19 pandemic on healthcare delivery and clinical trials for people with GU cancers in Australia. To share these learnings, workshop recordings were qualitatively investigated to address the following questions:

1. How has the pandemic affected the roles of nurses, allied health workers, and clinical trials personnel providing clinical care and trials for people with GU cancers?
2. How has the pandemic affected people with GU cancers (patient views and perceptions of nursing and allied health professionals)?
3. What lessons from the initial pandemic response can be continued beyond the pandemic?

2 | METHODS

2.1 | Design

The study used a pragmatic qualitative descriptive design[10] based on a half-day workshop conducted during the ANZUP Annual Scientific Meeting (ASM) in November 2020. There was no fee to attend this workshop. Ethics approval was obtained from the Royal Brisbane and Women's Hospital Human Research Ethics Committee (HREC/2020/QRBW/70096). To accommodate lockdowns across Australia and New Zealand, the workshop was conducted virtually through the Zoom Video Communications platform.[2]

2.2 | Participants

All ANZUP ASM delegates were invited to attend a workshop to discuss the impact of the pandemic. Participants were given a participant information statement which included resources to support participants if they become unsettled during discussions. Electronic written informed consent was provided by unique log-in via the ASM app. A total of 72 participants took part in the workshop. Participants were from a range of clinical and demographic backgrounds across Australia and New Zealand, including nurses, clinical trial/study coordinators, allied health professionals, medical oncologists, trial participants, consumer representatives, and employees of pharmaceutical companies representing partners in ANZUP trials.

2.3 | Data collection

The workshop session involved:

1. a panel discussion to elicit insights from a consumer, four nurses (with urology, clinical trials, and research expertise), and a clinical psychologist (see Table 1);
2. semi-structured break-out group discussions (see Box 1 for discussion topics) with all workshop participants; and
3. plenary discussion to share small group insights.

Participants were individually sent a secure link for the workshop, which could not be shared with others. The workshop was digitally audio-recorded using conference software and the recording was transcribed verbatim. The recordings were destroyed after transcription.

[1] ANZUP (https://anzup.org.au/) brings together all professional disciplines and groups involved in GU cancer research and treatment to develop and run investigator-initiated clinical trials addressing questions of importance to patients and clinicians. The membership meet regularly throughout the year and share research updates and expertise each year at the Annual Scientific Meeting.

[2] Zoom Video Communications, Inc copyright © 2012–2021

TABLE 1 Panelists

Perspective	Location
Consumer: A person living with prostate cancer who was participating in a clinical trial when the pandemic started	Receiving care through a specialist cancer center in a metropolitan setting
Urology Nurse	Metropolitan public hospitals servicing metropolitan and rural locations
Urology Nurse Practitioner	Private practice
Senior Research Nurse	Metropolitan public cancer center
Prostate Cancer Specialist Nurse/Health Research Ethics Committee member	Metropolitan public hospital
Clinical Psychologist	Public and private practice in a metropolitan setting

2.4 | Data analysis

The transcript of workshop discussions was coded and analyzed thematically with illustrative quotes selected to support key themes.[11,12] Data analysis was conducted by an experienced qualitative researcher who did not attend the meeting. The authors contributed to the development of the coding schema and final themes.

3 | RESULTS

3.1 | Panellist insights

3.1.1 | Consumer perspective: consumer representative, patient and clinical trial participant

Reflections from an individual with GU cancer who received clinical care and was a clinical trial participant during the pandemic highlighted several clinically important considerations about the impact of the pandemic on GU cancer care. During the early stages of the pandemic, the individual's fear of contracting COVID-19 took precedence over their pre-existing cancer diagnosis, ongoing GU cancer care, and clinical trial participation. This resulted in logistical changes in their ongoing cancer care, including:

1. avoiding the use of public transport to minimize the risk of COVID-19 exposure, with implications for parking, planning, and out-of-pocket costs associated with traveling to appointments;
2. dispensed medications sent directly to home address;
3. changes to the scheduling of blood tests; and
4. transition to telehealth appointments where possible.

