The development of radiotherapy quality indicators for lung cancer- a modified Delphi technique protocol

Kim-Lin Chiew (kim-lin.chiew@health.qld.gov.au)
Princess Alexandra Hospital

Candice Donnelly
University of Sydney

Susan Harden
Peter MacCallum Cancer Centre

Shalini Vinod
South Western Sydney Local Health District

Study protocol

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Abstract

Background

Radiotherapy is an effective evidence-based treatment modality for the definitive management of both early and locally advanced lung cancer. Whilst the literature reports a wide range of quality indicators (QIs) to assess the surgical management of lung cancer there is a deficit of robust QIs available to measure the quality of radiotherapy received by patients[1]. We propose a literature review and modified Delphi technique to develop a set of radiotherapy specific quality indicators and benchmarks aimed at evaluating the processes involved in the planning and delivery of radiotherapy for lung cancer.

Methods

A modified Delphi technique will be used and will include an international expert panel in two formal rounds with a target of 40 participants and intervening steering committee review with a minimum of 9 stakeholders. Candidate radiotherapy QIs will be selected from literature review and assessed by a steering committee to be included in the Delphi process. Both QIs and proposed benchmarks will be ranked by the expert panel in 2 rounds and included in the final set of QIs if a pre-defined consensus definition for importance is met by at least 70% of responses with a score of 7 or more on a 9-point Likert scale. Consensus criteria for feasibility and proposed benchmarks will be achieved if at least 70% of responses are reported as 3 or more on a 3-point Likert scale.

Discussion

We aim to address the current lack of quality indicators for assessing radiotherapy in lung cancer by using a robust modified Delphi method to attain international expert consensus for a set of QIs specific to the process involved in planning and delivering radiotherapy for definitive management of lung cancer. These have the potential to provide a foundation for QI measurement and benchmarking to guide quality improvement in radiotherapy for lung cancer.

Background

Lung cancer has the highest mortality rate for cancer worldwide[2] and treatment is rapidly evolving to involve a complex multidisciplinary approach involving surgery, radiotherapy and/or systemic therapy. Quality indicators (QIs) are evidence-based measures against best practice standards and outcomes in care. They aim to assess and detect variations in care[3, 4]. Radiotherapy as a component of treatment for lung cancer involves both clinical decision making and technical aspects which are potentially and readily measurable components of the process of care. Whilst studies have shown the optimal utilisation of radiotherapy should account for 61–82% of all treatments received by lung cancer patients[5], only 6% of QIs in lung cancer reported in the literature are related to the use of radiotherapy[1]. Considering radiotherapy is an important part of treatment determining health outcomes for a large number of lung cancer patients, there is a relative
limited number of developed indicators to measure the quality of radiotherapy received by patients in real-world health services.

This study will be the first developing a core set of QIs specific to the planning and delivery process of radiotherapy for lung cancer using an international consensus method with a modified Delphi technique. The use of a dephi panel is accepted as a formal standardised method for developing quality indicators that are evidence based through expert consensus[6]. The modified Delphi technique necessitates anonymous structured expert consensus via survey rounds with controlled feedback. During this process selected panel members independently rate indicators (often with a Likert scale) and provide feedback on certain criteria, commonly importance, validity and feasibility. This typically occurs over multiple structured survey rounds, in which consensus is met based on a pre-defined threshold and controlled feedback is provided to participants after each stage[7, 8]. Radiotherapy specific QIs have previously been published in the literature for the treatment of breast and prostate cancer also using a modified Delphi technique[9, 10]. A recent publication by Park et al has also described general radiotherapy QIs to be utilised regarding the radiotherapy for five cancer disease sites including lung but used a less structured methodology involving expert panel consensus[11]. Based on the deficit of QIs regarding the technical aspect and process of radiotherapy the scope of this project has been limited to the process of care once a decision to treat with radiotherapy has been made.

This study aims to develop a set of radiotherapy specific QIs for lung cancer by international consensus that are clinically important and feasible to measure. This set of QIs have the potential to be used routinely by health services to provide practical and measurable means of assessing quality and safety in radiotherapy for lung cancer. A secondary aim is to develop benchmarks for eligible QIs with the potential to guide quality improvement initiatives.

**Methods/design**

**Overview**

The set of radiotherapy specific QIs will be determined using a modified Delphi technique composed of two standardised rounds and intervening steering committee review, as described below (Figure 1).

