

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Identifying challenges to implementation of clinical practice guidelines for sentinel lymph node biopsy in patients with melanoma in Australia: a protocol paper for a mixed methods study
AUTHORS	Rapport, Frances; Smith, Andrea; Cust, Anne; Mann, Graham; Watts, Caroline; Gyorki, David; Henderson, Michael; Hong, Angela; Kelly, John; Long, Georgina; Mar, Victoria; Morton, Rachael; Saw, Robyn; Scolyer, Richard; Spillane, Andrew; Thompson, John; Braithwaite, Jeffrey

VERSION 1 – REVIEW

REVIEWER	Sandra Wong Dartmouth College Geisel School of Medicine
REVIEW RETURNED	07-Jul-2019

GENERAL COMMENTS	<p>This study protocol "Identifying challenges to implementation of clinical practice guidelines for sentinel lymph node biopsy in patients with melanoma in Australia: a protocol paper" is being considered for publication in BMJ Open. It represents ongoing research (since it appears that data have been collected since late 2018). As such, it makes sense that methodology should not be changed at this point. The enclosed materials were interesting and informative and results will be interesting for melanoma guidelines and beyond.</p> <p>Table 1 presents staging categories for melanoma and references the 8th edition of the AJCC in doing so. However, the categories are imprecise and should be corrected/updated to reflect the current (8th edition) staging system.</p> <p>In terms of how the data should be analyzed and interpreted, one suggestion would be to detail some principles of implementation science to be incorporated into the assessment of barriers and facilitators to uptake of SLNB guidelines for melanoma (e.g., Consolidated Framework for Implementation Research (CFIR) or Theoretical Domains Framework (TDF)). A theoretical construct for evaluation may be an important methodological consideration.</p>
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REVIEWER	Gerardo Ferrara Anatomic Pathology Unit - Macerata General Hospital - AV3-ASUR Marche - Via Santa Lucia, 2 - 62100 MACERATA, Italy
REVIEW RETURNED	23-Jul-2019

GENERAL COMMENTS	Rapport et al. present a study draft aimed at understanding the structural, contextual, and cultural factors affecting implementation
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	<p>of Australian guidelines for sentinel node biopsy in melanoma. The study will be performed by collecting data with questionnaires and semi-structured interviews from GPs, dermatologists, and other healthcare professionals involved in the care of melanoma patients. The Authors foresee that between 50 and 65 participants will be adequate to ensure the necessary variety of perspective and experiences.</p> <p>Major concern - The aim of National guidelines is to uniform healthcare levels across different areas of a given Country. The Authors would like to investigate the structural, contextual, and cultural factors affecting implementation of guidelines. I can guess that such factors greatly vary across the Australian sub-continent. Thus I think that the Authors should collect a greater number of questionnaires/interviews and evaluate them with reference to the different geographical areas (different contexts imply different problems)</p> <p>Minor queries - The Authors might itemize in detail expected structural, contextual, and cultural factors affecting implementation of guidelines.</p> <p>On line 139, 'stage 1b and stage 2' is probably not correct. Are 12 months of practice in Australia enough to enrol GPs?</p> <p>Questions for GPs: if a GP does not perform the biopsy, is a feedback info given/desirable? I guess it is.</p> <p>Factors influencing the decision to discuss or recommend sentinel node biopsy (question 15 for GPs; question 16 for Dermatologists): the Authors might consider including regression.</p>
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REVIEWER	Andreia Cristina de Melo National Cancer Institute of Brazil , Clinical Research Division, National Cancer Institute of Brazil (INCA)
REVIEW RETURNED	13-Sep-2019

GENERAL COMMENTS	Very interesting protocol paper addressing an important aspect of melanoma care. In my opinion no changes required for publication at BMJ
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VERSION 1 – AUTHOR RESPONSE

Reviewer: Sandra Wong

This study protocol “Identifying challenges to implementation of clinical practice guidelines for sentinel lymph node biopsy in patients with melanoma in Australia: a protocol paper” is being considered for publication in BMJ Open. It represents ongoing research (since it appears that data have been collected since late 2018). As such, it makes sense that methodology should not be changed at this point. The enclosed materials were interesting and informative and results will be interesting for melanoma guidelines and beyond.

Comment 1: Table 1 presents staging categories for melanoma and references the 8th edition of the AJCC in doing so. However, the categories are imprecise and should be corrected/updated to reflect the current (8th edition) staging system.

Response: Thank you for your comment. The table was designed to be informative to someone who may not have an in-depth knowledge of melanoma, in particular to aid understanding of primary tumour vs local vs distant spread and how this relates to staging. In the Introduction we say:

'Staging takes into account tumour thickness and ulceration and whether the melanoma has spread regionally (to the lymph nodes) or more distantly (to other parts of the body) (Table 1).' The table legend has been revised to say 'Adapted from AJCC 8th edition staging guidelines'.

