The research process: An introduction for the clinical radiation therapist

Abstract Research and quality assurance projects are imperative to the advancement of radiation therapy. This article will outline an easy to follow research process for clinical radiation therapists, aimed to equip the clinical radiation therapist with the knowledge to participate in and/or instigate research projects in the future.

Keywords: novice researcher, radiation therapy, research process.

Introduction

Research activities in radiation therapy centres have gradually increased over the last decade.[1] The ever changing world of technology has seen centres undertake research projects in an endeavour to adhere to evidence based practise and administer the best radiation treatments to cancer patients.

Research is defined by Clamp, *et al.* as "an attempt to extend the available knowledge by means of a systematic and scientifically defensible process of enquiry."[2] Not all radiation therapy investigations undertaken are considered research. Radiation therapists (RTs) also undertake quality assurance (QA) projects. QA projects or audits are "clinically led initiatives intended to improve the outcomes of patient care through structured peer review by enabling practitioners to benchmark their practices against nationally agreed standards and lead to improvements in practice".[3] Both types of investigation follow a similar process, as shown in Figure 1.

RTs can be challenged by the research process. The dread of the unknown is often the underlying factor for projects that are discussed in meetings, hallways and tearooms never coming to fruition. This article will guide those clinical RTs who are not familiar with the research process to undertake their research journey.

Identifying the research question

Identifying a research question for clinical RTs can be the easiest or hardest component of the research process. The question can arise easily within everyday work practices from observing problems, or aiming to improve techniques and processes. The clinical RT will need to consider the size of the project and ensure the question is valid and the answer is achievable. In other cases a clinical RT may wish to embellish their career and purposely seek out a research project. It is in these situations that clinical RTs can struggle with finding that so important question to answer. The question must be one that holds a strong interest for the potential researcher as this will ensure the project is completed. Radiation therapy practices encompass many research domains. The researcher should consider each domain carefully[4] (Figure 2).

Cox, *et al.* investigated the types of problems clinical RTs are exposed to in their working day, translating this into research areas and interests. These interests were then classified and ranked. The highest ranked research areas were imaging in radiation therapy, symptom management, accuracy of patient positioning, techniques/equipment, diversification, recognition and other professional issues and management and staff issues.[5] While lists such as these are a suitable starting point for radiation therapists, consideration must also be given to the research projects most likely to be completed. Chulay outlines the road blocks that need to be considered and the ideal characteristics a research

Figure 1: The research process.

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Figure 2: Radiation therapy research domains (Adapted from Cox and Davidson).[4]

Table 1: Common roadblocks to successful completion of a clinical research study by clinicians

Lack of time to identify a research project
Lack of time to review the literature or write the research proposal
Slow accrual of subject into the study due to lack of time for data collection and/or few patients eligible for the study
Inexperience conducting clinical research
Little or no experience in content area being studied
Lack of funding to purchase study supplies or hire data collectors to conduct study
Inadequate number of data collectors
Lack of administrative support

Adapted from Chulay[6]

Table 2: Characteristics of an ideal research question for busy clinicians.

Large number of patients (>1 or 2 per day) cared for within the department would be eligible for the study
Sample size requirements for study less than 75 subjects
Focuses on important patient outcomes (clinical and/or fiscal)
Additional funds not required to conduct the study
Research measurement tools available to study the question
Data collection easily integrated into usual patient care routines
Group project
Research question/topic of interest to staff
Special considerations for neophyte researchers
Replication study
Avoids politically charged areas of practice
Builds on clinical expertise of the clinician researcher
Within the scope/control of radiation therapy

Adapted from Chulay[6]

question should possess for busy clinicians[6] (see Tables 1 and 2).

Finding a suitable research mentor/supervisor

As a researcher it is imperative that feedback is always sought. In a busy radiation therapy department many different sources of feedback are available. Some departments have a research radiation therapist who can direct the researcher to the appropriate persons to assist them. No single person can give the clinical RT feedback on the whole project. The clinical RT should utilise different personnel for the appropriate feedback areas, such as:

Radiation oncologist – Disease processes and research experience
Nurses – Patient care
Clinical trial coordinators – Protocol development, data collection
Statisticians – Research design, protocol development
Radiation therapists – Radiation therapy techniques
Librarian – Literature searching.

Alternatively an appropriate way for novice researchers to receive feedback and guidance could be in a collaborative group. In a collaborative group all the research processes are shared allowing for lots of guidance and mentoring. It is important in a collaborative group that a person outside the group is approached to provide overall feedback on the project.

Table 3: Literature searching for the novice researcher

Literature source	Types
Databases	Medline Cinahl Embase Proquest Cochrane
Citation index	Web of Science Scopus Google Scholar
Public repository	Contact Library of University of Interest
Thesis and dissertation	Nationally – Australian Digital Thesis Program http://adt.caul.edu.au/ Internationally http://www.ndltd.org/find

Adapted from Findlay [7]

Literature search

For all research projects a literature search will need to be undertaken. A literature search can assist in developing your research question or in some cases will even answer a research question. Researchers should not be perturbed when previous research has been undertaken in their research area. The results from earlier projects will be able to inform the researcher if there is a need for further research. When establishing a change in practice it is far better to base your decision on the results from several projects.

