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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-032636
Article Type:	Protocol
Date Submitted by the Author:	01-Jul-2019
Complete List of Authors:	Rapport, Frances ; Macquarie University, Australian Institute of Health Innovation Smith, Andrea; Macquarie University, Australian Institute of Health Innovation Cust, Anne; The University of Sydney, Sydney Medical School Mann, Graham; University of Sydney, Western Clinical School, Westmead Millenium Institute Watts, Caroline; University of Sydney, Sydney School of Public Health Gyorki, David; Peter MacCallum Cancer Centre Henderson, Michael; Peter MacCallum Cancer Institute, Cancer Surgery Hong, Angela; Melanoma Institute Australia Kelly, John; Alfred Health, Victorian Melanoma Service Long, Georgina; Melanoma Institute Australia Mar, Victoria; Alfred Health, Victorian Melanoma Service Morton, Rachael; NHMRC Clinical Trials Centre Saw, Robyn; Melanoma Institute Australia Scolyer, Richard; University of Sydney, Sydney Medical School Spillane, Andrew; Melanoma Institute Australia Thompson, John ; Melanoma Institute Australia Braithwaite, Jeffrey; Macquarie University, Australian Institute of Health Innovation
Keywords:	QUALITATIVE RESEARCH, melanoma, sentinel lymph node biopsy, implementation science, systemic adjuvant therapy, Dermatological tumours < ONCOLOGY

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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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Journal: BMJ Open

Word count 3498 (excluding Abstract, Article Summary, tables and boxes, acknowledgements and references)

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

1 1 **ABSTRACT**

2 2 **Introduction:** Sentinel lymph node biopsy (SLNB) is a diagnostic procedure developed in the 1990s. It
3 3 is currently used to stage patients with primary cutaneous melanoma, provide prognostic
4 4 information and guide management. The Australian Clinical Practice Guidelines state that SLNB
5 5 should be considered for patients with cutaneous melanoma >1mm in thickness (or >0.75mm with
6 6 high-risk pathology features). Until recently, SLN status was used to identify patients who might
7 7 benefit from a completion lymph node dissection, a procedure that is no longer routinely
8 8 recommended. SLN status is now also being used to identify patients who might benefit from
9 9 systemic adjuvant therapies such as anti-PD1 checkpoint inhibitor immunotherapy or BRAF-directed
10 10 molecular targeted therapy, treatments that have significantly improved relapse-free survival for
11 11 patients with resected stage III melanoma and improved overall survival of patients with
12 12 unresectable stage III and stage IV melanoma. Australian and international data indicate that
13 13 approximately half of eligible patients receive a SLNB.

14 14 **Methods and analysis:** This mixed-methods study seeks to understand the structural, contextual and
15 15 cultural factors affecting implementation of the SLNB guidelines. Data collection will include: (1)
16 16 cross-sectional questionnaires and semi-structured interviews with general practitioners and
17 17 dermatologists; (2) semi-structured interviews with other healthcare professionals involved in the
18 18 diagnosis and early definitive care of melanoma patients, and key stakeholders including
19 19 researchers, representatives of professional colleges, training organisations, and consumer
20 20 melanoma groups; and (3) documentary analysis of documents from government, health services
21 21 and non-government organisations. Descriptive analyses and multivariable regression models will be
22 22 used to examine factors related to SLNB practices and attitudes. Qualitative data will be analysed
23 23 using thematic analysis.

24 24 **Ethics and dissemination:** Ethics approval has been granted by the University of Sydney. Results will
25 25 be disseminated through publications and presentations to clinicians, patients, policymakers and
26 26 researchers, and will inform the development of strategies for implementing SLNB guidelines in
27 27 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

60 implementation process is to identify and prioritise interventions with the greatest potential to
 61 impact positively on the quality of care for patients with melanoma. Between December 2018 and
 62 February 2019, meetings of Melanoma CRE members systematically mapped CRE projects across the
 63 melanoma care continuum (Supplementary file 1) and identified two in which implementation
 64 science had the greatest potential to identify pathways to practice change. One of these, 'SLNB for
 65 patients with melanoma', is outlined in this protocol paper.