Comment 2: In terms of how the data should be analyzed and interpreted, one suggestion would be to detail some principles of implementation science to be incorporated into the assessment of barriers and facilitators to uptake of SLNB guidelines for melanoma (e.g., Consolidated Framework for Implementation Research (CFIR) or Theoretical Domains Framework (TDF)). A theoretical construct for evaluation may be an important methodological consideration.

Response: Thank you for this suggestion. We have expanded the last paragraph of the Introduction to explicitly discuss the theoretical framework (the TICD Checklist) and our rationale for choosing this particular determinant framework. The TICD Checklist will be used to inform data analysis, identification of determinants of practice, and identification of appropriate implementation strategies. We have also added information about the TICD Checklist to the data analysis section.

Reviewer: Gerardo Ferrara

Rapport et al. present a study draft aimed at understanding the structural, contextual, and cultural factors affecting implementation of Australian guidelines for sentinel node biopsy in melanoma. The study will be performed by collecting data with questionnaires and semi-structured interviews from GPs, dermatologists, and other healthcare professionals involved in the care of melanoma patients. The Authors foresee that between 50 and 65 participants will be adequate to ensure the necessary variety of perspective and experiences.

Comment 1: Major concern - The aim of National guidelines is to uniform healthcare levels across different areas of a given Country. The Authors would like to investigate the structural, contextual, and cultural factors affecting implementation of guidelines. I can guess that such factors greatly vary across the Australian sub-continent. Thus I think that the Authors should collect a greater number of questionnaires/interviews and evaluate them with reference to the different geographical areas (different contexts imply different problems)

Response: Thank you for pointing this out. We agree that it is important to understand the varied perspectives of clinicians from across Australia, in particular from those practising outside of the major metropolitan centres. To this end, our recruitment strategy very much focuses on contacting as wide a range of clinicians and stakeholders as possible (see lines 259-263, Sampling and recruitment - interviews: 'Sampling will be driven by a number of purposive sampling strategies, including stratified purposive sampling and maximum variation sampling (to gain as wide a range of perspectives as possible from individuals with different professional backgrounds and responsibilities), key informant sampling (to ensure important informants are included) and snowball sampling (to ensure sampling is not restricted to key informants already known to the CRE in Melanoma members).

We have added in a couple of sentences (see below) to clarify that our recruitment strategy for the questionnaire will aim to include as many participants as possible (not just the 50-65 participants we anticipate that we will recruit for the interview part of the study):

Sampling and recruitment: questionnaires

Recruitment of dermatologists and GPs will take place at targeted conferences, training and skin cancer-focused continuing medical education events and through professional communications, for example by contacting organisations such as the Australian College of Dermatologists.

Comment 2: Minor queries - The Authors might itemize in detail expected structural, contextual, and cultural factors affecting implementation of guidelines.

Response: Thank you for this suggestion. In response to this (and to questions from Reviewer 1 about our theoretical framework), we have expanded the last paragraph of the Introduction to explicitly discuss the theoretical framework (the TICD Checklist) and our rationale for choosing this particular determinant framework. The TICD Checklist will provide a structured and systematic means of sensitising us to the structural, contextual and cultural factors affecting implementation of the

guidelines. References have been included to the TICD Checklist which includes 57 potential determinants (barriers and enablers of guideline implementation) grouped into seven domains: guideline factors; individual health professional factors; patient factors; professional interactions; incentives and resources; capacity for organisational change; and social, political, and legal factors.

Comment 3: On line 139, 'stage 1b and stage 2' is probably not correct.

Response: Thank you for pointing this out. We have checked with the original reference and can confirm that 'stage 1b and 2' is what appears in the original paper.

Comment 4: Are 12 months of practice in Australia enough to enrol GPs?

Response: We wished to include all GPs, from newly qualified to very senior, as we are aware that attitudes to the guidelines have been changing, and wanted to see if this varied according to years in practice.

Comment 5: Questions for GPs: if a GP does not perform the biopsy, is a feedback info given/desirable? I guess it is.

Response: In Australia a GP who has referred a patient to a specialist (dermatologist, surgeon) will always receive communications from the specialist summarising the tests undertaken, the results and the management plan for that patient.

Comment 6: Factors influencing the decision to discuss or recommend sentinel node biopsy (question 15 for GPs; question 16 for Dermatologists): the Authors might consider including regression.

Response: Thank you for this suggestion. We did not include tumour regression as it is not included in the AJCC staging criteria, although we appreciate that histologic regression may be considered an additional indicator for SLN biopsy in patients with a thin melanoma. In designing the survey, in order to capture this information, we provided participants with the option of selecting 'Other' and provided space for a free-text response.

Reviewer: Andreia Cristina de Melo

Very interesting protocol paper addressing an important aspect of melanoma care.

In my opinion no changes required for publication at BMJ.

VERSION 2 – REVIEW

REVIEWER	Gerardo Ferrara Anatomic Pathology Unit - ASUR Marche - Area Vasta 3 - Macerata General Hospital - Via Santa Lucia, 2 - I-62100 Macerata, ITALY
REVIEW RETURNED	27-Dec-2019
GENERAL COMMENTS	No further comment