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TITLE

Identifying challenges to implementation of clinical practice guidelines for sentinel lymph node biopsy in patients with melanoma in Australia: a protocol paper

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Keywords Mixed methods; melanoma; sentinel lymph node biopsy; implementation science; systemic adjuvant therapy; clinical practice guidelines

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 >1mm in thickness (or >0.75mm with high-risk pathology features). Until recently, 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-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 a 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 semi-structured interviews with general practitioners and dermatologists; (2) semi-structured 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.

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.

ARTICLE SUMMARY

This is the first Australian study to examine the structural, contextual and cultural factors affecting implementation of national clinical practice guidelines for SLNB in patients with melanoma.

The data generated may help to inform clinical guideline implementation strategies for melanoma and other cancers in Australia and internationally.

Strengths and limitations of this study

The mixed-method design, comprising cross-sectional questionnaires, in-depth interviews and documentary analysis, will generate rich data from a wide range of healthcare professional and stakeholder perspectives.

The purposive recruitment of healthcare professionals and stakeholders, and the sampling and selection of documents and policies, may introduce selection biases.

INTRODUCTION

Centre of Research Excellence in Melanoma

The Centre of Research Excellence (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 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 (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.[1] In 2019, it is estimated that 15,229 people will be diagnosed with invasive melanoma and that 1,725 people will die from it.[1] Between 2011 and 2015, an individual diagnosed with melanoma had a 91% chance of surviving for 5 years.[1] 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).[2,3] 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.[4] 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.[2]

Table 1. Staging categories for cutaneous melanoma [2,3]

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 to IV, which are referred to as invasive melanoma)
Stage I	The melanoma has not spread beyond the primary site (i.e. no metastases or lymph node involvement); the melanoma is: • ≤ 2mm in thickness without ulceration • ≤ 1mm in thickness with ulceration
Stage II	The melanoma has not spread beyond the primary site (i.e. no metastases or lymph node involvement); the melanoma is: • > 2mm in thickness without ulceration • > 1mm in thickness with ulceration

Stage	Definition
Stage III	The melanoma can be any thickness and locoregional metastasis is present (i.e. 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 e.g. lungs, liver, brain or bone

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 lymph nodes, and pathological assessment of the nodes 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.[5,6]

Prior to the introduction of SLNB by Morton *et al*. in 1992,[5] 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 all 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 localising nuclear medicine and vital blue dyes to identify the SLN, that is, the lymph node receiving direct lymphatic drainage from the primary melanoma site.[5] The rationale (which Morton referred to as the incubator hypothesis or step-wise 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 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. [7]

Contemporary melanoma management

Based on the results of two recent randomised controlled trials,[8,9] it is now widely accepted that a completion lymph node dissection in patients who are SLN-positive does not provide a survival benefit. Consequently, the role SLNB plays in contemporary melanoma management is changing. In Australia, 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[10] and have also been shown to improve recurrence-free survival when administered as adjuvant therapy in patients with resected stage III melanoma.[11–13] 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 (AJCC staging system) and national (Australian) guidelines for SLNB

The American Joint Committee on Cancer (AJCC) Staging Manual has become the benchmark for classifying patients' disease stage, outlining prognosis, and establishing the best treatment approaches.[14] 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 (i.e. melanomas ≥0.8mm with or without ulceration, or <0.8mm with ulceration) and who have clinically negative regional lymph nodes.[3] 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 >0.75 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.'[15]

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.[a] A population-based study in Queensland between 2010 and 2014 reported rates of SLNB of 33% (261 out of 787 study patients) for stage 1b and stage 2 melanoma patients.[16] The 2006 New South Wales Melanoma Patterns of Care Study reported that SLNB was performed in 45% of patients diagnosed with a melanoma >0.75mm thick.[17] SLNB rates in Australia are roughly comparable to rates reported internationally. Data from the US Surveillance Epidemiology and End Results (SEER) database for 2004-2006 indicate that 53% of eligible patients received a SLNB,[18] while data from a population-based study in the northeast of France indicated that 34% of patients with a melanoma >1mm in thickness received a SLNB.[19] Factors associated with having a SLNB included patient age <50 years,[17] primary tumour on upper limb,[17] treatment in an urban setting,[17,19–23] and hospital size (>50 beds)[24] 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.[25] The authors suggest 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 step-wise 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.[26] However, even guidelines that are based on rigorous evidence rarely penetrate medical practice as intended.[26] 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.[26]

Successful adoption and implementation of guidelines requires an understanding of the technical, social, political, economic, cultural, structural and psychological barriers to the use of research evidence.[27] As Greenhalgh and colleagues noted in 2004, clinicians are not passive recipients of innovations (such as guidelines).[28] 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

[a] 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 >1mm 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 >1.0mm in thickness should be given the opportunity to discuss sentinel lymph node biopsy to provide staging and prognostic information'.

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 noted in 2001, the research evidence for a particular practice is often ambiguous and contested.[29] 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'.[29] 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.[26]

Consequently, if widespread guideline implementation is to be achieved in Australia, it will be necessary to understand the complex contextual factors influencing clinicians' attitudes and behaviour in relation to the decision to discuss SLNB with an eligible melanoma patient or to refer the patient to an appropriate specialist for discussion of the pros and cons of SLNB. The knowledge generated in this project will be used to inform future efforts 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. Cross-sectional questionnaires and in-depth semi-structured interviews with GPs and dermatologists, and in-depth semi-structured 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 (e.g. 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.[30] The reporting of the study design as outlined in this protocol is informed by the consolidated Criteria for Reporting Qualitative Research (COREQ) checklist and the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines.[31,32]

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.

Table 2 Study aim, objectives and data collection methods

Aim	Objectives	Data collection
To understand the structural, contextual and cultural factors impacting the implementation of the national clinical practice guidelines for SLNB for melanoma patients in Australia	Understand GPs' and dermatologists' knowledge and attitudes towards SLNB in Australia Examine, document and analyse the discourse surrounding SLNB in Australia Provide an account of factors that have contributed to this discourse Assess the range of perspectives and opinions on SLNB among healthcare professionals and other stakeholders in Australia Contextualise data collected in the interviews with other documentation Provide an account of factors that have impacted on the implementation of Australia's clinical practice guidelines for SLNB for patients with melanoma Generate knowledge that will help inform the future work of the CRE in Melanoma, in	Questionnaires and follow-up semi-structured interviews with GPs (i.e. generalist GPs and GPs working in skin cancer clinics) and dermatologists in relation to management of melanoma and role of SLNB Semi-structured interviews with other healthcare professionals and key stakeholders in melanoma management (e.g. academics and researchers, representatives of professional colleges, healthcare training and education organisations, and consumer advocacy organisations) Documentary analysis of printed and electronic material relating to implementation of SLNB guidelines in Australia (e.g. commentaries and editorials, books and brochures, event programs, newspapers, press releases, program proposals, summaries, organisational and institutional

	particular strategies to improve uptake of the clinical practice guidelines for SLNB in melanoma patients in Australia	reports, questionnaire data, and public records)

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 (e.g. Royal Australian College of General Practitioners, Royal Australasian College of Surgeons, Australian College of Dermatologists, Skin Cancer College Australasia), healthcare training and education organisations (e.g. HealthCert, Australasian College of Cutaneous Oncology), and consumer advocacy organisations (e.g. Melanoma Patients Australia).

Box 1 Inclusion and exclusion criteria

Questionnaires and interviews (GPs and dermatologists)

- Must have worked as a general practitioner 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 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.

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).[33] Sampling will be iterative, with decisions informed by the ongoing data analysis.[34] 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 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 programs, newspapers, press releases, program 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 (Supplementary file 2). The questionnaires can be completed on paper or electronically. The questionnaire data will be managed using REDCap.[35]

Interviews

Semi-structured 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.

Table 3 Topics and example questions from semi-structured interview guides for melanoma healthcare professionals (GPs and dermatologists) and stakeholders

Topics	Example questions
Melanoma healthcare professionals	
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?
Stakeholders in melanoma care	
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 about SLNB, can you expand on that? There are some who hold quite extreme 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.

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 (ARIA), and Socio-Economic Indexes for Areas (SEIFA) classifications.[36,37] Descriptive analyses and multivariable 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% confidence intervals (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 version 9.4 (SAS Institute Inc).

Interviews

Analysis of interview data will be based on Braun and Clarke's method of thematic analysis and will initially be inductive and data driven.[38,39] In line with Braun and Clarke's methods, analysis will go beyond the semantic content of the data to: 'identify underlying ideas, assumptions and conceptualisations – and ideologies – that are theorised as shaping or informing the semantic content of the data'.[39] The de-identified 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 the 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 group 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.[40] As with the

interview data, the documentary data will be analysed using Braun and Clarke's method of thematic analysis.[39]

ETHICS AND DISSEMINATION

Ethics

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. Data collection and analysis will be conducted in accordance with the Australian National Health and Medical Research Council National Statement[41]. 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 multi-methods 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 statement

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Competing interests None.

Ethics approval University of Sydney Human Research Ethics Committee, project numbers 2018/713 and 2019/308.

Provenance and peer review Not commissioned; externally peer reviewed.

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.

