Continuous Improvement in Care *cancer*

Implementation of research to measure patient outcomes – bouquets and brickbats

Introduction

The Continuous Improvement in Care – Cancer (CIC Cancer) Project is a multi-institutional program of research that seeks to bring value-based healthcare (VBHC) to public and private healthcare settings in Western Australia (WA). The project aims to create value through improving outcomes whilst containing costs (www.ciccancer.com). This is achieved through measuring and acting on variations in outcomes that are important for people diagnosed with cancer.

The results of combined clinical and patient-reported outcome measures will feed back into clinical management processes to improve care; help determine needs for clinical intervention; and allow units to assess and improve their practices. To the best of our knowledge, this is the first time that VBHC processes have been implemented simultaneously across multiple hospitals in both public and private healthcare sectors within Australia.

The implementation of the CIC Cancer Project is multi-faceted and multi-dimensional with involvement of a data capture and analysis model over five overlapping stages. To date, only stages 1 and 2 are underway. The results of this work will ultimately drive improvements in care and patient outcomes. Integral to successful measurement of outcomes for cancer patients is effective engagement and development of an informatics system.

x:\0001- overall program\004- reporting\2019-8-5 bouquets and brickbats.docx
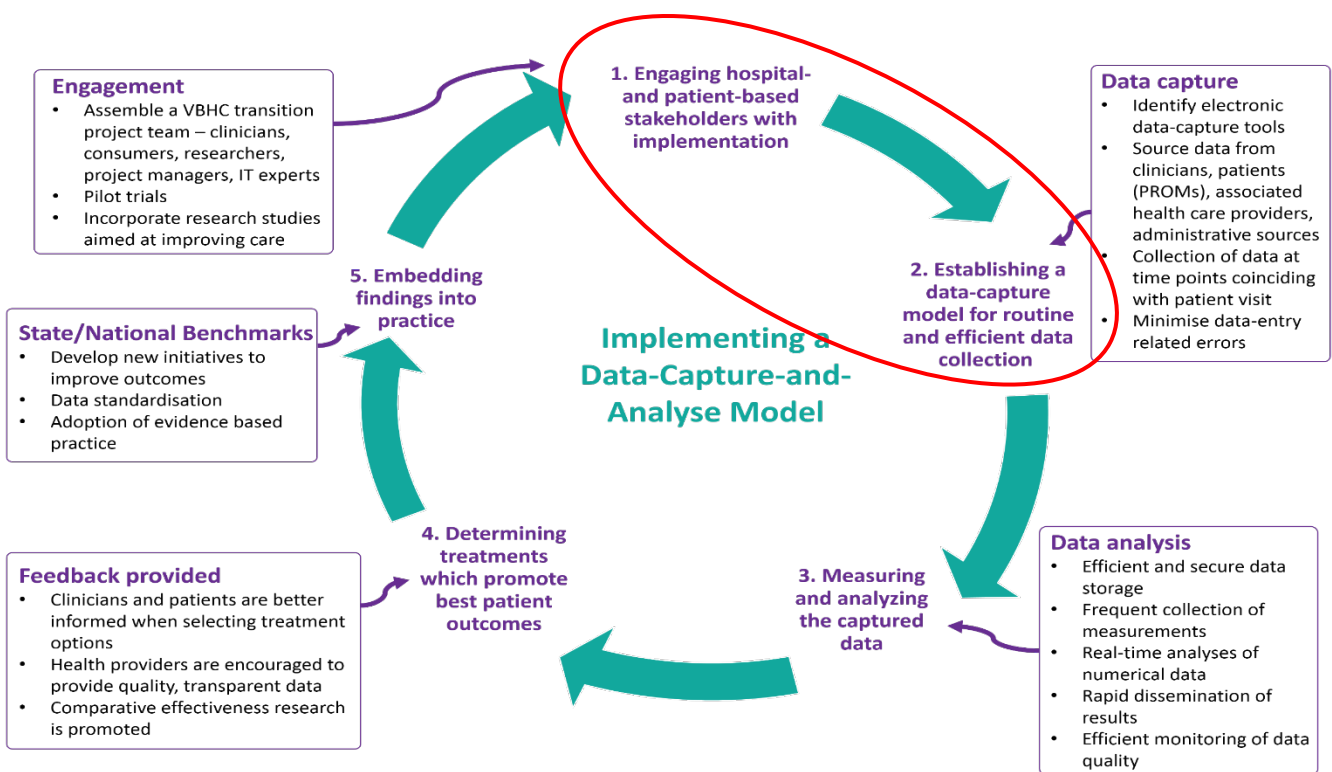
Learnings