The individual reported that, during the height of the pandemic, confidence that their health professionals "*had things under control*" was of the utmost importance. The knowledge that health professionals were continuing to prioritize their best interests was paramount.

> "*As a consumer, you like to see the swan going through water and not the legs paddling underneath.*" A person with GU cancer and a clinical trial participant

3.1.2 | Nursing perspective

Nurse panelists described a pragmatic response to adapting GU cancer care delivery due to the constraints of the pandemic on clinical services, with priority given to ensuring patient safety and maintaining ongoing clinical care. Nurses described using telephone and video consultations with patients, particularly for follow-up appointments, with face-to-face consultations used according to individual patient needs.

Nurses reported that the impact of the pandemic on GU cancer care varied with COVID-19 case numbers. While there was an initial, abrupt reduction in some clinical services such as diagnostics during the early stages of the pandemic, this was only temporary when the COVID-19 caseload was low. Where the COVID-19 caseload was higher, this resulted in ongoing delays in appointments and referrals, due in part to reported patient anxiety about attending face-to-face appointments. Nurses articulated concerns about the long-term implications of such delays. In particular, there were concerns about timely diagnosis, assessments, and treatment. Alternate pathways were instated to accommodate the emerging situation.

> "*Adhering to lockdown rules was important, and with people isolating and needing COVID-19 testing before procedures, this created an additional layer of stress. In general, patients have adjusted well, but it is important to be mindful of the impact, especially for people who may be deferring appointments because of COVID-19 concerns.*" Urology Advanced Nurse Practitioner

3.1.3 | Clinical trial nurse perspective

For nurses involved in GU cancer trials, the speed with which the pandemic developed necessitated pragmatic, responsive decision-making to ensure patients had ongoing access to treatment. There was an acceptance that protocol deviations would occur, but panelists noted the importance of capturing and reporting deviations appropriately. Clear communication with all relevant stakeholders was highlighted as a key enabler for maintaining confidence and consistency in trial activity locally, nationally, and internationally. Quick action to adapt processes to the pressures of the pandemic gave sponsors, ethics

committees, and, most importantly, participants confidence clinical trials could continue safely.

> "*We were making decisions that were sensible enough to be right and then getting agreement on that from the HREC and sponsors*." Senior Clinical Trials Nurse

3.1.4 | Clinical psychology perspective

The clinical psychologist on the panel highlighted the increasing demand for appointments during the pandemic as patients and health care professionals needed psychosocial support. As with other panelists, the clinical psychologist noted a transition to telehealth, but described the challenge of delivering a relationship-based healthcare service virtually.

> "*Psychological therapy is relationship-based and uses verbal and non-verbal cues; these get lost when using telehealth, particularly telephone*." Clinical Psychologist

A common theme reflected by all panelists was the need to balance requirements for telehealth and face-to-face consultations. Panelists reported trying to ensure that new patients had face-to-face appointments where possible, with telephone consultations used for longer-term patients. As the initial wave of COVID-19 cases passed, some patients asked to return to face-to-face appointments.

3.2 | Findings from the small group discussions ($n = 72$)

Insights shared during the small group discussions were grouped according to Clinical care, Clinical trials (see Table 2) and Future directions (see Table 3).

3.3 | Clinical care

The importance of maintaining patient confidence during the pandemic was a dominant theme during discussions about clinical care. Participants described strategies such as: being readily available to answer questions, continuing to provide patient support (both directly and indirectly), and advocating on behalf of the patient with other members of the healthcare team. Insights highlighted the important role of nurses and allied health professionals as both an information resource, and source of support for people with GU cancers regardless of how and where care is delivered.

> "*It sharpened your focus on what was important and what could be left. Patient care and patient safety came to the fore*." Urology Nurse

Participants noted that the pandemic response necessitated rapid changes in hospital procedures. The need for pre-appointment COVID-19 screening was added as part of routine practice. A rapid transition to appointments conducted via telephone or videoconference required an adjustment in processes, which in some instances occurred with limited supporting infrastructure. Varying reports were given about the impact of the transition to telehealth on workload: some participants reported increased convenience; others described an increased administrative burden. Regardless, the need for flexibility was identified as critical while services and health professionals responded to new policies and procedures, adapting these to the needs of individual patients.