To undertake a successful literature search researchers should be able to identify appropriate literature in databases, citation indexes, public repositories and theses[7] (Table 3). To use these databases effectively hospital libraries, university libraries and local public libraries run courses. Also most databases have online tutorials.

Findlay recommends an effective way of establishing suitable search words. First, when exploring the topic write down a list of search terms. Second, create all possible synonyms for these terms. Third, consider the different countries and the terms they may use. Additionally, develop your list further as you search and identify a perfect paper and add the keywords of this paper to your list.[7]

It is important when completing a literature search to keep a good record of your searches including search terms and dates of searches, to avoid unnecessarily repeating searches and to make it easier to update the literature as time goes on.

Table 4: Research protocol table of contents.

Section number	Research protocol content
1	Schema
2	Background
3	Objectives
4	Patient selection criteria
5	Registration/Randomisation
6	Treatment plan and modification
7	Patient monitoring procedures
8	Assessing outcomes
9	Forms and data handling
10	Statistical considerations
11	Ethical considerations
12	References
13	Appendices

Design of the study

The design of the study will be determined by the research question and desired outcomes. Utilising the assistance of the department statistician or an experienced researcher is important when selecting a research method. In general, quantitative research is used for most RT technical papers whilst qualitative research methods are used for patient care and staff satisfaction studies. Figure 3 presents an example of the spectrum of research designs and some radiotherapy examples.[8]

The number of participants, or the power analysis, is usually calculated by a statistician. The researcher will need to provide the statistician with the following information on the research project they would like to undertake.

a the size of difference that is considered clinically important
b the expected mean
c the expected standard deviation.

The mean and standard deviation may be hard to find, but are sometimes in similar previously published work. If the researcher is unable to obtain the expected mean and standard deviation an estimate will need to be obtained. Alternatively after collecting a certain amount of data the mean and standard deviation can be calculated, and the researcher can then revise the power and change the number of subjects if required.

Writing a research protocol

A research protocol can be considered the recipe for the specific research project. The document is written by the researcher and describes the formal design or specific plan for the research.

The components of a research protocol have many similarities to those in a scientific article. See Table 4 for an outline of a standard radiation therapy research protocol. The format of the research protocols will vary depending on the research committee/ organisation/ ethics group the researcher is submitting the document to. When writing a protocol that is endorsed by a hospital or large research institutions (eg Trans Tasman Radiation Oncology Group) they may provide you with a standardised research protocol template.

Funding

Funding is often the biggest hurdle for novice researchers. The amount

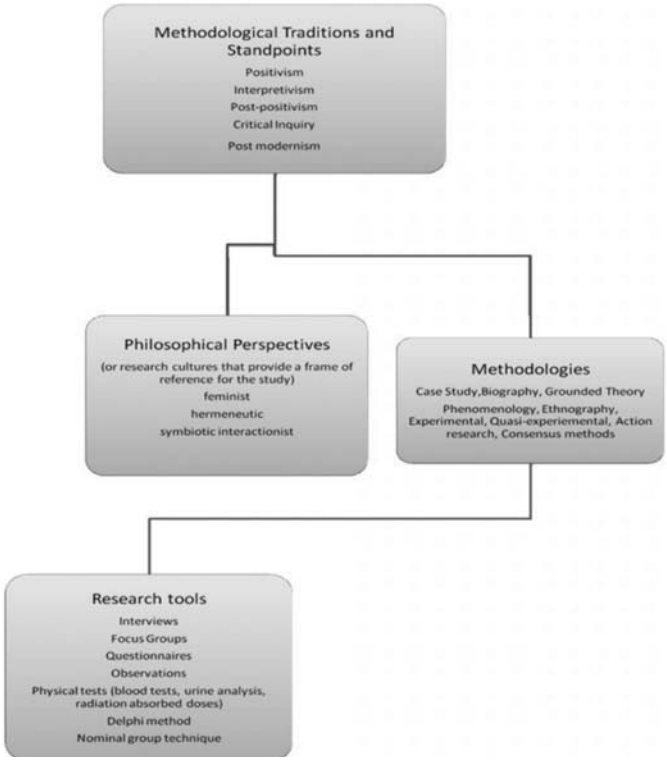

Figure 3: The spectrum of research methodologies, methods and tools (reproduced from Probst and Harris[8])

of financial support a research project requires is dependent on the resources already available to the researcher. A small departmental QA project will not usually require funding. Small research projects that use materials and services such as data management and statisticians that are already available in the department, will generally only require a small amount of funding for the cost of the ethics submission. This funding can be secured from the department research fund. To complete research projects in a timely manner it is an excellent idea, as suggested by Probst and Harris, to secure funds to buy the researcher time from normal clinical duties to dedicate to the recruitment of patients, collection of data and analysis of results.[8]

