Government of **Western Australia**
Department of **Health**

WA Continuous Improvement in Care (CIC) Transition Project:

Transition Plan – implementation of a simplified CIC methodology as a proof-of-concept

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Introduction

1.1 The issue

Cancer is a leading cause of disease burden in WA – especially for Aboriginal people and those living in rural and remote locations – with increasing incidence anticipated in line with population growth and ageing.[1,2] Cancer care can be complex with many clinical disciplines, therapies and support services involved. Survival does not necessarily equate to quality of life with many treatments causing long term health issues and the overall impact of a cancer diagnosis on a person's mental health and societal functions. This complexity of care and support needs can lead to many possibilities for someone to become 'lost' in the system, causing unnecessary morbidity and personal distress.[3] The experience of treatment and the quality of life of the patient living with cancer would greatly improve if deficiencies and inequities were addressed through urgent implementation of reforms associated with patient outcomes. In particular, the use of patient reported outcomes.[4]

1.2 What's required to address this issue

The potential of patient-reported measures (PRMs) to improve the care of those diagnosed and living with cancer is increasingly recognised because they allow accurate measurement of a range of outcomes through the patient's lens and throughout a patient's clinical journey. Collection of PRMs has been encouraged in the 2020-25 National Health Reform Agreement[5] to empower patients to be involved in their health care, improve care across the health system, and for clinicians to focus on outcomes that matter to patients.[6]

The WA Cancer Plan 2020-2025[2] seeks to guide optimal delivery of cancer control, treatment, and research. Priority two of the Cancer Plan focuses on strategies to improve outcomes through safe, coordinated and evidence-based care and to empower consumers to make well-informed decisions about their care. To support this, priority three of the Cancer Plan specifically identifies the need to collect, analyse and report on data about how patients perceive their outcomes and experience. This is to be achieved through the collection of patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) that can be used to monitor and evaluate how cancer control impacts consumers, and to inform improvements. Central to the achievement of these priorities, is access to contemporary information and communications technology (ICT) tools which support data collection, an understanding of what is important to patients, clinical decision-making, audit and feedback.

1.3 Gap identification

To date, WA Health has primarily focused on variation in terms of access to timely and appropriate clinical care and health outcomes for patients. With only some exceptions, this has been limited to key performance indicators such as unplanned readmissions, surgical waitlists and clinical outcomes. Existing deficiencies include inadequate measurement and reporting of patient outcomes and patient experiences; and insufficient collection of comprehensive and detailed clinical data to assess appropriateness of treatments prescribed and to identify unwarranted variation in outcomes. Access to contemporary tools to support appropriate data collection is essential to address these gaps.

1.4 Current work

A current state report of validated PRMs was undertaken from August 2022 to January 2023 across the WA health sector (Addendum A). This was commissioned by Health Networks at the Department of Health (WA) and performed by the Continuous Improvement in Care – Cancer (CIC Cancer) project. It evaluated the status of PREMs and PROMs, with a view to identifying and understanding their actual and potential use, associated processes, issues and any opportunities for improvement.

The current state report identified that some PROMs activities are occurring across WA. This includes work being progressed at a system level via Sustainable Health Review (SHR)[7] Recommendation 4 and the Outcome Measures Project. At the Health Service Provider (HSP) level, the majority of PROMs related initiatives have originated from siloed translational research or clinical quality projects aimed at driving improvements in patient-centred care. Unlike PREMs, these activities are not integrated nor is there any overall coordination or oversight. Currently, therefore, there is no capability to ensure that effective governance has been established and that any data outcomes or learnings from PROMs captured at a local level are being used to inform and effect change across the system; that is, either at HSP or Department of Health WA level. The fragmented nature of this approach means that there is no agreed framework, guiding principles or business rules to ensure improvements are being informed by evidence-based best practice and data collected is accurate and able to be benchmarked now and in the future.

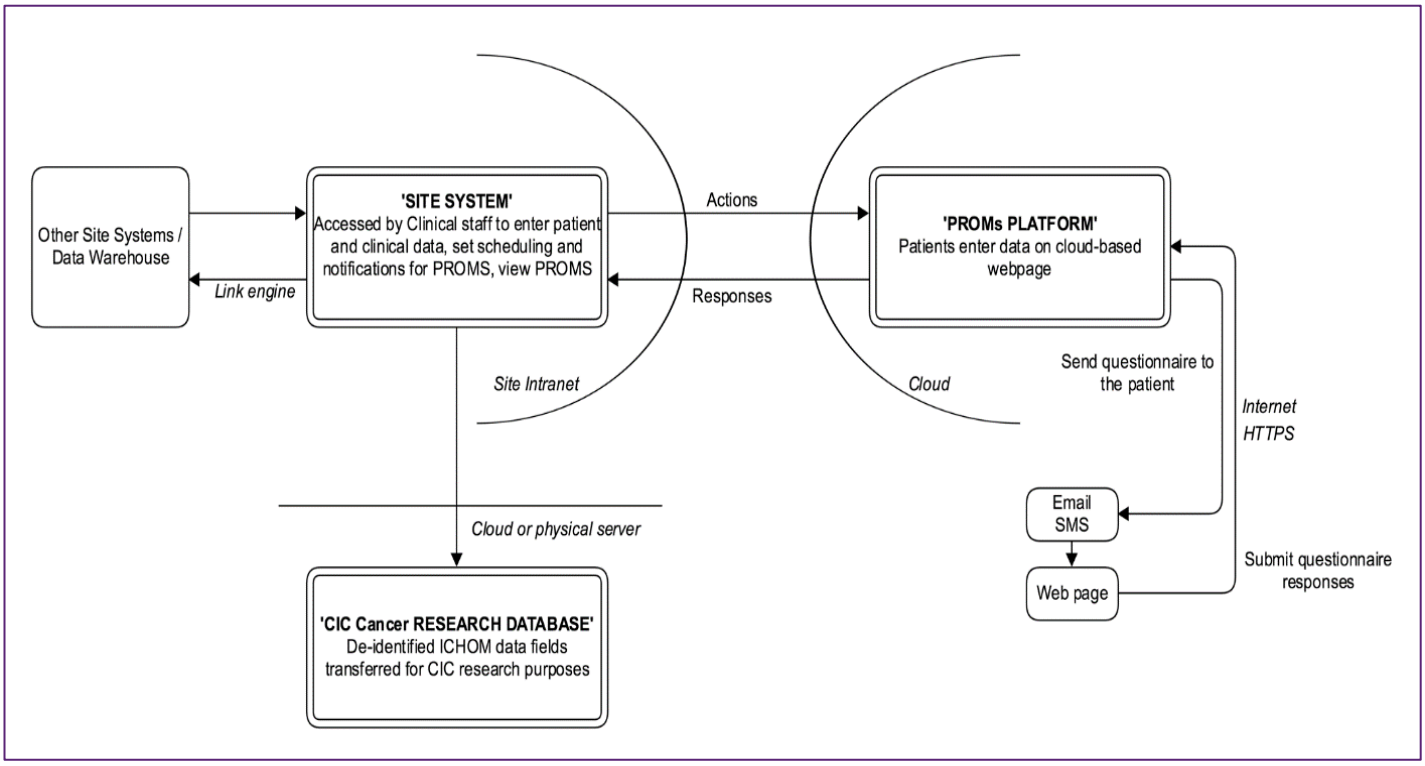
One recommendation from the current state report was development of a transition plan for the implementation of a PROMs proof-of-concept project based on the CIC Cancer project. The aim of the plan is to inform the future transition of a PRM Program into WA Health and the business requirements necessary to sustainably support an ongoing PRM program.

CIC Cancer Research Project

The CIC Cancer project – a research collaboration between the University of Western Australia (UWA), University of Notre Dame, Murdoch University, Curtin University, St. John of God (SJoG) Healthcare Group and WA Health – is a translational health research project focussed on capture of PRMs to inform patient care throughout the patient's cancer pathway and improve outcomes. This has resulted in the development and implementation of data collection and reporting of internationally validated PROMs and PREMs, in association with related clinical data for breast, lung, colorectal and ovarian cancers. Collaboration between clinicians, consumers, health providers and researchers has resulted in development of a custom-built informatics system for the collection of clinical and patient-reported data across public hospitals (Royal Perth, Fiona Stanley and King Edward Memorial hospitals plus probability of Sir Charles Gairdner Hospital joining the project) and SJoG hospitals (Subiaco and Midland hospitals). Research activities have also incorporated an exploration of how data collected in this way can inform health economic decisions, clinical workflow redesign and the development of bundles of care (Appendix 1).

The CIC informatics system (CICIS) is based on an open source clinical and patient-centred registry framework. This captures clinical and patient-reported outcomes data. The system (Figure 1) includes a 'site system' that is housed within the WA Health intranet, providing a repository for clinical information to be captured. This is linked to an external entity (referred to as the 'PROMs platform') that allows patients to record their patient-reported outcome measures. The PROMs information is securely and regularly transferred into the 'site system' to allow clinicians to visualise and discuss the results with patients during consultations. This capture and connection of information not previously captured will allow clinicians to have a much better understanding of what matters to patients about their care and its outcomes. The last part of the system is a database for use by researchers or those seeking to understand the outcomes. De-identified data can be securely transferred offsite to this third component ('CIC Cancer Research Database') to allow for analysis and evaluation of the data.

Figure 1: CIC informatics system components



2. Addressing the issue

The CIC Transition current state report provided a snapshot of both PROMs and PREMs to inform:

- the WA Health Executive Committee's (HEC) Safety and Quality Committee about the current PRMs approach in WA; and
- development of this Transition Plan for the future transition of the CIC Cancer project – including a custom-built information system – into WA Health.

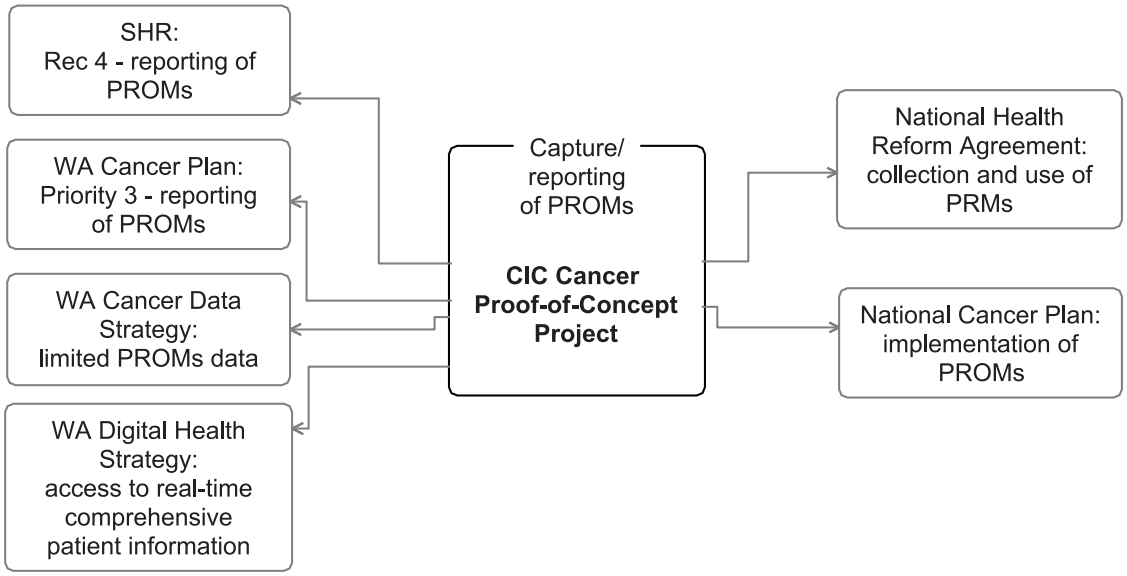
This proposal outlines a methodology to support the transition of a simplified version of the CIC project and informatics system into WA Health as a proof-of-concept for the collection and use of PRMs as part of standard care for cancer patients treated for breast, lung, colorectal and ovarian cancer within WA public hospitals. This proof-of-concept also has future potential for translation to implement PROMs systematically for other health conditions.

2.1 Strategic alignment

This proof-of-concept project strongly aligns with the strategic goals and priorities of the WA Department of Health and the National Health Reform agenda (Figure 2). The collection of PROMs will provide solutions which directly assist achievement of the following recommendations and strategies. Greater detail can be found in Appendix 2.

- Recommendation 4 of the WA Sustainable Health Review.[7]
- Priority 3, Strategy 8 WA Cancer Plan 2020-2025.[2]
- Work to develop a WA Cancer Data Strategy.[8]
- WA Digital Health Strategy.[9]
- Action 4.2.1 of the Draft Australian Cancer Plan.[10]

Figure 2: Strategic priorities addressed through capture of PROMs



2.2 Benefits

PROMs can be utilised at a micro, meso and macro level to improve care (Appendix 3). The potential benefits to be gained from the utilisation of CIC Cancer as a proof-of-concept project to capture PROMs include:

Benefits to patients (micro)	1. The opportunity to capture PROMs feedback throughout the patient pathway, to inform shared decision-making and promote person-centred care. 2. Reduced unwarranted variation in patient outcomes by providing a mechanism to measure patient outcomes and assess the effectiveness of care in real time. 3. Decreased variations in care through the enhanced ability to audit compliance with optimal care pathways and improve clinical appropriateness and clinical care standards. 4. Opportunities to reduce inappropriate care and retire obsolete practices by developing and influencing the uptake of clinical practice improvement activities.
Benefits to clinicians and health service providers (public and private) (meso)	1. Improved access to patient-reported information to facilitate patient centred decision-making and enhance multidisciplinary team (MDT) discussions. 2. Improved ability to audit through access to data that supports quality assurance and the implementation of improvement initiatives. 3. Improved ability to measure quality activities over time from both the clinical and patient perspective. 4. Capability to assess patient outcomes in a standardised manner using validated international tools.
Benefits to WA Health (macro)	1. Supported delivery of safe and high-quality care for patients and consumers through strengthened clinical governance oversight of healthcare outcomes reporting. 2. Broadened benchmarking of outcomes between sites and services. 3. Increased insight into consumer and carer experiences of healthcare to inform the design and delivery of effective high-quality care. 4. Improved linkages between the private and public sector for service planning. 5. Increased ability to reduce expenditure on low value care through better understanding of what matters to patients.

