




# BMJ Open Identifying challenges to implementation of clinical practice guidelines for sentinel lymph node biopsy in patients with melanoma in Australia: protocol paper for a mixed methods study

Frances Rapport <sup>1</sup>, Andrea L Smith <sup>1,2</sup>, Anne E Cust<sup>2,3</sup>, Graham J Mann<sup>3,4</sup>, Caroline G Watts<sup>2,5</sup>, David E Gyorki<sup>6</sup>, Michael Henderson<sup>6</sup>, Angela M Hong<sup>3,7</sup>, John W Kelly<sup>8</sup>, Georgina V Long<sup>3,7</sup>, Victoria J Mar<sup>8</sup>, Rachael L Morton<sup>3,9</sup>, Robyn PM Saw<sup>3,7</sup>, Richard A Scolyer<sup>3,7</sup>, Andrew J Spillane<sup>3,7</sup>, John F Thompson<sup>3,7</sup>, Jeffrey Braithwaite <sup>1</sup>

**To cite:** Rapport F, Smith AL, Cust AE, *et al.* Identifying challenges to implementation of clinical practice guidelines for sentinel lymph node biopsy in patients with melanoma in Australia: protocol paper for a mixed methods study. *BMJ Open* 2020;**10**:e032636. doi:10.1136/bmjopen-2019-032636

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2019-032636>).

FR and ALS are joint first authors.

Received 01 July 2019  
Revised 24 December 2019  
Accepted 28 January 2020



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For numbered affiliations see end of article.

## Correspondence to

Dr Andrea L Smith;  
[andrea.smith@mq.edu.au](mailto:andrea.smith@mq.edu.au)

## ABSTRACT

**Introduction** Sentinel lymph node biopsy (SLNB) is a diagnostic procedure developed in the 1990s. It is currently used to stage patients with primary cutaneous melanoma, provide prognostic information and guide management. The Australian Clinical Practice Guidelines state that SLNB should be considered for patients with cutaneous melanoma >1 mm in thickness (or >0.8 mm with high-risk pathology features). Until recently, sentinel lymph node (SLN) status was used to identify patients who might benefit from a completion lymph node dissection, a procedure that is no longer routinely recommended. SLN status is now also being used to identify patients who might benefit from systemic adjuvant therapies such as anti-programmed cell death 1 (PD1) checkpoint inhibitor immunotherapy or BRAF-directed molecular targeted therapy, treatments that have significantly improved relapse-free survival for patients with resected stage III melanoma and improved overall survival of patients with unresectable stage III and stage IV melanoma. Australian and international data indicate that approximately half of eligible patients receive an SLNB.

**Methods and analysis** This mixed-methods study seeks to understand the structural, contextual and cultural factors affecting implementation of the SLNB guidelines. Data collection will include: (1) cross-sectional questionnaires and semistructured interviews with general practitioners and dermatologists; (2) semistructured interviews with other healthcare professionals involved in the diagnosis and early definitive care of melanoma patients and key stakeholders including researchers, representatives of professional colleges, training organisations and consumer melanoma groups; and (3) documentary analysis of documents from government, health services and non-government organisations. Descriptive analyses and multivariable regression models will be used to examine factors related to SLNB practices and attitudes. Qualitative data will be analysed using thematic analysis.

## Strengths and limitations of this study

- The mixed-method design, comprising cross-sectional questionnaires, in-depth interviews and documentary analysis, will generate rich data about the determinants of sentinel lymph node biopsy (SLNB) guideline implementation.
- The Tailored Implementation for Chronic Disease (TICD) Checklist will be used to identify the determinants of implementation (ie, the barriers and enablers of implementation).
- The TICD Checklist will also help to inform possible implementation strategies that could be used to address some of these barriers to implementation of the SLNB guidelines.
- The purposive recruitment of healthcare professionals and stakeholders, and the sampling and selection of documents and policies, may introduce selection biases.

**Ethics and dissemination** Ethics approval has been granted by the University of Sydney. Results will be disseminated through publications and presentations to clinicians, patients, policymakers and researchers and will inform the development of strategies for implementing SLNB guidelines in Australia.

## INTRODUCTION

### Centre of Research Excellence (CRE) in Melanoma

The CRE in Melanoma is an Australian collaboration of clinicians, researchers and implementation scientists from melanoma centres and universities in New South Wales (Melanoma Institute Australia; The University of

Sydney; and the Australian Institute of Health Innovation, Macquarie University) and Victoria (Peter MacCallum Cancer Centre; Victorian Melanoma Service Alfred Hospital; The University of Melbourne; Monash University and the Skin and Cancer Foundation), Australia, and is funded by the Australian National Health and Medical Research Council (NHMRC). The Melanoma CRE, like all Australian government-funded CREs, is tasked with three primary objectives: pursuing collaborative research; developing capacity; and promoting translation of research outcomes into policy and practice. This third objective is the focus of the mixed-methods study outlined in this protocol paper, in particular to understand the structural, contextual and cultural factors affecting implementation of the recently updated national clinical practice guidelines for SLNB for melanoma patients in Australia.