66 *Melanoma diagnosis and staging*

67 Melanoma is the fourth most common cancer diagnosis in Australia.[1] In 2019, it is estimated that
 68 15,229 people will be diagnosed with invasive melanoma and that 1,725 people will die from it.[1]
 69 Between 2011 and 2015, an individual diagnosed with melanoma had a 91% chance of surviving for
 70 5 years.[1] Survival is influenced by the stage of the melanoma at diagnosis. Staging takes into
 71 account tumour thickness and ulceration and whether the melanoma has spread regionally (to the
 72 lymph nodes) or more distantly (to other parts of the body) (Table 1).[2,3] Accurate staging is a
 73 fundamental prerequisite for optimal melanoma management. From the perspective of the
 74 individual patient, staging provides important prognostic information, guides management and
 75 clinical decision-making, including whether a patient may benefit from adjuvant systemic therapy,
 76 shapes communication between the patient, their clinician, and the patient's family and may
 77 determine the patient's eligibility for clinical trials.[4] From a public health perspective, staging also
 78 facilitates standardised reporting, centralised cancer registry reporting, the design and conduct of
 79 clinical trials, and the analysis of clinical trial data.[2]

80 **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 <i>in situ</i> 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: <ul style="list-style-type: none"> • ≤ 2mm in thickness <u>without</u> ulceration • ≤ 1mm in thickness <u>with</u> ulceration
Stage II	The melanoma has not spread beyond the primary site (i.e. no metastases or lymph node involvement); the melanoma is: <ul style="list-style-type: none"> • > 2mm in thickness <u>without</u> ulceration • > 1mm in thickness <u>with</u> 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

81

82 *SLNB*

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

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

97 SLNB avoided this unnecessary morbidity by using localising nuclear medicine and vital blue
 98 dyes to identify the SLN, that is, the lymph node receiving direct lymphatic drainage from the
 99 primary melanoma site.[5] The rationale (which Morton referred to as the incubator hypothesis or
 100 step-wise model of disease progression) was that the most likely site of early metastases, the SLN,
 101 could then be removed and tested pathologically for clinically occult melanoma cells and, if found, a
 102 completion lymph node dissection performed. Conversely, if the SLN was clear of metastatic disease,
 103 then it was reasoned that it was unlikely that other, more distant nodes would be diseased, thereby
 104 saving the patient from an unnecessary lymph node dissection. In this context, SLNB has been
 105 reported to be cost-effective for the management of intermediate thickness melanoma. [7]

106

107

108 *Contemporary melanoma management*

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

124 *International (AJCC staging system) and national (Australian) guidelines for SLNB*

125 The American Joint Committee on Cancer (AJCC) Staging Manual has become the benchmark for
126 classifying patients' disease stage, outlining prognosis, and establishing the best treatment
127 approaches.[14] The recently updated eighth edition recommends that lymphatic mapping and SLNB
128 should be routinely used as a staging procedure for patients with T1b, T2, T3 or T4 primary
129 cutaneous melanomas (i.e. melanomas ≥ 0.8 mm with or without ulceration, or < 0.8 mm with
130 ulceration) and who have clinically negative regional lymph nodes.[3] Likewise, the 2018 Australian
131 Clinical Practice Guidelines for the Diagnosis and Management of Melanoma recommend that 'SLNB
132 should be considered for all patients with melanoma > 1 mm in thickness and for patients with
133 melanoma > 0.75 mm with other high risk pathological features to provide optimal staging and
134 prognostic information and to maximise management options for patients who are node
135 positive.'[15]

136 *Rates of SLNB in Australia and internationally*

1
2
3 137 The limited data that exist for rates of SLNB for melanoma in Australia indicate that these rates may
4
5 138 be lower than expected.^a A population-based study in Queensland between 2010 and 2014 reported
6
7 139 rates of SLNB of 33% (261 out of 787 study patients) for stage 1b and stage 2 melanoma
8
9 140 patients.[16] The 2006 New South Wales Melanoma Patterns of Care Study reported that SLNB was
10
11 141 performed in 45% of patients diagnosed with a melanoma >0.75mm thick.[17] SLNB rates in
12
13 142 Australia are roughly comparable to rates reported internationally. Data from the US Surveillance
14
15 143 Epidemiology and End Results (SEER) database for 2004-2006 indicate that 53% of eligible patients
16
17 144 received a SLNB,[18] while data from a population-based study in the northeast of France indicated
18
19 145 that 34% of patients with a melanoma >1mm in thickness received a SLNB.[19] Factors associated
20
21 146 with having a SLNB included patient age <50 years,[17] primary tumour on upper limb,[17]
22
23 147 treatment in an urban setting,[17,19–23] and hospital size (>50 beds)[24] Recent international data
24
25 148 indicate that rates of SLNB are increasing: in the Netherlands the SLNB rate increased from 39.0% in
26
27 149 2003 to 47.8% in 2014.[25] The authors suggest that changes in rates of SLNB may be related to
28
29 150 evolving views on SLNB as a staging or therapeutic procedure, changes to the AJCC staging system,
30
31 151 and less acceptance of the step-wise model of disease progression.