Some participants reported changes in the workflow as services worked to limit the potential risk of COVID-19 transmission across clinical teams. Nurses reported working with colleagues to limit face-to-face attendance at hospital appointments. Changes included partnering with primary care services where appropriate. However, partnering with primary care was not always a solution because some general practitioners also transitioned to telehealth.

Nurses reported that, while hospitals initially deferred some appointments and procedures for people with GU cancers, services resumed over time where COVID-19 caseloads were low. However, participants shared concerns about the unknown impact of delays or deferrals in patient appointments in the longer term. Participants indicated particular concern about people receiving a diagnosis of GU cancer during the pandemic, noting that limits on who could attend appointments meant some patients were unable to have family or carer support at the point of diagnosis. Participants also described concerns about the emotional toll of limitations to family and carer visits during end-of-life care due to restrictions in hospital attendance and social distancing.

3.4 | Clinical trials

Participants involved in GU cancer clinical trials reported the overarching priority during the pandemic was ensuring patient safety and maintaining confidence in processes so crucial treatment protocols could continue. Clinical trial professionals spoke of the need to accommodate changes in clinical trial and health service practices during the early stages of the pandemic. Adaptations included changes in clinical trial logistics and governance procedures, as well as protocol amendments and associated requirements for HREC reporting. Protocol deviations occurred as systems and processes were rapidly adapted.

Advice from coordinating centers to trial sites helped limit the impact of deviations, with information about levels of acceptability in relation to protocol deviations and advice about how to efficiently record deviations seen as valuable. The establishment of logs to capture protocol deviations helped visualize common issues and helped to inform decisions about process changes, such as facilitating blood collection closer to people's homes.

The need to report key changes, such as reconsenting processes and delegation models, for HREC review was noted as important. Individ-

TABLE 2 Impact of coronavirus disease 2019 (COVID-19) on genitourinary (GU) cancer clinical care and clinical trials

Theme	Impact	Quotes
Clinical care		
Impact on patient care	Initial deferral of appointments in the early stage of the pandemic. Increased waiting lists for some tests because of the burden of the pandemic on imaging and pathology. Potential to miss patient appointments because of issues with scheduling and timing of telehealth calls as new systems were established.	"*Generally, we're OK if you keep us informed. Rescheduling is fine as long as someone rings you to say the call may be delayed.*" Patient
Policy and procedure changes	Rapid changes in hospital policy. A need to adapt "on the go" and keep staff and patients updated. Incorporation of COVID-19 screening into all face-to-face patient appointments.	"*The role went from holistic nursing to administrative fire-fighting. That was a real shift.*" Clinical trial nurse
Changes in workflow	Shift to outpatient/GP setting for tests and assessments. Fewer opportunities for ad hoc allied health support and education with clinical appointments conducted via telehealth. Changes in shift patterns with clinicians working from home and/or changes to limit transmission across clinical teams. Increased involvement of primary care and shared care approaches.	"*We have been getting GPs more involved in patient care because it's had to happen. It's been really helpful.*" Prostate Cancer Nurse Coordinator
Service delivery	Rapid uptake of telehealth and less physical contact with the patient. A need to adapt to new systems and develop new skill sets quickly.	"*My skills in having conversations with patients on the phone developed over time.*" Senior Research Nurse
Patient support	Significant challenge for patients of not being able to attend face-to-face appointments with a family member. Additional support needed for patients to answer questions about COVID-19 risks and concerns as well as cancer-related questions.	*"For oncology patients not being able to come in with a carer for a diagnosis was traumatic for patients and staff."* Prostate Cancer Specialist Nurse
End-of-life care	Major change and challenge for provision of end-of-life care with strict limitations on family visits. Cause of high levels of anxiety for patients, families, and health professionals	"*End-of-life care was also a huge concern for our patients in pall care where they only had one visitor for two hours a day and couldn't see family and friends. So we found it a massive change in how we developed our care.*" Prostate Cancer Specialist Nurse *"I still get really teary thinking about end-of-life care. It's a long-lasting impact for people who work in health and for patients who have had to go through that."* Consumer
Clinical trials		
Patient engagement and communication	Need to keep patients informed about changes while maintaining their confidence in the process. Taking account of the clinical needs of individual patients (e.g. age, language, length of time on trial).	"*Our role during COVID as a coordinating center is around working out protocol assessments, ethical considerations and how to support trial staff to identify expected and unexpected [protocol] deviations and providing support around ethics considerations and what needs to be submitted for approval.*" Clinical trial coordinator
Sponsor engagement	Need for increased sponsor engagement to communicate changes in trial processes and their implications.	
Trial logistics	Review of trial processes to address constraints of social distancing, self-isolation, and protection of vulnerable people: 1. delivering investigational products to patients 2. working with other hospitals and practices to undertake assessments closer to where patients live 3. review of appointment scheduling use of telehealth.	"*Logs capturing protocol deviations helped visualize where most of the deviations were happening so we could make some umbrella decisions to manage those – e.g. people don't want to come in for blood collections so can we find ways for blood collection to occur closer to their homes?*" Prostate Cancer Specialist Nurse
Trial governance and ethics	Increase in the number of protocol deviations. Requirement for communicating changes to HREC for review.	