### Prioritisation of SLNB uptake as a key implementation goal

One of the rationales behind embedding implementation science expertise within the Melanoma CRE is to support the transfer of evidence-based, effective and efficient patient-centred care across and beyond the Melanoma CRE research sites so that all melanoma patients, regardless of location in Australia, can benefit from its generation of knowledge. A necessary first step in the implementation process is to identify and prioritise interventions with the greatest potential to impact positively on the quality of care for patients with melanoma. Between December 2018 and February 2019, meetings of Melanoma CRE members systematically mapped CRE projects across the melanoma care continuum (online supplementary file 1) and identified two in which implementation science had the greatest potential to identify pathways to practice change. One of these, 'SLNB for patients with melanoma', is outlined in this protocol paper.

### Melanoma diagnosis and staging

Melanoma is the fourth most common cancer diagnosis in Australia.<sup>1</sup> In 2019, it is estimated that 15 229 people will be diagnosed with invasive melanoma and that 1725 people will die from it.<sup>1</sup> Between 2011 and 2015, an individual diagnosed with melanoma had a 91% chance of surviving for 5 years.<sup>1</sup> Survival is influenced by the stage of the melanoma at diagnosis. 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).<sup>2,3</sup> Accurate staging is a fundamental prerequisite for optimal melanoma management. From the perspective of the individual patient, staging provides important prognostic information, guides management and clinical decision making, including whether a patient may benefit from adjuvant systemic therapy, shapes communication between the patient, their clinician and the patient's family and may determine the patient's eligibility for clinical trials.<sup>4</sup> From a public health perspective, staging also facilitates standardised reporting, centralised cancer registry reporting, the design and conduct of clinical trials, and the analysis of clinical trial data.<sup>2</sup>

**Table 1** Staging categories for cutaneous melanoma

Stage	Definition
Stage 0	The melanoma is confined to the cells in the top layer of the skin (epidermis) and has not invaded the deeper layers (dermis); also known as in situ melanoma (in contrast to stages I–IV, which are referred to as invasive melanoma).
Stage I	The melanoma has not spread beyond the primary site (ie, no metastases or lymph node involvement); the melanoma is: <ul style="list-style-type: none"> <li>▶ ≤2 mm in thickness <u>without</u> ulceration.</li> <li>▶ ≤1 mm in thickness <u>with</u> ulceration.</li> </ul>
Stage II	The melanoma has not spread beyond the primary site (ie, no metastases or lymph node involvement); the melanoma is: <ul style="list-style-type: none"> <li>▶ &gt;2 mm in thickness <u>without</u> ulceration.</li> <li>▶ &gt;1 mm in thickness <u>with</u> ulceration.</li> </ul>
Stage III	The melanoma can be any thickness and locoregional metastasis is present (ie, satellite, in-transit or microsatellite metastases or nodal metastases).
Stage IV	The melanoma can be any thickness and has spread to distant lymph nodes and organs, for example, lungs, liver, brain or bone.

Adapted from American Joint Committee on Cancer 8th edition staging guidelines.<sup>2,3</sup>

### Sentinel lymph node biopsy (SLNB)

An important primary melanoma staging tool is SLNB, a multiphase procedure involving cutaneous lymphatic mapping with lymphoscintigraphy in the nuclear medicine department, surgical removal of the localised SLNs and pathological assessment of the SLNs for the presence of metastatic disease. The procedure has a high degree of accuracy for identifying patients with melanoma who have clinically occult metastases in their regional lymph nodes.<sup>5,6</sup>

Prior to the introduction of SLNB by Morton *et al* in 1992,<sup>5</sup> the only way to detect spread from the primary tumour site to the regional lymph nodes was through clinical examination of the patient's lymph nodes or by performing an elective lymph node dissection with its attendant morbidity. Elective lymph node dissection was routinely offered to patients who were considered to be at risk of relapse in the belief that removal of all lymph nodes in the lymph node field would prevent distant spread of the melanoma to other parts of the body. However, as only a small proportion (about 20%) of those at-risk patients who had an elective lymph node dissection actually had nodal metastases, the procedure resulted in considerable unnecessary morbidity, primarily lymphoedema.

SLNB avoided this unnecessary morbidity by using nuclear medicine and vital blue dyes to identify the SLN, that is, the lymph node receiving direct lymphatic drainage from the primary melanoma site.<sup>5</sup> The rationale (which Morton referred to as the incubator hypothesis or stepwise model of disease progression) was that the most likely site of early metastases, the SLN, could then be removed and tested pathologically for clinically

occult melanoma cells, and if found, a completion lymph node dissection was performed. Conversely, if the SLN was clear of metastatic disease, then it was reasoned that it was unlikely that other, more distant nodes would be diseased, thereby saving the patient from an unnecessary lymph node dissection. In this context, SLNB has been reported to be cost-effective for the management of intermediate-thickness melanoma.<sup>7</sup>