Learnings arising from the initial 'bedding down' of the program over the first 18 months of implementation are identified below. A list of useful resources can be found at www.ciccancer.com.

Planning and project management

- Ensuring adequate time, resources, and expertise are available for project management and good governance is vital, particularly as meeting the differing requirements of different health systems can result in a duplication of effort.

- The use of logic modelling can assist in providing a basis for program planning.

- Formal identification of communication strategies during planning phases enhances efficiency and effectiveness of engagement activities.

- Implementation of good project management practices and involvement of clinical knowledge and health system awareness are important when seeking to introduce new systems.

Expectation management

- A complex and innovative project requires significantly more lead time than anticipated and delays have a 'snowball' effect.

- Realistic expectations about the potential for delays and implementation of effective communication streams are vital to maintain engagement.

- Full consumer involvement is ideal but may not be practical or achievable.

- Consumer and external support organisational involvement can be particularly challenging in terms of momentum, particularly when located interstate.

- Support groups and not for profit organisations can be complex entities and it takes time to develop an understanding of how to navigate the system. Staff turnover and changes to roles within these organisations creates challenges in terms of milestones and timelines to be met.

- Significant timeframes are required to introduce new ICT systems to health settings.

ITC system implementation

- Implementation of a new and customised informatics system within health systems is complex. Flexibility and adaptability are necessary to meet differing information management and interoperability requirements of sites, information flows, and clinicians.

- It is important to work through processes to identify data needs and make any necessary adjustments prior to commencement of data collection. This will assist in maximising consistent data collection over time, reduce the need for changes to IT systems, minimise re-training requirements, and limit potential for errors.

Customisation

- Commercial data collection systems may not fully meet complex tailoring, integration and linkage requirements and may therefore be a more expensive option than an easily adaptable, open source system that allows for future, long-term uptake and ownership by the public and private health services.

- A level of adaptation of standardised datasets is required to meet local conditions and enable practical implementation.

x:\0001- overall program\004- reporting\2019-8-5 bouquets and brickbats.docx

Findings

The key successes (bouquets) and challenges (brickbats) of the CIC Cancer project to date relate to implementation of effective program management, stakeholder engagement, and development of data capture systems.

Project Governance processes

The innovative nature of health services research involving value-based healthcare (VBHC) has meant that few points of reference or precedents are in place. When combined with dynamic, multi-site/multi-organisation requirements and involvement of both public and private health sectors, the project governance processes are complex and resource intensive. The key components affected by this complexity include program management and ethical considerations.

Bouquets	Brickbats
CIC Cancer is a program of research that is evolving over time. It is also expected to 'spin off' an even greater number of sub-projects as results become available and potential improvement activities are identified.	The project currently has nine project partners or contributors. This has required multi-organisational funding agreements with involvement of, and agreement by, several different legal teams, many of whom have worked in isolation with little or no collaboration. The time required for these processes is lengthy and has contributed to delays in commencement of project activities.
Members of the project team currently hold senior membership on Human Research Ethics Committee (HREC) committees. Access to this expertise, together with provision of sufficient resources to undertake the required processes, resulted in easy and fast passage of HREC applications.	HREC approval is required for WA Health, the private healthcare organisation involved, and the university partners. Even though reciprocal HREC approval is available, a significant level of duplication of submission documentation and processes is required.
	Site approval across each of the three WA Health sites has different requirements, including differing and separate legal agreements. Further documentation has been required to gain site approval for the two private facilities. In addition, the need for legal or contractual arrangements to be enacted prior to final ethics/site approval, combined with differing legal requirements for different organisations, has led to significant delays and affected timelines for project components.
The use of logic modelling, to identify desired outcomes and required outputs at the outset of the work, allowed for sufficient mapping of potential work. This ensured that the research protocol and HREC application addressed the wider potential and limited need for resubmission for many of the program changes.	A small number of pilot projects are underway within the CIC Cancer umbrella that are expected to be subsumed into the wider program. In addition, approval has been required to 'roll-in' allied or pilot projects that were commenced under separate HREC approval. Delays with finalisation of legal processes have delayed HREC acceptance of these sub-projects, creating a domino effect to delays in planned work.