TABLE 3 Recommendations for future directions

Key area	Recommendations
1. Telehealth	Health professionals indicated a need to improve their skills in telehealth. Skills strengthen confidence, which in turn will improve patient engagement and interactions. A training package to support effective communication using telehealth in cancer care would be beneficial, including: 1. strategies to support good communication 2. strategies to establish and build rapport 3. guidance for expectation and consultation management 4. tools to support patient assessment. Telehealth training should be incorporated into standard clinical training programs.
2. Health system	Health systems need to adapt to support the incorporation of telehealth into routine practice. This will require continued Medicare rebates for appointments conducted via telehealth (including nursing and allied health appointments). Hospital appointment systems need to be adapted to incorporate telehealth. Flexibility of telehealth platforms to accommodate patient needs and resources must be weighed against privacy concerns. The use of patient-reported outcome measures to assess symptoms and adverse events must be a priority to support the delivery of targeted high-quality care.
3. Clinical trials	A range of clinical trials processes would benefit from review, including: 1. use and funding for telehealth to streamline processes of informed consent and follow-up appointments 2. electronic data capture of patient-report outcome measures 3. critical review of processes for assessment and follow-up better aligned to standard-of-care 4. critical review of requirements for data collection to ensure only data critical to outcomes are collected and ensuring all data are reported 5. review of governance and ethics requirements including acceptable protocol deviations and delegations.

uals involved in HREC processes reflected on the significant increase in HREC workloads during the pandemic, noting the importance of taking a pragmatic approach whilst ensuring essential clear communication. Guidance from regulatory agencies, including the US Food and Drug Administration[13] allowed for some flexibility in managing and accommodating changes.

Proactive sponsor engagement was also noted as a critical enabler for maintaining consistency in clinical trial activity during the pandemic. As ANZUP sponsors and conducts investigator-initiated clinical trials in partnership with international trials groups, proactive communication from ANZUP was important. An ongoing challenge arose from some sponsor decisions being made based on the pandemic response in the sponsor's country rather than the Australian context.

3.5 | Enablers for delivery of GU cancer care and clinical trials during the pandemic

Actions reported to help facilitate consistent, safe, and high-quality GU cancer clinical care and clinical trials during the pandemic included:

1. use of telehealth where appropriate;
2. maintaining a focus on the patient and their safety;
3. clear communication with all relevant clinical and clinical trial stakeholders;
4. pragmatic decision-making in the face of frequent change, prioritizing what was important and could be achieved; and
5. keeping a big-picture view while tailoring approaches to individual patients and trials.