### Contemporary melanoma management

Based on the results of two recent randomised controlled trials,<sup>8,9</sup> it is now widely accepted that a completion lymph node dissection in patients who are SLN positive does not provide an overall survival benefit. Consequently, the role SLNB plays in contemporary melanoma management is changing. In Australia and in many other countries, in addition to providing staging and prognostic information, SLNB is now being used to identify patients who might benefit from adjuvant systemic therapy. Adjuvant systemic therapies, such as immunotherapies (in which the patient's own immune system is activated to target cancer cells) and BRAF-directed targeted molecular therapies (which block the growth and spread of cancer by interfering with specific abnormal molecules within the tumour cells themselves), have been developed on the basis of recent advances in our understanding of the molecular and immune biology of melanoma. These adjuvant systemic therapies have been shown to significantly prolong survival in patients with unresectable stage III and stage IV melanoma<sup>10</sup> and have also been shown to improve recurrence-free survival when administered as adjuvant therapy in patients with resected stage III melanoma.<sup>11–13</sup> However, they are not yet publicly funded in the adjuvant melanoma setting in Australia. Consequently, access is often restricted to clinical trials, eligibility for which requires staging via SLNB, and compassionate access schemes.

### International (American Joint Committee on Cancer (AJCC) staging system) and national (Australian) guidelines for SLNB

The AJCC Staging Manual has become the benchmark for classifying patients' disease stage, outlining prognosis and establishing the best treatment approaches.<sup>14</sup> The recently updated eighth edition recommends that lymphatic mapping and SLNB should be routinely used as a staging procedure for patients with T1b, T2, T3 or T4 primary cutaneous melanomas (ie, melanomas  $\geq 0.8$  mm with or without ulceration or  $< 0.8$  mm with ulceration) and who have clinically negative regional lymph nodes.<sup>3</sup> Likewise, the 2018 Australian Clinical Practice Guidelines for the Diagnosis and Management of Melanoma recommend that 'SLNB should be considered for all patients with melanoma  $> 1$  mm in thickness and for patients with melanoma  $> 0.8$  mm with other high risk pathological features to provide optimal staging and prognostic information and to maximise management options for patients who are node positive'.<sup>15</sup>

### Rates of SLNB in Australia and internationally

The limited data that exist for rates of SLNB for melanoma in Australia indicate that these rates may be lower than expected. Rates of SLNB are likely to be related to the guidelines in place at that point in time. In Australia, the 1999 guidelines stated 'Lymphatic mapping and sentinel node biopsy should be considered for all melanomas  $> 1$  mm thick provided they can be done in the context of a controlled clinical trial and by surgeons trained in these procedures'; the 2008 guidelines stated 'Patients with a melanoma  $> 1.0$  mm in thickness should be given the opportunity to discuss sentinel lymph node biopsy to provide staging and prognostic information'. A population-based study in Queensland between 2010 and 2014 reported rates of SLNB of 33% (261 of 787 study patients) for stage 1b and stage 2 melanoma patients.<sup>16</sup> The 2006 New South Wales Melanoma Patterns of Care Study reported that SLNB was performed in 45% of patients diagnosed with a melanoma  $> 0.75$  mm thick.<sup>17</sup> SLNB rates in Australia are roughly comparable with rates reported internationally. Data from the US Surveillance Epidemiology and End Results database for 2004–2006 indicate that 53% of eligible patients received an SLNB,<sup>18</sup> while data from a population-based study in the northeast of France indicated that 34% of patients with a melanoma  $> 1$  mm in thickness received an SLNB.<sup>19</sup> Factors associated with having an SLNB included patient age  $< 50$  years,<sup>17</sup> primary tumour on upper limb,<sup>17</sup> treatment in an urban setting<sup>17,19–23</sup> and hospital size ( $> 50$  beds).<sup>24</sup> Recent international data indicate that rates of SLNB are increasing: in the Netherlands, the SLNB rate increased from 39.0% in 2003 to 47.8% in 2014.<sup>25</sup> The authors suggested that changes in rates of SLNB may be related to evolving views on SLNB as a staging or therapeutic procedure, changes to the AJCC staging system and less acceptance of the stepwise model of disease progression.

### Challenges relating to implementation of clinical practice guidelines

Clinical practice guidelines synthesise and summarise complex research evidence into easily understandable recommendations. Clinical practice guidelines were initially heralded as a means of overcoming the knowledge gaps perceived to be behind observed variations in clinical practice.<sup>26</sup> However, even guidelines that are based on rigorous evidence rarely penetrate medical practice as intended.<sup>26</sup> It is now accepted that the distillation and summary of evidence into clinical practice guidelines, although a necessary step, is not in and of itself sufficient for the translation of research evidence into routine clinical practice.<sup>26</sup>