32 152 *Challenges relating to implementation of clinical practice guidelines*

33 153 Clinical practice guidelines synthesise and summarise complex research evidence into easily
34
35 154 understandable recommendations. Clinical practice guidelines were initially heralded as a means of
36
37 155 overcoming the knowledge gaps perceived to be behind observed variations in clinical practice.[26]
38
39 156 However, even guidelines that are based on rigorous evidence rarely penetrate medical practice as
40
41 157 intended.[26] It is now accepted that the distillation and summary of evidence into clinical practice
42
43 158 guidelines, although a necessary step, is not in and of itself sufficient for the translation of research
44
45 159 evidence into routine clinical practice.[26]

46
47 160 Successful adoption and implementation of guidelines requires an understanding of the
48
49 161 technical, social, political, economic, cultural, structural and psychological barriers to the use of
50
51 162 research evidence.[27] As Greenhalgh and colleagues noted in 2004, clinicians are not passive
52
53 163 recipients of innovations (such as guidelines).[28] Instead they 'seek innovations, experiment with
54
55 164 them, evaluate them, find (or fail to find) meaning in them, develop feelings (positive or negative)
56
57 165 about them, challenge them, worry about them, complain about them, "work around" them, gain

58
59
60
^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'.

1
2
3 166 experience with them, modify them to fit particular tasks, and try to improve or re-design them—
4
5 167 often through dialogue with other users.’ In addition, as Ferlie and colleagues noted in 2001, the
6
7 168 research evidence for a particular practice is often ambiguous and contested.[29] Consequently, the
8
9 169 evidence base, ‘must be continually interpreted and reframed in accordance with the local context, a
10
11 170 process that often involves power struggles among various professional groups’.[29] For their
12
13 171 widespread acceptance, guidelines need to be perceived as authoritative, credible and professional
14
15 172 documents that help healthcare professionals improve their practice, traits closely tied to the
16
173 provenance of the guidelines.[26]

17
18 174 Consequently, if widespread guideline implementation is to be achieved in Australia, it will
19
20 175 be necessary to understand the complex contextual factors influencing clinicians’ attitudes and
21
22 176 behaviour in relation to the decision to discuss SLNB with an eligible melanoma patient or to refer
23
24 177 the patient to an appropriate specialist for discussion of the pros and cons of SLNB. The knowledge
25
26 178 generated in this project will be used to inform future efforts to support effective and widespread
27
28 179 melanoma guideline implementation in Australia. A greater awareness of the guidelines, and the
29
30 180 melanoma patients to whom they apply, should in turn lead to improved melanoma management
31
32 181 and outcomes for patients, including more accurate information about prognosis and access to
33
34 182 systemic adjuvant therapies such as immunotherapy or targeted molecular therapy for eligible
35
36 183 patients with melanoma.

36 184 **METHODS AND ANALYSIS**

38 185 **Study design**

39
40 186 This protocol outlines the research design for a mixed-methods study. Cross-sectional
41
42 187 questionnaires and in-depth semi-structured interviews with GPs and dermatologists, and in-depth
43
44 188 semi-structured interviews with other healthcare professionals and stakeholders in melanoma care
45
46 189 in Australia will be complemented by data collected through documentary analysis of material such
47
48 190 as editorials, organisational and institutional reports, books and brochures relating to SLNB in
49
50 191 Australia, including policy documentation (Table 2). Data collection for GP questionnaires and
51
52 192 interviews commenced in December 2018; and for other healthcare professionals and stakeholders
53
54 193 in May 2019. The study runs until 2023. The credibility of the study’s findings will be enhanced
55
56 194 through the use of multiple sources of information, different methods of data collection and the
57
58 195 involvement of researchers with diverse areas of expertise (e.g. in clinical practice, melanoma,
59
60 196 implementation science, complexity science, behaviour change science and public health). This
197
198 197 triangulation of methods, data sources and investigator expertise will ensure that the findings are