A process map of lung cancer patient care receiving radiotherapy (Figure 2) was developed to guide the selection of candidate QIs to be included in the initial scoping review. Candidate QIs were selected from a systematic review of quality indicators for lung cancer and radiotherapy conducted by an expert group of three Radiation Oncologist reviewers and one health services researcher. The search inclusion criteria and scope of included QIs are shown in table 1. A steering committee will then review the candidate QIs.

**Steering committee**

The steering committee will consist of a core collaborative group of stakeholders who are recognised experts in radiation oncology and/or lung radiotherapy and an interest in quality of care. A minimum of 9 national and international experts will be included. The panel will include Radiation Oncologists specialising in lung cancer, at least one Radiation Therapist and one Medical Physicists. The role of the steering committee is outlined below:
1. Final selection of the QIs to be included in the first round of the Delphi survey

- Pre-selected potential QIs will have reached 70% consensus based on importance for inclusion by the panel
- The steering committee will review candidate QIs to adjust any definitions, change in wording or additional QIs to be considered if thought to be important and not identified in the literature search.

2. Review of Delphi survey results after round 1

- Final consensus decision on QI inclusion and exclusion in the second round
- Any free text feedback on QIs
- Provide opinion and consensus in regard to any potential adjustments or addition to QIs
- Provide opinion on QIs with overlapping subject matter to be combined
- Where there is indecision or reasonable consensus on wording or definition change to a QI that did not reach the pre-specified result for inclusion it may still be considered for inclusion in the second round
- Review of benchmarks

3. Review of Delphi survey results after round 2:

- Review of QIs that have and have not reached consensus
- Final consensus decision on the final QI set
- Review those that also reach further criteria of a median of 7-9 and Interquartile range (IQR) of < 3 as being most important
- Review of consensus on suggested benchmarks and provided comments regarding benchmarks

Participant Recruitment for Delphi expert panel

Published recommendations for Delphi consensus are for the inclusion of participants in the expert panel who should be “highly trained and competent within the specialized area of knowledge related to the target issue.”[12] For this purpose, in accordance with accepted methodology, appropriate potential participants will be individuals selected if they are a practicing Radiation Oncologist treating lung cancer patients who have expertise in the delivery of radiotherapy in the treatment of lung cancer. This is defined as the following: a current member of a society, committee or organisation or interest group in radiotherapy and lung cancer, or authored or co-authored peer reviewed article(s) related to radiotherapy for lung cancer.

The target participant recruitment is a minimum of 40 responders who complete both round 1 and 2 to the end of the survey. The survey will be sent to a minimum of 100 potential participants to account for a response rate as low as 40%. The optimal number of participants in Delphi expert panels and reported response rates vary widely in the literature[13]. For this study the number of participants was chosen based on what would be deemed to be reasonable to provide adequate expert opinion and feedback in this specific clinical domain and was within the acceptable range of what has been published in healthcare Delphi surveys previously[14]. Participants will be recruited by email invitation and social media from information provided by one of the following: professional networks; publicly available contact information from relevant societies,
committees, organisation or interest groups in radiotherapy and lung cancer; publicly available contact information as a corresponding author or co-author from a peer reviewed radiation oncology article regarding lung radiotherapy or QIs in lung radiotherapy; self-referral to investigators in person or via email as expressing interest in participating and has provided an email contact.

Delphi survey

The Delphi survey will be administered using an online survey with REDcap. The same participants invited to take part in the Delphi survey for round 1 will be invited to participate in round 2. The survey will include sections for demographics, definitions, QIs, benchmarks and a section for free text. Demographics to be collected include: country of practice, years of practice, number of linear accelerators in primary department, number of treatments per year, current participant in multidisciplinary team meeting, metropolitan or remote practice location.

Definitions will be provided for QIs and criteria for ranking (table 2). Participants will be asked to review and rank potential lung cancer radiotherapy QIs according to the criteria of importance on a 9-point Likert scale (table 3), and feasibility and suggested benchmarks on a 3-point Likert scale (table 4). Participants are asked to provide free text comments on the clarity of QIs and any suggested modifications, justifying the ranking of criteria and provide any suggestions to improve this ranking if applicable, justifying the ranking of suggested benchmark and provide any suggestion to change in benchmark.

