Research and Academia as Foundations of Future Practice

In this section

Key Issues

Research in radiation oncology provides direct clinical benefit to patients (measurable outcomes, used in diagnosis and treatment).

- Radiation oncology research in Australia lacks capacity and resources,
  - This limits capability for developing and implementing advances in patient care, and for workforce training and development;
  - There is disparity of research funding for radiation oncology compared to its clinical benefit to patients;
  - The impact of this may be greater in regional and rural facilities
- Research in radiation oncology is different to pharmacological based research in that:
  - randomised clinical trials are more difficult;
  - lack of clinical data collection to evaluate technologies;
  - novel methodologies are required to evaluate new technologies;
- There is further potential for collaboration between the various research groups, institutions, professions and individuals involved in cancer research.

Objective

World class research is part of the core business of radiation oncology services.

Defining Success

Australia is an international leader in radiation oncology research that improves patient outcomes:

- Local research that results in evidence based and timely implementation of new treatment techniques and technologies;
- Increased funding allocation to radiation oncology research that is commensurate with its contribution to cancer control;
- Dedicated radiation oncology research equipment and staff time are included into national service planning;
- Access to clinical radiation oncology equipment time for (translational and implementation) research is factored into facility service planning;
- Integration of radiation oncology treatments into comprehensive electronic medical records (EMR);
- Research is recognised as part of core business for all radiotherapy facilities;
- Multidisciplinary research teams are established, incorporating discovery, translational and implementation research.

Introduction

Medicine is reliant on extensive research and trials to adopt and integrate relevant findings into clinical practice in order to progress, develop and improve patient care outcomes. Cancer is the second most significant cause of mortality and morbidity in Australia[1]. Improvements in cancer treatment are dependent on effective research in identifying the causes and biology of cancer, developing new drugs and techniques for treating cancer and developing methods to evaluate and quantify the individual's response to treatment so that personalised medicine is enabled for the patient.

This section focuses on research and academia in the area of radiation oncology: clinical trials, discovery, translational research (see below), adoption of new technology into clinical practice (i.e. implementation research), and the constraints to research and development in Australia. Stakeholder consultation amongst members of the three professions sought comment on whether the institutions they were associated with participated in research or actively supported research, what the constraints were to conducting research and how research can be improved in Australia. The majority of the responses were concerned with the lack of collaboration and what respondents felt was inadequate support for research. The results of the stakeholder surveys and written submissions received are incorporated into the analysis below.

Current Status of Research in Australia

Research can be classified as discovery, translational and implementation. The majority of participants in the consultation process were of the opinion that Australia is not leading the way internationally in radiation oncology research. While many hospitals with radiotherapy facilities have some level of participation in research and/or clinical trials, most respondents deemed it inadequate. In addition, out of a total of 64 respondents, only 43.7% said that their workplace made time for people to do research during work hours with 32.8% of respondents using time after work hours to do research.

Radiation oncology clinical trial research is largely implementation based research and in Australia is mostly conducted under the umbrella of the Trans-Tasman Radiation Oncology Group (TROG). TROG is Australia and New Zealand's specialist clinical research group for cancers that can be treated with radiotherapy. TROG is a cooperative multi-disciplinary organisation dedicated to the control of a wide range of cancers through quality multi-centre research. To date, TROG has activated over 60 cancer research trials in Australia and New Zealand. Approximately 10 to 15 trials are open at any time, giving many patients the opportunity to access innovative therapeutic approaches. From the feedback obtained during the membership consultation process, of the 62 members who responded to the question of whether their workplace supports clinical trials, 35.5% answered occasionally, 30.6% answered regularly and 29.1% answered most of the time.

Descriptions of clinical trial phases have been developed for pharmaceutical studies. Their application to radiation oncology and other non-drug medical specialties is not straightforward as the implications of the unique dynamics faced by these specialties, particularly imaging[2], have not been widely recognized or articulated.

Phase of Trial[3,4]	*Medical Description*	*Application in Radiation Oncology*
1	Initial studies	Proof of concept
2	Short term side effects	Implemented (pilot studies, not altering treatment)
3	Effectiveness and risk benefit analysis	Evaluation of clinical implementation and risk benefit analysis
4	Post market surveillance	Post implementation studies

The above table shows the phases of medical clinical trials and the product components that are tested in each phase. The application of the trial phases to radiotherapy can be seen in the right column.