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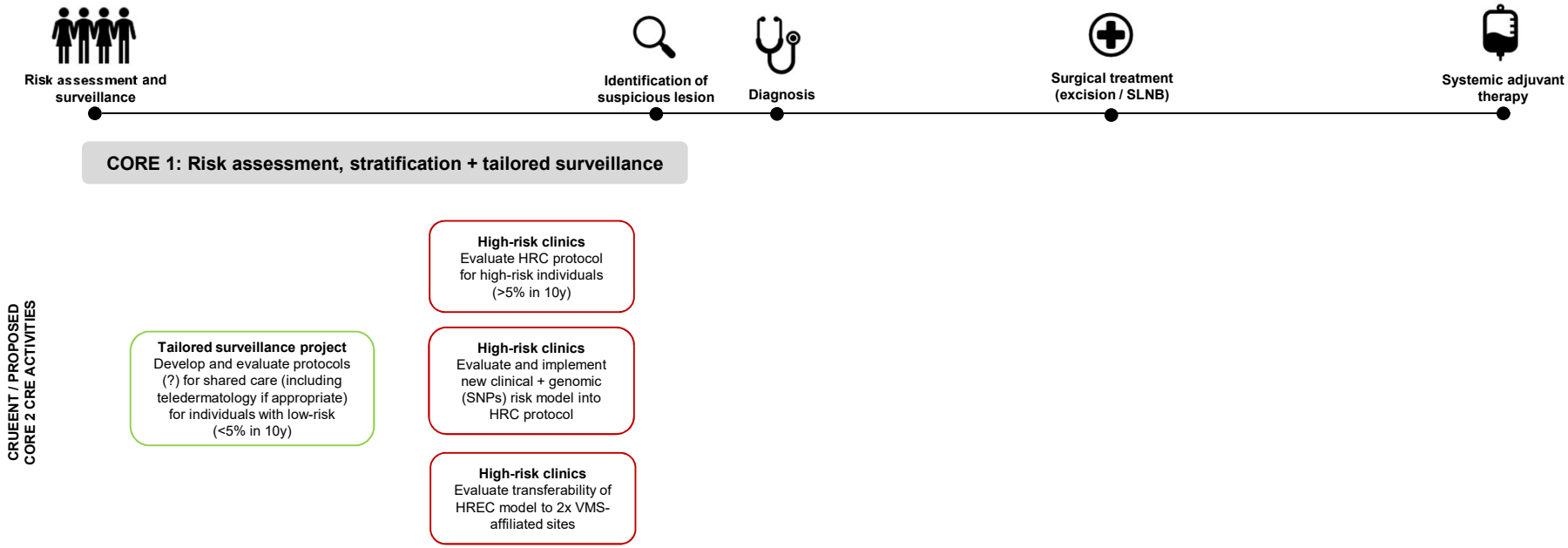
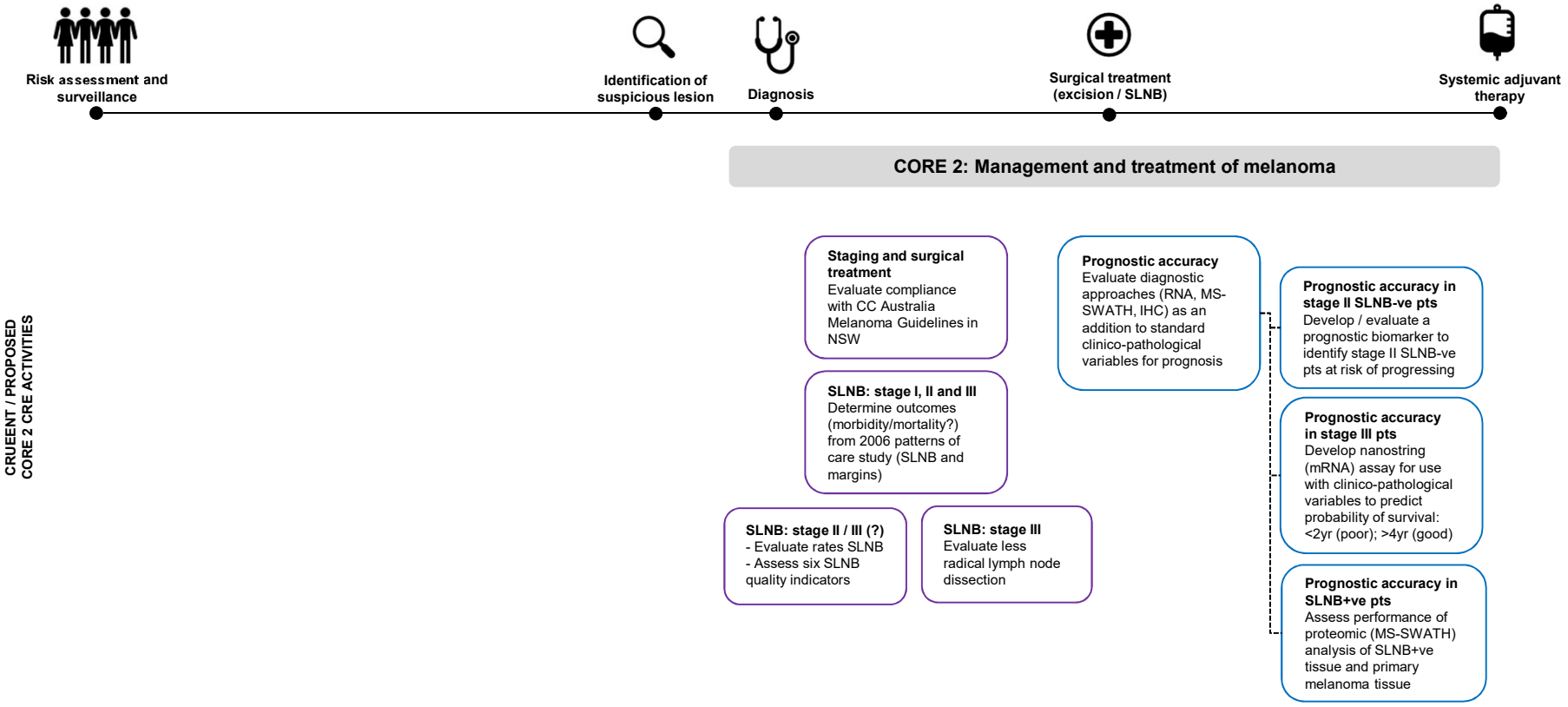
Preliminary mapping exercise: melanoma care continuum / CRE in Melanoma activities



Preliminary mapping exercise: melanoma care continuum / CRE in Melanoma activities



Preliminary mapping exercise: melanoma care continuum / CRE in Melanoma activities

CORE 3: Psychosocial care, survivorship and the patient experience

CRUEENT / PROPOSED CORE 3 CRE ACTIVITIES

TSP and HRC
Psychological distress associated with receiving personal risk assessment:
- Interventions to reduce fear of recurrence / new primary

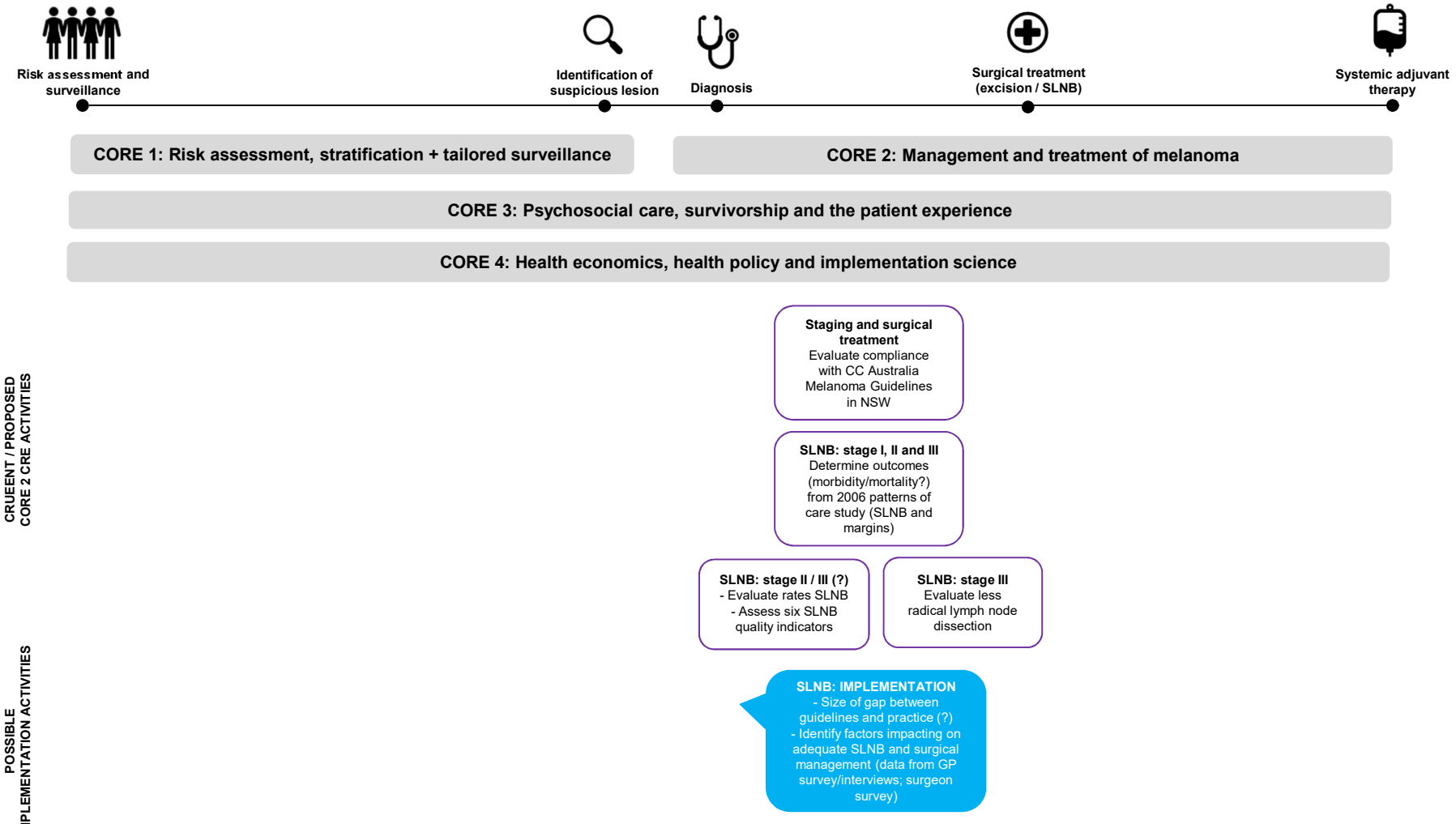
Health professional communication with pt
- Develop and evaluate online training module

Pts node +ve who are at risk of progression
- Identify baseline measures of distress
- Identify predictors of anxiety / depression
- Develop interventions to address anxiety / depression