1
2
3 198 data-rich and comprehensive.[30] The reporting of the study design as outlined in this protocol is
4
5 199 informed by the consolidated Criteria for Reporting Qualitative Research (COREQ) checklist and the
6
7 200 Strengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines.[31,32]
8

9 201 **Study aim and objectives**

10
11 202 The aim of this mixed-methods study is to understand the structural, contextual and cultural factors
12
13 203 impacting the implementation of the recently updated national clinical practice guidelines for SLNB
14
15 204 in melanoma patients. The study aim will be achieved by fulfilling the objectives outlined in Table 2.
16

17 205 **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	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
	Provide an account of factors that have contributed to this discourse	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)
	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	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
	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	

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

206

207 **Sample and setting**

208 *Participants*

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

218 **Box 1 Inclusion and exclusion criteria**

219 Questionnaires and interviews (GPs and dermatologists)

- 220 • Must have worked as a general practitioner or dermatologist in Australia in the previous
221 12 months.

222 Interviews (other healthcare professionals)

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

224 Interviews (stakeholders)

- 225 • Current or prior experience of managing patients with melanoma in Australia; or
- 226 • Current or prior experience of working for an organisation or institution that could have
227 influenced healthcare practitioners', policymakers' or patients' views on SLNB in Australia.

228 Documentary analysis

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

1
2
3 231 *Sampling and recruitment: interviews*
4

5 232 Sampling will be driven by a number of purposive sampling strategies, including stratified purposive
6
7 233 sampling and maximum variation sampling (to gain as wide a range of perspectives as possible from
8
9 234 individuals with different professional backgrounds and responsibilities), key informant sampling (to
10
11 235 ensure important informants are included) and snowball sampling (to ensure sampling is not
12
13 236 restricted to key informants already known to the CRE in Melanoma members).[33] Sampling will be
14
15 237 iterative, with decisions informed by the ongoing data analysis.[34] Recruitment strategies will
16
17 238 include: (1) recruitment of healthcare professionals at relevant conferences and professional
18
19 239 development activities; (2) identification of key stakeholders by members of the CRE in Melanoma;
20
21 240 and (3) identification of additional key stakeholders by participants. The overarching recruitment
22
23 241 strategy will be to select for interview individuals from around Australia whose experiences and
24
25 242 professional roles within melanoma healthcare put them in a position to provide rich and relevant
26
27 243 data. Recruitment will cease once data analysis indicates thematic saturation has been reached, this
28
29 244 being the point at which our analysis allows us to provide a comprehensive and credible account of
30
31 245 the structural, contextual and cultural factors impacting on implementation of the national clinical
32
33 246 practice guidelines for SLNB in patients with melanoma in Australia. It is anticipated that between 50
34
35 247 and 65 participants will be recruited in order to ensure a variety of perspectives and experiences
36
37 248 from all relevant sectors in Australian melanoma care (20-25 GPs; 10-15 dermatologists; 20-25 other
38
39 249 healthcare professionals and stakeholders).

40
41
42 250 *Sampling: documentary analysis*
43

44 251 Documentary materials relevant to the development and use of the national SLNB guidelines will be
45
46 252 purposively sampled and included, based on their potential to provide background and contextual
47
48 253 information relevant to study's aims (Box 1). Relevant documentary materials (such as
49
50 254 commentaries and editorials, journal articles and white papers, books and brochures, event
51
52 255 programs, newspapers, press releases, program proposals, summaries, organisational and
53
54 256 institutional reports, questionnaire data, and public records) will be used to uncover meaning,
55
56 257 develop understanding and discover insights relevant to the study's aim.

57
58
59 258 **Data collection**
60

61
62 259 *Questionnaires*

63 260 Questionnaires for GPs and dermatologists have been developed following a review of literature and
64
65 261 consultation with melanoma clinicians and dermatologists. Data captured will include demographic
66
67 262 characteristics, knowledge of melanoma guidelines, clinical management of patients with

263 melanoma, referral patterns, attitudes to SLNB, and experiences of sharing care of patients with
 264 melanoma with other healthcare providers (Supplementary file 2). The questionnaires can be
 265 completed on paper or electronically. The questionnaire data will be managed using REDCap.[35]

266 *Interviews*

267 Semi-structured interview guides have been developed for healthcare professionals and
 268 stakeholders based on a review of literature and through consultation with melanoma healthcare
 269 professionals (Table 3). The interview guides outline the major topics that will be discussed in the
 270 interviews and include a range of questions and prompts. Interviews will be face-to-face or by
 271 telephone (depending on participant preference) and will be audio-recorded and professionally
 272 transcribed. Field notes written up immediately after each interview will further inform and enrich
 273 data analysis.