Successful adoption and implementation of guidelines require an understanding of the technical, social, political, economic, cultural, structural and psychological barriers to the use of research evidence.<sup>27</sup> As Greenhalgh and colleagues<sup>28</sup> noted in 2004, clinicians are not passive recipients of innovations (such as guidelines). Instead they 'seek innovations, experiment with them,

evaluate them, find (or fail to find) meaning in them, develop feelings (positive or negative) about them, challenge them, worry about them, complain about them, “work around” them, gain experience with them, modify them to fit particular tasks, and try to improve or re-design them—often through dialogue with other users’. In addition, as Ferlie and colleagues<sup>29</sup> noted in 2001, the research evidence for a particular practice is often ambiguous and contested. Consequently, the evidence base ‘must be continually interpreted and reframed in accordance with the local context, a process that often involves power struggles among various professional groups’.<sup>29</sup> For their widespread acceptance, guidelines need to be perceived as authoritative, credible and professional documents that help healthcare professionals improve their practice, traits closely tied to the provenance of the guidelines.<sup>26</sup>

### Theoretical framework

The Tailored Implementation for Chronic Disease (TICD) Checklist is a comprehensive, integrated checklist that was designed to be used as a tool to identify determinants of practice that warrant further in-depth investigation.<sup>30</sup> Although originally designed to be used in the chronic disease setting, the authors advise that it can be used more broadly.<sup>31</sup> Determinants of practice are the barriers and facilitators that might impact on implementation of an intervention. The TICD Checklist includes 57 potential determinants of practice grouped into seven domains. These seven domains are: guideline factors; individual health professional factors; patient factors; professional interactions; incentives and resources; capacity for organisational change; and social, political and legal factors.

The TICD Checklist was selected for a number of reasons, specifically: (1) the TICD Checklist is a single comprehensive, integrated checklist of determinants of practice that was created through the systematic identification and synthesis of 12 previously published checklists, frameworks, taxonomies and classifications of determinants of healthcare professional practice; (2) the TICD Checklist focuses on provider behaviour rather than patient behaviour; (3) in addition to identifying determinants of practice, the TICD Checklist can also be used to inform the design of implementation strategies; and (4) the TICD Checklist includes a comprehensive range of worksheets designed to support its use.

The knowledge generated in this project will be used to inform future implementation strategies to support effective and widespread melanoma guideline implementation in Australia. A greater awareness of the guidelines, and the melanoma patients to whom they apply, should in turn lead to improved melanoma management and outcomes for patients, including more accurate information about prognosis and access to systemic adjuvant therapies such as immunotherapy or targeted molecular therapy for eligible patients with melanoma.

## METHODS AND ANALYSIS

### Study design

This protocol outlines the research design for a mixed-methods study informed by the TICD Checklist.<sup>30</sup> Cross-sectional questionnaires and in-depth semistructured interviews with general practitioners (GPs) and dermatologists and in-depth semistructured interviews with other healthcare professionals and stakeholders in melanoma care in Australia will be complemented by data collected through documentary analysis of material such as editorials, organisational and institutional reports, books and brochures relating to SLNB in Australia, including policy documentation (table 2). Data collection for GP questionnaires and interviews commenced in December 2018 and for other healthcare professionals and stakeholders in May 2019. The study runs until 2023. The credibility of the study’s findings will be enhanced through the use of multiple sources of information, different methods of data collection and the involvement of researchers with diverse areas of expertise (eg, in clinical practice, melanoma, implementation science, complexity science, behaviour change science and public health). This triangulation of methods, data sources and investigator expertise will ensure that the findings are data rich and comprehensive.<sup>32</sup> The reporting of the study design as outlined in this protocol is informed by the consolidated Criteria for Reporting Qualitative Research checklist and the Strengthening the Reporting of Observational studies in Epidemiology guidelines.<sup>33 34</sup>

### Study aim and objectives

The aim of this mixed-methods study is to understand the structural, contextual and cultural factors impacting the implementation of the recently updated national clinical practice guidelines for SLNB in melanoma patients. The study aim will be achieved by fulfilling the objectives outlined in table 2.

### Sample and setting

#### Participants

Participants will include GPs, dermatologists and other healthcare professionals involved in the diagnosis and early definitive care of melanoma patients in Australia (box 1). It is anticipated this will include generalist GPs, GPs working in skin cancer clinics, dermatologists and surgeons (general, plastic and surgical oncology). Participants will also include stakeholders involved in melanoma care in Australia, including researchers, representatives of professional colleges and organisations (eg, Royal Australian College of General Practitioners, Royal Australasian College of Surgeons, Australasian College of Dermatologists and Skin Cancer College Australasia), healthcare training and education organisations (eg, HealthCert and Australasian College of Cutaneous Oncology) and consumer advocacy organisations (eg, Melanoma Patients Australia).

