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|  |  | NSW Health ISLHD |

Evaluating the acceptability, feasibility and efficacy of a shared model of cancer follow-up care utilising digital health tools and the transfer of clinical information between general practitioners and radiation oncologists, for patients with breast, prostate or colorectal cancer.

**RESEARCH PROTOCOL**

**2020**

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# Protocol synopsis

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| --- | --- |
| **Title** | Evaluating a shared model of cancer follow-up care between general practitioners and radiation oncologists, for patients with breast, prostate or colorectal cancer |
| **Scientific title** | Evaluating the acceptability, feasibility and efficacy of a shared model of cancer follow-up care utilising digital health tools and the transfer of clinical information between general practitioners and radiation oncologists, for patients with breast, prostate or colorectal cancer. |
| **Objectives** | 1. To determine the level of agreement (correlation) between general practitioners and radiation oncologist completing a cancer follow-up care assessment 2. To implement a shared-care cancer follow-up model in general practice 3. To evaluate the feasibility, acceptability and efficacy of this shared-care follow-up model to patients, general practitioners and radiation oncologists. |
| **Study Design** | Multi-methods implementation study design |
| **Study sites** | * Wollongong Hospital * Shoalhaven District Memorial Hospital |
| **Planned Sample Size** | 20 triads comprised of patients, general practitioners and radiation oncologists.  10 from Wollongong and 10 from Nowra. |
| **Selection Criteria** | * Patient with a previous diagnosis of breast, colorectal or prostate cancer * Received curative radiotherapy treatment (not palliative treatment) * Approaching three-years post-radiotherapy treatment |
| **Data collection and**  **analysis:** | * Clinical assessment from Oncology Information System MOSAIQ:   - Cohen’s kappa   * Semi-structured interviews:   - Thematic analysis and triangulation |
| **Duration of the study** | 1 year |

# Definitions

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| **TERM** | **Definition** |
| Radiation oncology / Radiotherapy | Radiation oncology, also known as radiotherapy, uses x-ray beams to kill cancer cells. A machine called a linear accelerator delivers radiation only to the specific area that is being treated.  Sometimes radiotherapy is used in conjunction with chemotherapy. |
| Radiation oncologist | A radiation oncologist is a specialist doctor who prescribes radiotherapy and organises treatment.  A radiation oncologist will decide how much radiation is given and how many times (the prescription). |

# 1. Investigators

|  |  |
| --- | --- |
| **Investigator Name** | Dr Heike Schütze |
| **Contact Details** | 4221 4582  [hschutze@uow.edu.au](mailto:hschutze@uow.edu.au) |
| **Role** | Coordinating principal investigator  Supervisor to PhD Candidate Tiffany Sandell |
| **Responsibilities & tasks in this research project** | Dr Heike Schütze will oversee and assist all research activities of the PhD candidate. |
| **Relevant Qualifications** | PhD, MPH, BSc (Biomed) |
| **Experience relevant to this project** | Experienced in research with a focus on general practice and cancer follow-up shared-care. |

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| **Investigator Name** | Tiffany Sandell |
| **Contact Details** | 0479136404  [tem785@uowmail.edu.au](mailto:tem785@uowmail.edu.au)  [tiffany.sandell@health.nsw.gov.au](mailto:tiffany.sandell@health.nsw.gov.au) |
| **Role** | Principal investigator and PhD Candidate |
| **Responsibilities & tasks in this research project** | Responsible for all research activities: ethics, managing recruitment, data collection, coding and analyses. Compiling findings for publication.  Site principal investigator for ISLHD. |
| **Relevant Qualifications** | MHSM, MPH, BA (Pop Hlth) |
| **Experience relevant to this project** | Project Manager, quality improvement initiatives Radiation Oncology, ISLHD, as project manager on. |
| **Expertise relevant to this project** | Project management in radiation oncology, previous experience on research in shared care |

|  |  |
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| **Investigator Name** | Prof Andrew Miller |
| **Contact Details** | [andrew.miller@health.nsw.gov.au](mailto:andrew.miller@health.nsw.gov.au)  [amiller@uow.edu.au](mailto:amiller@uow.edu.au) |
| **Role** | Co-investigator  Co-supervisor (Tiffany Sandell) |
| **Responsibilities & tasks in this research project** | Prof Andrew Miller will co-supervise and oversee the research, assist in data extraction of patient lists, technological management issues, collaboration for study publications. |
| **Relevant Qualifications** | BSc, GradDipEd(CCAE), BMed MInfCommTech[Res], FRANZCR, FACHI |
| **Experience relevant to this project** | Radiation Oncologist, ISLHD |
| **Expertise relevant to this project** | Honorary Professional Fellow, School of EIS |