x:\0001- overall program\004- reporting\2019-8-5 bouquets and brickbats.docx

Clinicians treating prostate cancer within WA are very keen to use CIC Cancer as the key platform for capturing Prostate Cancer Outcomes Registry (PCOR) data. Whilst this will require careful consideration to effectively integrate the two programs of work, the benefits to long-term acceptance of outcomes measurement as normal practice are significant.	Within WA, legislation restricts the use of 'opt-out' consent within the public health sector. This is not the case, however, within the private health sector. This has required the use of differing processes to recruit patients and will require special arrangements to ensure consent is captured, where required. Particular issues will arise with the implementation of the prostate cancer stream of the CIC Cancer project to ensure that consent requirements for WA are met as national PCOR work currently uses 'opt out' consent.

Learnings

- **A complex and innovative project requires significantly more lead time than anticipated and delays have a 'snowball' effect.**
- **Ensuring adequate time, resources, and expertise are available for project management and good governance is vital, particularly as meeting the differing requirements of different health systems can result in a duplication of effort.**
- **The use of logic modelling can assist in providing a basis for program planning.**

x:\0001- overall program\004- reporting\2019-8-5 bouquets and brickbats.docx

Engagement

Engagement of clinicians and health services is vital to the success of this work, both for the research project and for long-term implementation into everyday clinical practice. Consumers input to the development and implementation phase of the project is also vital. Regular communication and interaction is required to raise awareness and maintain involvement. Moving timeframes and delays are key risks to the maintenance of engagement and require careful management.

Bouquets	Brickbats
Identification of desired communication outcomes provided a framework for effective communication planning and clearly highlighted opportunities to effectively build and maintain engagement.	
	Delays with project governance delay commencement activities, risking a loss of engagement from stakeholders not fully familiar with these requirements. In addition, those working on the project for a specified timeframe (e.g. fellowship funding) are unable to fully complete planned work within their particular research component when specific ethics submissions for these sub-projects are held up until overarching HREC approval is provided.
	Delays in terms of engagement can be precipitated with high staff turnover in support and community organisations. Systems within these organisations can prove complex in terms of roles and responsibilities.
Clinician engagement has been targeted through providing opportunities to customise the dataset and IT system to meet their requests for additional data items, incorporate external registry requirements, and enhance efficiency during patient consultations.	Clinician customisation of the dataset, combined with customisation required for each health sector and integration with other IT platforms, has resulted in additional and iterative manipulation of the dataset to ensure consistency across tumour streams. Each iteration requires consistency checks and testing, resulting in much greater development time than anticipated/planned. A better, more effective, and user-friendly end-product will likely result from this additional work but this has potential for a negative impact on timeframes.
Inclusion of a senior consumer representative as an associate investigator on the project resulted in easy implementation and involvement of a Consumer Reference Group. Ongoing involvement of this investigator within the project's Steering Committee has resulted in a continued and consistent 'consumer voice'.	It is important to ensure that all consumer types are well represented in a consumer reference group with sufficient diversity of social and cultural identities, particularly people who may feel unable to take part in consumer engagement activities. This can however, be difficult to achieve. The nature of some of the cancers included within CIC Cancer has also resulted in 20% attrition because of disease progression. Other member's busy lives, as they seek to recover from their cancer and/or treatment, has led to challenges in scheduling and maintaining engagement as the group is rebuilt.

x:\0001- overall program\004- reporting\2019-8-5 bouquets and brickbats.docx

Although often challenging, the qualitative nature of engaging consumers in focus groups had brought about a richness of information that would be otherwise unachievable. Those who participated have expressed and willingness to be further involved in the project depending on their health status.	When engaging consumers in focus groups that may bring about distress during discussions – such as the development of ovarian cancer patient –reported outcome measures – it is important to ensure that mechanisms are in place to immediately address this distress. Linking focus group meetings to cancer support groups would address this but can be seen as contrary to support group principles.
	Within the research project, only English language surveys will be used and significant additional work will be required to include other languages for long-term use in everyday clinical practice. This is a limitation of the project but unavoidable in the current 5-year funding timeframe.