Case study

Clinical and PROMs data have been captured for consenting participants with lung, colorectal and breast cancer at Royal Perth Hospital since October 2018 as part of the CIC Cancer research program. This data has been used for several purposes: understanding patient outcomes in comparison to treatments; identification of improvements to quality of care; an economic evaluation; mapping of care against the optimal care pathways; better understanding of Covid 19 experiences; submission to the Organisation for Economic Co-operation and Development's (OECD) Patient-Reported Indicator Surveys (PaRIS) initiative; and understanding patient perspectives on completion of PROMs.

Analysis of PROMs data was undertaken in early 2022 and the results provided to hospital management and the clinical champions within each of the three cancer types. The information was also presented to the relevant MDTs.

Based on the findings for lung cancer – statistically significant changes seen in appetite loss, dyspnoea, haemoptysis, sore mouth, dysphagia, peripheral neuropathy, alopecia and pain in chest – site stakeholders explored interventions to address the distress and symptoms expressed by patients. Consequently, changes were made to improve patient care such as the new role of Lung Nodule Clinical Nurse Consultant providing a pivotal role in case management, establishment of relationships early in the care pathway, incorporation of screening tools and development of referral pathways for persistent symptoms.

A member of the senior Royal Perth Hospital (RPH) management team at the time these results were presented has since taken up a role at North Metro Health Service (NMHS). Once settled into the position at NMHS, a request was made to incorporate the lung cancer service at Sir Charles Gairdner Hospital into the CIC Cancer project so that similar information could be utilised to improve care services. Relevant processes are currently underway.

In practical terms, ongoing utilisation of a system already functioning within the WA Health Cloud[11] and being utilised in a number of HSPs, provides an opportunity to efficiently test the collection of PROMs on a small scale and identify the best approach to widen scale and applicability. The CIC Cancer informatics system (CICIS) (refer Figure 1) is a custom-built web-based application – using an open-source framework – that systematically collects comprehensive PROMs and health-related information over time. CICIS is already integrated into the ICT environment of Health Support Services (HSS) – currently under a Hybrid Operational Service Transition Agreement (H-OSTA) with work underway to convert this to a full operational services transition agreement once an HSS applications team has been assigned – and is currently in use across a small number of sites. The system is also integrated into SJoG HealthCare.

The system design is highly reliable, secure, scalable, and sustainable and can easily be adapted to incorporate other cancers, conditions and disease types. A data analytics and visualisation system is also incorporated into the CICIS that displays, in near real time, the functional and symptomatic outcomes experienced by the patient. This information can inform discussions about care provision and empower patients to partner with their healthcare team to make informed, shared decisions about their care through a better understanding of the actual and potential outcomes of care. The potential of this data visualisation and analytic tool to encourage engagement of clinicians and patients further strengthens this proof-of-concept work as a prudent investment.

2.3 Options available

A review of execution options available to address the need for systematic and managed capture of patient reported measures within WA identifies the advantages to be gained from the utilisation of CIC Cancer as a proof-of-concept project to capture PROMs (Table 1).

Table 1: Option summary

Option	What this looks like?
Do nothing (*no execution*)	• A few clinical teams or research teams continue to collect PROMs data in isolation (as identified in recent current state report). • Policy and governance requirements (SHR, WA Cancer Plan, Australian Cancer Plan) are not met. • Data remains siloed and unable to be effectively used to improve quality of care.
Proof-of-concept using a system already in place within a select group of conditions with subsequent determination of next steps (*Test case/partial execution*)	• Effective and efficient methodology for PROMs capture is enacted with minimal effort and policy obligations are partially met within stipulated timeframes. • The informatics platform is already firmly embedded within public and private IT infrastructures. • Preparatory work for a wider implementation of CIC can be put in place to ensure smoother transition processes. • Current sites (public and private) are already engaged, invested, and local systems are in place. Other sites also exhibited interest in involvement whilst CIC was still a research project. • Already enrolled patients will continue unaffected, providing a rich data source spanning several years. • Easy extension to collection of data from non-cancer related respiratory, breast, colorectal and gynaecology conditions. • Resourcing can be provided by current CIC team for first 12 months, allowing for continued engagement and ICT development by the original researchers. • Potential for easy access to comparable data from a private provider. • Sites using nurse led clinics are keen to use the PROMs data as part of their assessment processes.
Statewide implementation of PROMs collection process (*Full execution*)	• Long-term solution is expensive and takes considerable time to employ. • A tailor made, software as service solution is possible; but significant stakeholder consultation/procurement processes will be required. Recent MDT software procurement experiences have demonstrated the length of time required with subsequent impacts on adherence to policy timeframes.

3. Transition and proof-of-concept project

The purpose of the CIC transition and proof-of-concept project is to identify how best to embed PROMs capture and use in care delivery provided in WA Health through use of an already available methodology. It is proposed that the methodology and infrastructure already developed as part of the CIC Cancer research project be utilised as a proof-of-concept project within the WA Department of Health. This could be achieved in a phased approach over 2 years. Phase 1 - 12 months (2023/24 FY) to prepare and set up the transition whilst still under the auspices of UWA; and the second year (Phase 2, 2024/25 FY) for the Department of Health WA to embed and evaluate the proof-of-concept project and consider expansion and applicability options beyond 2025.

This plan will identify:

- the activities required for simplifying the CIC project framework in phase 1;
- the activities required for transitioning the CIC project framework and information system in phase 2; and
- the possible strategic and operational requirements for support of the transition and proof-of-concept.

3.1 Phase 1 – simplification and continued CIC Cancer involvement

In phase 1 the activities of the CIC Cancer research project will be simplified to capture PROMs only data for the existing patient cohort across the current public and private sector sites for a further 12 months with funding and support provided by the current CIC Cancer research team (refer Table 2). The minimal level of PROMs collection will be as outlined in Appendix 5: PROMs survey tools. As the 12 months of phase 1 progress, revised methodologies for data collection, analysis and reporting will be determined. Work will also be undertaken to identify the requirements necessary to capture patients with similar health conditions (e.g. non-lung cancer specific respiratory conditions) managed in the outpatient clinic setting. Inclusion of phase 1 in the transition process will allow implementation and testing of planned simplification of the PROMs collection system and processes to ensure the application is fit for purpose for the proof-of concept project within phase 2.

This simplification is proposed because a greater level of resource provision is required to manually transfer clinical data to CICIS. The ability to enter clinical data into the system will remain but this will not occur as part of the transition and proof-of-concept work. Whilst clinical data capture is important to understand the cause or effect of changes in PROMs responses over time (cancer diagnosis, treatment and post treatment) the collection of clinical data is more complex and will need to be considered further. It is possible for clinical data to be extracted electronically from other systems, albeit convoluted because of variability in systems and data definitions. However, this may be made simpler following the implementation of recommendations that may arise from the future WA Cancer Data Strategy and the electronic health record.

Preparation work for the transition and proof-of-concept project will be viewed as a test for standard care – but success will not be fully attained until CICIS is owned, and managed, by the Department of Health WA under agreed governance arrangements. Consent will need to be investigated and resolved during phase 1 to ensure ethical considerations and future research/analytical requirements are met. Currently, patients provide written consent at baseline (Appendix 4A). Ongoing consent is also provided whenever a PROMs form is completed (Appendix 4B) and, as such, consent can be withdrawn at any follow up PROMs review. During phase 1, therefore, advice will be sought to confirm the appropriate approach for ethics and governance surrounding consent and data utilisation – The Research Governance Office at Department of Health WA have already been approached and made suggestions.

Currently, the data capture process is managed by research-funded staff within the clinical setting, which is time consuming. Phase 1 simplification of data capture process is, therefore, paramount in order for the proof-of-concept to be successfully implemented in phase 2. This will occur by automation of the PROMs survey process, including the initial send out and subsequent follow up. Activities will also be undertaken to identify ways in which to refine processes further to ensure resource minimisation and sustainability.

Resources and funding – phase 1

In phase 1, funding and resources will be provided by the current CIC Cancer team (Table 2) to undertake the activities outlined within this plan. Funding provided for CICIS IT development/enhancements and site engagement activities will include work undertaken at both public sites and SJoG Midland and Subiaco hospitals. Activities involving sites, HSPs and Department of Health WA will be undertaken within current resourcing available to these groups (i.e. in-kind capacity). Some funding is available to cover ad hoc project management by HSS teams.

Table 2: Phase 1 funding availability

Funding for	Funds provided by CIC	Period
IT Developer (up to 1.0 FTE). Ideally this would include some level of in-reach to HSS determined applications team so that handover is effective. This includes maintaining consistency of the CICIS within SJoG IT infrastructure	$150,000	12 months
Amazon Web Services (AWS) hosting site maintenance	$50,000	12 months
Involvement of HSS teams in integration and required project management	$40,000	12 months
Engagement/expansion/project mgt (in reach at Department of Health) (0.6FTE); including maintaining consistency of activities at SJoG sites	$95,000	12 months
Site engagement/co-ordination/integration (0.6FTE); including maintaining consistency of activities at SJoG sites	$95,000	12 months
Research Officer assisting sites with data collection during phase 1 and change management	$50,000	
TOTAL	**$430,000**	

Out of scope – phase 1

The following activities do not fall within the scope of phase 1.

- Manual collection of additional clinical data for current patients or any clinical data for new patients.
- Integration of data captured within SJoG sites, including SJoG Midland.
- Whilst efforts will be made to ensure that any additional work to the CICIS will be mirrored in the CICIS located within the SJoG IT architecture, development of automated system or identification of potential links to clinical data at private sites is not guaranteed.

Constraints – phase 1

- Data collection will remain at four cancers only at current CIC Cancer research project sites.
- CICIS has not yet been assigned to an allocated team within HSS. This results in interactions with HSS that are more complex, often fractured and less efficient.
- HSS and SJoG IT architecture is vastly different and each activity that requires tailoring to a specific architecture increases the potential for gaps in comparability.

3.2 Phase 2 – embed within WA Health (proof-of-concept project)

The proposed purpose of phase 2 is to implement the proof-of-concept project – in full control of Department of Health WA and within current CIC Cancer project sites, – and consider expansion to other sites and conditions beyond 2025. As such, this 12-month trial could incorporate activities to embed the application and evaluate the implementation work to date.

It is suggested that phase 2 activities focus on full implementation to standard care for cancer, and appropriate other, patients within current public sites. Simple modifications to CICIS during phase 1 will allow for capture of PROMs data, in phase 2, from patients with similar health conditions who attend the same lung, colorectal, breast, and gynaecological clinics (e.g. patients with chronic obstructive pulmonary disease who attend the same 'lung clinic' as those with lung cancer). These modifications will include removal of all references to 'cancer' within the PROMs survey form to permit similar conditions to be included in PROMs capture. As such, by building on an already functioning project and successful implementation of datasets, phase 2 will effectively capture PROMs for patients with breast, respiratory, colorectal and ovarian conditions within several HSPs. In addition to

achievement of strategic policy requirements, this will provide a rich data registry – with some PROMs data captured for 5 years or more.

During phase 2, additional, unrelated conditions – such as diabetes, cardiovascular disease – can also be considered for implementation beyond July 2025. This will require the creation of new CICIS registries with relevant, recognised datasets. It is suggested that WA Health continue to access ICHOM standard datasets for this purpose. The CICIS has been set up for easy creation of new registries by personnel with limited IT knowledge. It is, however, recommended that such personnel have a level of clinical knowledge to maximise clinical implementation. The efforts to seek interest from other sites during phase 2 will assist Department of Health WA in preparing for widespread, public-sector roll out of PROMs after July 2025.

Investigation of the potential for links with the private sector could provide an understanding of ways to access comparable de-identified PROMs for greater population level analysis. Longer term, data merged through such link processes will provide an understanding of the 'whole story' for patients and enhance sustainability and utility. It is suggested that further investigation is undertaken of how clinical data can be extracted electronically from other systems to complement PROMs capture.

Resources and Funding – phase 2

As part of phase 1, the Department of Health WA should determine the business requirements and resources that will be necessary for the phase 2 proof-of-concept. This will potentially inform resource allocation for the longer-term collection and use PROMs.

Out of scope – phase 2

- Continued support from UWA will not be possible without renumeration from the Department of Health WA.
- Extension to other sites or new conditions by UWA.

3.3 Proof-of-concept project plan

A summary of the project activities is provided in Table 3. More detailed activities for each phase are outlined in the Implementation Plan (Appendix 6).

Table 3: Summary - Suggested phased proof-of-concept approach

Phase	Timeframe	Responsibility/ funding	Activities
1	Jul 23 - Jun 24	Current CIC Cancer team with input from WA Department of Health & HSPs as required	Preparatory activities for implementation of PROMs capture as part of standard care in WA. This preparatory work will involve current CIC Cancer sites (public and private) and health conditions.
		CIC Cancer team, IT software developer	**Outputs:** • Ongoing collection of data for patients already recruited under CIC Cancer research and capture of data on new patients. • Automation of despatch processes for PROMs requests. • Finalisation of HSS integration processes (e.g. Operational Services Transition Agreement (OSTA)) and identification of potential HSS application team.