# 2. Rationale for the research

The increasing incidence of cancer, coupled with the decreasing mortality rate, has resulted in higher demand for cancer follow-up care 1–3. This has led researchers and health services to question the sustainability of oncologist-led cancer follow-up care in hospitals 4,5 and driven the need to find alternative models of care. The number of follow-up consultations at the Radiation Oncology Department, Illawarra Shoalhaven Local Health District has increased 20% over the past five years. This is expected to continue to rise with no planned increase in resources. Additionally, patients that live south of Nowra, have long distances (six-hour round trips) to travel to attend follow-up appointments at the hospital outpatient cancer centre.

The purpose of cancer follow-up care is to monitor and treat late side effects of treatment, monitor for recurrence, and to support psychosocial care 6–8. During the cancer follow-up period, patients receive follow-up care from medical oncologists, radiation oncologists, surgeons and other allied health professionals at different appointments 9. The follow-up care period is generally five years; however, this varies depending on the type and stage of cancer, and the treatment required.

According to literature, hospital-based cancer follow-up care by an oncologist is the preferred model of care 10–19, however, there are currently no alternatives for patients to choose their care based on their circumstances, such as where they live. Hence, effectively, hospital-based follow-up care is the only model of care available. As the demand for cancer follow-up care grows, new approaches to delivering cancer follow-up care have been reviewed. Randomised control trials have shown that there is no difference in the rate of recurrence or quality of life when a general practitioner delivers cancer follow-up care compared to cancer follow-up with an oncologist 20–24. The evidence for the benefits of general practitioner-led and shared-care cancer follow-up models of care is growing 23. Despite the acknowledgement of the benefits of cancer follow-up care with the general practitioner, no mechanisms are allowing effective two-way communication in real-time between oncologists and general practitioners 5,25–27, there is currently no model where the general practitioner performs routine cancer follow-up care, and the oncologist oversees it.

This research will address this two-way communication gap and determine if shared-care cancer follow-up care between a general practitioner and radiation oncologist is feasible and acceptable to the patient, general practitioner and radiation oncologist. Radiation oncology has been selected as it is a starting point for cancer shared-care.

## 2.1 Significance of the research

This research explores a shared care model of follow-up care for breast, colorectal and prostate cancer patients that have been treated with radiotherapy. In Australia, radiotherapy follow-up is usually managed by the treating radiation oncologist and usually involves regular hospital visits. This research will involve general practitioners performing some of the routine radiotherapy follow-up visits, whilst ensuring the patient’s care continues to be overseen by the radiation oncologist. This research will explore the acceptability and feasibility of this model of care. Whilst research has shown cancer follow-up care with general practitioners to be safe and acceptable there has not been a study where the oncologist oversees the care in real-time.

# 3. Aim and Objectives

Aim: To determine the feasibility, acceptability and efficacy of shared-care cancer follow-up care.

Objectives:

1. To determine the level of agreement (correlation) between general practitioners and radiation oncologist completing a cancer follow-up care assessment
2. To implement shared-care cancer follow-up care in general practice
3. To evaluate the feasibility, acceptability and efficacy of this shared care model to patients, general practitioners and radiation oncologists.

# 4. Study sites

The research will be conducted within the Illawarra Shoalhaven Local Health District region, at the Radiation Oncology Outpatient Service at the Wollongong Hospital and the Shoalhaven District Memorial Hospital. The study will take place at these two radiation oncology outpatient clinics and in the referring general practices.

# 5. Study design

This research is a multi-methods implementation study to recruit 20 triads comprised of radiation oncologists, general practitioners and patients. It comprises two stages.

Stage 1. To determine the level of agreement (correlation) between general practitioners and radiation oncologists, completing a standard cancer follow-up clinical assessment. This is important, as the radiation oncologists need to know the level of agreement before they are willing to transfer care to the general practitioner (for the implementation stage).

Stage 2. Implementation and evaluation of shared-care cancer follow-up in general practice.

## 5.1 Recruitment and selection of participants

A list of radiation oncologists with eligible patients at Wollongong Hospital and Shoalhaven District Memorial Hospital will be drawn from the Oncology Information System MOSAIQ. Radiation oncologists will be invited to participate in the research via an email which contains the Participant Information Sheet and Consent Form (see Attachment A).