For round 2 of the Delphi survey participants will be provided with a summary of QI and ranking on criteria with consensus on inclusion or exclusion. Survey respondents will be provided with a summary of benchmark for included QIs. This may also include descriptive feedback from round 1. The expert panel will be asked to:

- Rank potential lung cancer radiotherapy QIs according to the criteria of importance and feasibility as round 1.
- Rank suggested benchmarks for selected RT QIs as round 1
- Comment on reasoning for non-consensus of feedback on definition or wording if relevant
- Comment on reasoning for non-consensus of benchmark if relevant

Inclusion Criteria

For Round 1 a candidate QI will meet the consensus definition applied for “inclusion” if 70% or more of responders provide a score rating for importance of ≥ 7 on a 9-point Likert scale. A 3-point Likert scale will be used for feasibility with a threshold of 70% or more providing a score of 3 (table 3). Round 2 has the same criteria as round 1. Consensus criteria for benchmarks will be the same as for importance. Proposed benchmarks will meet consensus definition if 70% or more of responders provide a score of 3 to “agree.”

Data analysis

Data will be de-identified prior to analysis. All data will be exported from the secure survey platform and analysis performed using SAS statistical software. Survey results will be reviewed for data quality including missing data, indiscriminate ranking and outliers. Any missing answers will be regarded as nonparticipation.
The number of participants and demographic descriptors will be summarised. For the Likert scales the mean rating, range and interquartile range will be reported. Review of those that meet threshold will be performed. Statistical analysis for each criteria and benchmark ranking will be conducted for means, medians, standard deviations and interquartile ranges. QIs will be assessed for meeting the predefined threshold as shown in table 5. Those that reach further criteria of a median of 7-9 and IQR of < 3 will be reviewed as being most important.

**Discussion**

Previous research regarding currently utilised QIs in the management of lung cancer show a lack of radiotherapy related QIs despite radiotherapy being a relevant component of treatment for a large proportion of these patients. Those QIs related to radiotherapy are largely measuring adherence to clinical practice guidelines with a lack of QIs reporting specifically on the technical aspects of radiotherapy for lung cancer patients[1]. Research has shown that patients who receive radiotherapy that deviates from the radiotherapy planning and treatment study protocol, as a benchmark of the quality of radiotherapy, compromises patient outcomes including reduced effectiveness or worse complication rates[15]. Accordingly, in the real world setting there is a need for the development of lung cancer QIs specific to radiotherapy treatment in order to assess the quality of radiotherapy delivered and provide optimal patient outcomes.

With the rapid adoption of new technology in radiotherapy, it is especially important that the quality of the technical aspects of treatment delivered are considered. The process of radiotherapy is complex from pre-treatment assessment, radiotherapy simulation, dosimetry, delivery and post-treatment care. These can be wide ranging and of varying importance to the clinical practice of care and patient outcomes. Examples include the recommendation for PET fusion for target volume delineation, motion management during radiotherapy delivery and adhering to dose limits to organs at risk. In order to be relevant to real world health services settings, this study aims to develop a core set of QIs of radiotherapy in lung cancer that are the most important to the delivery of clinical care whilst also assessing the potential feasibility and benchmarks.

The role of the core QI set developed is to be readily adaptable for practical use in departments in order to both measure the quality of radiotherapy in lung cancer and also guide quality improvement initiatives. The QIs included should be feasible or potentially feasible to be measurable as part of usual radiotherapy practice and data collection. The selected QI set are not necessarily required to be feasible with current practice of departments and QIs will not be excluded due to the feasibility criteria. Rather, this will provide useful information for the potential to be used as a measure or the need to identify barriers to measurement or data collection for ease of use.

Strengths of this study include the methodology of a modified Delphi technique. This is a commonly accepted technique recognised for development of QIs. This technique provides a structured format with controlled feedback and is anonymous in nature in order to reduce group pressure or external influences to responses. The assessment of the QIs is further strengthened by the inclusion of 2 Delphi rounds for international expert panel consensus with an intervening steering committee review. This allows for adjustments to wording of the potential QIs to be included in the final set to ensure validity[16, 17]. A similar methodology has previously been used to develop QIs specifically related to radiotherapy for breast cancer and prostate cancer[9, 10].
The main limitations of using the modified Delphi technique is the uncertainty regarding consensus thresholds. There is no generally accepted threshold for consensus and our study was based on what was reasonable with the expected number of QIs and scales used in previous research[13], with a 70% consensus using a 9 point Likert scale chosen for importance. Other limitations and potential barriers include possible lack of participation due to the survey design or survey burden. In an attempt to address this, we have identified core stakeholders in the field internationally to advocate contribution from international centres. There is also an inherent risk of incomplete surveys and with multiple rounds there is likely attrition of responders between these rounds. There will be efforts to counteract this with both reminder emails and the provision of responses and feedback in a reasonable time frame to maintain interest with participants. The aim of the steering committee will also be to initially include a reasonable number of QIs that can be assessed in the Delphi rounds in an acceptable timeframe and avoid repetitive questions.