			• Enhancements to CICIS to meet any additional IT requirements arising from the OSTA. • Identification of potential links with other HSS data capture systems for capture of clinical data. • Appropriate amendments to CIC HREC approval to allow suggested simplification and identification of ongoing ethics requirements. • Discussions with Department of Health WA ethics and governance units to expand HREC approval to cover all WA Health sites. If successful, commence processes to do so.
		CIC, current sites *CIC, Department of Health*	• Possible testing of activities to extend data capture to additional, related conditions (e.g. colorectal conditions that may lead to a cancer diagnosis or patients with respiratory disease displaying similar symptoms) within a current site clinic. • Identification of processes required to interact with patients long term, including consent to participate.
		WA Department of Health	• Preliminary understanding of resources necessary for continuation of the PROMs collection. • Business requirements for phase 2 identified. • Preparation for implementation of relevant information management policies (e.g. Retention and Disposal, Quality, Storage, Classification, Governance). • Finalise appropriate Data steward, Data Custodian and Data Sponsor arrangements.
			<u>Outcomes:</u> Automated PROMs collection system and processes implemented and tested in readiness for the proof-of concept project.
2	Jul 24 - Jun25	WA Department of Health	Proof-of-concept project to test implementation of PROMs capture as part of standard care in WA. This could include extension of the PROMs collection to non-cancer respiratory, breast, colorectal and gynaecology patients within the auspices of conditions seen in the same clinic setting (as tested in phase 1).
		HSS *WA Department of Health/HSPs* *WA Department of Health*	**<u>Suggested Outputs:</u>** • Extension of data capture to non-cancer patients seen in current clinics (i.e. conditions also managed in current settings). • Acceptance of CICIS into a relevant HSS applications team. • Potential linkages with other IT systems enabled to automatically transfer clinical data. • Identification of suitable mechanisms for public reporting of PROMs. • Implementation of governance model under the WA Cancer Data Strategy – potentially including a Business User Group (BUG). • Determination of activities required to link with the private sector to access comparable de-identified PROMs for analysis. • Ensure appropriate ethics and governance approvals for on-going use of CICIS at WA Health sites are sought. • Implementation of relevant information management policies (e.g. Retention and Disposal, Quality, Storage, Classification, Governance). • Proof of concept evaluation including user acceptance, data capture, use of data, and feedback. If evaluation successful:

			○ Assessment made for implementation/adaptation of CICIS to deploy PROMs for use in other health conditions as standard care. ○ Business requirements determined for beyond 2025. **Suggested Outcomes**: • Beginning attainment of national and state level policy initiatives. • A rich data registry is available within 2 years with some data capturing PROMs over 5 years or more.
Post project	Beyond 2025	WA Department of Health/HSPs	• Capture of PROMs could be extended to cancer and similar conditions at all WA public sector sites. • Implementation of new registries to capture additional conditions, such as other cancers, diabetes or cardiovascular disease. • Development of policies and agreements to access de-identified PROMs data from private sector. • Use of data to assist in determining policy. • Development of policies and procedures for access to data by external researchers.

3.4 Risk management

A detailed risk management plan is provided in Appendix 7 .

The key risks associated with the continued use of CICIS are as follows. Mitigation strategies to manage these are discussed in detail in the risk management plan.

- Patient care is compromised. This is deemed to be of low risk as there is no foreseeable harm to patients - the project involves collection of data about care provided and patient outcomes in an effort to improve care provision.
- CICIS infrastructure ineffective or inadequate (including issues with personnel or technology). This is deemed to be of low risk as the CICIS framework already in use and PROMs data collection is already proven.
- Data security is breached or there is an inadvertent data loss/physical security breach. These risks are all rated as medium. As the CICIS is already incorporated into the HealthNext secure cloud - and required to meet Department of Health data policy requirements – these risks already have significant mitigation strategies in place.
- Data access benefits of CICIS not fully realised because of limited integration with other clinical IT systems within HSS. This risk is also rated as medium as efforts to date – business engagement and consultation with data custodians – integration with other enterprise clinical systems has not resulted in the level of integration hoped when the CIC Cancer research project commenced.
- Risks associated with inadequate funding/resourcing for phase 2 of transition/proof of concept and non-sustainable continued translation of research or non-adoption by WA Health are rated as medium as this is complex project that will require full and successful integration/resourcing/input across the Department of Health and HSS, with co-operation from three HSPs to be successful in long term.

3.5 Governance

Agreement is to be reached on a preferred governance model in partnership between CIC Cancer and the Health Networks Branch, Clinical Leadership & Reform and Patient Safety & Clinical Quality.

- Data governance:

    - seek advice regarding consent model and enact any subsequent ethics requirements;
    - identify requirements for information governance and enact as relevant;
    - seek ethics and research governance advice from Department of Health WA and HSPs;
    - identify processes to establish the CICIS as a WA Health information asset, as per Information Management Governance Policy;
    - identify need to include a record of informatics system on WA Health information register; and
    - if required, request for transition from research project to WA Health Data Collection.
- Project governance – review the ongoing/changing needs for:
    - HREC and management of same;
    - Project Advisory Group oversight of proof-of-concept and management of same; and
    - identification of needs for effective information access, use and disclosure, data quality standard operating procedures, and possible transition of data analysis processes to interface with WA Health reporting.

For more detail see Appendix 6 – Implementation plan.

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Glossary

Glossary of Terms

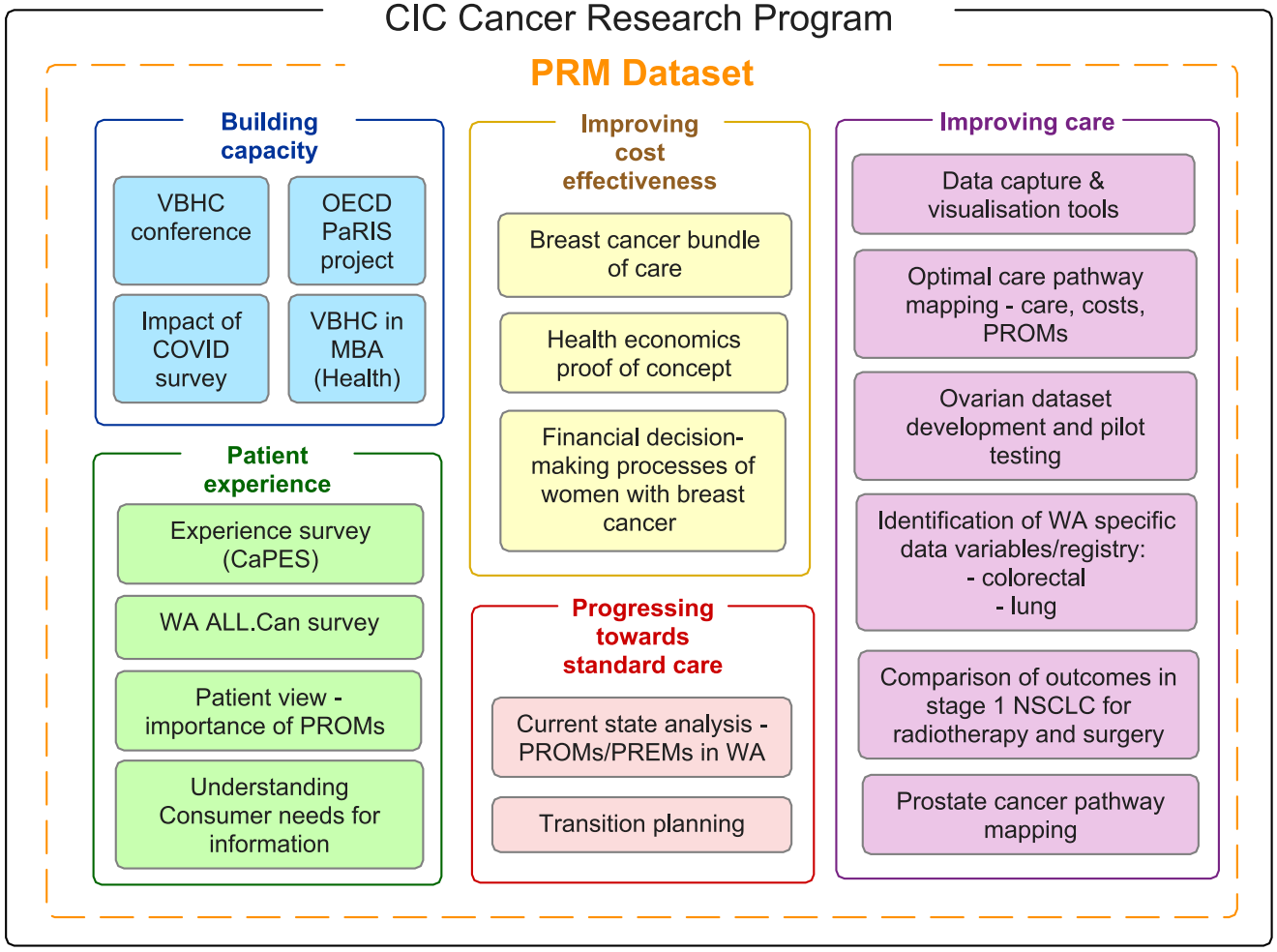
Name/Abbreviation	Definition
Patient Reported Measures (PRMs)[12]	A distinct type of metrics which capture a patient's perspective of their care and are integral to building a patient-centred system of structuring, monitoring, delivering, and financing health care. There are two types of PRMs – PROMs and PREMs.
Patient Reported Outcome Measures (PROMs)	Capture patients' views on how their illness or care has impacted their overall health and wellbeing.
Patient Reported Experience Measures (PREMs)	Capture patients' experiences of their healthcare and services.

List of Abbreviations

BUG	Business User Group
CIC	Continuous Improvement in Care
CICIS	Continuous Improvement in Care Informatics System
FY	Financial Year
H-OSTA	Hybrid Operational Service Transition Agreement
HREC	Human Research Ethics Committee
HSP	Health Service Provider
HSS	Health Support Services
ICD	International Classification of Diseases
ICT	Information and Communication Technology
ICHOM	International Consortium of Health Outcome Measures
MDT	Multidisciplinary Team
NMHS	North Metropolitan Health Service
OECD	Organisation for Economic Co-operation and Development
OPD	Outpatient Department
OSTA	Operational Service Transition Agreement
PaRIS	Patient-Reported Indicator Surveys
PRM	Patient Reported Measure
PREM	Patient Reported Experience Measure
PROM	Patient reported Outcome Measure
RPH	Royal Perth Hospital
SHR	Sustainable Health Review
SJoG	St John of God
URMN	Unique Medical Record Number
UWA	University of Western Australia

Appendices

Appendix 1: CIC Research Project - program of work



Appendix 2: Alignment with strategic directions

WA Sustainable Health Review (SHR)

The ongoing use of the CIC Cancer methodology and infrastructure to capture PROMs directly addresses Recommendation 4 of the WA Sustainable Health Review.[7]

SHR Recommendation
Strategy 1, Rec 4 Transparent public reporting of patient and carer reported experience and outcomes (PREMs and PROMs) by July 2021 with ongoing development of measures in line with emerging best practice

WA Cancer Plan 2020-2025

Implementation of the CIC Transition proof of concept project directly addresses the PROMs component of Priority 3, Strategy 8 WA Cancer Plan 2020-2025.[2]

WA Cancer Plan Recommendation
Priority 3, Strategy 8 Establish transparent public reporting of patient reported experience and outcomes and monitoring of systemwide performance indicators.

WA Cancer Data Strategy

The need to provide a sustainable approach to cancer data collection, analysis and reporting was identified as a priority within the WA Cancer Plan 2020-2025.[2] Work is currently underway to develop a WA Cancer Data Strategy[13] and patient reported measures (PREMs and PROMs) are being considered within this broader strategy.

WA Digital Health Strategy 2020-2030

The WA Digital Health Strategy[9] identified a need to improve the quality of information available to clinicians. The survey metrics collected through PROMs provide information to health teams that informs patient interactions, promotes communication, allows shared decision-making and improves the quality of care. This information provides the greatest benefit at point of care; however, it can also be used in aggregated form – at both service and system levels – to drive continuous improvement, encourage sharing of innovative and effective practices and inform value-based health care models.[14] Whilst the WA Digital Health Strategy does not specifically refer to PROMs, patient related information requires input from the patient to be seen as truly comprehensive. The ICT platform integrations already in place within the CIC Cancer infrastructure will easily allow PROMs to become an integral part of any electronic medical record and provide measures which are consistent – with data that are comparable across time (and between patients) – and reportable.