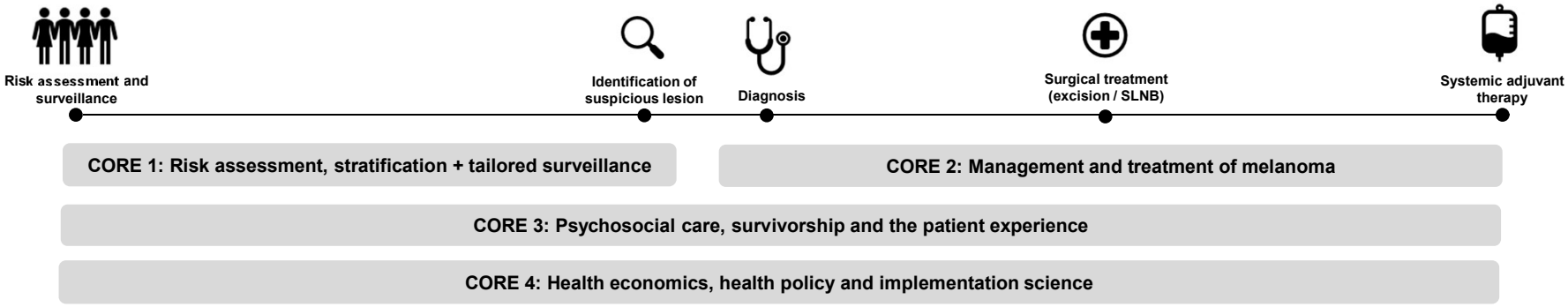
Early melanoma pts (stage II and II) on adjuvant therapy at high risk of progression
- Evaluate QoL
- Evaluate support needs
- PROMs and PREMs

Pt support groups for early melanoma pts
- Develop and evaluate training (of staff?) for pt support groups
- Develop and evaluate resources for pt support groups

Preliminary mapping exercise: melanoma care continuum / CRE in Melanoma activities



Preliminary mapping exercise: melanoma care continuum / CRE in Melanoma activities



CRUEENT / PROPOSED CORE 1 CRE ACTIVITIES

TSP
Develop and evaluate protocols (?) for shared care (including teledermatology if appropriate) for individuals with low-risk (<5% in 10y)

HRC
Evaluate HRC protocol for high-risk individuals (>5% in 10y)

HRC
Evaluate and implement new clinical + genomic (SNPs) risk model into HRC protocol

HRC
Evaluate transferability of HREC model to 2x VMS-affiliated sites

POSSIBLE IMPLEMENTATION ACTIVITIES

TSP IMPLEMENTATION OUTCOMES
- Acceptability (to patients)
- Feasibility (in clinic setting)
- Fidelity (to surveillance schedule)

TSP IMPLEMENTATION
- What's in place regarding shared-care / teledermatology protocols, feasibility, GP buy-in, resources?
- Once established, how will this be evaluated?

SCALING up HRCs beyond hospital setting
- Lack of consensus re which clinicians (dermatologists only or dermatologists + GPs) should implement the HRC protocol
- Uptake and sustainability reliant on successful MBS item listing and subsidisation
- Concerns over implementation fidelity in particular unwanted increase in excision rates

ID Number:_____

THE UNIVERSITY OF SYDNEY
Melanoma Centre of Research Excellence
Cancer Epidemiology and Prevention Research
School of The University of Sydney
Faculty of Medicine and Health

Melanoma management survey for GPs

1. What best describes the type of practice you work in?
   - ☐ Independent GP practice
   - ☐ Medical centre practice
   - ☐ Skin cancer clinic
   - ☐ Other (please specify):_____

2. What is the postcode or suburb/town of your practice? _____

3. What is your gender?
   - ☐ Female
   - ☐ Male

4. What is your age?
   - ☐ < 30 years
   - ☐ 30-39 years
   - ☐ 40-49 years
   - ☐ 50-59 years
   - ☐ 60-69 years
   - ☐ 70+ years

5. How many patients would you usually see with invasive melanoma in one year (i.e. not including melanoma in situ/lentigo maligna)?
   - ☐ None
   - ☐ 1 patient per year
   - ☐ 2-5 patients per year
   - ☐ 6-10 patients per year
   - ☐ 11-30 patients per year
   - ☐ >30 patients per year

6. How many years have you been practising as a GP?
   - ☐ <5 years
   - ☐ 6-10 years
   - ☐ 11-20 years
   - ☐ 21-30 years
   - ☐ 31-40 years
   - ☐ >40 years

7. On a scale of 1 to 5, how familiar are you with the national clinical practice guidelines for melanoma management? **(tick one only)**
   - ☐ 1 - Very unfamiliar
   - ☐ 2 - Somewhat unfamiliar
   - ☐ 3 - A little familiar
   - ☐ 4 - Quite familiar
   - ☐ 5 - Very familiar

8. Have you accessed the recent update of the national clinical practice guidelines for melanoma on the Cancer Council Australia website/Wiki?
   - ☐ No
   - ☐ Yes

9. Have you read any articles (e.g. in journals, magazines, newsletters) or listened to talks about sentinel lymph node biopsy (SLNB) for melanoma in the last 3 years?
   - ☐ No → go to question 11
   - ☐ Yes → **tick all that apply**
     - ○ Australian Family Physician
     - ○ Australian Journal of General Practice (AJGP)
     - ○ Medical Journal of Australia (MJA)
     - ○ Other peer-reviewed journal, please specify: _____
     - ○ Newspaper
     - ○ Conference lecture
     - ○ Workshop or seminar
     - ○ Other, please specify _____

10. Do you think these articles or presentations have influenced your attitude to sentinel lymph node biopsy for melanoma?
    - ☐ No
    - ☐ Yes → How have they influenced you? _____

11. Do you think that sentinel lymph node biopsy has an important role in the management of melanoma patients?
    - ☐ No → Why not? _____
    - ☐ Yes
    - ☐ Unsure

12. Would you usually discuss and recommend sentinel lymph node biopsy to a patient with a newly diagnosed melanoma, if eligible for sentinel lymph node biopsy?
    - ☐ No → go to question 21
    - ☐ Yes → go to question 13

13. Why do you believe that sentinel lymph node biopsy may be of value? **(tick all that apply)**
    - ☐ More accurate staging and prognostic information
    - ☐ Likely survival benefit
    - ☐ Influence of the results on patient management
    - ☐ To assess suitability for adjuvant systemic therapies for melanoma patients who are found to be sentinel lymph node positive
    - ☐ To select patients for completion lymphadenectomy
    - ☐ Other (please specify): _____

14. At what Breslow thickness or other criteria would you tell a patient that sentinel lymph node biopsy would be appropriate? **(tick all that apply)**
    - ☐ <0.80 mm
    - ☐ <0.80 mm and other high-risk pathological feature/s
    - ☐ 0.80 - 1.00 mm
    - ☐ 0.80 - 1.00 mm and other high-risk pathological feature/s
    - ☐ 1.01 - 2.00 mm
    - ☐ 2.01 - 4.00 mm
    - ☐ >4.00 mm
    - ☐ Other criteria, please specify_____

15. Would any of these factors influence your decision to discuss or recommend sentinel lymph node biopsy to patients? **(tick all that apply)**
    - ☐ Breslow thickness
    - ☐ Presence of ulceration
    - ☐ Mitotic rate of the melanoma
    - ☐ Lymphovascular invasion in the melanoma
    - ☐ Body site of the melanoma
    - ☐ Presence of palpable regional lymph nodes
    - ☐ Histological subtype, e.g. superficial spreading, nodular, lentigo maligna melanoma
    - ☐ Age of the patient
    - ☐ Comorbidities of the patient
    - ☐ The morbidity of the sentinel lymph node biopsy procedure
    - ☐ The morbidity of completion lymphadenectomy
    - ☐ The likelihood that the results will influence patient management
    - ☐ Access to services for sentinel lymph node mapping and biopsy
    - ☐ Distance to services for sentinel lymph node mapping and biopsy
    - ☐ Costs to the patient
    - ☐ Patient level of anxiety
    - ☐ Patient preference
    - ☐ Other, please specify_____

16. For patients for whom sentinel lymph node biopsy would be suitable, who would you <u>usually</u> refer the patient to for definitive management? **(tick one only)**
    - ☐ A local general surgeon
    - ☐ Any surgical oncologist
    - ☐ A melanoma-trained surgical oncologist
    - ☐ Any plastic surgeon
    - ☐ A melanoma trained plastic surgeon
    - ☐ A Skin Cancer Clinic colleague
    - ☐ Any Dermatologist
    - ☐ A melanoma specialist dermatologist
    - ☐ A specialist melanoma service where there is a multidisciplinary team
    - ☐ Other, please specify: _____

17. Would you expect the clinician to whom you refer the patient, to recommend a sentinel lymph node biopsy if they were eligible? **(tick one only)**
    - ☐ No, never
    - ☐ Occasionally
    - ☐ Most of the time
    - ☐ Yes, always

18. After a negative sentinel lymph node biopsy, are you wanting to be involved in ongoing patient follow-up? **(tick one only)**
    - ☐ No
    - ☐ Yes, with follow-up managed mainly by myself
    - ☐ Yes, with follow-up managed mainly by the specialist
    - ☐ Yes, with follow-up managed in a shared care arrangement between the specialist and myself

19. After a positive sentinel lymph node biopsy, are you wanting to be involved in ongoing patient follow-up? **(tick one only)**
    - ☐ No
    - ☐ Yes, with follow-up managed mainly by myself
    - ☐ Yes, with follow-up managed mainly by the specialist
    - ☐ Yes, with follow-up managed in a shared care arrangement between the specialist and myself

20. Are there any tests or scans that you would arrange for patients eligible for sentinel lymph node biopsy? **(tick all that apply)**
    - ☐ No other tests or scans
    - ☐ Ultrasound examination of regional nodes
    - ☐ Chest X ray
    - ☐ CT Chest/abdomen/pelvis
    - ☐ Whole body PET-CT
    - ☐ CT or MRI scan of brain
    - ☐ Other, please specify: _____

→ Please go to question 22

[Note Question 21 is only for those who selected 'No' at Question 12]

21. Why would you not usually recommend sentinel lymph node biopsy? **(tick all that apply)**
    - ☐ Don't know much about it
    - ☐ Difficulty in accessing facilities for sentinel lymph node biopsy
    - ☐ No confirmed survival benefit
    - ☐ Does not add sufficient additional prognostic information
    - ☐ Does not impact subsequent management
    - ☐ The morbidity of the procedure
    - ☐ The morbidity of completion lymphadenectomy if the sentinel node is positive
    - ☐ Costs to the patient
    - ☐ Other, please specify: _____

ID Number:_____

22. Would you be willing to be contacted by the research team for a 20 minute confidential interview to discuss risk factors, diagnosis and management of patients with melanoma by general practitioners? We would reimburse your time with a $100 Coles/Myer gift voucher.
    - ☐ Yes → Please enter your contact details below and ask the research team for a Participant Information Sheet and Consent form for the interview study. Your contact details will be stored separately to your survey and interview data.
    - ☐ No → continue to next page

Your Name: _____

Best contact phone number:_____

Email address:_____

Best time and/or day of the week:_____

Continue to next page

23. Would you like to receive a summary of the results of this study after it has been completed, in about 1 year's time?