Funding for Research

The majority of cancer research funding in Australia is provided by:

- The Australian Cancer Research Foundation (ACRF)
- The Australian Research Council (ARC)
- The National Health and Medical Research Council (NHMRC)
- State branches of Cancer Councils
- Cancer Australia (Commonwealth Government funding)
- The Victorian Cancer Agency
- Cancer Institute NSW
- Queensland Institute of Medical Research
- State and Territory Health Departments
- International agencies
- Donations (private and institutional)
- And other specific cancer support groups

Funding of radiotherapy research represents a disproportionately small percentage of total cancer research funding. For example, between 2000 – 2001 and 2011 – 2012 the NHMRC directed 18.5% ($232.8 Million) of total cancer research funding ($1269 Million) towards cancer treatment research. It is estimated that only 15.1% ($35 million)[5] of that sum was allocated to radiotherapy related treatment research. Similarly, in 2011, 30%[6] of the NSW Cancer Council research grants funding was disbursed to cancer treatment research. Approximately 6% of that total was for radiotherapy treatment research. These allocations can be contrasted to the recommended radiotherapy utilization rate of 52.3%[7] of cancer cases, and that radiotherapy is involved in 40%[8] of cancer cures. As a result, donations, which are irregular and unsustainable, form a significant proportion of research funding for some radiation oncology facilities. Increased investment in radiotherapy treatment research will enable greater and faster improvements in treatments that are applicable to large numbers of cancer patients.

Discovery Research

In cancer, discovery research, also known as basic research, is the exploration of underlying biological, chemical and physical processes related to cancer induction, growth and treatment responses. This research is undertaken to generate new knowledge with the aim that it may enable the development of new diagnostic and therapeutic techniques. The results of this research sometimes cannot be directly applied to cancer treatment; further translational research is generally required for clinical application.

This research is important, for example to:

1. Improve clinical decision making, e.g. discovery research should be supported to allow studies on associated physiology, genetics or pathology that could add to the clinical picture in the future;
2. Discover and develop technical materials and equipment, allowing improved understanding and characterisation of complex radiation delivery being considered for clinical use;
3. Improve understanding of cellular biology and genetics and their influence on diagnosis and treatment in radiation oncology, leading to the possibility of individualised treatment and incorporation of radiobiology into treatment management;
4. Generate knowledge to be used in the development of targeted therapies for treatment of systemic disease.

Translational Research

To improve human health, scientific discoveries must be translated into practical applications. Such discoveries typically begin at "the bench" with discovery research in which scientists study disease at a molecular or cellular level and then progress to the clinical level, or the patient's "bedside"[9]. Translational research supports collection of evidence which indicates patient outcomes, shortens the time needed to prove value of treatment before it can be adopted and made available to patients. Typically this involves laboratory or Phase 1 and 2 clinical trials. Successful translational research also provides the basis for making treatments available to patients through Medicare. This applies to radiation oncology as well.

Rapid advances in radiation oncology mean the development of new treatment techniques and technologies to deliver them. The section on Keeping Pace with Radiotherapy Techniques and Technologies (on page 47) explores challenges in evaluating and adopting innovations at the national level. However, survey responses indicate that the adoption of radiation oncology techniques and technologies into patient care in Australia occurs at a limited pace, partly limited by research related factors. These include:

1. Limited access to research expertise in the clinical environment especially in regional and rural facilities;
2. Inadequate access to diagnostic and radiotherapy equipment for research (including clinical trials) purposes;
3. Insufficient staff resources;
4. Lack of availability of translational research funding allocated to radiation oncology;
5. Insufficient interdisciplinary and inter-institutional collaboration.