WA Digital Health Strategic theme
2. Informed clinicians – Ensuring clinicians are informed to make effective decisions that advance quality and safety (*…access to real-time comprehensive patient information*)

National Health Priorities

There are a number of national health priorities which the CIC proof-of-concept project also addresses. This includes, but is not limited to, strategic priorities and associated reform objectives of the 2020–25 Addendum to National Health Reform Agreement (NHRA).[v]

- Delivering safe, high-quality care in the right place at the right time, including long-term reforms in:

- paying for value and outcomes through use of *appropriate data and performance measures, including from enhanced data and performance reforms (e.g., patient reported measures).*

- Prioritising prevention and helping people manage their health across their lifetime, including long-term reforms in:
  - empowering people through health literacy - *Systematically measure patient reported health outcomes and care experiences.*
- Driving best practice and performance using data and research, including long-term reforms in:
  - enhanced health data - *Develop and implement a consistent approach to the collection and use of Patient Reported Measures.*

National Cancer Plan

The routine capture of PROMs directly addresses Action 4.2.1 of the Draft Australian Cancer Plan.[15]

DRAFT Australian Cancer Plan Objective
Strategic Objective 4, Strong and dynamic foundations/Action 4.2.1 – Design and embed patient reported experience and patient reported outcomes into a national performance monitoring and reporting for all providers, to assess services for all population groups and establish evidence base

Appendix 3: Patient reported outcome measures – micro | meso | macro

PATIENT REPORTED OUTCOME MEASURES

Key ways to use PROMs data at the micro, meso, and macro levels within the healthcare system

MICRO	MESO	MACRO
Patient and Clinician Informs point of care communication and shared decision-making	Healthcare Organisation Informs the measurement and evaluation of service delivery	Healthcare System Informs system-wide risk, resource and policy planning
Patient completes the PROMs prior to or during a clinical encounter. The PROMs can be used to: • Identify health issues as reported by patients, especially those that may go unnoticed without specific prompting (e.g. pain, anxiety). • Screen for specific symptoms or health problems. • Monitor patients' outcomes over time to inform treatment decisions. • Triage patients according to their self-reported health problems to inform care delivery. • Empower patients to share how they feel about their health with their care providers and foster shared decision-making.	Data collected through PROMs from multiple patients across a number different healthcare services, at specific times throughout their patient care journey, is aggregated and analysed to: • Assess and monitor patients' health outcomes at a service level. • Evaluate the outcomes of an organisation in comparison with best practice and benchmarks. • Examine the effectiveness of a health intervention or program. • Establish benchmarks and best practice for specialties and providers (individuals). • Measure outcomes as compared to cost and healthcare utilisation at the organisation level.	Data collected via PROMs from multiple patients, over specific time periods from different healthcare sites and services is aggregated and analysed to: • Compare provider effectiveness and efficiency of outcomes across the healthcare system. • Compare patients' response to treatments or interventions across healthcare delivery services. • Identify key health issues at the system level. • Establish benchmarks and best practices for providers and organisations. • Measure outcomes as compared to cost and healthcare utilisation at the system level.

Adapted from the Al Sayah et al. J Patient Rep Outcomes 2021, 5(Suppl 2):98

WA CIC Transition Project 2022

Appendix 4A: Current CIC Cancer participant information and consent form

Participant Information and Consent Form

[SITE Listing – (*Master Form: to be adapted for each site and cancer type)*]

Title	Patients First: Continuous Improvement in Care – Cancer Project
Short Title	CIC Cancer Project
Protocol Number	Version 5, 13 May 2020
Coordinating Principal Investigator	Professor Christobel Saunders AO, FRCS, FRACS

You are invited to take part in a research project, called Patients First: Continuous Improvement in Cancer (CIC Cancer) Project. We are inviting you to take part in this project because you have been diagnosed with *[cancer type to be inserted]* cancer. This Participant Information and Consent Form tells you about our research and explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part.

Please read this information carefully. You may contact the Principal Investigator at any time to ask questions or have anything explained that you don't understand. You may also like to discuss it with your friends, family, or your doctor before making your decision to participate. Participation in this research is voluntary. If you do not wish to take part, you don't have to. If you decide you want to take part in the project, you will be asked to sign the consent form. By signing it, you are telling us that you:

- understand what you have read
- consent to take part in the research project, and
- consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

What is the purpose of this research?

The CIC Cancer Project is a new program of research that will consider what is important to cancer patients in order to directly improve the lives of those diagnosed with cancer. This collaborative research involves several universities, health services, and consumer groups.

The research will collect information about your cancer care and outcomes of care that are important to you. Your information will be combined with similar data from other people diagnosed with cancer. Using clinical and patient reported outcome measures that have been used internationally, the research will trial collection of these in five public and private hospital settings in Perth, including [*site to be inserted*]. We will use the information collected to:

- provide information to individual health services on the care they provide;
- work with health providers to identify gaps in services and variations in patient outcomes; and
- develop new research and development programs to address these gaps and improve clinical practice.

What does participation in this research involve?
There are five parts to this project for which we request your consent. You may consent to participate in any or all of these parts. Your care will not be affected should you choose not to participate in any or all of the research parts.

Part 1: Participating in the project
Participation in the project involves you filling in questionnaires over a number of different times during your cancer care. These questionnaires are known as Patient Reported Outcome Measures, and they seek to understand how the healthcare provided has impacted on you and your life. The time taken to complete the questionnaires each time will vary depending on where you are in your care and the treatment/s you receive. If possible, we would like you to complete the questionnaires at each time point; however, you can decline to complete further questionnaires at any time and your treatment will not be affected in any way. Your doctor will also collect a standard set of information about your care.

You may also be contacted and asked questions about your experiences in taking part in the project. This will allow the researchers to look at ways to improve the research and better understand if we are achieving our aims.

You will be sent email or SMS messages to remind you to complete the questionnaires. You can complete the questionnaires online – using a secure 'app' on your mobile phone, a 'tablet' device, or your computer. These may be completed at home or in the doctor's rooms. Your doctor/s can then discuss any health concerns with you that are identified from these questionnaires.

Part 2: Access to information collected by your doctor
We ask for permission to access the clinical information collected during your appointments with your doctor about your current cancer care and follow up.

Part 3: A*ccess to your Patient Reported Outcome Measures data*
We are asking for your permission for your treating doctor and researchers to access the personal information collected in the Patient Reported Outcome Measures questionnaires (Part 1).

Part 4: Access to clinical data from other health services accessed as part of your cancer care
We are asking for your permission to access your clinical data from other health services you use or attend as part of your cancer care (e.g. pathology, chemotherapy, radiotherapy or surgery).

Part 5: Use of your data for associated research projects
We are asking for your permission to use your data for related research projects and clinical quality registries that will seek to improve the care provided to people with cancer, including those that have not yet been designed. This may include sharing of non-identifiable information about the outcomes of your care to approved organisations outside Australia in order to allow comparisons of care provision across different health systems.

Please note: There are no costs associated with participating in this research project, and you will not be paid.

Who can participate?
We invite all patients over 18 years of age who are able to complete the questionnaires and who have been diagnosed with [*cancer type to be inserted*] cancer at this hospital to participate in this project.

What choice do I have?
Participation in this study is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any time. If you do decide to take part, you will be asked to sign the consent form and given a copy of the Patient Information and Consent Form to keep.

Your decision to take part, not to take part, or to take part and then withdraw, will not affect your routine care, your relationship with staff involved in your care or your relationship with the health service.

If you decide to leave the research project, the researchers will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research can be measured properly and to comply with law. You should be aware that information collected up to the time you withdraw will form part of the research project results but will not be identifiable. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

What will happen to my information?
There are 3 different parts of the information system for this project – the part held at the health service, the part where you answer the questionnaire, and the research database. A unique identifier will be developed for every person involved in this project so that your identify is protected. The only people who can de-code this identifier is your healthcare team.

- Information about your care will be collected in the hospital. This identified information about you will be stored on their secure systems.
- Your patient reported outcomes information will be collected through a questionnaire using this unique identifier. The information will be temporarily stored on an Australian-based web cloud before being transferred into the record kept at the hospital where it is combined with your clinical information and available for discussion with your healthcare team. Once transferred, the patient reported outcomes information will be deleted from the cloud.
- Following discussions with your health care team, the combined de-identified information will be securely transferred to a database accessible only by the research team. This will be used for analysis of grouped information to understand ways to improve care for people with cancer. This research database will be stored on either an Australian-based cloud or a secure server of one of the WA universities involved in the research. The data provided to the research team will be securely stored for 7 years and in accordance with Australian Code for the Responsible Conduct of Research.
- Should your de-identified information be used in any other research project, including approved organisations outside Australia, all efforts will be made to ensure full confidentiality and security of your personal and health information.

How will my privacy be protected?
By signing the consent form, you consent to collection and access to health-related information about your cancer care and to access the information from your questionnaire responses. The information will be stored as part of your electronic record by your health service. Your information will only be transferred between systems using your unique identifier. Any information about you, held outside your health service, will not be able to identify you.

In accordance with relevant Australian and/or Western Australian privacy and other relevant laws, you have the right to request access to the information about you that is collected and stored by the health service. You also have the right to request correction of any information with which you disagree. Please inform your health service if you would like to access your information.

Any information provided to the research team in connection with this research project will remain confidential. Information from all participants will be grouped so no individual information will be

identifiable. Information received for the purpose of this research project will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing Part 4 of the consent form, you agree to the research team accessing health records if they are relevant to your participation in this research project.

What do I need to do to participate?
Please sign the consent form attached to this information sheet if you are willing to participate in this research.

How will I benefit from the research?
The direct benefit to you will be timely discussions with your doctor about the outcomes measures you have completed to assist in a better understanding of the impact of the care on your life and may lead to improved care for you. The overall benefits of the research will be that the questionnaires you complete will become routine for all people diagnosed with cancer in WA. This will provide continued best care for all people diagnosed with cancer into the future.

What are the risks with taking part?
There are no foreseeable risks to taking part. You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you can skip it and go to the next question, or you may stop immediately. Speak to your doctor if you experience distress.

What will be done with the results?
The results of this research project will be used to identify best practice and we will work with health services and other researchers to improve cancer care where needed. The results will also be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

Who has reviewed this study?
All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the South Metropolitan Health Service HREC. To contact the HREC please email SMHS.HREC@health.wa.gov.au or call 6152 2064. This project will be carried out according to the National Statement on Ethical Conduct in Human Research. This statement has been developed to protect the interests of people who agree to participate in human research studies.

More Information about the study
For more information, or if you have any comments, please contact Professor Christobel Saunders, Chief Investigator, University of Western Australia by telephone on (08) 6151 1107, on our website (www.ciccancer.com) or by email (ciccancer-smed@uwa.edu.au).

If you wish to contact someone, independent of the study, about ethical issues, your rights, or to make a complaint, you may contact the Manager of the South Metropolitan Health Service Research Support and Development Unit on 6152 3214 or SMHS.RGO@health.wa.gov.au quoting RGS1117.

Participant Consent Form

Title	Patients First: Continuous Improvement in Care – Cancer Project
Short Title	CIC Cancer Project
Protocol Number	Version 5, 13 May 2020
Project Sponsor	Cancer Research Trust
Coordinating Principal Investigator	Professor Christobel Saunders AO, FRCS, FRACS
Location	*[To be adapted for each location]*

Declaration by Participant

- ✓ I have read this Participant Information and Consent Form, or someone has read it to me in a language that I understand.
- ✓ I have been advised of, and understand, the purposes and risks of the research described in the project.
- ✓ I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- ✓ I freely agree to participate in the parts of this research project marked as 'Yes' below and understand that I am free to withdraw from any part of the research at any time during the project without affecting my health care.
- ✓ I understand that I will be given a signed copy of this document to keep.
- ✓ I give permission for the research team to access information concerning my condition and investigations for the purposes of this project from my doctors, other health professionals, hospitals or laboratories outside this hospital. I understand that such information will remain confidential and that all information about me will be de-identified in any reports, research papers or presentations.

I consent to:

- participate in the study ☐Yes ☐No

I consent to CIC Cancer research personnel accessing:

- information collected by my doctor ☐Yes ☐No
- my Patient Reported Outcome Measures data ☐Yes ☐No
- clinical data from other health services ☐Yes ☐No

I consent to CIC Cancer research personnel

- using the information collected for associated research and clinical quality registries, including approved organisations outside Australia ☐Yes ☐No

Name of Participant (please print)

_____

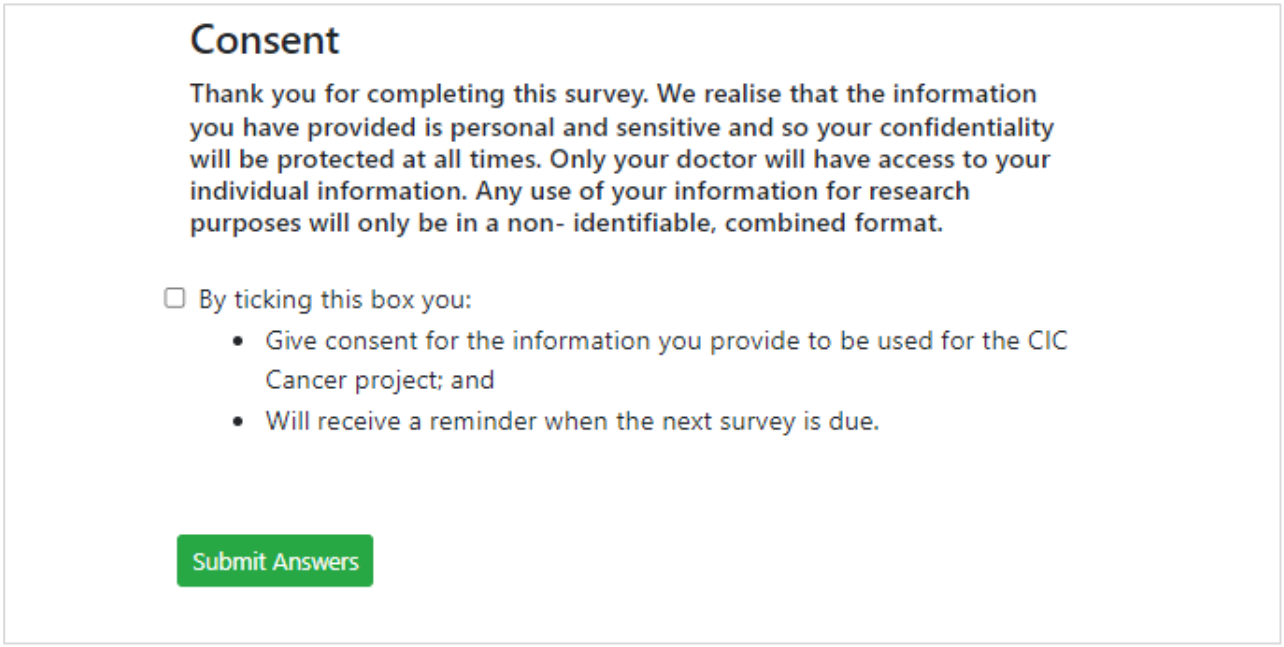
Signature _____ Date _____

Email address _____ Mobile _____

Appendix 4B: Dynamic consent for future contact

A framework of ongoing and dynamic consent [16] is used within CIC Cancer. To permit ongoing collection of information, patients indicate their ongoing and continued consent for capture and use of PROMs in each PROMs form completed via the online PROMs platform.