☐ Yes → please enter your email address:_____.
Your email address will not be linked to your survey responses and will be stored separately.

☐ No

24. Please enter your email address if you would like to go into a lucky draw to win one of three iPads. The draw will take place when recruitment to the study is complete.

Email address:_____

Your email address will not be linked to your survey responses and will be stored separately.

You have completed the questionnaire! Thank you very much for your time.

ID number: _____

THE UNIVERSITY OF SYDNEY

Melanoma Centre of Research Excellence

Melanoma management survey for Dermatologists

1. What best describes the type of practice you work in?

- ☐ Independent specialist practice
- ☐ Dermatology group specialist practice
- ☐ Melanoma Unit
- ☐ Other (please specify):_____

2. What is the postcode or suburb/town of your practice? _____

3. What is your gender?

- ☐ Female
- ☐ Male

4. What is your age?

- ☐ < 30 years
- ☐ 30-39 years
- ☐ 40-49 years
- ☐ 50-59 years
- ☐ 60-69 years
- ☐ 70+ years

5. How many patients would you usually see with invasive melanoma in one year (i.e. not including melanoma in situ/lentigo maligna)?

- ☐ None
- ☐ 1 patient per year
- ☐ 2-4 patients per year
- ☐ 6-10 patients per year
- ☐ 11-30 patients per year
- ☐ >30 patients per year

ID number: _____

6. How many years have you been practising as a Dermatologist?

- ☐ <5 years
- ☐ 6-10 years
- ☐ 11-20 years
- ☐ 21-30 years
- ☐ 31-40 years
- ☐ >40 years

7. On a scale of 1 to 5, how familiar are you with the Australian "Clinical Practice Guidelines for the Diagnosis and Management of Melanoma"?

(tick ONE only)

- ☐ 1 - Very unfamiliar
- ☐ 2 - Somewhat unfamiliar
- ☐ 3 - A little familiar
- ☐ 4 - Quite familiar
- ☐ 5 - Very familiar

8. Have you accessed the recent update of the Australian "Clinical Practice Guidelines for the Diagnosis and Management of Melanoma" on the Cancer Council Australia website/Wiki?

- ☐ No
- ☐ Yes

9. Have you read any articles (e.g. in journals, magazines, newsletters) or listened to talks about sentinel lymph node biopsy (SLNB) for melanoma in the last 3 years?

- ☐ No → go to question 11
- ☐ Yes → **tick ALL that apply**
  - ☐ Australasian Journal of Dermatology
  - ☐ Medical Journal of Australia (MJA)
  - ☐ Journal of the American Academy of Dermatology (JAAD)
  - ☐ British Journal of Dermatology (BJD)
  - ☐ New England Journal of Medicine (NEJM)
  - ☐ Other peer-reviewed journal, please specify: _____
  - ☐ Australian Conference
  - ☐ International Conference
  - ☐ Other, please specify _____

10. Do you think these articles or presentations have influenced your attitude to sentinel lymph node biopsy for melanoma?

ID number: _____

☐ No

☐ Yes – more likely to recommend SLNB

☐ Yes – less likely to recommend SLNB

How have they influenced you? _____

11. Do you think that sentinel lymph node biopsy has an important role in the management of melanoma patients?

☐ No → Why not? _____

☐ Yes

☐ Unsure→ Why not? _____

12. Would you usually discuss and recommend sentinel lymph node biopsy to a patient with a newly diagnosed melanoma, if eligible for sentinel lymph node biopsy?

☐ No → *go to question 13*

☐ Yes → *go to question 14*

[Note Question 13 is only for those who selected 'NO' at Question 12]

13. Why would you not usually recommend sentinel lymph node biopsy?

(tick ALL that apply)

☐ Don't know much about it

☐ No added value of sentinel lymph node biopsy

☐ Difficulty in accessing facilities for sentinel lymph node biopsy

☐ No confirmed overall survival benefit

☐ Does not add additional prognostic information beyond what is provided by Breslow thickness

☐ Does not impact subsequent management

☐ The morbidity of the procedure

☐ The morbidity of completion lymphadenectomy if the sentinel node is positive

☐ Costs to the patient

☐ Other, please specify: _____

Continue to Question 23 [page 6]

ID number: _____

[Note Question 14 is only for those who selected 'YES' at Question 12]

14. Why do you believe that sentinel lymph node biopsy may be of value for eligible patients?

(tick ALL that apply)

- ☐ More accurate staging
- ☐ To provide prognostic information
- ☐ Likely survival benefit
- ☐ Results may influence follow-up plan
- ☐ To assess suitability for adjuvant systemic therapies if found to be sentinel lymph node positive
- ☐ To select patients for completion lymphadenectomy
- ☐ Improved regional control
- ☐ Other (please specify): _____

15. At what Breslow thickness would you advise a patient that sentinel lymph node biopsy would be appropriate and refer them to a surgeon for management?

(tick ALL that apply)

- ☐ <0.80 mm
- ☐ <0.80 mm with high-risk pathological feature/s
- ☐ 0.80 - 1.00 mm
- ☐ 0.80 - 1.00 mm with high-risk pathological feature/s
- ☐ 1.01 - 2.00 mm
- ☐ 2.01 - 4.00 mm
- ☐ >4.00 mm
- ☐ None of the above (I would not refer for SLNB)

ID number: _____

16. Would any of these factors influence your decision to discuss or recommend sentinel lymph node biopsy to patients?

(tick ALL that apply)

- ☐ Breslow thickness
- ☐ Presence of ulceration
- ☐ Mitotic rate of the melanoma
- ☐ Lymphovascular invasion in the melanoma
- ☐ Body site of the melanoma
- ☐ Wide excision already performed
- ☐ Type of wound closure following diagnostic biopsy
- ☐ Presence of palpable regional lymph nodes
- ☐ Histological subtype, e.g. desmoplastic, nodular, lentigo maligna melanoma
- ☐ Age of the patient
- ☐ Comorbidities of the patient
- ☐ Possible morbidity of the sentinel lymph node biopsy procedure
- ☐ Possible morbidity of completion lymphadenectomy
- ☐ The likelihood that the results will influence patient management
- ☐ Access to services for sentinel lymph node mapping and biopsy
- ☐ Distance to services for sentinel lymph node mapping and biopsy
- ☐ Costs to the patient
- ☐ Patient level of anxiety
- ☐ Patient preference
- ☐ Other, please specify_____

17. For patients for whom sentinel lymph node biopsy would be suitable, who would you <u>usually</u> refer the patient to for definitive management?

(tick ONE only)

- ☐ A local general surgeon
- ☐ Any surgical oncologist
- ☐ A melanoma-trained surgical oncologist
- ☐ Any plastic surgeon
- ☐ A melanoma-trained plastic surgeon
- ☐ A melanoma specialist dermatologist
- ☐ A specialist melanoma service where there is a multidisciplinary team
- ☐ None of the above (I would not refer for SLNB)

☐ Other, please specify: _____

18. Would you expect the clinician to whom you refer the patient to recommend a sentinel lymph node biopsy if they were eligible?

(tick ONE only)

☐ No, never

☐ Occasionally

☐ Most of the time if appropriate for the patient's situation

☐ Yes, always

☐ I would not refer to a surgeon who routinely recommends SLNB

19. After a negative sentinel lymph node biopsy for melanoma, do you wish to be involved in ongoing patient follow-up for recurrence?

(tick ONE only)

☐ No

☐ Yes, with follow-up managed mainly by myself

☐ Yes, with follow-up managed mainly by the surgeon

☐ Yes, with follow-up managed in a shared care arrangement between the surgeon and myself

20. After a positive sentinel lymph node biopsy for melanoma, do you wish to be involved in ongoing patient follow-up for recurrence?

(tick ONE only)

☐ No

☐ Yes, with follow-up managed mainly by myself

☐ Yes, with follow-up managed mainly by the surgeon or medical oncologist

☐ Yes, with follow-up managed in a shared care arrangement between the surgeon or medical oncologist and myself

21. Are there any tests or scans that you would arrange for patients eligible for sentinel lymph node biopsy at the time of diagnosis?

(tick ALL that apply)

☐ No other tests or scans

☐ Ultrasound examination of regional nodes

☐ Chest X ray

☐ CT chest/abdomen/pelvis

☐ Whole body PET-CT

☐ CT or MRI scan of brain

☐ Other, please specify: _____

ID number: _____

22. Are there any tests or scans that you would arrange for follow-up of patients diagnosed with melanoma >1 mm?

(tick ALL that apply)

- ☐ No other tests or scans
- ☐ Ultrasound examination of regional nodes
- ☐ Chest X ray
- ☐ CT chest/abdomen/pelvis
- ☐ Whole body PET-CT
- ☐ CT or MRI scan of brain
- ☐ Other, please specify: _____

Continue to next page

ID number: _____

23. Would you like to receive a summary of the results of this study after it has been completed, in about 1 years' time?