RT is an integral part of lung cancer treatment and there is a lack of consensus-driven valid QIs to measure the quality of radiotherapy, especially technical aspects. This study aims to develop a robust set of core QIs and potential benchmarks specific to the planning and delivery of radiotherapy in lung cancer. These have the potential to provide a foundation for QI measurement and impetus for quality improvement for health services providing radiotherapy for lung cancer.

**List Of Abbreviations**

QI quality indicator

RT radiotherapy

IQR interquartile range

**Declarations**

**Ethics approval and consent to participate:**

Ethical review was undertaken by the HREC at South Western Sydney Local Health District. Prior to participation in the surveys all participants will be asked for their consent. All procedures in this study will be conducted in compliance with the Declaration of Helsinki. Results will be disseminated to participants upon request by the co-ordinating investigator.

**Consent for publication:** Not applicable

**Availability of data and materials:**

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request

**Competing interests:**

The authors declare that they have no competing interest
Funding: Nil to declare

Author's contributions:
Kim-Lin Chiew- protocol development, protocol primary author, literature search, manuscript.
Shalini Vinod- input to protocol development, literature search, manuscript review
Susan Harden- input to protocol development, literature search, manuscript review
Candice Donnelly- input to protocol development, literature search, manuscript review

Acknowledgements: Not applicable

References


**Tables**

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<th>Table 1</th>
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<tr>
<td><strong>Scope of selected QIs</strong></td>
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</table>

**Inclusion/Exclusion criteria**

A QI or guideline with a potential to be developed into a QI and that involves the radiotherapy process once a decision for radiotherapy has been made

This includes pre-treatment assessment for radiotherapy, planning or delivery of radiotherapy

This excludes pre-treatment assessment for diagnosis and staging or follow-up

<table>
<thead>
<tr>
<th>Table 2</th>
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<tr>
<td><strong>Definitions</strong></td>
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<table>
<thead>
<tr>
<th>Importance</th>
<th>The importance in determining the quality of radiotherapy received for lung cancer</th>
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<tbody>
<tr>
<td>Feasible</td>
<td>The information is available in your health system to report this indicator</td>
</tr>
<tr>
<td>Benchmark</td>
<td>Best practice care considered to be achieved above this level</td>
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Table 3
9-point Likert scale

<table>
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<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
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<th>7</th>
<th>8</th>
<th>9</th>
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<tbody>
<tr>
<td></td>
<td>Strongly disagree</td>
<td>Disagree</td>
<td>Moderately disagree</td>
<td>Mildly disagree</td>
<td>Undecided</td>
<td>Mildly agree</td>
<td>Moderately agree</td>
<td>Agree</td>
<td>Strongly agree</td>
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Table 4
3-point Likert scale

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<th>3</th>
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<tbody>
<tr>
<td></td>
<td>Disagree</td>
<td>Undecided</td>
<td>Agree</td>
</tr>
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Table 5
Delphi rounds inclusion and exclusion criteria

<table>
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<th>Criteria</th>
<th>Thresholds</th>
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<tr>
<td>Importance</td>
<td>≥ 70% of respondents provide a score of ≥ 7 on a 9-point Likert scale</td>
</tr>
<tr>
<td>Feasible</td>
<td>≥ 70% of respondents provide a score of ≥ 3 on a 3-point Likert scale</td>
</tr>
<tr>
<td>Benchmark</td>
<td>≥ 70% of respondents provide a score of ≥ 3 on a 3-point Likert scale</td>
</tr>
<tr>
<td>MDT</td>
<td>multidisciplinary team</td>
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Figures
Figure 1

Study design
Figure 2

Process Map for lung cancer patients receiving radiotherapy

MDT multidisciplinary team