Consenting radiation oncologists will review a list of their eligible patients and invite them to the study via a mail-out with a reply paid envelope (see Attachment B). A follow-up phone call will be made two weeks after the mail out as a reminder to the invitation to participate. Once the patient consents, their referring general practitioner will be invited to participate by letter (see Attachment C). A follow-up phone call will be made two weeks after the mail-out as a reminder to the invitation to participate. If the general practitioner declines, the patient will be ineligible to participate. Once all three have been recruited, the patient will be sent a welcome pack (see Attachment D).

## 5.2 Inclusion criteria

**Radiation oncologist:**

1. Treats breast, colorectal or prostate cancer

**Patient:**

* 1. With a previous diagnosis of colorectal, breast or prostate cancer
  2. Received **curative** radiotherapy treatment (not palliative radiotherapy treatment)
  3. Patient is nearing three years post-radiotherapy treatment; and has a scheduled follow-up appointment with radiation oncologist within a three month period of the study (e.g. already scheduled for May, June, July 2020)
  4. Can understand and speak English.

**General practitioner:**

1. Referring general practitioner of breast, colorectal or prostate cancer patient who has consented to taking place in the study, and whose radiation oncologist has also consented to taking part
2. Has internet access

**Administration:**

a) Team leader administration, Cancer Care Centre (see attachment G).

## 5.3 Population/Sample size and justification

A sample of 20 triads will be recruited: comprised of radiation oncologists, patients, and their general practitioners.

The goal of recruiting the 20 triads is to ensure depth of data saturation. The 20 triads could potentially equate to 45 participants (e.g. 20 patients, 20 general practitioners, 5 radiation oncologists); it is also anticipated that there may be general practitioners that have more than one patient, and hence the total number of general practitioners may be fewer.

## 5.4 Expected duration and what is involved for participants of the study

The expected duration of the research is one year. The duration for participants from the time of recruitment to the final interview is approximately 8 months.

## 5.5 Study outline

To determine the feasibility and acceptability of shared cancer follow-up model, patients are being offered an additional two appointments with their general practitioner to check on their health and wellbeing following radiotherapy treatment, with their radiation oncologist overseeing this care and rapid referral pathway if required. Patients will maintain their standard care with the radiation oncologist, and continue with standard care upon completion of the research.

Below shows what is involved for the participants of this study:

|  |  |
| --- | --- |
| **Radiation oncologist:** |  |
| **Patient:** |  |
| **General practitioner:** |  |

# 6 Data collection and analyses

## 6.1 Clinical assessment

The follow-up assessment data by the radiation oncologists and general practitioners will be entered into MOSAIQ. The assessment is based on standardised clinical assessments that are used for the follow-up of cancer patients at the Illawarra Shoalhaven Local Health District (see Attachment E). The assessments will first be piloted with general practitioners for readability and usability.

The assessments ask the doctor to review physical items on a scale of 0 to 4 specific to radiotherapy follow-up (pain, fatigue, physical performance, bowel issues, urinary issues and appetite).

These clinical assessments will be made available to general practitioners via a website link. The software is PROsaiq, which has been deemed feasible in terms of usability from a previous study conducted locally called PROMPT (Patient Reported Outcome Measures for Personalised Treatment and Care). This software satisfies ISLHD Information Technology requirements for security.

6.1.1 Data analyses

The data from the clinical assessments will be extracted from the oncology information system MOSAIQ. The data will be matched using the patient’s medical record number, and then replaced with the unique ID. As multiple raters are involved, Cohen’s Kappa will determine the level of agreement for each item between general practitioners and radiation oncologists. The agreement looks at the concordance between two measurements of one variable, whereas correlation refers to the presence of a relationship between two different variables 28. Percent agreement will also be used; the intention is to achieve near-perfect agreement on each item (>0.81). The results of the analysis will be presented to the general practitioners and radiation oncologists and will guide any additional education and training needed prior to the GPs performing the assessment on any patient.

## 6.2 Semi-structured interviews

The research student will conduct the interviews pre- and post-implementation with the 20 triads, using a topic guide (see Attachment F). Interviews will be audio-recorded using a digital dictaphone and transcribed verbatim. The interviews will be conducted at an agreeable and accessible location, either via Skype, phone or at the participants’ home or radiation oncology clinic, according to the participants’ preference.