Despite the challenges of incorporating translational research into the clinical environment, some examples of recent successes in translational research include:

1. The incorporation of ideas from other areas of sciences, for example combining patient images from different imaging modalities including CT/PET/MRI;
2. Development of an MRI Linear Accelerator[10,11];
3. Biologically optimised treatment planning[12-16];
4. Cone beam CT incorporated into the linear accelerator for image guided and adaptive radiotherapy[17, 18];
5. Adaptive radiotherapy utilizing tumour tracking and response[19,20];
6. Use of tin foil modified electrons to treat superficial cancers[21];

According to the Cancer Institute NSW, "the translation of research discoveries into public benefit has become a focus for many research funding agencies and is particularly relevant for the Cancer Institute with a core aim of impacting upon population health"[22]. This view on translational research is shared by Cancer Australia[23], commenting "that the main goal is the uptake of best practice cancer care through the translational research into evidence based information and improvements in cancer control, this includes new models of care that are effective and relevant to the Australian health system and -clinical practice guidance for health professionals and relevant information for patients and the community". Increased translational research in Australia will allow the assessment and incorporation of the results of discovery research into clinical practice in a more timely and efficient manner than currently occurs.

Implementation Research

Implementation research is the evaluation of new or clinically utilised diagnostic or treatment techniques in the clinical environment. Due to the time delay required to assess some endpoints (such as cancer specific survival), many radiotherapy techniques and technologies are assessed using shorter term endpoints (such as associated toxicity and dosimetry).

Once sufficient evidence is gathered in translational research, the modality or technique can be implemented on a large scale for the benefit of patients. This research is typically conducted through the equivalent of phase 3 and 4 clinical trials. In Australia, these clinical trials are principally conducted through TROG. This research is designed so that the results of translational research become routine and deliver efficient, effective and sustainable patient outcomes.

This research should include areas such as:

1. Early and late treatment toxicities;
2. Quality of life;
3. Survivorship;
4. Evaluation of processes and efficiency;
5. Patient selection for specific treatments.

Successful implementation research may result in infrastructure investment associated with new technology, if it has not already occurred at the translational research stage. In addition, the technique may then attract reimbursement from public funding; one example of this occurring was the radiotherapy treatment verification using electronic portal imaging (EPID).

In the future, the electronic medical record and the minimum radiation oncology data set, linked to the radiotherapy record will allow the equivalent of phase 4 trials to be undertaken. Phase 4 trials are post market surveillance studies. This has the power to improve the personalisation of treatment. Future data collection would allow discovery based research to flow out of these data. For example, genome wide association studies may be able to be performed which could lead to discovery of biomarkers directly relevant to clinical practice. The aim would be to enhance implementation research by linking to future discovery research.

Constraints to Research and Trials

Inadequate funding or lack of dedicated funding and support are the major constraints to radiation oncology research. Although many of the professionals noted during consultation that they participate in research projects in some form, there is a concern that the clinical workload is significant and that available time to do research is minimal. The hospitals are prioritising everyday patient care over research, which is understandable, however in most institutions research is not tangibly recognised as part of core business. The time and resources allocated to research are inadequate and often lack essential administrative or data support.

One of the reasons for the disproportionately low allocation of cancer research funding to radiation oncology may be the challenge in translating a research design that is appropriate for radiation oncology into a form similar to that used in pharmaceutical trials, as this is often the basis for funding applications.

Delays in ethics and governance approvals for multi-site clinical trials lead to delays in recruitment and low engagement. Lack of participation by patients from population sub-groups with poorer outcomes, such as people from regional and rural areas and people from Aboriginal and Torres Strait Islander origin, as well as insufficient resources to support clinical trials at the site level are other challenges restricting research activities.

At the professional level, there are limited opportunities for employment in designated research positions. This is exacerbated by the highly variable and often limited allocation of protected time for research at facility level across all specialties in radiation oncology. Many professionals strongly interested in conducting research feel that they would need to go overseas if they want a prominent career in research. The situation presents an even greater challenge in regional and rural facilities where maintaining appropriate staffing levels can be difficult. Additional full time equivalent (FTE) positions or effective management of existing workforce to ensure that protected research time is recognised and made available would be a solution to this challenge.