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

Topics	Example questions
<i>Melanoma healthcare professionals</i>	
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?
<i>Stakeholders in melanoma care</i>	
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?

276 SLNB: sentinel lymph node biopsy.

277

1
2
3 278 *Documentary analysis*
4

5 279 Documents will initially be identified through discussion with members of the Melanoma CRE, and
6
7 280 then through targeted, systematic searches of electronic and print-based resources relating to SLNB
8
9 281 and SLNB guidelines in Australia. Searching will be iterative and cease only when a comprehensive
10
11 282 understanding of the background and context of SLNB in Australia has been reached.

12
13 283 **Data analysis**

14
15 284 *Questionnaires*

16
17 285 Postcode will be classified using the Accessibility/Remoteness Index of Australia (ARIA), and Socio-
18
19 286 Economic Indexes for Areas (SEIFA) classifications.[36,37] Descriptive analyses and multivariable
20
21 287 regression models will be used to examine factors related to SLNB practices and attitudes, and
22
23 288 familiarity with the Australian clinical practice guidelines for melanoma management, estimated
24
25 289 using probability ratios and 95% confidence intervals (CIs). Potential predictors that will be assessed
26
27 290 in the regression models include age, sex, type of practice, years of practice, number of invasive
28
29 291 melanomas diagnosed in a year, location of practice and GPs' exposure to information relating to
30
31 292 SLNB. All analyses will be conducted using SAS version 9.4 (SAS Institute Inc).

32
33 293 *Interviews*

34 294 Analysis of interview data will be based on Braun and Clarke's method of thematic analysis and will
35
36 295 initially be inductive and data driven.[38,39] In line with Braun and Clarke's methods, analysis will go
37
38 296 beyond the semantic content of the data to: 'identify underlying ideas, assumptions and
39
40 297 conceptualisations – and ideologies – that are theorised as shaping or informing the semantic
41
42 298 content of the data'.[39] The de-identified transcripts will be read by two members of the research
43
44 299 team. Data will be compared within and across interviews in order to identify commonalities,
45
46 300 differences and patterns in the data. Transcripts will be coded by the two researchers and a list of
47
48 301 themes and categories relevant to the study's aim generated. These themes will then be discussed
49
50 302 with other members of the research team and refined until group agreement is reached on those
51
52 303 most relevant to the study's aim. A thematic map will be developed and the data recoded to these
53
54 304 themes. Analytic memos will be written throughout the data analysis process.

55
56 305 *Documentary materials*

57 306 The analysis process will commence by assessing the authenticity and usefulness of each document,
58
59 307 taking into account the document's relevance to the study's aim, the original purpose of the
60
308 document, the context in which it was produced, and the intended audience.[40] As with the

1
2
3 309 interview data, the documentary data will be analysed using Braun and Clarke's method of thematic
4
5 310 analysis.[39]

6 7 311 **ETHICS AND DISSEMINATION**

8 9 312 **Ethics**

10
11 313 Ethical approval for the study has been granted by the University of Sydney Human Research Ethics
12
13 314 Committee (HREC), project numbers 2018/713 and 2019/308. Data collection and analysis will be
14
15 315 conducted in accordance with the Australian National Health and Medical Research Council National
16
17 316 Statement[41]. All participants will provide informed consent prior to taking part in the study.

18 19 317 **Data storage and protection**

20
21 318 Participant privacy and confidentiality will be maintained by removing all identifying information
22
23 319 from the transcripts, by assigning pseudonyms to participants, and by storing study data securely on
24
25 320 password-protected computers or in locked filing cabinets within university premises, to which only
26
27 321 named researchers from the research team will have access. Deidentified interview transcripts will
28
29 322 be stored separately from the file containing participant identifiers. All data will be destroyed 7 years
30
31 323 after completion of the study in accordance with standard ethical guidelines around storage of study
32
31 324 data.

32 33 325 **Dissemination of study findings**

34
35 326 Study findings will be disseminated via peer-reviewed journal publications, generalist publications,
36
37 327 presentations to the public, academics, clinicians, policymakers, melanoma consumers, and at
38
39 328 scientific conferences.