3.6 | Future directions

Participants reflected on lessons learned during the early stages of the pandemic and on how some present opportunities to optimize future models of care.

> "*COVID has caused a shift in mindset. A lot of things happen because they have always been done that way and nothing has forced us to change. But COVID has made us think differently*." Workshop participant

3.6.1 | Telehealth

Telehealth was highlighted as a key enabler for clinical care and clinical trials for people with GU cancers during the pandemic, allowing service delivery to continue while limiting the need for face-to-face appointments. This resource helped to reduce anxiety about the risk of COVID-19 transmission and allowed patients to have family members with them for support during appointments. Participants identified family and carer support as a crucial part of quality care for people with GU cancers, with significant limitations placed on such support in face-to-face appointments due to COVID-19 restrictions. Other ben-

efits noted for telehealth included convenience for patients and health professionals and a reduction in travel-related out-of-pocket expenses.

Telehealth appointments have been supported during the pandemic through Australia's universal health care system by a medicare benefits schedule (MBS) item. However, the MBS item is currently only approved for December 2021[14] and is not expected to be maintained beyond the pandemic for nurse and allied health appointments, which may result in increased costs of telehealth participation for patients.

> "*We run a state-wide service, so it's been great to access telehealth instead of making [patients] travel 3–5 h for a 15-min consultation.*" Prostate cancer nurse coordinator

Some limitations of telehealth were noted by participants. It was recognized that while telehealth improved access to health services in some areas, it created inequities for other patients. From an access perspective, challenges were reported for people with lower digital literacy, those for whom English was not a first language, and people with limited internet or mobile telephone access.

Crucially, telehealth does not support physical assessments or interventions and limits the detection of non-verbal cues. As such, telehealth is not suitable for patients for whom physical assessments were needed and are not ideal for new patient consultations and assessments. Workshop participants highlighted that telehealth is more appropriately used when a relationship has been established between health professionals and patients.

While the issues described in relation to GU cancer telehealth are translatable to other cancer populations, the provision of comprehensive supportive care is particularly important for people diagnosed with cancer. Nurses and allied health professionals described being on a learning curve, during the pandemic, adapting their communication skills, and having to rely on other information with limited non-verbal cues to ensure the provision of supportive care during telehealth appointments.

> "*You get so much from seeing a patient walking into the room. You lose some of that with telehealth. Even with a videoconference, you only see the person's head and shoulders.*" Senior Research Nurse

> "*You may be doing 30 calls a day but it's just one call for the patient. Ask them – are you feeling comfortable with this? Or give them encouragement. Small things can make a difference.*" Patient

Workshop participants suggested that, given the convenience of telehealth, a hybrid approach of face-to-face and telehealth appointments would likely be useful in the future. Participants noted that as health professionals' and patients' digital literacy and confidence with remote consultations improves, the process becomes more streamlined and health professionals can adapt to telehealth to better read and respond to patient cues and needs. Key lessons learned about digital literacy during the pandemic can be applied in the future by GU cancer and clinical trials teams (see Box 2).

3.6.2 | Clinical trial protocols

Participants noted the COVID-19 pandemic forced the introduction of greater flexibility into clinical trial protocols. The opportunity to think critically about what is important for trials on an ongoing basis was welcomed by research nurses, clinical trial coordinators, and patients.

> "*We have a perception that everything needs to be covered by the trial. Perhaps we now need to be asking what should be covered by the trial compared with the standard of care. Are we asking for anything extra to be implemented? It would make trials easier to open if we're not asking for visits above the standard of care.*" Senior Research Fellow

Potential areas for improvement in clinical trial protocols and processes, drawing on lessons learned during the pandemic are listed below.