Learnings

- **Realistic expectations about the potential for delays and implementation of effective communication streams are vital to maintain engagement**
- **Full consumer involvement is ideal but may not be practical or achievable.**
- **Consumer and external support organisational involvement can be particularly challenging in terms of momentum, particularly when located interstate.**
- **Support groups and not for profit organisations can be complex entities and it takes time to develop an understanding of how to navigate the system. Staff turnover and changes to roles within these organisations creates challenges in terms of milestones and timelines to be met.**
- **Formal identification of communication strategies during planning phases enhances efficiency and effectiveness of engagement activities.**

x:\0001- overall program\004- reporting\2019-8-5 bouquets and brickbats.docx

Datasets

The CIC Cancer project is utilising the International Consortium for Health Outcomes Measurement (ICHOM) standard datasets for colorectal, breast, lung, and prostate cancer and developing a dataset for ovarian cancer as this is not yet available via ICHOM. This use of ICHOM datasets will allow comparability and benchmarking with international teams.

Bouquets	Brickbats
Use of the ICHOM datasets will allow comparison across many sites and health systems around the world, allowing for a more complete picture of what is working well, or otherwise, within WA.	Many of the ICHOM datasets have included consumers in identification of appropriate and relevant patient reported outcome measures. It is recognised, however, that these standard sets are not capable of identifying what is important to all cultural groups. A limitation of the CIC Cancer project, as with many other research projects, is that as only participants capable of reading and understanding English will be asked to take part, and so an understanding of culturally-specific outcomes will be reduced.
In an effort to ensure clinician engagement, opportunities have been provided for CIC Cancer clinical champions to incorporate additional fields, including items particular to their clinical practice, processes, or clinical research interests. This also ensures data and outcomes relevant to WA patients are captured.	Data set customisation has the potential to increase the number of outcome measures. The resultant increase in data capture risks creation of large and cumbersome surveys and may impact on completion rates. An important component of program evaluation will be to gain an understanding of the minimum number of variables required to adequately measure clinical and patient outcomes.
	Processes required to include the ICHOM standard datasets in the CIC Cancer informatics system identified that a level of adaptation is required to ensure practical application of the dataset. This has resulted in changes to; - include additional date fields so that time periods between episodes can be determined; - include additional data fields relevant to the WA health system; - how the variables were presented, this included moving the variables around so that they followed the patient journey or clinic workflows, thus making the dataset more intuitive to use; - rewording some of the questions and responses to allow for better interpretation while retaining the meaning of the question; - include fields necessary for College audit datasets; and - combine or replace fields to work in with other data registry fields.
	The time delay between development of the ICHOM standard datasets and CIC Cancer implementation has resulted in some data items becoming out-of-date (e.g. tumour staging). The standard dataset currently captures data relating to the American Joint Committee on Cancer staging system 5th – 7th Edition. A new edition (8th edition), however, is now in use and these