☐ Yes → please enter your email address:_____

Your email address will not be linked to your survey responses and will be stored separately.

☐ No

24. Would like to go into a lucky draw to win one of three iPads? The draw will take place when recruitment to the study is complete.

☐ Yes → please enter your email address:_____

Your email address will not be linked to your survey responses and will be stored separately.

☐ No

25. Would you be willing to be contacted by the research team for a 20-minute confidential interview to discuss risk factors, diagnosis and management of patients with melanoma by dermatologists? We would reimburse your time with a $100 Coles/Myer gift voucher.

☐ Yes → Please enter your contact details below and ask the research team for a Participant Information Sheet and Consent form for the interview study. Your contact details will be stored separately to your survey and interview data.

☐ No

Your Name: _____

Best contact phone number:_____

Email address:_____

Best time and/or day of the week:_____

You have completed the questionnaire! Thank you very much for your time.

BMJ Open

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

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TITLE

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

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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 >1mm in thickness (or >0.8mm with high-risk pathology features). Until recently, 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-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 a 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 semi-structured interviews with general practitioners and dermatologists; (2) semi-structured 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.

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.

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 SLNB guideline implementation.
- The TICD Checklist will be used to identify the determinants of implementation (that is, 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.

INTRODUCTION

Centre of Research Excellence in Melanoma

The Centre of Research Excellence (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 (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.[1] In 2019, it is estimated that 15,229 people will be diagnosed with invasive melanoma and that 1,725 people will die from it.[1] Between 2011 and 2015, an individual diagnosed with melanoma had a 91% chance of surviving for 5 years.[1] 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).[2,3] 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.[4] 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.[2]

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 to IV, which are referred to as invasive melanoma)
Stage I	The melanoma has not spread beyond the primary site (i.e. no metastases or lymph node involvement); the melanoma is: • ≤ 2mm in thickness without ulceration • ≤ 1mm in thickness with ulceration
Stage II	The melanoma has not spread beyond the primary site (i.e. no metastases or lymph node involvement); the melanoma is: • > 2mm in thickness without ulceration • > 1mm in thickness with ulceration
Stage III	The melanoma can be any thickness and locoregional metastasis is present (i.e. satellite, in-transit or microsatellite metastases or nodal metastases)

Stage	Definition
Stage IV	The melanoma can be any thickness and has spread to distant lymph nodes and organs e.g. lungs, liver, brain or bone

Adapted from AJCC 8th edition staging guidelines[2,3]

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.[5,6]

Prior to the introduction of SLNB by Morton *et al*. in 1992,[5] 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.[5] The rationale (which Morton referred to as the incubator hypothesis or step-wise 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 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. [7]

Contemporary melanoma management

Based on the results of two recent randomised controlled trials,[8,9] 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[10] and have also been shown to improve recurrence-free survival when administered as adjuvant therapy in patients with resected stage III melanoma.[11–13] 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 (AJCC staging system) and national (Australian) guidelines for SLNB

The American Joint Committee on Cancer (AJCC) Staging Manual has become the benchmark for classifying patients' disease stage, outlining prognosis, and establishing the best treatment approaches.[14] 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 (i.e. melanomas ≥0.8mm with or without ulceration, or <0.8mm with ulceration) and who have clinically negative regional lymph nodes.[3] 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 >1mm in thickness and for patients with melanoma >0.8mm with other high risk pathological features to provide optimal staging and prognostic information and to maximise management options for patients who are node positive.'[15]

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.[a] 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.[16] The 2006 New South Wales Melanoma Patterns of Care Study reported that SLNB was performed in 45%

[a] 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 >1mm 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 >1.0mm in thickness should be given the opportunity to discuss sentinel lymph node biopsy to provide staging and prognostic information'.

of patients diagnosed with a melanoma >0.75mm thick.[17] SLNB rates in Australia are roughly comparable to rates reported internationally. Data from the US Surveillance Epidemiology and End Results (SEER) database for 2004-2006 indicate that 53% of eligible patients received a SLNB,[18] while data from a population-based study in the northeast of France indicated that 34% of patients with a melanoma >1mm in thickness received a SLNB.[19] Factors associated with having a SLNB included patient age <50 years,[17] primary tumour on upper limb,[17] treatment in an urban setting,[17,19–23] and hospital size (>50 beds)[24] 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.[25] 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 step-wise 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.[26] However, even guidelines that are based on rigorous evidence rarely penetrate medical practice as intended.[26] 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.[26]

Successful adoption and implementation of guidelines requires an understanding of the technical, social, political, economic, cultural, structural and psychological barriers to the use of research evidence.[27] As Greenhalgh and colleagues noted in 2004, clinicians are not passive recipients of innovations (such as guidelines).[28] 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 noted in 2001, the research evidence for a particular practice is often ambiguous and contested.[29] 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'.[29] 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.[26]

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.[30] Although originally designed to be used in the chronic disease setting, the authors advise that it can be used more broadly.[31] 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.[30] Cross-sectional questionnaires and in-depth semi-structured interviews with GPs and dermatologists, and in-depth semi-structured 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 (e.g. 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.[32] The reporting of the study design as outlined in this protocol is informed by the consolidated Criteria for Reporting Qualitative Research (COREQ) checklist and the Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines.[33,34]

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.

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	Understand GPs' and dermatologists' knowledge and attitudes towards SLNB in Australia Examine, document and analyse the discourse surrounding SLNB in Australia Provide an account of factors that have contributed to this discourse Assess the range of perspectives and opinions on SLNB among healthcare professionals and other stakeholders in Australia Contextualise data collected in the interviews with other documentation	Questionnaires and follow-up semi-structured interviews with GPs (i.e. generalist GPs and GPs working in skin cancer clinics) and dermatologists in relation to management of melanoma and role of SLNB Semi-structured interviews with other healthcare professionals and key stakeholders in melanoma management (e.g. academics and researchers, representatives of professional colleges, healthcare training and education organisations, and consumer advocacy organisations) Documentary analysis of printed and electronic material

	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 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	relating to implementation of SLNB guidelines in Australia (e.g. commentaries and editorials, books and brochures, event programs, newspapers, press releases, program proposals, summaries, organisational and institutional reports, questionnaire data, and public records)

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 (e.g. Royal Australian College of General Practitioners, Royal Australasian College of Surgeons, Australian College of Dermatologists, Skin Cancer College Australasia), healthcare training and education organisations (e.g. HealthCert, Australasian College of Cutaneous Oncology), and consumer advocacy organisations (e.g. Melanoma Patients Australia).

Box 1 Inclusion and exclusion criteria

Questionnaires and interviews (GPs and dermatologists)

- Must have worked as a general practitioner 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 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.

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).[35] Sampling will be iterative, with decisions informed by the ongoing data analysis.[36] 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 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 programs, newspapers, press releases, program 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 (Supplementary file 2). The questionnaires can be completed on paper or electronically. The questionnaire data will be managed using REDCap.[37]

Interviews

Semi-structured 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.

Table 3 Topics and example questions from semi-structured interview guides for melanoma healthcare professionals (GPs and dermatologists) and stakeholders

Topics	Example questions
Melanoma healthcare professionals	
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?
Stakeholders in melanoma care	
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 about SLNB, can you expand on that? There are some who hold quite extreme 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.

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 (ARIA), and Socio-Economic Indexes for Areas (SEIFA) classifications.[38,39] Descriptive analyses and multivariable 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% confidence intervals (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 version 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.[40,41] 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.[30] The de-identified 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.[42] As with the interview data, the documentary data will be analysed using thematic analysis.[41]

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

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. Data collection and analysis will be conducted in accordance with the Australian National Health and Medical Research Council National Statement.[43] 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 multi-methods 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 statement

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of the work; ALS drafted the manuscript; FR, ALS, AEC, GJM, CGW, DEG, MH, AMH, JWK, GVL, VJM, RLM, RPMS, RAS, AJS, JFT and JB were involved in critically revising the manuscript.

Ethics approval University of Sydney Human Research Ethics Committee, project numbers 2018/713 and 2019/308.