1. **Consent**: written participant information statements and consent forms continue to be overly long and written in complex language that fails to facilitate patient understanding. The move towards e-consent and telehealth during the pandemic has highlighted the need for simplified processes and alternatives to paper-based information.
2. **Data collection**: some clinical trial protocols require the collection of data that are not always used. The pandemic required pragmatic decisions to be made about data collection. A critical review of what data are collected and why would be welcomed by participants.
3. **Assessments**: clinical trials often involve more frequent assessments than the standard of care and/or require face-to-face appointments at a specialist center. The pandemic has highlighted the potential to reduce the number and complexity of assessments, perhaps mirroring the timing, format, and location of standard-of-care assessments, especially for people who have been on a trial for a period.
4. **Clinical trial protocols**: the value of pragmatic clinical trial design, including data collection limited to primary and secondary endpoints, should be noted. The pandemic highlighted that with ongoing rapid change in health services, it is challenging to mitigate deviations from rigid complex clinical trial protocols

4 | DISCUSSION

This qualitative study provides 'real-world' and practical insights into the impact of the COVID-19 pandemic on cancer care and clinical trials for people with GU cancers in Australia. Common themes reflected concerns about the impact of the pandemic on the supportive care and well-being of people with GU cancers due to ongoing

Box 1 Question topic guide

1. How was your role affected when the COVID-19 pandemic was declared?
2. What is most important to you in your role? How has this changed during COVID-19?
3. How do you think your patients have been affected?
4. What about clinical trials? Have you seen an impact?
5. Have there been any 'silver linings' for patient care?
6. What do you think the future holds?

Box 2 Lessons learned during COVID-19 about digital literacy in healthcare

1. Telehealth platforms differ between hospitals – while a health professional may only need to use one platform, patients may be asked to use multiple platforms depending on who is providing care.
2. Patient confidence and comfort using digital communication platforms vary – asking patients whether telehealth is working for them is a helpful way of checking for unmet needs.
3. It is important to reassure patients about using telehealth so nervousness is not a barrier to open communication; health professionals' familiarity with telehealth platforms allows them to help patients as needed.
4. Platforms need to be as easy as possible for patients to use – it is easier for patients to use a platform that does not require software to be downloaded and installed in advance of a call.
5. Patient preference is important – offer a telephone call as an alternative if a videoconference is not possible or not acceptable for the patient.
6. Telehealth appointments can be undertaken safely – while some patients have concerns about the privacy of telehealth, it is important to remember that in many cases, conversations can be held in a more private setting than would occur in a hospital.
7. The rapid introduction of telehealth in clinical trials proved to be effective and ensured ongoing study participation
8. There are opportunities for embracing digital consent in clinical trials

rapid innovation in hybrid telehealth models of care and approaches to clinical trials.

People living with a cancer diagnosis are at increased risk of anxiety related to their disease, treatment, fear of recurrence, and general health status.[15,16] A recent systematic review and meta-analysis in men with prostate cancer found depressive, anxiety, and suicidal symptoms to be common, with a high suicide mortality rate compared with the general population.[17] Moreover, evidence has identified that prior to the pandemic people affected by GU cancers can experience profound unmet supportive care needs in routine service delivery.[18–22] Therefore, participants in this study highlighted the need to ensure changes to care delivery, particularly in supportive care, during the COVID-19 pandemic do not have lasting harmful effects on patients in the future. Each participant told stories and shared their perceptions of how they aimed to consider the longer-term implications for their patients in their day-to-day practice.

Inevitably, societal changes caused by the pandemic are likely to affect people's sense of connection and social support.[23] A recent study found an increased risk of depression in people with cancer during the pandemic.[24] This study has highlighted the potential for additional stress and anxiety caused by COVID-19 for people already dealing with a potentially life-limiting cancer diagnosis. The lack of partner/family support for patients attending appointments alone has been challenging, particularly at diagnosis and at points of treatment decision-making. Similarly, restrictions on the presence of family and carers at end-of-life have been profoundly difficult for patients, families, and health professionals.[25] While the pandemic generated considerable uncertainty, it has created opportunities for more streamlined and patient-centered approaches to clinical care delivered as part of clinical trial protocols.[26] Outpatient and primary care appointments and the use of telehealth have provided created greater convenience for patients, particularly those on maintenance therapy and/or long-standing clinical trial participants.