Limited access to radiation oncology equipment can constrain research initiatives. Flexible hours (i.e. outside of patient treatment times) and protected time on the equipment or dedicated research equipment (such as linacs, planned on a national level) need to be planned. With any purchase of radiation oncology equipment, the utilization of that equipment should be planned such that provisions for patient treatment, research access, as well as maintenance and quality assurance are included within operating hours. These factors should also be considered in service planning and reporting.

A constraint to implementational and some translational research is that there are commercial-in-confidence considerations for manufacturers of radiotherapy equipment. There is a perceived risk that competitors may use research results to support similarly designed products without the associated research investment.

A strong focus is needed on leadership and fostering collaboration between disciplines and organisations and international collaboration. At present, the academic, research and clinical components continue to function as disconnected silos. Often, radiotherapy research in Australia is conducted in isolation and as a result it takes longer for research projects to generate meaningful data sets, reducing the academic impact of the work. International collaboration with sector partners would make research activities increasingly financially viable and give better client participation with access to larger populations.

Academia and Education

Initial education for all radiation oncology professions is provided in universities and is supplemented with a mandatory clinical training program delivered either within the degree program, or following graduation. Specialised education and training as well as continuing professional development (CPD), is governed, administered, and in part provided by the professional associations often in collaboration with universities and facilities. Academia refers to both the universities and the professional associations.

Training for all radiation oncology professions has a clinical component aligned with current clinical practice. There is also a requirement for a research component for most programs. There is a link between providing education in research in an academic environment and practicing it in a clinical environment. Supporting this link is particularly important for those professionals whose exposure to research in their education and training is limited.

It is equally important for contemporary clinical practice to be continuously incorporated into education and training programs for the radiation oncology professions as this ensures that trainees have the necessary knowledge to work effectively. The links between the academic and clinical environments are important as they enable the education of quality trainees, the enhancement of research capability, and the implementation of techniques and technologies for the benefit of patients.

Future Directions

The technological advancements and understanding of the molecular basis of cancer will influence the approaches to cancer prevention, early detection, diagnosis, tumour classification, treatment and monitoring of disease. New radiotherapy techniques and technologies will continue to improve the accuracy and effectiveness of cancer treatments, while minimising treatment-related side effects and improving patient quality of life. Increased understanding of cancer biology/radiobiology and the development and application of new targeted technologies will enhance patient outcomes, quality of life and survivorship. Translational research will be increasingly important in the incorporation of sophisticated technologies into standard clinical care and delivering cost-effective and equitable cancer care across Australia. Implementation research is necessary to compare effectiveness of various treatment modalities using wider population database to determine the impact of new techniques and technologies on patient outcomes.

There is a strong trend internationally for the installation of proton and heavy ion treatment facilities[24-27]. Australia is likely to adopt this technology, primarily for research purposes in coming years, and is currently developing world leading capabilities in micro-beam research at the National Synchrotron Centre in Victoria. This will in turn have implications for the availability of a suitably trained workforce and the identification of investment in infrastructure. Similar to the Synchrotron, the planning of this type of facility would require a national approach and its introduction would enhance Australia's ability to conduct research at the forefront of radiation science. Such facilities would provide opportunities to attract international research leaders to Australia and to retain more of the best and brightest research scientists.

Future research also needs to address variations in cancer outcomes for different cancers and population groups. The newer technologies with their increasing integration with patient management systems will be increasingly developed to facilitate data capture and sharing. This will also require consolidated approaches to manufacturers to ensure that appropriate data fields can be built into the record and verify systems to meet Australian data requirements. Such data collection will strengthen the quality, consistency and availability of national data on cancer treatment and research and will assist policy decisions and service planning and delivery of equitable radiotherapy for all cancer patients.

The workforce will need to be flexible and knowledgeable to adopt the outcomes of research not yet identified as having direct application to radiation oncology. For example, the implementation of nanotechnology in the medical environment may introduce new diagnostic and treatment techniques. Research opportunities and corresponding management support should be available to the workforce, irrespective of the geographic location of their workplace.

Similarly, patients should have access to participation in implementation research opportunities (e.g. through clinical trials) so that this choice is available, irrespective of the treatment facility location. It is recognised that patient participation in clinical trials is associated with the development of refined treatment regimens resulting in improved patient outcomes[28].