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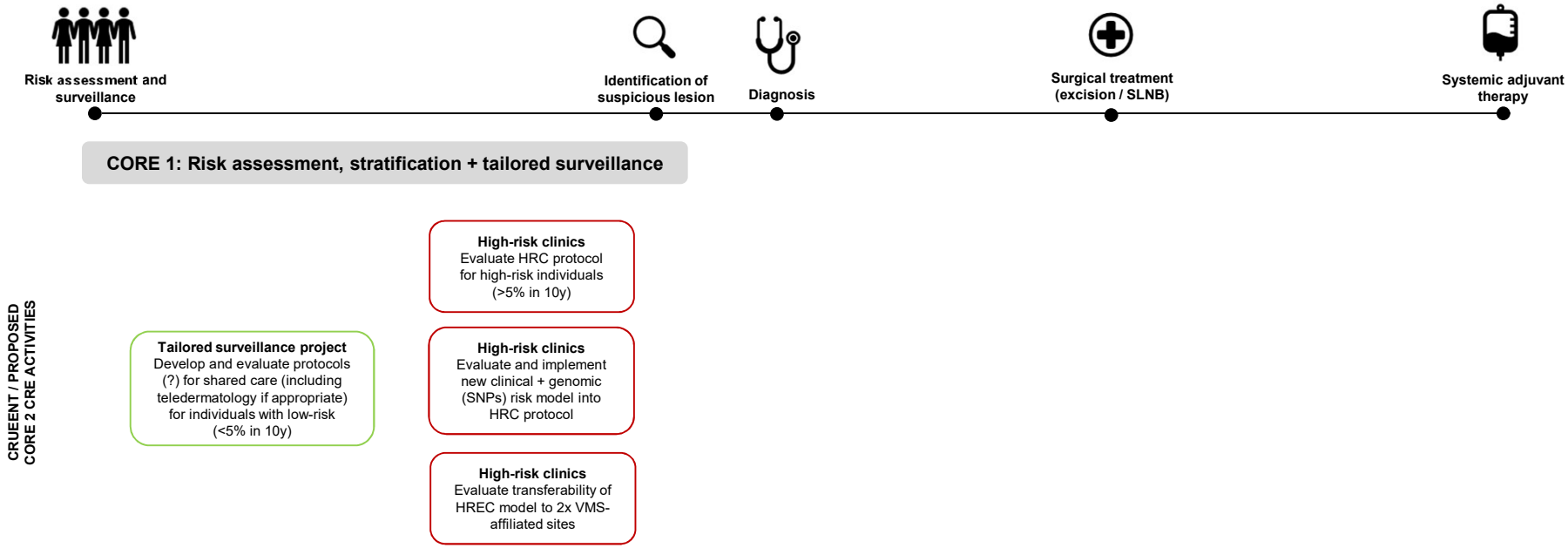
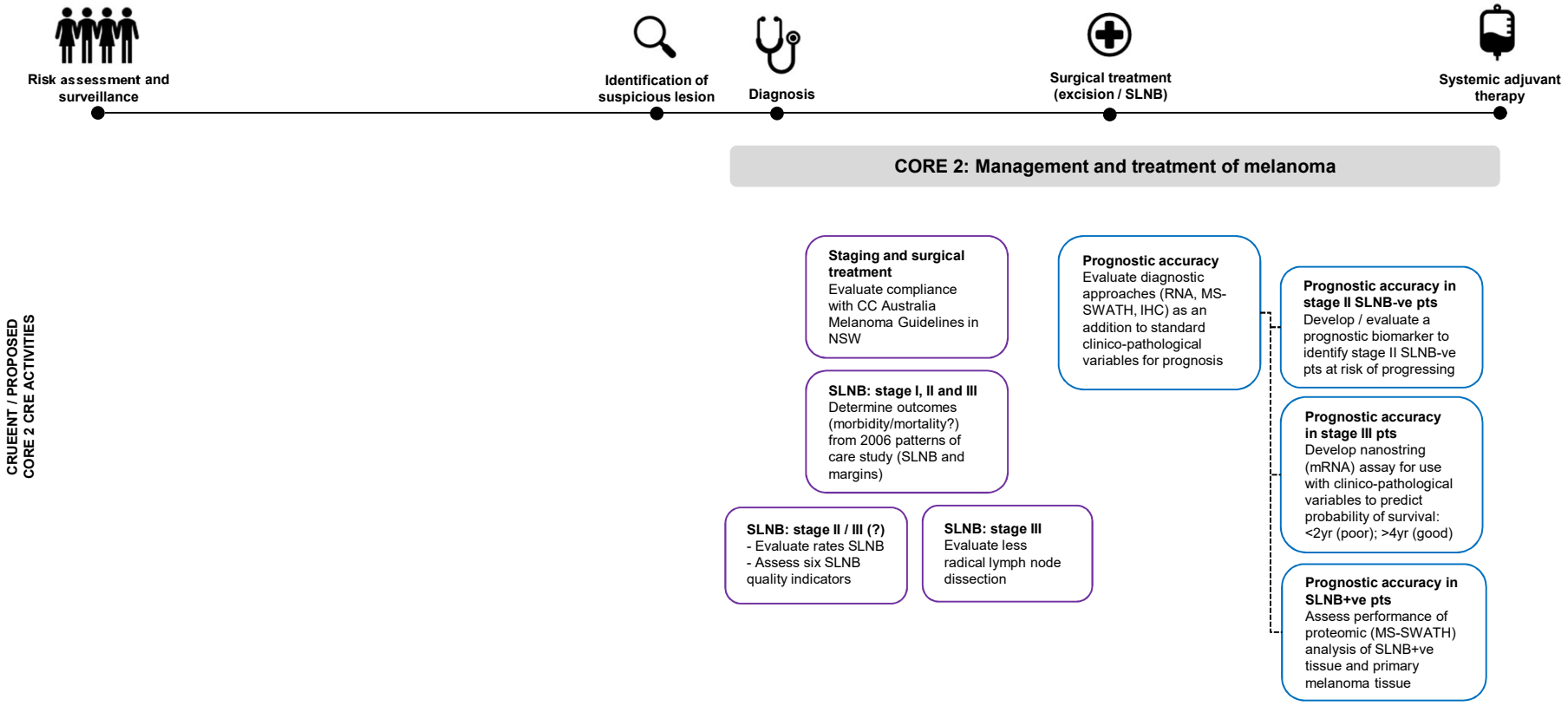
Preliminary mapping exercise: melanoma care continuum / CRE in Melanoma activities



Preliminary mapping exercise: melanoma care continuum / CRE in Melanoma activities



Preliminary mapping exercise: melanoma care continuum / CRE in Melanoma activities

CORE 3: Psychosocial care, survivorship and the patient experience

CRUEENT / PROPOSED CORE 3 CRE ACTIVITIES

TSP and HRC
Psychological distress associated with receiving personal risk assessment:
- Interventions to reduce fear of recurrence / new primary

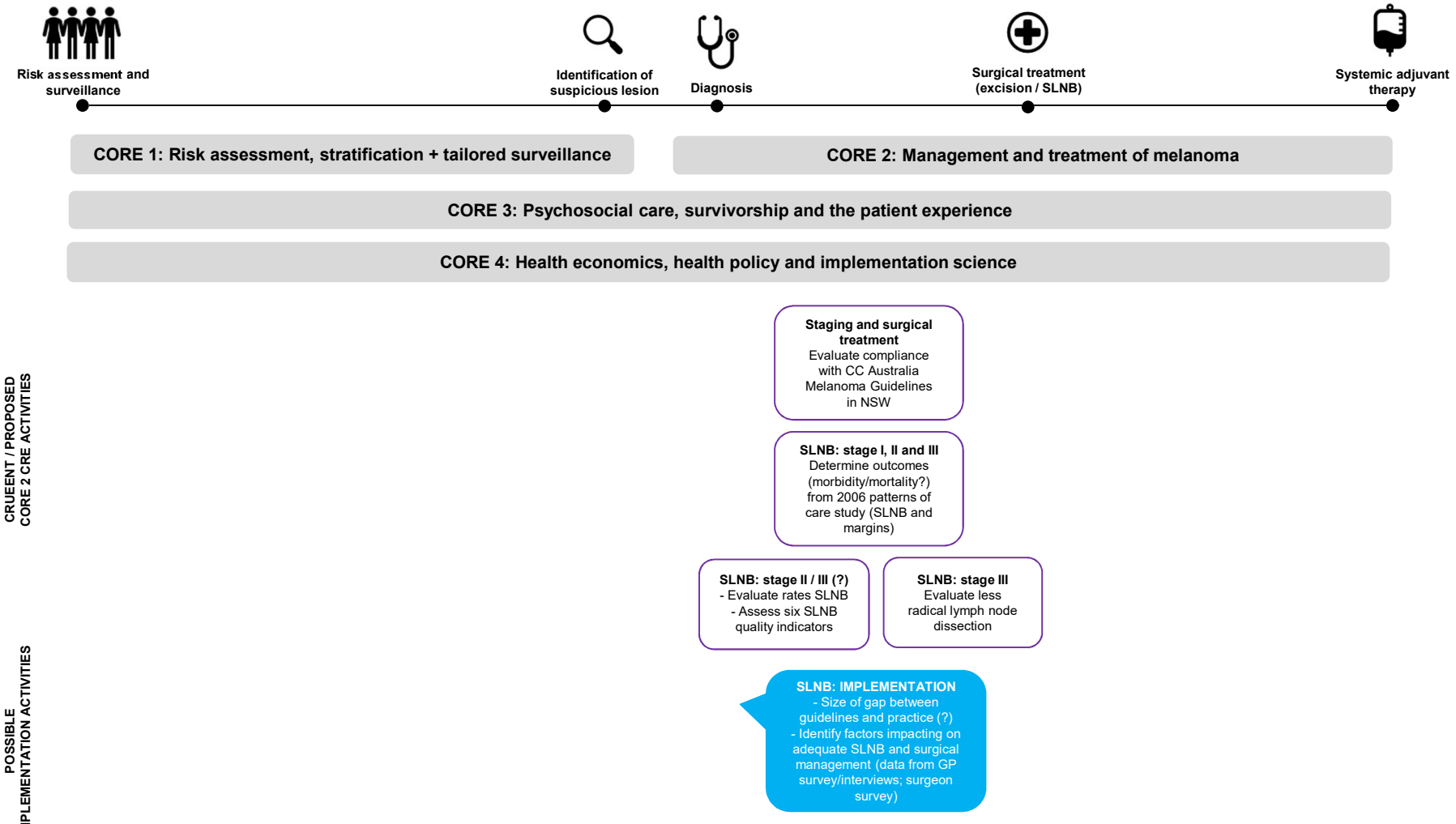
Health professional communication with pt
- Develop and evaluate online training module

Pts node +ve who are at risk of progression
- Identify baseline measures of distress
- Identify predictors of anxiety / depression
- Develop interventions to address anxiety / depression

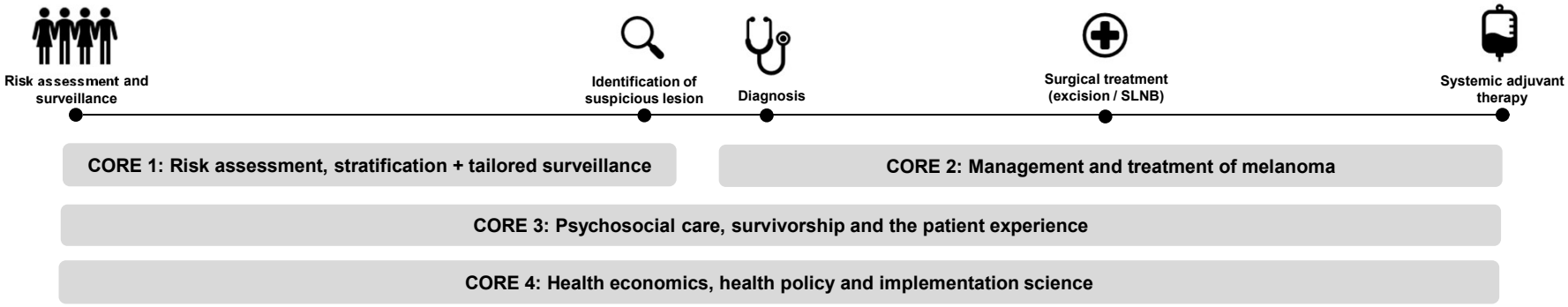
Early melanoma pts (stage II and II) on adjuvant therapy at high risk of progression
- Evaluate QoL
- Evaluate support needs
- PROMs and PREMs