Participants reflected on the ability to accommodate rapid changes during the pandemic response and expressed interest in maintaining the flexibility and adaptability of health service delivery models and embedding clinical innovations within mainstream service delivery longer-term. The need for critical reflection to optimize new models and approaches was highlighted, noting that innovations such as telehealth and e-consent should not be at the expense of, but facilitate and safely embed patient-centered care. Evidence internationally has identified that increased health disparities are likely when relying on new technologies alone.[27] Standards for use of telehealth have been developed both nationally and internationally.[28] However, governance, policy, and funding implications also need ongoing consideration. In Australia, telehealth appointments have been reimbursed through Medicare for clinical appointments during the pandemic, but such funding models are not set to continue for nursing and allied health professionals after the pandemic response. This raises important issues about inequality in funding models for nursing and allied health-led models of cancer care going forward. Participants reported that HRECS is considering guidance and future implications of the pandemic on clinical trial processes. Funding implications of new approaches to clinical trial delivery may also need consideration, and work that was already underway before the pandemic using telehealth to expand access to clinical trials continues.[29]

The COVID-19 pandemic has been a catalyst for change in both clinical trials and clinical care. Collaborative trial groups, such as ANZUP, can ensure that we can continue to establish evidence that can continue to improve clinical practice, to the highest standard. Adopting both a pragmatic and innovative lens can ensure that both patients and health care professionals benefit. For example, individual preferences can be supported by drawing on clinical research which has identified that patient-reported outcome measures (PROMs) have been shown to improve health service outcomes when applied in routine clinical practice.[30–33] There can be little doubt the inclusion of remote capture of PROMs in real time would contribute to overcoming some limitations of telehealth monitoring of patients in clinical trials and routine care. Participants noted challenges in holistic patient assessment via telehealth. However, studies using electronic capture of PROMs in conjunction with telehealth are building an evidence base with opportunities for improved morbidity and mortality for individual patient consultations.[31,34–37] Hospital consultations are limited by time and resource pressures, likely contributing to lower rates of symptom detection. When considered in the context of a pandemic, streamlined, accessible remote capture of PROMs must be prioritized within the health system.[38]

> "*It's made us think. The new normal will be different. There will be people who will want to go back to how it was before because it's more comfortable. But the momentum has to continue. It won't always be better but it's an opportunity to review approaches.*"

This study focused on GU cancers. However, the findings are likely to be broadly representative of the experiences of cancer care and clinical trial activity during the pandemic, globally. With the pandemic response continuing across Australia, cancer care delivery continues to be affected. It will be some time before the longer-term impacts of the pandemic can be measured. However, work to reflect on innovations can start now. Nurses, allied health professionals, researchers, clinical trial coordinators, and patients involved in this study were united in their hope that lessons learned during the early stages of the pandemic can be used to improve and streamline health services and trial processes in the future.

These findings are limited by the selected sample of respondents, participants who volunteered to attend the workshop and may not be generalizable to a broader group or other health settings. The analysis was undertaken by one experienced qualitative researcher. The Australian and New Zealand experience of the COVID-19 pandemic differs from most of the rest of the world.

5 | CONCLUSION

Embedding innovations such as telehealth and teletrials into standard care and streamlining clinical trial processes will require changes in policy, practice, education, and research. While change continues, there is a great deal of work required to ensure changes are evaluated and implemented in an evidence-based way. The COVID-19 pandemic response in Australia and New Zealand has provided an opportunity to build further insights and opportunities to improve cancer care and clinical trials beyond the crisis of COVID-19.

AUTHOR CONTRIBUTIONS

Natasha Roberts: Conceptualization, methodology, interpretation, writing original draft, writing, reviewing, and editing.

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Catherine Paterson: Conceptualization, methodology, interpretation, writing original draft, writing, reviewing, and editing.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

DATA AVAILABILITY STATEMENT

No data available

ETHICS APPROVAL

Ethics approval was obtained from the Royal Brisbane and Women's Hospital Human Research Ethics Committee (HREC/2020/QRBW/70096).

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