Figure 3: Screenshot of the consent page of the electronic CICIS PROMs form



Appendix 5: PROMs survey tools

PROMs data collection via CIC				
Colorectal, Lung, Breast registries	**Breast registry**	**Lung registry**	**Colorectal registry**	**Ovarian registry**
EORTC QLQ-C30	**EORTC QLQ-C30 + EORTC QLQ-BR23 + EQ5D**	**EORTC QLQ-C30 + EORTC QLQ-LC13 + EQ5D**	**EORTC QLQ-C30 + EORTC QLQ-C29 * + EQ5D**	**MOST Followup + EQ5D**
Functional scales				
Global Health status	Sexual functioning		Body Image	Physical wellbeing
Physical functioning	Sexual enjoyment		Anxiety	Emotional wellbeing
Role functioning	Future perspective		Weight	Overall wellbeing
Emotional functioning			Sexual interest	Treatment concerns
Cognitive functioning				Sexual function
Social functioning				
Symptom scales				
Fatigue	Systemic therapy side effects	Dyspnoea	Urinary frequency/incontinence	Abdominal pains, swelling
Nausea and vomiting	Breast symptoms	Coughing	Dysuria	Appetite
Pain	Arm Symptoms	Haemoptysis	Blood and mucus in stool	Fatigue
Dyspnoea	Upset by hair loss	Sore mouth	Flatulence; faecal frequency/incontinence	Nausea and vomiting
Insomnia		Dysphagia	Abdominal pain	Constipation
Appetite loss		Peripheral neuropathy	Buttock pain	Shortness of breath
Constipation		Alopecia	Bloating	Leg swelling
Diarrhoea		Pain in chest	Dry mouth	Numbness
Financial difficulties		Pain in arm or shoulder	Taste	Sore hands and feet
		Pain in other parts	Hair loss	Anxiety/depression
			Sore skin	
			Embarrassment	
			Stoma care problems	
			Impotence/Dyspareunia	
		EQ5D Mobility Self-care Usual activities Pain/discomfort Anxiety/depression		

* EORTC QLQ-C29 not collected at baseline

EORTC QLQ-C30

The European Organisation for Research and Treatment of Cancer (EORTC) has developed a self-reported questionnaire (QLQ-C30), to assess the quality of life of cancer patients. The questionnaire comprises of 30 questions divided separately by function items (five), symptom items (nine), and global health status.

- Function items included Global health status (QoL), physical functioning, emotional functioning, cognitive functioning, and social functioning. Within the functional scale, a high score indicates a better level of functioning.
- The symptom scale included fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhoea, and financial difficulties. Within the symptom scale, a high score indicates worse symptoms.

- All items employ a 4-point Likert scale, ranging from 1 (not at all) to 4 (very much), apart from two items in the global health status, which use a 7-point scale.

EQ-5D

The EQ-5D is the most widely used multi attribute utility instrument for measuring health-related quality of life in cost-effectiveness analysis. This instrument allows longitudinal data to be collected and used at an individual level to monitor a patient's health status over time. Within a hospital setting this can be used to monitor an institution's performance as a health care provider, or at a national level to monitor the population's health over time.

EORTC QLQ-BR23

The EORTC QLQ-BR 23 measures the quality of life of breast cancer patients specifically. The scoring approach for the QLQ-BR23 is identical in principle to that for the function and symptom scales/single items for the QLQ-C30. Similarly, the questionnaire is divided by functional and symptom items. The functional items include body image, sexual functioning, sexual enjoyment, and future perspective. In line with the QLQ-C30, the functional scale, a high score indicates a better level of functioning. The symptom scale includes systemic therapy side effects, breast symptoms, arm symptoms, and upset by hair loss. Again, for this symptom scale, a high score indicates worse symptoms.

EORTC QLQ-LC13

The QLQ-LC13 is a tumour-specific questionnaire consisting of 13 items on lung cancer symptoms (cough, haemoptysis, dyspnoea, site-specific pain) and its treatment-related side-effects (sore mouth, dysphagia, peripheral neuropathy, alopecia). Higher scores indicate worse symptoms compared to lower scores that indicate mild symptoms.

EORTC QLQ-C29

The *EORTC QLQ-CR29* contains four combined subscales (urinary frequency, blood and mucus in stool, stool frequency, and body image). Single variables relate to colorectal treatment and side effects and include urinary incontinence, dysuria, abdominal pain, buttock pain, bloating, dry mouth, hair loss, taste, anxiety, weight, flatulence, faecal incontinence, sore skin, embarrassment, stoma care problems, sexual interest. Higher scores represent better function on functional scales, whereas for symptom scales, a higher value translates into worse symptoms.

The EORTC QLQ-C29 is not collected at Baseline with collection only commencing at the 6 months timepoint.

Extra socio-demographic data is also captured e.g. What type of work do you do? (CRC)

Appendix 6: Implementation plan

Phase 1 (2023/24 FY)

Simplification of the collection of data over the course of phase 1 will consist of five key strategies.

- Collection of PROMs only for current and new patients.
- Revised process for internal creation of patient records within CICIS.
- Automation of the PROMs capture (at different time points) requests.
- Enhancements to CICIS application to limit manual processing.
- Progression of HSS integration processes.

Figure 4 provides an overview of the complete process to be associated with collection of PROMs.

PROMs only

The manual collection of clinical data is currently undertaken by research funded research officers. This is unsustainable within the processes of standard care provision. As such, from phase 1 commencement, data collection within CICIS – for both current and new patients – will be confined to a transfer of demographic information from WebPAS plus PROMs only.

A CIC project-funded research officer will be provided for at least 6 months of phase 1 to collect PROMs data on current CIC project and new patients whilst enhancement activities discussed below are implemented.

During phase 1, de-identified data will be extracted from CICIS. This will be analysed, and results fed back to clinicians and HSPs. An ethics amendment will be enacted in phase 1 to seek permission for CIC to also provide the Department of Health WA with these reports and de-identified data extracts. Should this information be deemed suitable for public reporting, the Department of Health WA could commence preparation (including ethics/governance approval) for such use. If required, further extracts can be provided in phase 1 for analysis and use in quality improvement activities by sites, HSPs (meso level), and policy makers (macro level) (refer to Appendix 2). Once the activities are fully determined in phase 2 –and appropriate ethics approval obtained by the Department of Health WA – this data will be directly accessible by Department of Health WA for decisions about ongoing use in appropriate public reporting.

CICIS record creation – test case

In phase 1, as a test case, the CIC team will seek to work with site staff to develop a process whereby outpatient department clerical staff in at least one applicable clinic (lung, colorectal, breast or ovarian), in at least one of the current public sites, complete the CICIS set-up for all new referrals to the clinic. Implementation of the new referral processes for CICIS patient record creation as part of outpatient/assessment clinic processes will assist in the aim to have PROMs capture become part of normal care. Inclusion of all patients attending specific clinic will also improve processing and take-up by outpatient clerical staff as there would be no requirement to determine which of the referrals relate to a possible cancer diagnosis.

The process of patient record creation is simple in CICIS and should not have a major impact on the workload of the clerical staff. It involves opening the CICIS application – approved clerical staff will be provided with CICIS access – and entering the patient's medical record number in the 'Patient Query' function of the application. This action automatically pulls a patient's information from WebPAS and creates a patient record in CICIS. The user then closes the application, and the automated PROMs survey despatch process will be enacted.

Implementation of this test case will also identify how well the capture of PROMs data can be extended to patients with similar health conditions who are also managed within the outpatient clinics that provide care to cancer patients. For example, patients with lung cancer attend the clinic alongside patients with other respiratory conditions and these patients would also benefit from review of PROMs during clinical consultations.

Prior to commencement of the test case, enhancements will be made to CICIS to address the capture of consent. This will seek to change the process from paper-based consent forms to e-consent. Work will also be undertaken to ensure that the patient facing components of CICIS have no mention of the term 'cancer'. Potentially, consent for PROMs collection can be implied by completion of the PROMs questionnaire/s (NHMRC guidelines) but advice sought indicates that an amendment should be made to seek e-consent under the current ethics arrangements.
Advice will be sought as to whether WA Health ethics approval is also required for long term use of CICIS. If this approval can be provided by building on the current research protocol and approval this process will be undertaken by the CIC team in the latter half of phase 1. If this is not permitted, WA Health personnel will need to commence the required processes for obtaining this approval prior to phase 2. Information and training support will be provided to site staff to assist with implementation activities and determine acceptability of the test case.

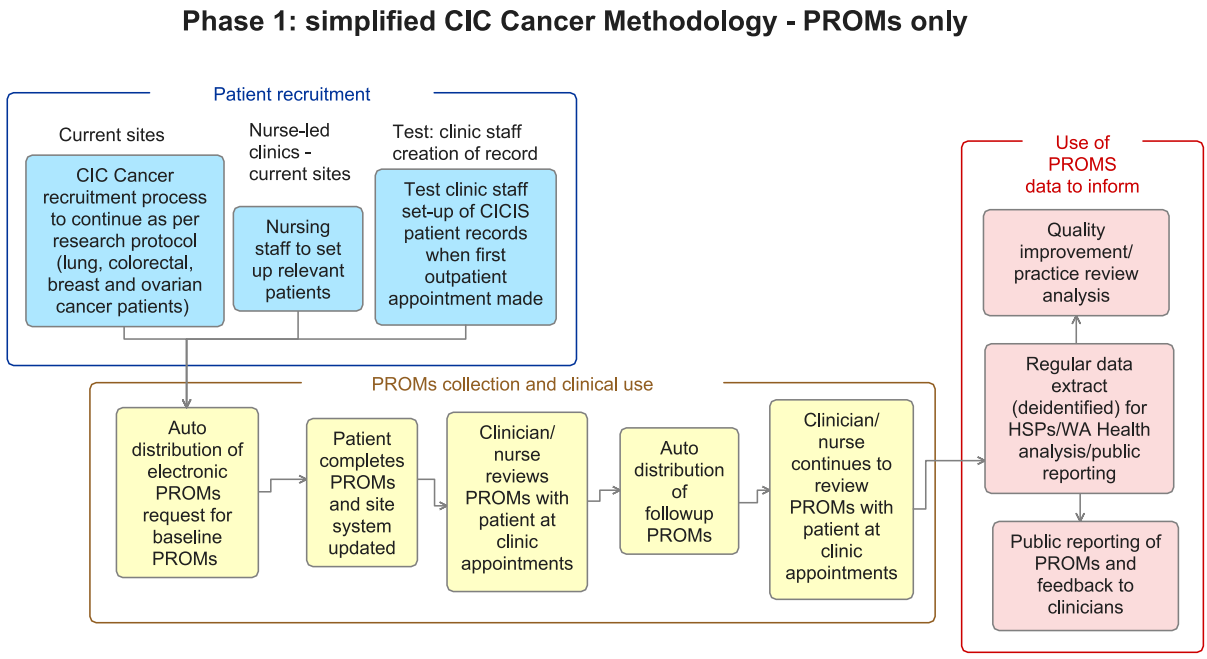
Relevant nursing staff will continue to create patient records for new patients managed within a nurse-led clinic at the public sites. Private sites will also continue to set up patients and operate as they do under the CIC Cancer research project.

<u>Automated despatch of PROMs requests</u>
Enhancements will be made to CICIS in phase 1 to automate PROMs processes, thereby limiting the current need for research officers to manually set up the electronic despatch of the PROMs requests at each time point. The revised process will be (new processes highlighted in bold font):

- Once a patient record is set up within CICIS, **a secure automated process will run overnight and despatch a PROMs survey** to the patient via email.
- The patient will complete the PROMs survey electronically, indicate their willingness to be contacted for future PROMs surveys, and submit the form.
- This survey form is held on the dedicated PROMs server and then loaded back into the patient record within 5 minutes of being received.
- Once the information has been transferred to the site system it will be deleted from the PROMs server. This additional process is in place to protect the security of the patient record.

When the patient attends their clinic appointment the clinical staff will be able to easily identify the key patient reported issues via the visualisation platform built into CICIS. This will enable targeted discussion about the patient's functional or symptom issues and allow care to be planned appropriately. If a patient has not yet completed the PROMs survey this can be completed in the waiting room (via a QR code and entry via a tablet device or personal smartphone) or directly into the patient record as part of a nurse-led assessment process. Visualisation of the results are also compared to time-point averages for the cohort – this will enhance discussions about normalcy, or otherwise, of symptoms.