Pt support groups for early melanoma pts
- Develop and evaluate training (of staff?) for pt support groups
- Develop and evaluate resources for pt support groups

Preliminary mapping exercise: melanoma care continuum / CRE in Melanoma activities



Preliminary mapping exercise: melanoma care continuum / CRE in Melanoma activities



CRUEENT / PROPOSED CORE 1 CRE ACTIVITIES

TSP
Develop and evaluate protocols (?) for shared care (including teledermatology if appropriate) for individuals with low-risk (<5% in 10y)

HRC
Evaluate HRC protocol for high-risk individuals (>5% in 10y)

HRC
Evaluate and implement new clinical + genomic (SNPs) risk model into HRC protocol

HRC
Evaluate transferability of HREC model to 2x VMS-affiliated sites

POSSIBLE IMPLEMENTATION ACTIVITIES

TSP IMPLEMENTATION OUTCOMES
- Acceptability (to patients)
- Feasibility (in clinic setting)
- Fidelity (to surveillance schedule)

TSP IMPLEMENTATION
- What's in place regarding shared-care / teledermatology protocols, feasibility, GP buy-in, resources?
- Once established, how will this be evaluated?

SCALING up HRCs beyond hospital setting
- Lack of consensus re which clinicians (dermatologists only or dermatologists + GPs) should implement the HRC protocol
- Uptake and sustainability reliant on successful MBS item listing and subsidisation
- Concerns over implementation fidelity in particular unwanted increase in excision rates

ID Number:_____

THE UNIVERSITY OF SYDNEY

Melanoma Centre of Research Excellence

Cancer Epidemiology and Prevention Research
School of The University of Sydney
Faculty of Medicine and Health

Melanoma management survey for GPs

1. What best describes the type of practice you work in?
   - ☐ Independent GP practice
   - ☐ Medical centre practice
   - ☐ Skin cancer clinic
   - ☐ Other (please specify):_____

2. What is the postcode or suburb/town of your practice? _____

3. What is your gender?
   - ☐ Female
   - ☐ Male

4. What is your age?
   - ☐ < 30 years
   - ☐ 30-39 years
   - ☐ 40-49 years
   - ☐ 50-59 years
   - ☐ 60-69 years
   - ☐ 70+ years

5. How many patients would you usually see with invasive melanoma in one year (i.e. not including melanoma in situ/lentigo maligna)?
   - ☐ None
   - ☐ 1 patient per year
   - ☐ 2-5 patients per year
   - ☐ 6-10 patients per year
   - ☐ 11-30 patients per year
   - ☐ >30 patients per year

6. How many years have you been practising as a GP?
   - ☐ <5 years
   - ☐ 6-10 years
   - ☐ 11-20 years
   - ☐ 21-30 years
   - ☐ 31-40 years
   - ☐ >40 years

7. On a scale of 1 to 5, how familiar are you with the national clinical practice guidelines for melanoma management? **(tick one only)**
   - ☐ 1 - Very unfamiliar
   - ☐ 2 - Somewhat unfamiliar
   - ☐ 3 - A little familiar
   - ☐ 4 - Quite familiar
   - ☐ 5 - Very familiar

8. Have you accessed the recent update of the national clinical practice guidelines for melanoma on the Cancer Council Australia website/Wiki?
   - ☐ No
   - ☐ Yes

9. Have you read any articles (e.g. in journals, magazines, newsletters) or listened to talks about sentinel lymph node biopsy (SLNB) for melanoma in the last 3 years?
   - ☐ No → go to question 11
   - ☐ Yes → **tick all that apply**
     - ○ Australian Family Physician
     - ○ Australian Journal of General Practice (AJGP)
     - ○ Medical Journal of Australia (MJA)
     - ○ Other peer-reviewed journal, please specify: _____
     - ○ Newspaper
     - ○ Conference lecture
     - ○ Workshop or seminar
     - ○ Other, please specify _____

10. Do you think these articles or presentations have influenced your attitude to sentinel lymph node biopsy for melanoma?
    - ☐ No
    - ☐ Yes → How have they influenced you? _____

11. Do you think that sentinel lymph node biopsy has an important role in the management of melanoma patients?
    - ☐ No → Why not? _____
    - ☐ Yes
    - ☐ Unsure

12. Would you usually discuss and recommend sentinel lymph node biopsy to a patient with a newly diagnosed melanoma, if eligible for sentinel lymph node biopsy?
    - ☐ No → go to question 21
    - ☐ Yes → go to question 13

13. Why do you believe that sentinel lymph node biopsy may be of value? **(tick all that apply)**
    - ☐ More accurate staging and prognostic information
    - ☐ Likely survival benefit
    - ☐ Influence of the results on patient management
    - ☐ To assess suitability for adjuvant systemic therapies for melanoma patients who are found to be sentinel lymph node positive
    - ☐ To select patients for completion lymphadenectomy
    - ☐ Other (please specify): _____

14. At what Breslow thickness or other criteria would you tell a patient that sentinel lymph node biopsy would be appropriate? **(tick all that apply)**
    - ☐ <0.80 mm
    - ☐ <0.80 mm and other high-risk pathological feature/s
    - ☐ 0.80 - 1.00 mm
    - ☐ 0.80 - 1.00 mm and other high-risk pathological feature/s
    - ☐ 1.01 - 2.00 mm
    - ☐ 2.01 - 4.00 mm
    - ☐ >4.00 mm
    - ☐ Other criteria, please specify_____

15. Would any of these factors influence your decision to discuss or recommend sentinel lymph node biopsy to patients? **(tick all that apply)**
    - ☐ Breslow thickness
    - ☐ Presence of ulceration
    - ☐ Mitotic rate of the melanoma
    - ☐ Lymphovascular invasion in the melanoma
    - ☐ Body site of the melanoma
    - ☐ Presence of palpable regional lymph nodes
    - ☐ Histological subtype, e.g. superficial spreading, nodular, lentigo maligna melanoma
    - ☐ Age of the patient
    - ☐ Comorbidities of the patient
    - ☐ The morbidity of the sentinel lymph node biopsy procedure
    - ☐ The morbidity of completion lymphadenectomy
    - ☐ The likelihood that the results will influence patient management
    - ☐ Access to services for sentinel lymph node mapping and biopsy
    - ☐ Distance to services for sentinel lymph node mapping and biopsy
    - ☐ Costs to the patient
    - ☐ Patient level of anxiety
    - ☐ Patient preference
    - ☐ Other, please specify_____

16. For patients for whom sentinel lymph node biopsy would be suitable, who would you <u>usually</u> refer the patient to for definitive management? **(tick one only)**
    - ☐ A local general surgeon
    - ☐ Any surgical oncologist
    - ☐ A melanoma-trained surgical oncologist
    - ☐ Any plastic surgeon
    - ☐ A melanoma trained plastic surgeon
    - ☐ A Skin Cancer Clinic colleague
    - ☐ Any Dermatologist
    - ☐ A melanoma specialist dermatologist
    - ☐ A specialist melanoma service where there is a multidisciplinary team
    - ☐ Other, please specify: _____

17. Would you expect the clinician to whom you refer the patient, to recommend a sentinel lymph node biopsy if they were eligible? **(tick one only)**
    - ☐ No, never
    - ☐ Occasionally
    - ☐ Most of the time
    - ☐ Yes, always

18. After a negative sentinel lymph node biopsy, are you wanting to be involved in ongoing patient follow-up? **(tick one only)**
    - ☐ No
    - ☐ Yes, with follow-up managed mainly by myself
    - ☐ Yes, with follow-up managed mainly by the specialist
    - ☐ Yes, with follow-up managed in a shared care arrangement between the specialist and myself

19. After a positive sentinel lymph node biopsy, are you wanting to be involved in ongoing patient follow-up? **(tick one only)**
    - ☐ No
    - ☐ Yes, with follow-up managed mainly by myself
    - ☐ Yes, with follow-up managed mainly by the specialist
    - ☐ Yes, with follow-up managed in a shared care arrangement between the specialist and myself

20. Are there any tests or scans that you would arrange for patients eligible for sentinel lymph node biopsy? **(tick all that apply)**
    - ☐ No other tests or scans
    - ☐ Ultrasound examination of regional nodes
    - ☐ Chest X ray
    - ☐ CT Chest/abdomen/pelvis
    - ☐ Whole body PET-CT
    - ☐ CT or MRI scan of brain
    - ☐ Other, please specify: _____

→ Please go to question 22

[Note Question 21 is only for those who selected 'No' at Question 12]

21. Why would you not usually recommend sentinel lymph node biopsy? **(tick all that apply)**
    - ☐ Don't know much about it
    - ☐ Difficulty in accessing facilities for sentinel lymph node biopsy
    - ☐ No confirmed survival benefit
    - ☐ Does not add sufficient additional prognostic information
    - ☐ Does not impact subsequent management
    - ☐ The morbidity of the procedure
    - ☐ The morbidity of completion lymphadenectomy if the sentinel node is positive
    - ☐ Costs to the patient
    - ☐ Other, please specify: _____

ID Number:_____

22. Would you be willing to be contacted by the research team for a 20 minute confidential interview to discuss risk factors, diagnosis and management of patients with melanoma by general practitioners? We would reimburse your time with a $100 Coles/Myer gift voucher.
    - ☐ Yes → Please enter your contact details below and ask the research team for a Participant Information Sheet and Consent form for the interview study. Your contact details will be stored separately to your survey and interview data.
    - ☐ No → continue to next page

Your Name: _____

Best contact phone number:_____

Email address:_____

Best time and/or day of the week:_____

Continue to next page

23. Would you like to receive a summary of the results of this study after it has been completed, in about 1 year's time?