Increased investment in research will increase access to treatments, improve the quality of the overall service, improve treatment outcomes for patients and holds the promise to increase the throughput and productivity of radiation oncology practice. A stronger investment in radiation oncology research should also enhance the transfer of knowledge from the academic to the clinical environment, allowing the timely adoption of new treatment techniques. In part, the results of investment would be measurable by the number of scientific papers published and patents issued.

Recommendations

Local research that results in evidence based and timely implementation of new treatment techniques and technologies

77. Specific support for radiation oncology research is required:

    77.1. Clinical and health systems research in radiation oncology that produces timely evidence of safety, efficacy and cost effectiveness of new techniques and technologies must be specifically funded through a dedicated funding stream.

    77.2. Expansion of research support in radiation oncology that advance our understanding of biological mechanisms translating into clinical practice through specific measures such as translational training fellowships, to maximise benefits for patients.

78. Patient awareness of clinical research needs to be increased:

    78.1. Health care consumers must be educated in the availability and importance of clinical research, leading to increased participation in clinical research.

Increased funding allocation to radiation oncology research that is commensurate with its contribution to cancer control

79. It is recommended that radiation oncology research funding is increased so that:

    79.1. Research processes are developed from current levels and are sustainable with adequate dedicated funding

    79.2. Additional translational research capacity enables faster identification and adoption of new techniques and technologies that improve efficiency

80. Workforce and equipment planning and implementation at site, jurisdiction and national levels must include the requirements to support research as an integral component of care delivery.

81. A small grants program must be introduced to develop projects to a level of national competitiveness.

Dedicated radiation oncology research equipment and staff time are included into national service planning

82. Infrastructure planning at jurisdiction, state and national level needs to accommodate research requirements.

Access to clinical radiation oncology equipment time for (translational and implementation) research is factored into facility service planning

83. Facility planning needs to accommodate research requirements including discovery, translational and implementation research.

Integration of radiation oncology treatments into comprehensive electronic medical records (EMR)

84. All treatment facilities must have the capability to collect comprehensive data sets including treatment details that can be shared through national collaborative research programs.

85. Strategies for data support and sharing between facilities must be in place.

Research is recognised as part of core business for all radiotherapy facilities

86. The importance of research positions needs to be recognised:

    86.1. research career path must be developed

    86.2. radiation oncology services should support research activities within their facilities

86.3. Programs should be developed (if not yet in place) that combine professional with academic (doctoral or masters) qualifications.

86.4. Mentorship programs must be introduced to link experienced researchers with early career professionals.

87. The ethics and governance approval process needs to be streamlined to enable efficient collaboration.

88. Professions must build ethics and governance literacy amongst their members.

89. It is essential that healthcare consumers are involved in the development of trials and represented on decision-making bodies.

Multidisciplinary research teams established, incorporating discovery, translational and implementation research

90. Active cooperation and collaboration between various departments, jurisdictions, disciplines and manufacturers must be actively encouraged.

91. Clinical professionals must have protected time to conduct research.

92. International collaboration in research and participation in international research projects must be encouraged and supported.

93. Collaborative links between treatment facilities and universities need to be developed or increased (where already in place):

93.1. Co-operation between universities and treatment facilities has to extend beyond teaching hospitals.

93.2. Reciprocal support arrangements need to be established between universities and treatment facilities, whereby facilities provide clinical placements and universities provide research support to facilities.

93.3. Support for the establishment of conjoint academic and clinical positions in all three professional groups.

93.4. Research training and the creation of roles for practitioner-scientists must be fostered across the radiation oncology professions.

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Current Research and Trials/Grants

More information available from:

1. http://www.acrf.com.au/cancer-research-grants/cancer-research-projects/
2. http://www.cancersa.org.au/cms_resources/2011%20Research%20Funding.pdf
3. http://www.cancerwa.asn.au/research/successfulresearchfunding/
4. http://www.trog.com.au/Default.aspx?tabid=70
5. http://www.canceraustralia.gov.au/research-and-funding
6. http://www.cancercouncil.com.au/wp-content/uploads/2011/12/CAN626-Cancer-Council-Donor-Servicing-16pp-DL-Brochure-v7.pdf