Figure 4: Phase 1 processes to capture PROMs



The recommended scheduling for follow-up PROMs surveys has been built into CICIS. In most instances this covers a period from a few months after treatment commences to long-term survival (up to 10 years). This scheduling will inform ongoing automatic despatch of follow-up PROMs at appropriate time points. Transfer of PROMs data into the site system will follow the same uploading process noted above and be made available within the patient record for ongoing clinic visits and review of care/needs. Should the patient require additional follow up, a PROMs survey can be requested manually via CICIS at any time and emailed to the patient or completed via a tablet/smartphone in the outpatient/clinic waiting room.

Changes will also be made to CICIS to allow for the efficient capture of consent with automated despatch of baseline PROMs. An additional page will be added to CICIS that will require patients to acknowledge that they have read an information sheet supplied with the initial clinic appointment documentation and consent to their data being used for clinical and quality improvement initiatives. Dynamic consent is already built into CICIS with patients consenting to future contact for follow-up PROMs each time they complete a PROMs survey.

<u>HSS Integration</u>

The CICIS application is already housed within HSS as an enterprise system, with links to the Health Information Hub (HIH) for the purpose of pulling in patient data from other enterprise systems. A hybrid Operational Services Transition Agreement (H-OSTA) is already in place and during phase 1 this will be upgraded to OSTA level. Any requirements necessary, for this to be approved, will be enacted.

Work will be undertaken to fully transfer ongoing CICIS ICT management to HSS by June 2024. This will include readiness for acceptance of CICIS to a relevant HSS applications team, finalisation of HSS integration processes (e.g. completion of a full OSTA) and implementation of any additional IT requirements arising from the OSTA.

Prior to implementation of CICIS, discussions were held with data stewards and custodians around potential integrations with other enterprise systems in an effort to reduce duplication of effort for clinical

data capture. Much of this agreed integration has been unable to be progressed, however, due to difficulties obtaining atomic level data or poor access to data dictionaries for commercial products. During phase 1 such discussions will continue in an effort to find effective ways of pulling appropriate clinical data into CICIS.

Governance

Governance for phase 1 will be managed under the current CIC Cancer Executive and CIC Cancer Steering committees. The Department of Health WA is already represented on the steering committee, with Dr Audrey Koay a member. During phase 1, consideration of the most appropriate governance arrangements for phase 2 and beyond will be undertaken by the Department of Health WA.

It is suggested that appropriate teams within the Department of Health WA work with the CIC Cancer team to:

- understand the potential resources necessary for continuation of the PROMs collection;
- identify the potential business requirements for implementation of phase 2; and
- finalise possible longer-term governance arrangements for the proof-of-concept. This will likely include discussions between the transition team (CIC Cancer Team and Department of Health WA) with relevant research ethics and governance personnel at the Department of Health and HSPs.

Ongoing arrangements for a Data Steward, Data Custodian and Data Sponsor will be required. Both a steward and custodian are currently in place for the CIC research project and ongoing suitability of this will need to be assessed with relevant recommendations made and submitted, by WA Health personnel, under the Information Management Governance Model and associated policies. Inclusion of the CICIS on the Information Register and preparation for appropriate WA Health plans, policies, procedures should also be undertaken.

Activities Matrix

The activities (Table 4) associated with phase 1 outputs (Table 3) will be undertaken between July 2023 and June 2024. All CICIS enhancement activities and site engagement activities undertaken by the CIC team will occur at both current HSP sites and SJoG sites to ensure consistency of approach and data capture.

Table 4: Detailed activities phase 1

Activity	Responsibility	Due date
Ongoing collection of PROMs data for patients already recruited under CIC Cancer research		
• Research Officer in place to continue to collect follow-up PROMs data	CIC	Pre Jul 23/ongoing to at least Dec 23
• Development of user guide/data dictionaries (WA Health and SJoG versions)	CIC	Jul 23
• User authentication/authorisation for all relevant staff to access CICIS application	CIC	Jul 23/ongoing to Jun 24
• CICIS demonstration to clinical teams	CIC, current sites	Jul 23/ongoing to Jun 24
• CICIS demonstration to relevant HSP teams/management	CIC, current sites	Oct 23/ongoing to Jun 24
• CICIS demonstration to MDTs to provide understanding of PROMs data and how this can inform MDT deliberations	CIC, current sites	Nov 23/ongoing to Jun 24

• Data analysis and reporting undertaken and fed back to HSPs and clinicians	CIC	Dec 23
• Provision of de-identified PROMs data extracts on a 6 monthly basis to involved HSPs (and potentially the Health Networks team pending Health Executive Committee (HEC) and ethics approval)	CIC	Dec 23, Jun 24
• Ad hoc data analysis	Site teams	As required
• Permission sought from HEC for Dept. of Health access to data reports pertaining to HSPs	Department of Health WA	Prior to Jun 24
Capture of PROMs data on new patients		
• Recruitment of new cancer patients from designated clinics in current sites as per current research protocol	CIC, current sites	Jul 23/ongoing to Jun 24
Potential test case - patient record creation by clerical staff (identification of how to effectively extend data capture to related conditions)		
• Work with site-based contacts to engage potential test outpatient clinic	CIC, current sites	Oct 23
• Removal of any patient facing reference to cancer within CICIS (cancer specific diagnostic/condition description fields within the clinical dataset to remain)	CIC, IT developer	Oct 23
• Obtain HREC approval for capture of e consent	CIC	Oct 23
• IT development of e-consent page in PROMs survey	CIC, IT developer	Nov 23
• Update current CICIS versions (including SJoG)	CIC, IT developer	Nov 23
• Preparation of information sheet for distribution with clinic appointment papers	CIC, sites teams	Nov 23
• Provide information support to sites to assist with implementation activities	Sites teams, CIC	Oct 23/ongoing to Jun 24
• CICIS training for clerical staff in test outpatient clinic	CIC	Oct 23/ongoing to Jun 24
• Provide information support to assist site teams with understanding acceptability	Site teams, CIC	Nov 23/ongoing to Jun 24
Enhancements to CICIS to automate processes to despatch of PROMs requests		
• Obtain HREC approval for changes	CIC	Oct 23
• Development of e-consent page in PROMs survey	CIC, IT developer	Dec 23
• Update current CICIS versions (including SJoG)	CIC, IT developer	Dec 23
• Automation of Baseline PROMs (incl. development, testing, user acceptance testing, production)	CIC, IT developer	Functioning prior to Mar 24
• Automation of Follow up PROMs as per ICHOM schedule (incl. development, testing, user acceptance testing, production)	CIC, IT developer	Functioning prior to Apr 24
Finalisation of HSS integration processes (e.g. Operational Services Transition Agreement (OSTA))		
• Identification of appropriate relevant HSS apps team	CIC Team/HSS	By Mar 24
• Transfer from H-OSTA to Operational Service Transition Agreement (OSTA)	CIC Team/HSS	May 2024
• Any development work required as part of the OSTA development	CIC, IT developer	By Jun 24
• 12 months of CIC funded, HSS based, IT server hosting	CIC Team/HSS	Jul 23 – Jun 24
Implementation of any development activities required, by HSS, for full OSTA finalisation		
• Maintenance of annual security certification for CICIS	CIC Team/HSS/IT developer	Before Jun 24
• Annual penetration testing	HSS	Before Jun 24
• Update current CICIS versions (including SJoG)	CIC, IT developer	Before Jun 24

• Identification of requirements for HSS take-up of AWS hosting	CIC Team/HSS	Before Jun 24
Identification of potential links with other HSS data capture systems for capture of clinical data		
• Engagement with relevant clinical enterprise systems re possibilities for clinical data sharing	CIC Team/HSS	Before June 24
Governance Model		
• Acceptance of Transition Plan	Department of Health WA	Sept 23
• Via current ethics arrangements, seek extension of CIC ethics to Jun 24 and obtain approval for changes made as part of simplification activities and access to data by WA Health.	CIC	Oct 23
• Access to advice from WA Health Research Governance Officer re ongoing requirements	CIC, Department of Health	By Dec 23
• Development of e-consent approach (see Enhancements to CICIS above)	CIC	By Dec 23
• Continuation of CIC Cancer Steering Committee	CIC	Until Jun 24
• Identify need to seek WA Health HREC approval for proof-of-concept project (advice to be sought from Research Governance Officer) and, if approval provided to build on current ethics approval, commence processes.	CIC, Department of Health WA	By Jun 24
• Identification of suitable ongoing governance model under Cancer Data Strategy	Department of Health WA	By Jun 24
• Determine if need for changes to approved consent approach to allow future use of PROMs data for research/policy development within, and external to, the Department of Health WA	Department of Health WA, WA Health HREC	By Jun 24
• Register CICIS as an information asset as per the Information Management Governance Model	Department of Health WA	
Preliminary understanding of resourcing necessary for continuation of PROMs collection		
• Implementation of any additional, relevant public sites that express an interest in being involved	CIC	By Jun 24
• Early scoping of the work needed to extend to other WA public sites and conditions (e.g. networking with other HSPs for interest in being involved and identification of priority for additional conditions)	Department of Health WA	By Jun 24
• Early scoping of public reporting requirements	Department of Health WA	By Jun 24
• Business requirements identified and appropriate funds options sourced	Department of Health WA	By Jun 24

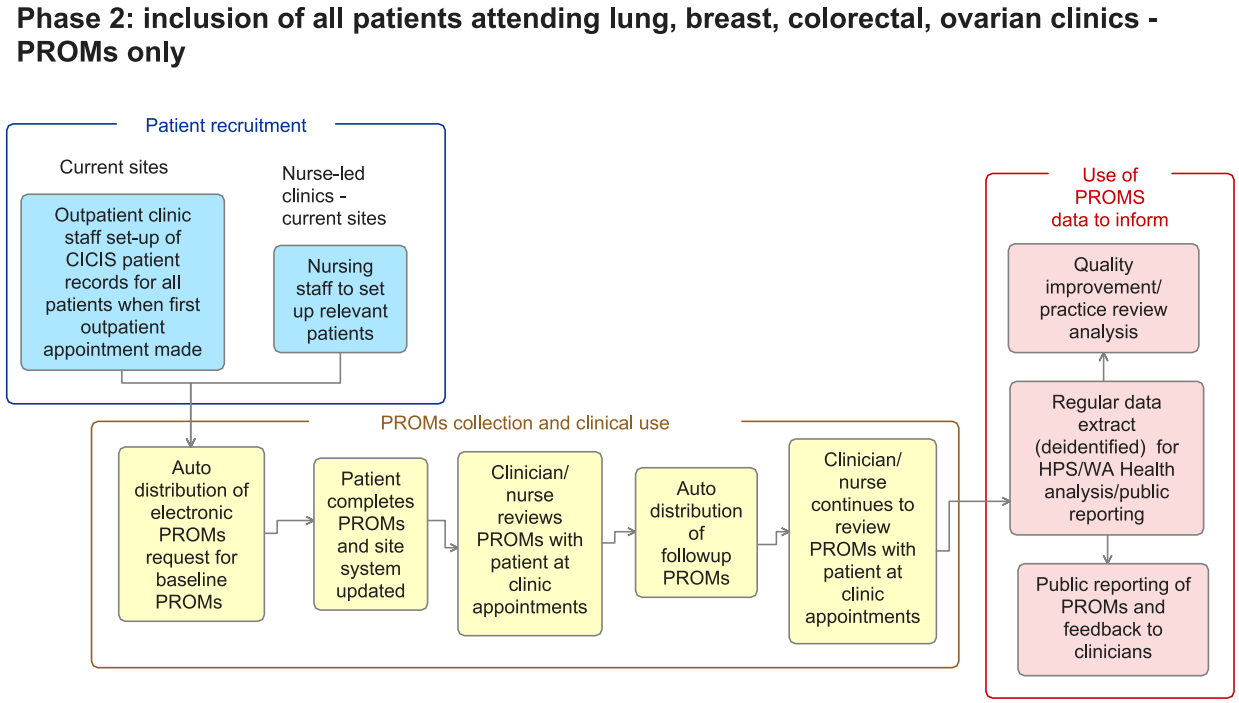
Phase 2 (2024/25 FY)

Extension of data capture to non-cancer patients

It is suggested that a proof-of-concept project be undertaken for 12 months (phase 2) under full control of the Department of Health WA. The process (Figure 5) for collection of PROMs could remain as it was for phase 1, the only change being that, based on the results of the test case in phase 1, use of CICIS could be extended to other conditions managed by outpatient clinics caring for people with lung, colorectal, breast and ovarian cancer across all current sites.

Should other public hospital sites who provide colorectal, breast, lung, or ovarian cancer care express an interest in being involved, the collection of PROMs can be extended to additional sites with minimal additional work. Such extensions of data capture will be commenced in phase 1, if interest is expressed.

Figure 5: Phase 2 processes to capture PROMs



Acceptance of CICIS to HSS applications team

Work undertaken in phase 1 to complete an operational services transition agreement should identify the HSS applications team responsible for oversight of CICIS in phase 2. It is assumed that once allocated to a team the management of CICIS will transfer at the conclusion of phase 1.

Linkages to enable automatic transfer of clinical data

Potential linkages with IT systems identified in phase 1 will need development and enactment to enable automated transfer of clinical data from other HSS enterprise systems. This will require 1) engagement with the WA Cancer Data Strategy team to understand state priorities, and 2) discussions with HSS – strategic and architecture teams to determine the most effective means of mapping and integration of CICIS to other clinical data sources.

This is to ensure the most accurate and comprehensive collection of cancer data for use at the micro, meso and macro levels of health in order to provide the best value and quality of care for cancer patients in WA. Integration to capture clinical data may be easier once the entire all HSPs are upgraded to BOSSnet.