	changes will need to be incorporated into the data capture system, particularly if interoperability with other enterprise data collection systems is to be successful. Poor access to ICHOM staff to allow for follow-up of this issue is hampering resolution.
Clinicians are keen to minimise duplicate data capture and try wherever possible to capture information that will satisfy both the ICHOM standard dataset and any clinical quality registers in place locally, nationally or internationally. To this end, activities have been undertaken to amalgamate and map the clinical variables required for these different databases.	Although the PROMS variables from the ICHOM set have been adopted as a whole, data mapping identified that the clinical variables across these different data models employed different nomenclature for anatomical location categorisation, surgical techniques, and adjuvant treatment regimes. This will require additional software coding to allow for cross population of databases. In some instances, this also necessitated additions to the ICHOM response options within the CIC Cancer dataset.
	Amalgamation of the ICHOM dataset for colorectal cancer and the Bi-National Colorectal Cancer Audit (BCCA) and ICHOM standard set for colorectal cancer has identified that neither dataset fully accounted for local process variations and adherence to national/international best practice guidelines. This has necessitated incorporation of even further variables.
An understanding of quality-adjusted life years (QALYs) gained will allow comparison of the benefit and cost of health care programs or interventions when undertaking cost-utility analysis, a of health program evaluation widely accepted by policy makers.	Inclusion of the EQ-5D instrument further increases the size of the patient-reported outcomes survey. Furthermore, when combined with the ICHOM patient-reported measures duplication exists with similar, or near similar, questions across the different instruments. This has necessitated inclusion of additional text to notify patients of the reasons behind the seemingly repetitious questions.

Learnings

- **Implementation of a new and customised informatics system within health systems is complex. Flexibility and adaptability are necessary to meet differing information management and interoperability requirements of sites, information flows, and clinicians.**
- **A level of adaptation of standardised datasets is required to meet local conditions and enable practical implementation.**
- **It is important to work through processes to identify data needs and make any necessary adjustments prior to commencement of data collection. This will assist in maximising consistent data collection over time, reduce the need for changes to IT systems, minimise re-training requirements, and limit potential for errors.**

x:\0001- overall program\004- reporting\2019-8-5 bouquets and brickbats.docx

Data Collection System

Following identification and mapping of data needs and flows, an informatics platform has been developed to collect/extract/integrate data to enable purposeful application of the collected information. This bespoke, open source solution incorporates the full ICHOM standard dataset, as well as customisation and adaptation to meet specific clinical needs per tumour stream or site, and potential to be fully integrated. A review of commercially available systems identified that none appeared capable, at the time of review, of fully meeting the complex needs of the project. All commercial systems considered required supplementary work to integrate into the differing needs of sites and information flows, reducing the cost effectiveness or long-term sustainability of any commercially available application.

Bouquets	Brickbats
Engagement by health service providers and policy makers has been significant, with both private and public health services keen to accept and integrate CIC cancer into existing systems and infrastructures. Data custodians of current enterprise systems are willing to share data and work together to improve data collection and limit duplication of effort.	The time and resources required for the due processes necessary to introduce new ICT systems to healthcare settings is significant. Differing ICT governance requirements between the public and private health sectors have also resulted in significant duplication of effort to introduce the CIC Cancer informatics platform as an enterprise system and integrate this to other enterprise systems, many of which are unique to the specific environment – public hospital, private hospital, and clinician's private rooms.
	The best way of identifying patients who move between public and private settings during their treatment has not yet been identified. The required separation of the informatics platforms between health systems will likely exacerbate difficulties in identifying shared care and understanding outcomes arising from these arrangements.
Early and thorough preparation of a comprehensive risk management plan is vital in adequately meeting ICT governance requirements relating to data protection and privacy.	
An understanding that it is impossible for tech-based projects to be concurrently fast, good, and cheap also assists in managing the inevitable delays associated with informatics system development. Use of an agile process methodology of building, testing, and learning assists in managing changing needs and adaptations as the work evolves. Effective utilisation of any timeline deferments through ongoing refinements to the usability of the dataset, in consultation with users, has improved the final product and will ultimately save development costs required.	

Clinical knowledge is of significant benefit when preparing the dataset and working with clinicians to finalise data items.	Attrition and staff changes in the ICT team posed risks to timeframe adherence but management of these concerns resulted in upskilling opportunities and inclusion of a clinical viewpoint.

Learnings

- **Commercial data collection systems may not fully meet complex tailoring, integration and linkage requirements and may therefore be a more expensive option than an easily adaptable, open source system that allows for future, long-term uptake and ownership by the public and private health services.**
- **Significant timeframes are required to introduce new ICT systems to health settings.**
- **Implementation of good project management practices and involvement of clinical knowledge and health system awareness are important when seeking to develop and introduce new ICT systems.**

x:\0001- overall program\004- reporting\2019-8-5 bouquets and brickbats.docx