6.2.1 Data analyses

A commonly used analytical approach to qualitative data in implementation studies is thematic analysis 29. The thematic analysis technique will be primarily deductive by applying a framework (the Normalisation Process Theory 30). This involves mapping the transcribed data and emergent themes onto a priori domains (coherence, cognitive participation, collective action and reflexive monitoring). The themes will be compared across the two sites (Wollongong and Nowra) and triangulated (between radiation oncologists, patients and general practitioners).

HS and TS will code the first 10% of the transcripts (1 radiation oncologist, 1 general practitioner and 3 patients). Cohens Kappa will determine inter-rater reliability with a goal of 0.81-1 (near perfect agreement). HS and TS will review and discuss any discrepancies and achieve near perfect agreement before TS continues with the remaining transcripts.

## 6.3 Data dissemination

The data collected in the proposed research is for use in Tiffany Sandell’s doctoral thesis. The findings from the survey may be presented in peer-reviewed journals or academic conferences. The potential uses of information gathered during the project will be stated in the consent form.

# 7 Ethical considerations

## 7.1 Informed consent

All participants will be provided with the opportunity to read the Participant Information Sheet informing them of the purpose of the study, risks and benefits, and ask any questions before giving informed written consent. All participants will be informed that they have a right to refuse to participate in the study and can withdraw at any time without prejudice and that a decision to withdraw will not affect the care they receive from their general practitioner and radiation oncologist, or their relationship with the University of Wollongong.

All participants will be provided with the details of the student researcher, her supervisors, and the University of Wollongong and the Illawarra Shoalhaven Local Health District Human Research Ethics Committee, should they have any queries regarding the study.

Participants will be able to select if they would like a summary of the results, and a copy of their interview transcripts after the follow-up interview on the consent form.

## 7.2 Confidentiality and Privacy

Confidentiality/anonymity of participants (radiation oncologists, patients and general practitioners) will be maintained by assigning unique participant ID numbers, as per the following table:

|  |  |  |
| --- | --- | --- |
|  | **Wollongong** | **Shoalhaven** |
| **Patient** | WOL001… | SHO001… |
| **Radiation oncologist** | WOLRO001… | SHORO001… |
| **General practitioner** | WOLGP001… | SHOGP001…. |

Table. Unique identifier system

All interview recordings will be downloaded to a University of Wollongong Cloudstor that is shared by the study researchers. The recordings will be outsourced for transcription to a reliable transcription company that Research Central at the Illawarra Shoalhaven Local Health District has as an approved provider. The transcription service will be directed to remove any identifying information from the transcripts. The student will check all transcripts to ensure this has been done. Transcripts and audio recordings will be saved according to a unique numerical participant identification number to ensure confidentiality is maintained. The files will be stored on a secure password-protected University of Wollongong computer, protected by the University firewall.

Consent forms will be stored separately and securely in a locked filing cabinet in Dr Schutze’s office.

The information in the clinical assessments will be stored in the Oncology Information System at the ISLHD.

The data has to be kept for a minimum of 5 years after publication. After this period, all audio and computer files will be permanently deleted.

## 7.3 Risk and benefits to participants

There is no foreseeable risk of harm or discomfort; and any foreseeable risk is no more than inconvenience, being a burden of time.

There are two additional appointments for the patient to attend their general practitioner; one day before, day of, or day after their scheduled appointment with their radiation oncologist, and one, six months later. This appointment six-months later (for a 3.5 year review) is provided as an additional opportunity to monitor the patients during the follow-up period. The foundation of this cancer follow-up model with the general practitioner is that clinician communication exchange is in real-time and the follow-up care is overseen by the radiation oncologist. The model includes real-time transfer of results, alerts and rapid referral to address any issues that may arise. Patients recruited will maintain their standard follow-up care with their medical oncologist and surgeon. Upon completion of the study, patients maintain standard follow-up care with their radiation oncologist.

General practitioners will be incentivised by offering Continuing Professional Development points.

Research in general practice is not eligible to be covered by Medicare Benefits Scheme (MBS). The funding of general practice consultation fees will be paid for by ISLHD Research Central. Participating GPs will receive $80 for each patient consultation as part of the study, which includes the MBS standard consultation schedule fee of $36.30 and any gap payments. The general practice will be required to bill ISLHD Research Central.

There is no specific incentive advertised or communicated to the patients to participate in the research. However, all patients who participate in the semi-structured interviews will receive a $30 Coles Myer gift voucher as a token of appreciation for their time.

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