A future enhancement to CICIS to pull and thus capture of the International Classification of Diseases (ICD) code within WebPAS into the CICIS demographics form could assist in ongoing comparison of PROMs reported by patients with different condition types.

Mechanisms for public reporting of PROMs

During phase 2, the Department of Health WA will be responsible for identification of suitable mechanisms for public reporting of PROMs. The provision of data extracts in phase 1 (pending ethics approval sought by CIC) could assist in early scoping activities prior to phase 2.

Linkages with the private sector to access comparable PROMs data

The potential for linkages with the private sector could be considered during phase 2 to allow access to comparable de-identified PROMs from private sector sites such as SJoG in the longer-term.

Governance

Project governance requirements are needed for oversight of the proof-of-concept project and beyond. During phase 2 ongoing formal governance arrangements will be determined by the Department of Health WA. It is suggested that this be managed under the WA Cancer Data Strategy Advisory and a Business User Group (BUG) convened.

Agreement for use of PROMs data in policy development within the Department of Health WA is implied within current ethics approval but a further amendment to the current research protocol will be sought in phase 1 to confirm this. During phase 2, however, consideration will need to be given to the ongoing use of de-identified CICIS data for research/policy development and the appropriate ethics approval will need to be obtained by the proposed Department of Health WA investigators.

Data governance policies will also need to be developed by WA Health personnel for both project and research activities. It is suggested that preparatory work be implemented as soon as possible to allow this to occur once the proof-of-concept project is complete.

Proof-of-concept evaluation

It is suggested that the proof-of-concept project be evaluated by the Department of Health WA to assess the success of the CICIS transition into standard clinical care. This will include:

- acceptance of the system to users;
- ease of use and completion of data capture;
- use of data in clinical interactions; and
- use of data analysis in care improvement.

The results of this evaluation will lead to an understanding of changes needed for successful ongoing implementation/adaptation of CICIS to deploy PROMs for use as standard care in cancer and similar conditions across all sites and the potential for application within additional health conditions.

At this time, the business requirements and resources can also be identified for continuation beyond 2025 and, if necessary, a business case submitted.

Table 5: Suggested detailed activities phase 2

Activity	Responsibility	Due date
Extension of data capture to non-cancer patients seen in current clinic settings		
• CICIS extended to similar conditions managed by all outpatient clinics caring for people with lung, colorectal, breast and ovarian cancer within all current sites	Department of Health WA, HSPs	July 24
• Inclusion of all patients attending specific clinic settings to improve processing and take-up by outpatient clerical staff	Department of Health WA, HSPs	July 24
• Inclusion of any additional, relevant public hospital sites providing colorectal, breast, lung, or ovarian cancer care expressing an interest in being involved	Department of Health WA, HSPs	By Jun 2025
• Scoping of the work needed to extend PROMs collection to other WA public sites and conditions (e.g. networking with other HSPs for interest in being involved)	Department of Health WA, HSPs	By Jun 2025

• Identification of priorities for additional conditions and appropriate clinical champions to assist with registry determination	Department of Health WA, HSPs	By Jun 2025
Acceptance of CICIS into a relevant HSS applications team		
• Transfer of oversight of CICIS from CIC Cancer to the appropriate HSS applications team, including amendments to OSTA to reflect this	HSS	Jul 2024
• Management of CICIS by the appropriate HSS applications team commencement	HSS	Jul 2024
Potential linkages with other IT systems enabled to automatically transfer clinical data		
• Identify need, and state priorities, for potential clinical data transfer to address the policy requirements of the WA Cancer Data Strategy	Department of Health WA	By Jun 25
• Consideration of the need for further development of CICIS to allow importation of the International Classification of Diseases (ICD) code captured within WebPAS	Department of Health WA, HSS	By Jun 25
• Discussions with HSS – strategic and architecture teams to determine the most effective means of mapping and integration of CICIS to other clinical data sources (once rollout of Bossnet/digital medical record is complete)	HSS – strategic and architecture team, Department of Health WA	By Jun 25
Identification of suitable mechanisms for public reporting of PROMs		
• Scoping of suitable mechanisms for public reporting of PROMs including identification of data requirements and effective communication channels	Department of Health WA, HSPs	Dec 24
• Commencement of public reporting	Department of Health WA	By Jun 24
Determination of activities required to link with the private sector PROMs		
• Determine need for collection of private hospital data and options for integration	Department of Health WA	By Jun 24
Implementation of governance model		
• If not already undertaken, obtain WA Health HREC approval and governance from HSPs as appropriate	Department of Health WA	By Jul 24
• Development of project governance model (suggested to sit under Cancer Data Strategy)	Department of Health WA	July 24
• Implementation of Business User Group (BUG)	Department of Health WA	Aug 24
Proof of concept success evaluated including user acceptance, data capture, use of data, and feedback		
• Measure acceptance of the system to users and usage of data collected	Department of Health WA, HSPs	Jun 25
• Assessment made for full implementation of CICIS in cancer and similar conditions across all WA sites	Department of Health WA, HSPs	Jun 25
• Assessment made for implementation/adaptation of CICIS to deploy PROMs in additional health conditions as standard care	Department of Health WA, HSPs	Jun 25
• Business case developed for 2025 and beyond	Department of Health WA, HSPs	Jun 25
• Appropriate funds sourced and approved	Department of Health WA, HSPs	Jun 25

Beyond 2025

Implementation/adaptation of CICIS to deploy PROMs assessed for use in other health conditions as standard care

It is suggested that site personnel, and Department of Health WA work together to identify additional activities to extend data capture to additional conditions where an International Consortium of Health Outcome Measures (ICHOM) standard dataset is already available (e.g. diabetes or cardiovascular disease). This collaboration will also allow for determination of effective processes to interact with patients' long term and identify practises for effective use of the information collected.

It is also suggested that formal agreements for access to private sector data are considered/negotiated by Department of Health WA and SJoG group after the completion of the proof-of-concept evaluation.

The importance of the data is such that external researchers will be keen to access the PROMs information. It is suggested that research governance policies be developed by WA Health to manage this.

Table 6: Suggested detailed activities beyond 2025

Activity	Responsibility	Due date
Extension of data capture in whole of WA Health		
• CICIS extended to cancer and similar conditions managed by all outpatient clinics caring for people with lung, colorectal, breast and ovarian conditions across WA Health.	Department of Health WA, HSPs	By Jun 26
• Develop new registries to capture other conditions e.g. other cancers, diabetes or cardiovascular disease, and trial prior to extension to all sites	Department of Health WA, HSPs, HSS	By Jun 26
• Data is analysed for quality improvement activities and policy determination	Department of Health WA, HSPs	Ongoing
• Routine public reporting is in place	Department of Health WA, HSPs	Ongoing
Maintenance of project governance model		
• Ensure adherence to local plans, polices, procedures to ensure compliance with State Records Commission endorsed standards and schedules (retention/disposal, quality, storage, classification).	Department of Health WA, HSPs via BUG	Ongoing
• Undertake initial 2-yearly self-assessed Information Management Maturity Assessment.	Department of Health WA, HSS	After Jun 26
Potential linkages with other IT systems enabled to automatically transfer clinical data		
• Continue links with digital health record work to enhance potential for clinical data transfer	Department of Health WA	Ongoing
• Development of policy for the ongoing use of de-identified CICIS data for research/policy development where appropriate ethics approval is obtained	Department of Health WA, HSPs via BUG,	By Jun 25

Appendix 7: Risk Management Matrix

CIC Transition:
Risk Management Plan

Introduction

This Risk Management Plan identifies the risks associated with implementing the CIC Cancer transition by listing the potential project risks, evaluating the severity of those risks, and outlining activities/strategies to mitigate/reduce the risks. This has been developed to ensure levels of risk and uncertainty are foreseen, the potential impact is estimated and responses to those risks are properly managed.

As a Department of Health managed proof-of-concept project, is governed by the Department of Health (WA) Risk, Compliance and Audit Policy Framework version 7. That framework sits, in turn, within WA Health Compliance Management Policy- MP 0007/16, Risk Management Policy- MP 0006/16, and Risk Assessment Tables for the WA Health System.

Risk Ratings

The Department of Health risk tables has been used to assist in assessing the risk ratings of the CIC Cancer transition activities. Risk is rated using a risk assessment matrix. This matrix considers the likelihood of a risk occurring (Table and Table) against the consequence of the risk (Table). These are then colour coded for ease of identification. (Table).

Likelihood

The likelihood of the identified risk occurring with the controls in place is rated as Rare, Unlikely, Possible, Likely, or Very Likely.

Table 1: Likelihood ratings and definitions

Likelihood		Consequence				
		1	2	3	4	5
		Insignificant	Minor	Moderate	Major	Catastrophic
1	Rare	1	2	3	4	5
2	Unlikely	2	4	6	8	10
3	Possible	3	6	9	12	15
4	Likely	4	8	12	16	20
5	Very Likely	5	10	15	20	25

Table 2: Likelihood rating

Likelihood Rating		Clinical	Corporate	
Level	Descriptor	Per separations/ occasions of service	% Chance during life of project or financial year for budget risk	Time Scale for ongoing non-project activities or exposures
1	Rare	1 in 100,000 or more	≤5%	Once in more than 10 years
2	Unlikely	1 in 10,000	> 5% to 30%	Once in 5 to 10 years
3	Possible	1 in 1,000	> 30% to 60%	Once in 3 to 5 years
4	Likely	1 in 100	> 60% to 90%	Once in 1 to 3 years
5	Very Likely	1 or more in 10	>90%	More than once a year

Consequence

The consequence to the project outcomes of the identified risk occurring with the controls in place is rated as Insignificant, Minor, Moderate, Major, or Catastrophic. Definitions of these consequences have been outlined against the key risk categories.

Table 3: Consequence categories and definitions

Severity Level	1	2	3	4	5
Consequences categories	**Insignificant**	**Minor**	**Moderate**	**Major**	**Catastrophic**
Health impact on patients	Increased level of care (minimal). No increase in length of stay. Not disabling.	Increased level of care (minimal). Increased length of stay (up to 72 hours). Recovery without complication or permanent disability.	Increased level of care (moderate). Extended length of stay (72 hours to 1 week). Recovery without significant complication or significant permanent disability.	Increased level of care (significant). Extended length of stay (greater than 1 week). Significant complication and/or significant permanent disability	Death or permanent total disability.
Health impact on staff or others	First aid or equivalent only.	Routine medical attention required. Up to 1 week incapacity/time lost. No disability.	Increased level of medical attention required. 1 week to 1 month incapacity/time lost. No significant permanent disability.	Severe health crisis and/or injuries. Prolonged incapacity or absence for more than 1 month. Significant permanent disability.	Death or permanent total disability.
Critical services interruption	No material disruption to dependent work.	Short-term temporary suspension of work. Backlog cleared in day. No public impact.	Medium-term temporary suspension of work. Backlog requires extended work, overtime, or additional resources to clear. Manageable impact.	Prolonged suspension of work. Additional resources, budget and/or management assistance required. Performance criteria compromised.	Indeterminate prolonged suspension of work. Impact not manageable. Non-performance. Other providers appointed.
Organisational objectives or outcomes	Little impact.	Inconvenient delays.	Material delays. Marginal under achievement of target performance.	Significant delays. Performance significantly under target.	Non-achievement of objective/ outcome. Total performance failure.
Project deliverables	≤ 1 % variation to deliverables	> 1 % to 5% variation to deliverables	> 5% to 10% variation to deliverables	> 10% to 20% variation to deliverables	> 20% variation to deliverables
Project budget	≤ 1 % over budget	> 1 % to 5% over budget	> 5% to 10% over budget	> 10% to 20% over budget	> 20% over budget
Project time delay	≤ 5% delay	> 5% to 10% delay	> 10% to 25% delay	> 25% to 100% delay	> 100% delay
Legislative Compliance	Procedural or good faith breach	Breach of regulation; complaint lodged or minor investigation	Negligent breach; warning from regulator; lack of good faith or poor performance	Deliberate breach; gross negligence resulting in successful prosecution; regulatory involvement	Criminal negligence or act; prosecution or dismissal; ministerial censure
Financial loss	Financial or asset loss = <0.15% of operating budget	Financial or asset loss = Up to 0.5% operating budget	Financial or asset loss = up to 1% of operating budget	Financial or asset loss = up to 3% of operating budget	Financial or asset loss = >3% of operating budget

Risk Matrix

Table4: Risk Matrix

	Ratings	Consequences				
		1. Insignificant	2. Minor	3. Moderate	4. Major	5. Catastrophic
Likelihood	1. Rare	Low	Low	Low	Low	Medium
	2. Unlikely	Low	Low	Medium	Medium	High
	3. Possible	Low	Medium	Medium	High	High
	4. Likely	Low	Medium	High	High	Extreme
	5. Very likely	Medium	High	High	Extreme	Extreme

Management of risk

Once a risk has been identified and rated through use of the risk matrix, risk mitigation may be required.

Table 5: Risk acceptance management levels

Risk Level	Level of Management required
Low	Risk is generally acceptable. Manage by comprehensive effective controls and procedures. Review risk at least annually.
Medium	Risk is generally tolerable. Implement sufficiently effective controls to substantially manage the risk. Periodic monitoring and testing are undertaken.
High	Risk is generally intolerable. Reduce risk to at least medium through an action plan to mitigate or remove risk as necessary such that a low level of risk can be attained as soon as practicable.
Extreme	Risk is generally intolerable. Implement immediate management to control risk and urgent mitigation action such that a low level of risk can be attained.