40 41 329 **SIGNIFICANCE AND IMPACT OF STUDY**

42
43 330 This is the first multi-methods study to investigate the structural, contextual and cultural factors
44
45 331 impacting the implementation of national SLNB guidelines in Australia. The study will bring to light
46
47 332 the range of professional perspectives on SLNB, document the discourse surrounding SLNB in
48
49 333 Australia and report on how these may be affecting uptake of SLNB in patients with melanoma. The
50
51 334 knowledge generated by this project will be used to inform future efforts to support effective and
52
53 335 widespread melanoma guideline implementation in Australia and internationally. A greater
54
55 336 awareness of the guidelines, and the patients with melanoma to whom they apply, should in turn
56
57 337 lead to improved melanoma management and outcomes for patients, including more accurate
58
59 338 information about prognosis and access to adjuvant systemic therapies such as immunotherapy or
60
339 BRAF-directed targeted molecular therapy for eligible melanoma patients. And finally, the

1
2
3 340 knowledge generated in this study will focus attention on the role of SLNB as a diagnostic and
4
5 341 prognostic tool in melanoma, the role it has to play in accurate melanoma staging and cancer
6
7 342 registry reporting, and the role SLNB plays in the design and conduct of melanoma clinical trials both
8
9 343 now and in the future.

10 344 **Author statement**

11
12
13 345 **Acknowledgements** We thank Sam Robinson for help in preparing the ethics application.

14
15 346 **Funding** This work was funded by the Melanoma Centre of Research Excellence grant (1135285)
16
17 347 from the Australian National Health and Medical Research Council. RLM received funding from an
18
19 348 NHMRC Translating Research into Practice (TRIP) Fellowship (1150989). AEC received a NHMRC
20
21 349 Career Development Fellowship (1147843) and Cancer Institute NSW Career Development
22
23 350 Fellowship (15/CDF/1-14).

24 351 **Competing interests** None.

25
26
27 352 **Ethics approval** University of Sydney Human Research Ethics Committee, project numbers 2018/713
28
29 353 and 2019/308.

30 354 **Provenance and peer review** Not commissioned; externally peer reviewed.

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39 358 on different terms, provided the original work is properly cited and the use is non-commercial. See:
40
41 359 <http://creativecommons.org/licenses/by-nc/4.0/>

42 360 **Indirect Patient and Public Involvement**

43
44 361 We did not directly include PPI in the design of this study, but the melanoma guidelines used in the
45
46 362 study were developed and updated by a committee that includes patient representatives.