**Table 2** Study aim, objectives and data collection methods

Aim	Objectives	Data collection
To understand the structural, contextual and cultural factors impacting on the implementation of the national clinical practice guidelines for SLNB for melanoma patients in Australia	<ul style="list-style-type: none"> <li>► Understand GPs' and dermatologists' knowledge and attitudes towards SLNB in Australia.</li> <li>► Examine, document and analyse the discourse surrounding SLNB in Australia.</li> <li>► Provide an account of factors that have contributed to this discourse.</li> <li>► Assess the range of perspectives and opinions on SLNB among healthcare professionals and other stakeholders in Australia.</li> <li>► Contextualise data collected in the interviews with other documentation.</li> <li>► Provide an account of determinants of practice that have impacted on the implementation of Australia's clinical practice guidelines for SLNB for patients with melanoma.</li> <li>► Generate knowledge that will help inform the future work of the CRE in Melanoma, in particular the design of implementation strategies appropriate to the determinants to improve uptake of the clinical practice guidelines for SLNB in melanoma patients in Australia.</li> </ul>	<ul style="list-style-type: none"> <li>► Questionnaires and follow-up semistructured interviews with GPs (ie, generalist GPs and GPs working in skin cancer clinics) and dermatologists in relation to management of melanoma and role of SLNB.</li> <li>► Semistructured interviews with other healthcare professionals and key stakeholders in melanoma management (eg, academics and researchers, representatives of professional colleges, healthcare training and education organisations and consumer advocacy organisations).</li> <li>► Documentary analysis of printed and electronic material relating to implementation of SLNB guidelines in Australia (eg, commentaries and editorials, books and brochures, event programmes, newspapers, press releases, programme proposals, summaries, organisational and institutional reports, questionnaire data and public records).</li> </ul>

### 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 Australasian College of Dermatologists.

### 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).<sup>35</sup> Sampling will be iterative, with decisions informed by the ongoing data analysis.<sup>36</sup> Recruitment strategies will include: (1) recruitment of healthcare professionals at relevant conferences and professional development activities; (2) identification of key stakeholders by members of the CRE in Melanoma; and (3) identification of additional key stakeholders by participants. The overarching recruitment strategy will be to select for interview individuals from around Australia whose experiences and professional roles within melanoma healthcare put them in a position to provide rich and relevant data. Recruitment will cease once data analysis indicates thematic saturation has been reached, this being the point at which our analysis allows us to provide a comprehensive and credible account of the structural, contextual and cultural factors impacting on implementation of the national clinical practice guidelines for SLNB in patients with melanoma in Australia. It is anticipated that between 50 and 65 participants will be recruited in order to ensure a variety of perspectives and experiences from all relevant sectors in Australian melanoma care (20–25 GPs; 10–15 dermatologists; 20–25 other healthcare professionals and stakeholders).

### Sampling: documentary analysis

Documentary materials relevant to the development and use of the national SLNB guidelines will be purposively sampled and included, based on their potential to

## Box 1 Inclusion and exclusion criteria

### Questionnaires and interviews (general practitioners (GPs) and dermatologists)

- Must have worked as a GP or dermatologist in Australia in the previous 12 months.

### Interviews (other healthcare professionals)

- Must have worked as a health professional in Australia in the previous 12 months.

### Interviews (stakeholders)

- Current or prior experience of managing patients with melanoma in Australia; or
- Current or prior experience of working for an organisation or institution that could have influenced healthcare practitioners', policymakers' or patients' views on sentinel lymph node biopsy (SLNB) in Australia.

### Documentary analysis

- Australian online or print-based materials that could have influenced healthcare practitioners', policymakers' or patients' views on SLNB in Australia.

**Table 3** Topics and example questions from semistructured interview guides for melanoma healthcare professionals (GPs and dermatologists) and stakeholders

Topics	Example questions
<b>Melanoma healthcare professionals</b>	
Risk factors, diagnosis and management	If you identified a suspected melanoma, how would you usually go about getting a biopsy? If you perform the biopsy yourself, how does the information in the pathology report help guide your subsequent management decisions?
SLNB	Do you have any thoughts about the role of SLNB in the management of patients with melanoma? What do you see as the benefits and risks of SLNB?
Shared decision making	How comfortable would you feel about discussing melanoma management options with a patient? How do you usually tell your patient about different options for managing their melanoma?
<b>Stakeholders in melanoma care</b>	
Professional/organisational role	Can you tell me about your involvement/your organisation's involvement in SLNB for melanoma? Can you tell me about how you/your organisation regards SLNB for melanoma?
Views on current SLNB guidelines	I know you have written/talked publicly about SLNB, can you expand on that? There are some who hold quite strong views on SLNB. How do you respond to these views?
Making changes in relation to SLNB	What might be the barriers to change? What do you think will happen in relation to use of SLNB in the next 5 years/10 years?

SLNB, sentinel lymph node biopsy.

provide background and contextual information relevant to study's aims (box 1). Relevant documentary materials (such as commentaries and editorials, journal articles and white papers, books and brochures, event programmes, newspapers, press releases, programme proposals, summaries, organisational and institutional reports, questionnaire data and public records) will be used to uncover meaning, develop understanding and discover insights relevant to the study's aim.

## Data collection

### Questionnaires

Questionnaires for GPs and dermatologists have been developed following a review of literature and consultation with melanoma clinicians and dermatologists. Data captured will include demographic characteristics, knowledge of melanoma guidelines, clinical management of patients with melanoma, referral patterns, attitudes to SLNB and experiences of sharing care of patients with melanoma with other healthcare providers (online supplementary file 2). The questionnaires can be completed on paper or electronically. The questionnaire data will be managed using REDCap.<sup>37</sup>

### Interviews

Semistructured interview guides have been developed for healthcare professionals and stakeholders based on a review of literature and through consultation with melanoma healthcare professionals (table 3). The interview guides outline the major topics that will be discussed in the interviews and include a range of questions and prompts. Interviews will be face to face or by telephone (depending on participant preference) and will be audio-recorded and professionally transcribed. Field notes

written up immediately after each interview will further inform and enrich data analysis.