For larger studies that will use equipment, materials or services not readily available, a funding grant may be required. Radiation therapists requiring small funding grants can apply to the Australian Institute of Radiography (up to $5000) and for larger grants the National Health and Medical Research Council. Community groups may also have funding available (e.g. banks, volunteer organisations, commercial organisations, universities). It is very competitive to secure funding and a proven track record in research is imperative. Novice researchers are advised to join an established research group to gain research experience prior to embarking on a large project that will require funding. An established research group will want to know what skills the novice researcher will contribute, so previous completion of a publication of a small, non-funded project, would be good evidence of the researchers value to the group.

Ethics

Ethics are the rules of conduct governing a particular class of

Table 5: Ethics process for research and quality assurance processes in NSW.

	Research ethics process	Quality assurance ethics process
Form 1	NEAF form Protocol Patient information Consent form	Low risk research form Protocol
Reviewing Group	Scientific Advisory Committee Human Research Ethics Committee	Scientific Advisory Committee Human Research Ethics Committee
Form 2	Site Specific Assessment	–
Reviewing Group	Research Governance	–

human actions or a particular group, or culture.[9] Medicalresearchers across Australia adhere to "The National Statement on Ethical Conduct in Human Research".[9] This statement clarifies the responsibilities of institutions and researchers for the ethical design, conduct and dissemination of results of human research; and review bodies in the ethical review of research.

The ethics structure varies across states. In NSW the Department of Health has implemented a single ethics review process, which allows single ethics review of multicentre research projects. The ethical and scientific review of a project is carried out by a lead Human Research Ethics Committee (HREC) for a multicentre project or a local HREC for single project sites. Ethics applications require a substantial investment of the researcher's time to complete. Both low risk projects (eg. quality assurance) and high risk projects (research) require ethics approval. The requirements vary by area health service and also by state. A National Ethics Application Form (NEAF) is in a web-based format that enables researchers of all disciplines in Australia to complete research ethics proposals for submission to HRECs. After a NEAF form is completed a site specific assessment (SSA) form is completed. The SSA is used to determine the suitability of the project to be undertaken at this site. The forms can be located at www.ethicsform.org/au. Table 5 demonstrates the forms and respective reviewing committees for NSW Hospitals. Ethics approval will take between six to eight weeks from submission to letter of approval. Ethics approval must be granted prior to commencing data collection.

Data Collection

Data collection is a vital part of the research process. The rigour used to collect the data will influence the quality of the results. It is important all patient data collected is de-identified. It is also important that all data collected can be traced to the source. For example, when collecting patient blood results it should be recorded in the patient record and then transcribed to a Case Record Form (CRF) . In this way, if results need to be checked there is a reliable source. Data must be collected in a systematic way. The CRF should list all the information required to be collected. A CRF should be completed for each patient. Data kept as a hard copy will be kept in a locked filing cabinet for fifteen years after the last patient's final visit. Electronic data will be de-identified and kept in a password protected file and backed up regularly.

Data analysis

Data analysis will occur at specified time periods throughout the project. An interim analysis is always recommended to ensure the research is being conducted in an effective and safe manner. If the preliminary results show the intervention being tested is causing undue harm to the research participants the project might need to be stopped prematurely. A statistician will be able to assist you in determining a suitable time period for the preliminary analysis.

Trials that go to completion will have the data analysed in relation to the primary and secondary end points. The primary endpoint is considered the main purpose/intention of the research project, whilst secondary end points are additional relevant findings.

Distribution of results

Researchers have a moral obligation to disseminate the results of their project. Unfortunately, the dissemination of results occurs towards the end of the research process, at a time when researchers are often burnt out. Hence the ways the researcher chooses to disseminate the results are not always the most suitable, but often the easiest or quickest way.

The researcher should base the medium to disseminate the information on what audience needs to know the results. There are several ways to report results. For local dissemination, a departmental report or inservice meeting would be suitable. An oral or poster presentation, a note in a professional magazine, or an article in a journal are encouraged for results of national or international interest. Researchers should take seriously the fact that staff and often patients have contributed to this work, and future patients might benefit from the findings, so publication or presentation of the results is very important.

Conferences and journals have specific formats and submission procedures to be followed. Prior to writing an article or presentation researchers are advised to go to the conference or journal website to view author guidelines.

Changing clinical practice

If the results are of clinical significance it may be appropriate to implement new department practices. The researcher might, however, wish to test the results on a larger scale before implementing. This can be achieved by continuing the research project for a longer time period or using a different patient subgroup.

Conclusion

Projects can inform practice and have a direct impact on radiation therapy treatment, patient care and staff satisfaction. Completing a research or quality assurance project can be an enjoyable and rewarding milestone in a clinical radiation therapist's career. By following the research process a project can be completed in a logical manner and to a high research standard.

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