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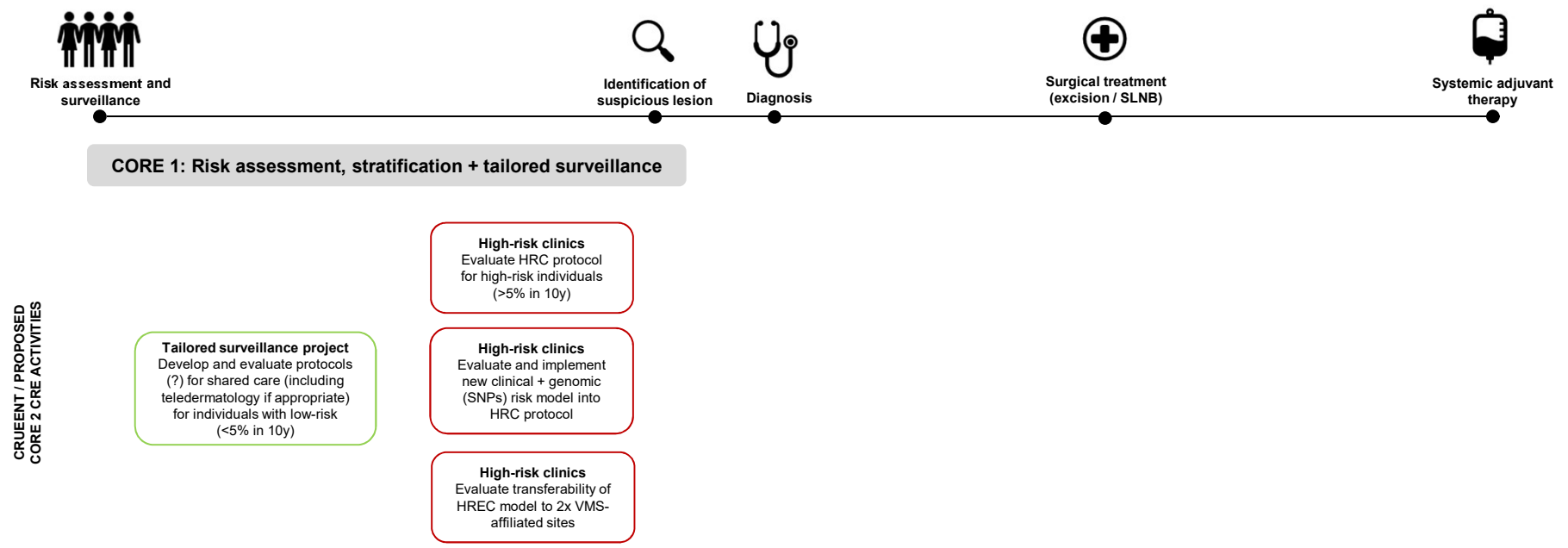
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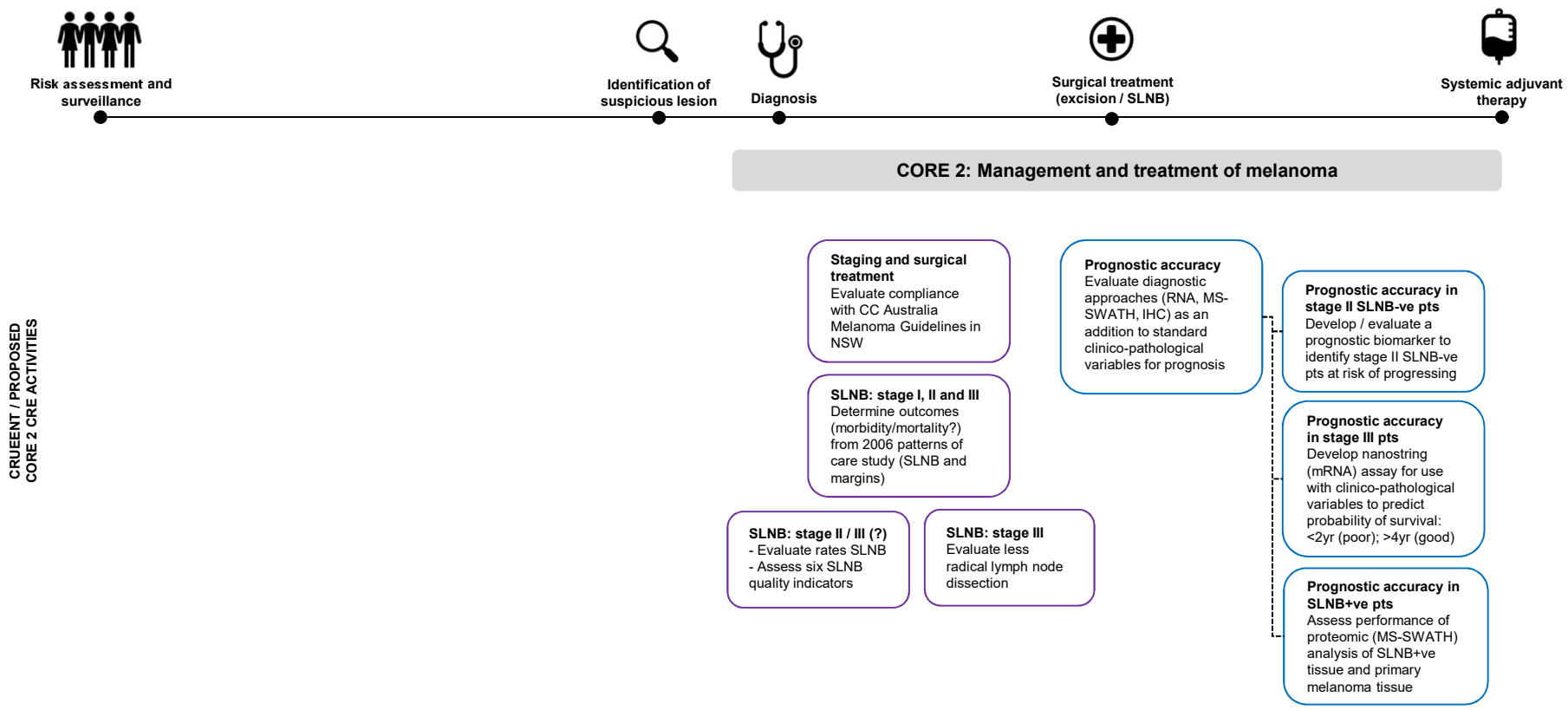
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Preliminary mapping exercise: melanoma care continuum / CRE in Melanoma activities