### Documentary analysis

Documents will initially be identified through discussion with members of the Melanoma CRE, and then through targeted, systematic searches of electronic and print-based resources relating to SLNB and SLNB guidelines in Australia. Searching will be iterative and cease only when a comprehensive understanding of the background and context of SLNB in Australia has been reached.

## Data analysis

### Questionnaires

Postcode will be classified using the Accessibility/Remoteness Index of Australia and Socio-Economic Indexes for Areas classifications.<sup>38 39</sup> Descriptive analyses and multi-variable regression models will be used to examine factors related to SLNB practices and attitudes, and familiarity with the Australian clinical practice guidelines for melanoma management, estimated using probability ratios and 95% CIs. Potential predictors that will be assessed in the regression models include age, sex, type of practice, years of practice, number of invasive melanomas diagnosed in a year, location of practice and GPs' exposure to information relating to SLNB. All analyses will be conducted using SAS V.9.4 (SAS Institute Inc).

### Interviews

The interview data will be analysed using thematic analysis and this analysis will initially be inductive and data driven.<sup>40 41</sup> The analysis will be informed by, but not necessarily limited to, the TICD Checklist's 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.<sup>30</sup> The deidentified transcripts will be read by two members of the research team. Data will be compared within and across interviews in order to identify commonalities, differences and patterns in the data. Transcripts will be coded by two researchers and a list of themes and categories relevant to the study's aim generated. These themes will then be discussed with other members of the research team and refined until agreement is reached on those most relevant to the study's aim. A thematic map will be developed and the data recoded to these themes. Analytic memos will be written throughout the data analysis process.

### Documentary materials

The analysis process will commence by assessing the authenticity and usefulness of each document, taking into account the document's relevance to the study's aim, the original purpose of the document, the context in which it was produced and the intended audience.<sup>42</sup> As with the interview data, the documentary data will be analysed using thematic analysis.<sup>41</sup>

### Indirect patient and public involvement

We did not directly include PPI in the design of this study, but the melanoma guidelines used in the study were developed and updated by a committee that includes patient representatives.

## ETHICS AND DISSEMINATION

### Ethics

Data collection and analysis will be conducted in accordance with the Australian HMRC National Statement.<sup>43</sup> All participants will provide informed consent prior to taking part in the study.

### Data storage and protection

Participant privacy and confidentiality will be maintained by removing all identifying information from the transcripts, by assigning pseudonyms to participants and by storing study data securely on password-protected computers or in locked filing cabinets within university premises, to which only named researchers from the research team will have access. Deidentified interview transcripts will be stored separately from the file containing participant identifiers. All data will be destroyed 7 years after completion of the study in accordance with standard ethical guidelines around storage of study data.

### Dissemination of study findings

Study findings will be disseminated via peer-reviewed journal publications, generalist publications, presentations to the public, academics, clinicians, policymakers, melanoma consumers and at scientific conferences.

## SIGNIFICANCE AND IMPACT OF STUDY

This is the first multimethods study to investigate the structural, contextual and cultural factors impacting the

implementation of national SLNB guidelines in Australia. The study will bring to light the range of professional perspectives on SLNB, document the discourse surrounding SLNB in Australia and report on how these may be affecting uptake of SLNB in patients with melanoma. The knowledge generated by this project will be used to inform future efforts to support effective and widespread melanoma guideline implementation in Australia and internationally. A greater awareness of the guidelines, and the patients with melanoma to whom they apply, should in turn lead to improved melanoma management and outcomes for patients, including more accurate information about prognosis and access to adjuvant systemic therapies such as immunotherapy or BRAF-directed targeted molecular therapy for eligible melanoma patients, and finally, the knowledge generated in this study will focus attention on the role of SLNB as a diagnostic and prognostic tool in melanoma, the role it has to play in accurate melanoma staging and cancer registry reporting and the role SLNB plays in the design and conduct of melanoma clinical trials both now and in the future.

### Author affiliations

<sup>1</sup>Australian Institute of Health Innovation, Macquarie University, Sydney, New South Wales, Australia

<sup>2</sup>Sydney School of Public Health, University of Sydney, Sydney, New South Wales, Australia

<sup>3</sup>Melanoma Institute Australia, Sydney, New South Wales, Australia

<sup>4</sup>The John Curtin School of Medical Research, Australian National University, Canberra, Australian Capital Territory, Australia

<sup>5</sup>Kirby Institute, University of New South Wales, Sydney, New South Wales, Australia

<sup>6</sup>Peter MacCallum Cancer Centre, Melbourne, Victoria, Australia

<sup>7</sup>Sydney School of Medicine, University of Sydney, Sydney, New South Wales, Australia

<sup>8</sup>Victorian Melanoma Service, The Alfred Hospital, Melbourne, Victoria, Australia

<sup>9</sup>NHMRC Clinical Trials Centre, University of Sydney, Sydney, New South Wales, Australia

**Twitter** Rachael L Morton @RachaelMorton12

**Acknowledgements** We would like to thank Sam Robinson for help in preparing the ethics application.

**Contributors** All authors were involved in the conception of the work; AEC, GJM, RAS, JB, JWK, RLM, AJS, RPMS and MH were involved in acquisition of the funding; ALS, FR, JB and AEC were involved in the design of the work; ALS drafted the manuscript; all authors were involved in critically revising the manuscript.