CIC transition risk identification and assessment matrix

Description of risk	Likelihood	Consequence	Risk rating	Strategies for mitigating risk
Impact on patients				
Patient care is compromised	**Unlikely –** No foreseeable harm to patients - the project will not affect care provision as it only involves collection of data about care provided and patient outcomes	**Insignificant –** No foreseeable harm to patients - the project involves collection of data about care provided and patient outcomes in an effort to improve care provision. • Some psychological distress only may be encountered by some participants if questions trigger an unexpected response • Level of care/length of stay/complications of care unlikely to be affected Safety of patient data is the key potential risk and this has been addressed below.	Low	• Ensure detailed information is provided to patients to allow project. • Consent for Baseline PROMs will be implied on completion contact on completion of each survey. Patients can withdra • Ensure participants are advised to discuss any psychological completing PROMs. • Tailor patient information to applicable condition to avoid c conditions. • Ensure effective feedback to clinicians and patients to allow • Identifying data maintained at treatment site/enterprise lev
Objectives - Data collection and management				
CICIS infrastructure ineffective or inadequate (including issues with personnel or technology)	**Possible** – ICT framework already in use and PROMs data collection already proven. Loss of local key personnel, delayed translation, or minimal ongoing software development will result in inability to meet stakeholder needs. Any non-integration with current hospital systems for clinical data will result in inefficiencies and duplication of data collection.	**Insignificant –** No foreseeable harm to patients - the project will not affect care provision as it only involves collection of data about care provided and patient outcomes. • Project aims not fully met • The work is not sustainable beyond the life of the project • Loss of engagement from clinicians and health services • Escalation of costs • Project not completed within timeframe.	Low	**Planning** • Develop comprehensive project planning and management activities, milestones, and timeframes and use these to mon • Manage IT development timeframes and certainty of systen information on requirements (including clear use-case base produced and design specifications are suitable. **Stakeholder communication** • Communicate with site/service/IT personnel early and main amongst stakeholders. • Ensure that site/group IT departments are provided with su • Identify and communicate project scope to stakeholders wh • Engage end users early and regularly for input and feedback • Ensure use cases are well defined. **Project management** • Ensure management structure includes technical managem complex ICT projects. • Foster a collaborative culture and ensure sufficient human r defined roles and responsibilities) are in place to meet miles • Provide support for continuing development of an open-sou and project teams developing the same or similar open-sou • Adoption of contemporary best practices in software develo (automation, documentation, team-based development) an training, and implementation planning is undertaken, docur **Development/deployment** • Utilise issue tracking systems. • Manage possibility of system failure due to bugs through im allow bugs to be dealt with in a timely fashion (e.g. a new co production errors are automatically reported to the system • Ensure developed product meets actual use-cases through implementation of 'use-case driven agile development' met • Minimise potential for runtime errors in application through and automated testing. • Ensure CIC Cancer informatics system has capability and cap through upfront knowledge and specification of all required • Ensure systems are accessible to all users through adequate documentation and provision of early information about co

Description of risk	Likelihood	Consequence	Risk rating	Strategies for mitigating risk
				• Ensure system is useable on all required devices through ide applications (e.g. OS versions, allowed browser versions, mo pre-test processes.
Data security is breached	**Possible –** Research and ICT teams are experienced, but the system is complex with several elements and there is need for secure transfer of information between system components. The CICIS is hosted within the secure Zone A of the WA Department of Health cloud (HealthNext), however, unauthorised access or disclosure could cause risk to business and damage to credibility.	**Moderate –** • A negligent breach would result in non-compliance with regulations and could result in warning from regulator. • Loss of data with data capture compromised. • Some psychological distress may be encountered by participants. • Organisational reputation impacted. Potential for litigation	Medium	**Patient care** • Data collection does NOT include restricted authorised acces status or sexually transmitted disease notifications. • Ensure participants are advised to discuss any psychological • Both the site system and the PROMs Platform sit in the Zone Australian data centre. This is subject to WA Health and the • Identifiable clinical data hosted only on WA Health managed identifiable data is maintained outside this zone. Only de-ide • Users accessing named data are WA Health staff who are su guidelines. Access privileges are based on WA Health Inform Steward. **Planning** • A WA Health based Data Steward responsible for overall ma structure, control, and authorisation is appointed. • Data Custodian ensures fitness of data elements - both the c **Development/Deployment** • Modular "hardened" design methodology in place to minimi volumes). • Separation of demographic data from clinical data in the Site • Potential for 'attack vectors' are reduced through reduction hardening of the admin Interface. • Implementation of MD5 hashing of the data to limit data tar • Password mitigation controls in place - 2 factor authenticatio phone), system locked after 3 failed attempts, account locko 10 minutes). Admin user on PROMs system deactivated, rer making it truly 'headless'. The use of 13+ characters as a mi used with password length of 13+ characters). • System released in non-design mode which switches off cust • Non-admin users have restricted views (role-based security) • User actions are logged (form data is snapshotted internally fields). Regular audits conducted. • User training includes discussion about non-disclosure of co allow access to confidential information. • Information stored on server-based storage only (protected processes) with no use on local PC hard drives. • Encryption or secure file transfer software is used for transm the Data Steward (SCP/SSH). • Only those staff who "need to know" to perform their role a • Implement processes to guard against malicious users such a security roles (admin, curator, clinical staff); all security roles rights; make use of principle of least privilege (restrict permi required tasks). • Disk Drive encryption is used on any external laptops so data accessed. Any site-based desktop or laptop equipment used relation to security of information and authorised access. • No identifying data is made available to unauthorised staff. authorised site personnel. • Data extract functionality is locked down to control the infor Only a limited set of views are exposed and there is no expo no exposure of the reporting framework or reporting interfa • User accounts are managed via a web-based administration functionality is in place and user roles will be limited to 1 wh WA Health/HSS are responsible for assigning users to the cli systems/policies in place for other enterprise clinical data ca • Implement system activity records: Physical log files (web se for information messages); populate the database with trace

Description of risk	Likelihood	Consequence	Risk rating	Strategies for mitigating risk
				logins, IP addresses and user agent strings of users + PROMs over time (longitudinal data); and physical logfiles read by H **Governance** • Data management guidelines implemented including incorp out-of-office including home. • Implement processes, policies, and guidelines for administer information access and disclosure policies and/or regulatory
Inadvertent data loss	**Unlikely –** ICT teams are experienced, and sites are aware of patient confidentiality issues and have put necessary processes in place.	**Moderate -** • Loss of data and diminished understanding of opportunities for improvements to care. • Loss of ability to meet agreed strategic priorities. • A negligent breach would result in non-compliance with regulations and could result in warning from regulator. • Loss of data with data capture compromised. • Some psychological distress may be encountered by participants. • Organisational reputation impacted. • Potential for litigation.	Medium	**Patient Care** • Data collection does NOT include restricted authorised acces status or sexually transmitted disease notifications. • Ensure participants are advised to discuss any psychological • Both the site system and the PROMs Platform sit in the Zone Australian data centre. This is subject to WA Health and the • Identifiable clinical data hosted only on WA Health managed identifiable data is maintained outside this zone. Only de-ide • Users accessing named data are WA Health staff who are su guidelines. Access privileges are based on WA Health Inform Steward. **Planning** • A WA Health based Data Steward is responsible for overall structure, control, and authorisation. • Data Custodian in place to ensure fitness of data elements **Development/deployment** • Build auditing capabilities into application to track user beh • Develop "reversion" capability to allow reversal of some cha • Ensure adequate and timely database backups so data can • The confidential nature of the information collected and sto information access and disclosure policies. • Users accessing named data will be WA Health staff who ar guidelines. • Information stored on server-based storage only (protected processes) with no use on local PC hard drive. **Governance** • Processes, policies, and guidelines for administering data co obligations.
Physical security is breached	**Unlikely –** Work within sites is conducted in suitable environments and necessary processes are in place. Staff at sites are aware of patient confidentiality issues.	**Moderate –** • Loss of data or data contaminated • Theft/loss of, or damage to, equipment • A negligent breach would result in non-compliance with regulations and could result in warning from regulator. • Organisational reputation impacted. • Potential for litigation.	Medium	• Ensure participants are advised to discuss any psychological • Ensure adequate security, such as swipe card access to all ar • Ensure staff understand, and adhere to, security and compli • Disk Drive encryption will be used on any external laptops so accessed. • No identifying data is made available to unauthorised staff. authorised site personnel. • Any site-based desktop or laptop equipment used is subject information and authorised access. • There is no exposure of the reporting framework or reportin allowed. • Two-factor authentication is in place using the Google Authe standards are built into the system. • User accounts managed via a web-based administration inte functionality is in place and user roles are limited to 1 to elin Health/HSS is responsible for assigning users to the clinical s place for other enterprise clinical data capture systems. • Both the site system and the PROMs Platform sit in the Zone Australian data centre. This is subject to WA Health and the • Implement system activity records: Physical log files (web se for information messages); populate the database with trace logins, IP addresses and user agent strings of users + PROMs over time (longitudinal data); and physical logfiles read by H

Description of risk	Likelihood	Consequence	Risk rating	Strategies for mitigating risk
				• The Data Custodian and Data Steward play a role in day-to-d
Data access benefits of CICIS not fully realised because of limited integration with other clinical IT systems within HSS.	**Possible –** Despite business engagement and consultation with data custodians, integration with other enterprise systems has not progressed thus far. Much of the required clinical data is not available at an atomic level.	**Moderate –-** • Understanding of impact of care provision on patient outcomes is reduced. • Additional resources will be required to manually transfer clinical data from current data storage points to CICIS. • Potential for research using full dataset is compromised. • Little to no automated transfer of clinical data may result in poor compliance by clinicians as 'toggling' between systems is cumbersome. • Manual transfer of data is resource intensive and open to errors. • Project aims only partially met. • Escalation of costs as manual entry of clinical data required. • Sustainability of ongoing comprehensive, routine clinical and PROMs data capture, as part of normal care, is compromised.	Medium	**Planning** • Continue consultation with site specific Business Engagemer systems. • Ensure use cases and deployment scenarios are well defined • Manage IT development timeframes and certainty of system detailed information on requirements (including clear use-ca are suitable. • Seek data custodian support for any system that requires int • Data Steward responsible for overall management and auth data to day management including accuracy, usability, and a • Adoption of contemporary best practices in software develo (automation, documentation, team-based development) an training, and implementation planning is undertaken, docum • Ensure adequate specification of interfaces/APIs. • Ensure clear, correct information about software/platforms required, how they are deployed, input/output formats requ exposed. • Ensure clear understanding of ontology and external system **Stakeholder communication** • Ensure effective communication between CICIS developers, system administrators with collaborative culture fostered. • Minimise blocks/bottlenecks caused by development across **Development/deployment** • Ensure CICIS has the capability and capacity to connect to cu knowledge and specification of all required communications • Ensure that data elements between CICIS and other enterpri • Develop and maintain 'Master' metadata registry document • Ensure well defined and robust linkages are established betv Where possible and appropriate, avoid linkages that require teams. • Minimise integrations to those that are absolutely necessary
Project objectives				
Funding/ resourcing inadequate for Phase 2 of Transition	**Possible** – This project requires resources/input across Dept. of Health and HSS, with co-operation from 3 HSPs to be successful in long term.	**Moderate –** • Understanding of impact of care provision on patient outcomes is reduced. • Strategic objectives or requirements not met within timeframe. • Uptake of VBHC within WA maybe jeopardised.	Medium	• Focus is given in Phase 1 of transition proof-of-concept proj • CIC data collection simplified to PROMs collection only initia • Realistic budget for Phase 2 to be worked up by relevant De team. • Engage and involve senior health managers at all points in t • Identify strategic objectives that are met through wider imp • Ensure system adoption costs are minimal through use of a • Department of Health staff to leverage funding opportunitie • Advocate for support from Health Network leads. • Ensure effective feedback form PROMs collection is provided changing patient outcomes for the individual and how aggre care options can assist in making evidence-based care decisi
Translation of research is not sustainable and not adopted by WA Health	**Possible** – Complex project that will require full and successful integration with WA health systems for ongoing uptake.	**Minor –** • Understanding of impact of care provision on patient outcomes is reduced. • Strategic objectives or requirements not met within timeframe. • Uptake of VBHC within WA maybe jeopardised.	Medium	• Engage and involve senior health managers at all points in t • Identify strategic objectives that are met through wider imp • Ensure system adoption costs are minimal through use of a • Undertaken a current state analysis. • Prepare a transition plan. • Continue to attempt to link in with current enterprise data duplication such that clinician requirements for data entry i • Place CIC researcher on in-reach arrangement to engage in

Description of risk	Likelihood	Consequence	Risk rating	Strategies for mitigating risk
		• Data collected on current research patients is of limited use.		
Governance				
Breach of ethics	**Rare** – Investigators and clinicians are experienced. Approved protocol has been successfully adhered to since 2018. This risk will only be in place in phase 1 whilst HREC approval is required.	**Minor –** Well-being of participants may be at risk; however, the project will not affect care provision as it only involves collection of data about care provided and patient outcomes. Some psychological distress only may be encountered by some participants.	Low	• Implement a comprehensive and detailed Research Protocol • Maintain currency of research protocol and any amendment required. • Ensure the project meets the requirements of the Australian • Ensure staff understand, and adhere to, security and compli • Implement monitoring processes and ensure issues are repo • Ensure training program in place for clinicians and relevant s and systems. • Ensure appropriate record keeping is maintained. • Ensure GCP training for all research staff involved with the p • Timely and accurate completion and submission of HREC rep • Ensure participants are advised to discuss any psychological

Addendum A: Current State - The use of Patient Reported Experience and/or Outcome Measures