☐ Yes → please enter your email address:_____.
Your email address will not be linked to your survey responses and will be stored separately.

☐ No

24. Please enter your email address if you would like to go into a lucky draw to win one of three iPads. The draw will take place when recruitment to the study is complete.

Email address:_____

Your email address will not be linked to your survey responses and will be stored separately.

You have completed the questionnaire! Thank you very much for your time.

ID number: _____

THE UNIVERSITY OF SYDNEY

Melanoma Centre of Research Excellence

Melanoma management survey for Dermatologists

1. What best describes the type of practice you work in?

- ☐ Independent specialist practice
- ☐ Dermatology group specialist practice
- ☐ Melanoma Unit
- ☐ Other (please specify):_____

2. What is the postcode or suburb/town of your practice? _____

3. What is your gender?

- ☐ Female
- ☐ Male

4. What is your age?

- ☐ < 30 years
- ☐ 30-39 years
- ☐ 40-49 years
- ☐ 50-59 years
- ☐ 60-69 years
- ☐ 70+ years

5. How many patients would you usually see with invasive melanoma in one year (i.e. not including melanoma in situ/lentigo maligna)?

- ☐ None
- ☐ 1 patient per year
- ☐ 2-4 patients per year
- ☐ 6-10 patients per year
- ☐ 11-30 patients per year
- ☐ >30 patients per year

ID number: _____

6. How many years have you been practising as a Dermatologist?

- ☐ <5 years
- ☐ 6-10 years
- ☐ 11-20 years
- ☐ 21-30 years
- ☐ 31-40 years
- ☐ >40 years

7. On a scale of 1 to 5, how familiar are you with the Australian "Clinical Practice Guidelines for the Diagnosis and Management of Melanoma"?

(tick ONE only)

- ☐ 1 - Very unfamiliar
- ☐ 2 - Somewhat unfamiliar
- ☐ 3 - A little familiar
- ☐ 4 - Quite familiar
- ☐ 5 - Very familiar

8. Have you accessed the recent update of the Australian "Clinical Practice Guidelines for the Diagnosis and Management of Melanoma" on the Cancer Council Australia website/Wiki?

- ☐ No
- ☐ Yes

9. Have you read any articles (e.g. in journals, magazines, newsletters) or listened to talks about sentinel lymph node biopsy (SLNB) for melanoma in the last 3 years?

- ☐ No → go to question 11
- ☐ Yes → **tick ALL that apply**
  - ☐ Australasian Journal of Dermatology
  - ☐ Medical Journal of Australia (MJA)
  - ☐ Journal of the American Academy of Dermatology (JAAD)
  - ☐ British Journal of Dermatology (BJD)
  - ☐ New England Journal of Medicine (NEJM)
  - ☐ Other peer-reviewed journal, please specify: _____
  - ☐ Australian Conference
  - ☐ International Conference
  - ☐ Other, please specify _____

10. Do you think these articles or presentations have influenced your attitude to sentinel lymph node biopsy for melanoma?

ID number: _____

☐ No

☐ Yes – more likely to recommend SLNB

☐ Yes – less likely to recommend SLNB

How have they influenced you? _____

11. Do you think that sentinel lymph node biopsy has an important role in the management of melanoma patients?

☐ No → Why not? _____

☐ Yes

☐ Unsure→ Why not? _____

12. Would you usually discuss and recommend sentinel lymph node biopsy to a patient with a newly diagnosed melanoma, if eligible for sentinel lymph node biopsy?

☐ No → *go to question 13*

☐ Yes → *go to question 14*

[Note Question 13 is only for those who selected 'NO' at Question 12]

13. Why would you not usually recommend sentinel lymph node biopsy?

(tick ALL that apply)

☐ Don't know much about it

☐ No added value of sentinel lymph node biopsy

☐ Difficulty in accessing facilities for sentinel lymph node biopsy

☐ No confirmed overall survival benefit

☐ Does not add additional prognostic information beyond what is provided by Breslow thickness

☐ Does not impact subsequent management

☐ The morbidity of the procedure

☐ The morbidity of completion lymphadenectomy if the sentinel node is positive

☐ Costs to the patient

☐ Other, please specify: _____

Continue to Question 23 [page 6]

ID number: _____

[Note Question 14 is only for those who selected 'YES' at Question 12]

14. Why do you believe that sentinel lymph node biopsy may be of value for eligible patients?

(tick ALL that apply)

- ☐ More accurate staging
- ☐ To provide prognostic information
- ☐ Likely survival benefit
- ☐ Results may influence follow-up plan
- ☐ To assess suitability for adjuvant systemic therapies if found to be sentinel lymph node positive
- ☐ To select patients for completion lymphadenectomy
- ☐ Improved regional control
- ☐ Other (please specify): _____

15. At what Breslow thickness would you advise a patient that sentinel lymph node biopsy would be appropriate and refer them to a surgeon for management?

(tick ALL that apply)

- ☐ <0.80 mm
- ☐ <0.80 mm with high-risk pathological feature/s
- ☐ 0.80 - 1.00 mm
- ☐ 0.80 - 1.00 mm with high-risk pathological feature/s
- ☐ 1.01 - 2.00 mm
- ☐ 2.01 - 4.00 mm
- ☐ >4.00 mm
- ☐ None of the above (I would not refer for SLNB)

ID number: _____

16. Would any of these factors influence your decision to discuss or recommend sentinel lymph node biopsy to patients?

(tick ALL that apply)

- ☐ Breslow thickness
- ☐ Presence of ulceration
- ☐ Mitotic rate of the melanoma
- ☐ Lymphovascular invasion in the melanoma
- ☐ Body site of the melanoma
- ☐ Wide excision already performed
- ☐ Type of wound closure following diagnostic biopsy
- ☐ Presence of palpable regional lymph nodes
- ☐ Histological subtype, e.g. desmoplastic, nodular, lentigo maligna melanoma
- ☐ Age of the patient
- ☐ Comorbidities of the patient
- ☐ Possible morbidity of the sentinel lymph node biopsy procedure
- ☐ Possible morbidity of completion lymphadenectomy
- ☐ The likelihood that the results will influence patient management
- ☐ Access to services for sentinel lymph node mapping and biopsy
- ☐ Distance to services for sentinel lymph node mapping and biopsy
- ☐ Costs to the patient
- ☐ Patient level of anxiety
- ☐ Patient preference
- ☐ Other, please specify_____

17. For patients for whom sentinel lymph node biopsy would be suitable, who would you <u>usually</u> refer the patient to for definitive management?

(tick ONE only)

- ☐ A local general surgeon
- ☐ Any surgical oncologist
- ☐ A melanoma-trained surgical oncologist
- ☐ Any plastic surgeon
- ☐ A melanoma-trained plastic surgeon
- ☐ A melanoma specialist dermatologist
- ☐ A specialist melanoma service where there is a multidisciplinary team
- ☐ None of the above (I would not refer for SLNB)

☐ Other, please specify: _____

18. Would you expect the clinician to whom you refer the patient to recommend a sentinel lymph node biopsy if they were eligible?

(tick ONE only)

☐ No, never

☐ Occasionally

☐ Most of the time if appropriate for the patient's situation

☐ Yes, always

☐ I would not refer to a surgeon who routinely recommends SLNB

19. After a negative sentinel lymph node biopsy for melanoma, do you wish to be involved in ongoing patient follow-up for recurrence?

(tick ONE only)

☐ No

☐ Yes, with follow-up managed mainly by myself

☐ Yes, with follow-up managed mainly by the surgeon

☐ Yes, with follow-up managed in a shared care arrangement between the surgeon and myself

20. After a positive sentinel lymph node biopsy for melanoma, do you wish to be involved in ongoing patient follow-up for recurrence?

(tick ONE only)

☐ No

☐ Yes, with follow-up managed mainly by myself

☐ Yes, with follow-up managed mainly by the surgeon or medical oncologist

☐ Yes, with follow-up managed in a shared care arrangement between the surgeon or medical oncologist and myself

21. Are there any tests or scans that you would arrange for patients eligible for sentinel lymph node biopsy at the time of diagnosis?

(tick ALL that apply)

☐ No other tests or scans

☐ Ultrasound examination of regional nodes

☐ Chest X ray

☐ CT chest/abdomen/pelvis

☐ Whole body PET-CT

☐ CT or MRI scan of brain

☐ Other, please specify: _____

ID number: _____

22. Are there any tests or scans that you would arrange for follow-up of patients diagnosed with melanoma >1 mm?

(tick ALL that apply)

- ☐ No other tests or scans
- ☐ Ultrasound examination of regional nodes
- ☐ Chest X ray
- ☐ CT chest/abdomen/pelvis
- ☐ Whole body PET-CT
- ☐ CT or MRI scan of brain
- ☐ Other, please specify: _____

Continue to next page

ID number: _____

23. Would you like to receive a summary of the results of this study after it has been completed, in about 1 years' time?

☐ Yes → please enter your email address:_____

Your email address will not be linked to your survey responses and will be stored separately.

☐ No

24. Would like to go into a lucky draw to win one of three iPads? The draw will take place when recruitment to the study is complete.

☐ Yes → please enter your email address:_____

Your email address will not be linked to your survey responses and will be stored separately.

☐ No

25. Would you be willing to be contacted by the research team for a 20-minute confidential interview to discuss risk factors, diagnosis and management of patients with melanoma by dermatologists? We would reimburse your time with a $100 Coles/Myer gift voucher.

☐ Yes → Please enter your contact details below and ask the research team for a Participant Information Sheet and Consent form for the interview study. Your contact details will be stored separately to your survey and interview data.

☐ No

Your Name: _____

Best contact phone number:_____

Email address:_____

Best time and/or day of the week:_____

You have completed the questionnaire! Thank you very much for your time.