**Funding** This work was funded by the Melanoma Centre of Research Excellence grant (1135285) from the Australian National Health and Medical Research Council (NHMRC). RLM received funding from an NHMRC Translating Research into Practice Fellowship (1150989). AEC received an NHMRC Career Development Fellowship (1147843) and Cancer Institute NSW Career Development Fellowship (15/CDF/1-14).

**Competing interests** JFT has received honoraria for advisory board participation from BMS Australia, MSD Australia, GSK and Provectus Inc, and travel support from GSK and Provectus Inc.

**Patient consent for publication** Not required.

**Ethics approval** Ethical approval for the study has been granted by the University of Sydney Human Research Ethics Committee (HREC), project numbers 2018/713 and 2019/308.

**Provenance and peer review** Not commissioned; externally peer reviewed.

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# ORCID iDs

Frances Rapport <http://orcid.org/0000-0002-4428-2826>

Andrea L Smith <http://orcid.org/0000-0002-9194-4888>

Jeffrey Braithwaite <http://orcid.org/0000-0003-0296-4957>

# REFERENCES

- 1 Australian Institute of Health and Welfare (AIHW). 2018 cancer data in Australia; Australian cancer incidence and mortality (ACIM) books: melanoma of the skin. Canberra: AIHW, 2019. <https://www.aihw.gov.au/reports/cancer/cancer-data-in-australia/>
- 2 Gershenwald JE, Scolyer RA, Hess KR, et al. Melanoma staging: Evidence-based changes in the American Joint Committee on Cancer eighth edition cancer staging manual. *CA Cancer J Clin* 2017;67:472–92.
- 3 Mahul AB, Edge S, Greene F, et al. *AJCC cancer staging manual*. 8th ed. Chicago: Springer International Publishing, 2017..
- 4 Gershenwald JE, Scolyer RA. Melanoma staging: American Joint Committee on Cancer (AJCC) 8th edition and beyond. *Ann Surg Oncol* 2018;25:2105–10.
- 5 Morton DL, Wen DR, Wong JH, et al. Technical details of intraoperative lymphatic mapping for early stage melanoma. *Arch Surg* 1992;127:392–9.
- 6 Mitra A, Conway C, Walker C, et al. Melanoma sentinel node biopsy and prediction models for relapse and overall survival. *Br J Cancer* 2010;103:1229–36.
- 7 Morton RL, Howard K, Thompson JF. The cost-effectiveness of sentinel node biopsy in patients with intermediate thickness primary cutaneous melanoma. *Ann Surg Oncol* 2009;16:929–40.
- 8 Faries MB, Thompson JF, Cochran AJ, et al. Completion dissection or observation for sentinel-node metastasis in melanoma. *N Engl J Med Overseas Ed* 2017;376:2211–22.
- 9 Leiter U, Stadler R, Mauch C, et al. Complete lymph node dissection versus no dissection in patients with sentinel lymph node biopsy positive melanoma (DeCOG-SLT): a multicentre, randomised, phase 3 trial. *Lancet Oncol* 2016;17:757–67.
- 10 Schuchter LM. Adjuvant melanoma therapy - head-spinning progress. *N Engl J Med* 2017;377:1888–90.
- 11 Long GV, Hauschild A, Santinami M, et al. Adjuvant dabrafenib plus trametinib in stage III BRAF-mutated melanoma. *N Engl J Med* 2017;377:1813–23.
- 12 Weber J, Mandala M, Del Vecchio M, et al. Adjuvant nivolumab versus ipilimumab in resected stage III or IV melanoma. *N Engl J Med* 2017;377:1824–35.
- 13 Eggermont AMM, Blank CU, Mandala M, et al. Adjuvant pembrolizumab versus placebo in resected stage III melanoma. *N Engl J Med* 2018;378:1789–801.
- 14 Amin MB, Greene FL, Edge SB, et al. The Eighth Edition AJCC Cancer Staging Manual: Continuing to build a bridge from a population-based to a more "personalized" approach to cancer staging. *CA Cancer J Clin* 2017;67:93–9.
- 15 Gyorki D, Barbour A, Mar V, et al. Cancer Council Australia melanoma guidelines Working Party. when is a sentinel node biopsy indicated? 2019. Available: [http://wiki.cancer.org.au/australia/Clinical\\_question:When\\_is\\_a\\_sentinel\\_node\\_biopsy\\_indicated%3F](http://wiki.cancer.org.au/australia/Clinical_question:When_is_a_sentinel_node_biopsy_indicated%3F) [Accessed 19 Dec 2019].
- 16 Smithers BM, Hughes MCB, Beesley VL, et al. Prospective study of patterns of surgical management in adults with primary cutaneous melanoma at high risk of spread, in Queensland, Australia. *J Surg Oncol* 2015;112:359–65.
- 17 Valey AHR, Madronio CM, Cust AE, et al. Poor adherence to national clinical management guidelines: a population-based, cross-sectional study of the surgical management of melanoma in New South Wales, Australia. *Ann Surg Oncol* 2017;24:2080–8.
- 18 Silva E. Adjunct primer for the use of national comprehensive cancer network guidelines for the surgical management of cutaneous malignant melanoma patients. *World J Surg Oncol* 2012;10:54.
- 19 Grange F, Vitry F, Granel-Brocard F, et al. Variations in management of stage I to stage III cutaneous melanoma: a population-based study of clinical practices in France. *Arch Dermatol* 2008;144:629–36.
- 20 Shah DR, Yang AD, Mavarakis E, et al. Assessing rural-urban disparities in the use of sentinel lymph node biopsy for melanoma. *J Surg Res* 2013;184:1157–60.
- 21 Sant M, Minicozzi P, Allemanni C, et al. Regional inequalities in cancer care persist in Italy and can influence survival. *Cancer Epidemiol* 2012;36:541–7.
- 22 Look Hong NJ, Cheng SY, Baxter NN, et al. Melanoma patterns of care in Ontario: a call for a strategic alignment of multidisciplinary care. *J Surg Oncol* 2018;117:597–617.
- 23 Rivard J, Kostaras X, Shea-Budgell M, et al. A population-based assessment of melanoma: does treatment in a regional cancer center make a difference? *J Surg Oncol* 2015;112:173–8.
- 24 Garreau JR, Nelson J, Cook D, et al. Geographic variation in sentinel node adaptation by practicing surgeons in Oregon. *Am J Surg* 2005;189:616–20.
- 25 El Sharouni M-A, Witkamp AJ, Sigurdsson V, et al. Trends in sentinel lymph node biopsy enactment for cutaneous melanoma. *Ann Surg Oncol* 2019;26:1494–502.
- 26 Dopson S, Locock L, Gabbay J, et al. Evidence-based medicine and the implementation gap. *Health* 2003;7:311–30.
- 27 Bosk CL, Dixon-Woods M, Goeschel CA, et al. Reality check for checklists. *The Lancet* 2009;374:444–5.
- 28 Greenhalgh T, Robert G, Macfarlane F, et al. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Q* 2004;82:581–629.
- 29 Ferlie E, Gabbay J, Fitzgerald L, et al. Evidence-based medicine and organisational change: an overview of some recent qualitative research. In: Ashburner L, ed. *Organisational behaviour and organisational studies in health care: reflections on the future*. Basingstoke: Palgrave Macmillan, 2001: 18–42.
- 30 Flottorp SA, Oxman AD, Krause J, et al. A checklist for identifying determinants of practice: A systematic review and synthesis of frameworks and taxonomies of factors that prevent or enable improvements in healthcare professional practice. *Implementation Science* 2013;8:35.
- 31 Wensing M, Oxman A, Baker R, et al. Tailored implementation for chronic diseases (TICD): a project protocol. *Implement Sci* 2011;6:103.
- 32 Rapport F, Hogden A, Faris M, et al. *Qualitative research in healthcare: modern methods, clear translation. A white paper*. Sydney: Macquarie University, 2018.
- 33 Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *Int J Qual Health Care* 2007;19:349–57.
- 34 von Elm E, Altman DG, Egger M, et al. The strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. *Int J Surg* 2014;12:1495–9.
- 35 Miles M, Huberman M. *Qualitative data analysis: an expanded sourcebook*. Thousand Oaks: SAGE Publishing, 1994.
- 36 Charmaz K. *Constructing grounded theory: a practical guide through qualitative analysis*. Thousand Oaks: SAGE Publications, 2006.
- 37 Harris PA, Taylor R, Thielke R, et al. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
- 38 Australian Bureau of Statistics (ABS). Socio-economic indexes for areas (SEIFA), 2018. Available: <http://www.abs.gov.au/websitedbs/censushome.nsf/home/seifa>
- 39 Australian Bureau of Statistics (ABS). The Australian statistical geography standard (ASGS) remoteness structure, 2018. Available: <http://www.abs.gov.au/websitedbs/d3310114.nsf/home/remoteness+structure13>
- 40 Clarke V, Braun V. Reflecting on thematic analysis. *Qual Res Sport Exercise Health* 2019;11:1–2.
- 41 Braun V, Clarke V. Using thematic analysis in psychology. *Qual Res Psychol* 2006;3:77–101.
- 42 Bowen GA. Document analysis as a qualitative research method. *Qual Res J* 2009;9:27–40.
- 43 The National Health and Medical Research Council, the Australian Research Council and Universities Australia. *National statement on ethical conduct in human research 2007 (updated 2018)*. Canberra: Commonwealth of Australia, 2018.