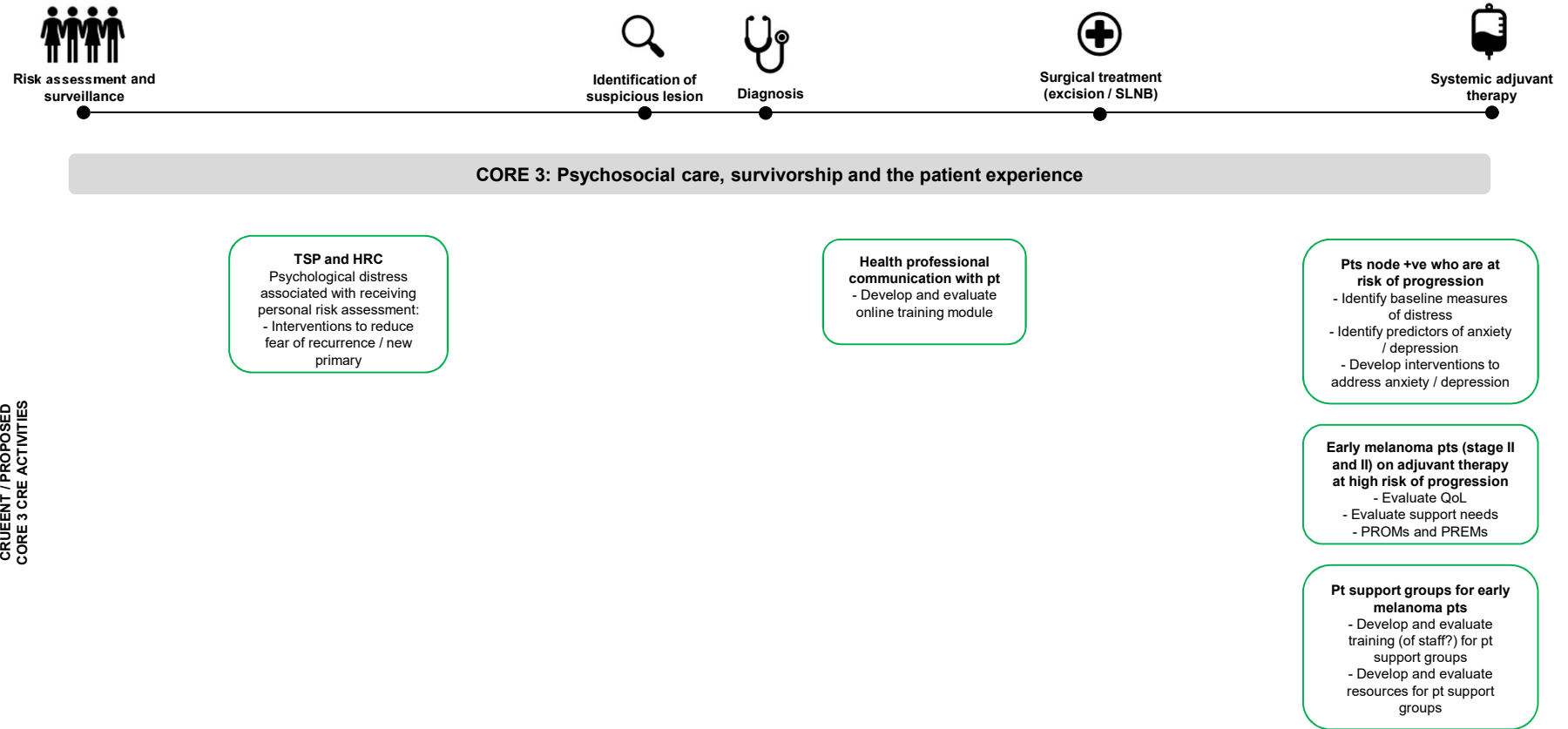


Preliminary mapping exercise: melanoma care continuum / CRE in Melanoma activities

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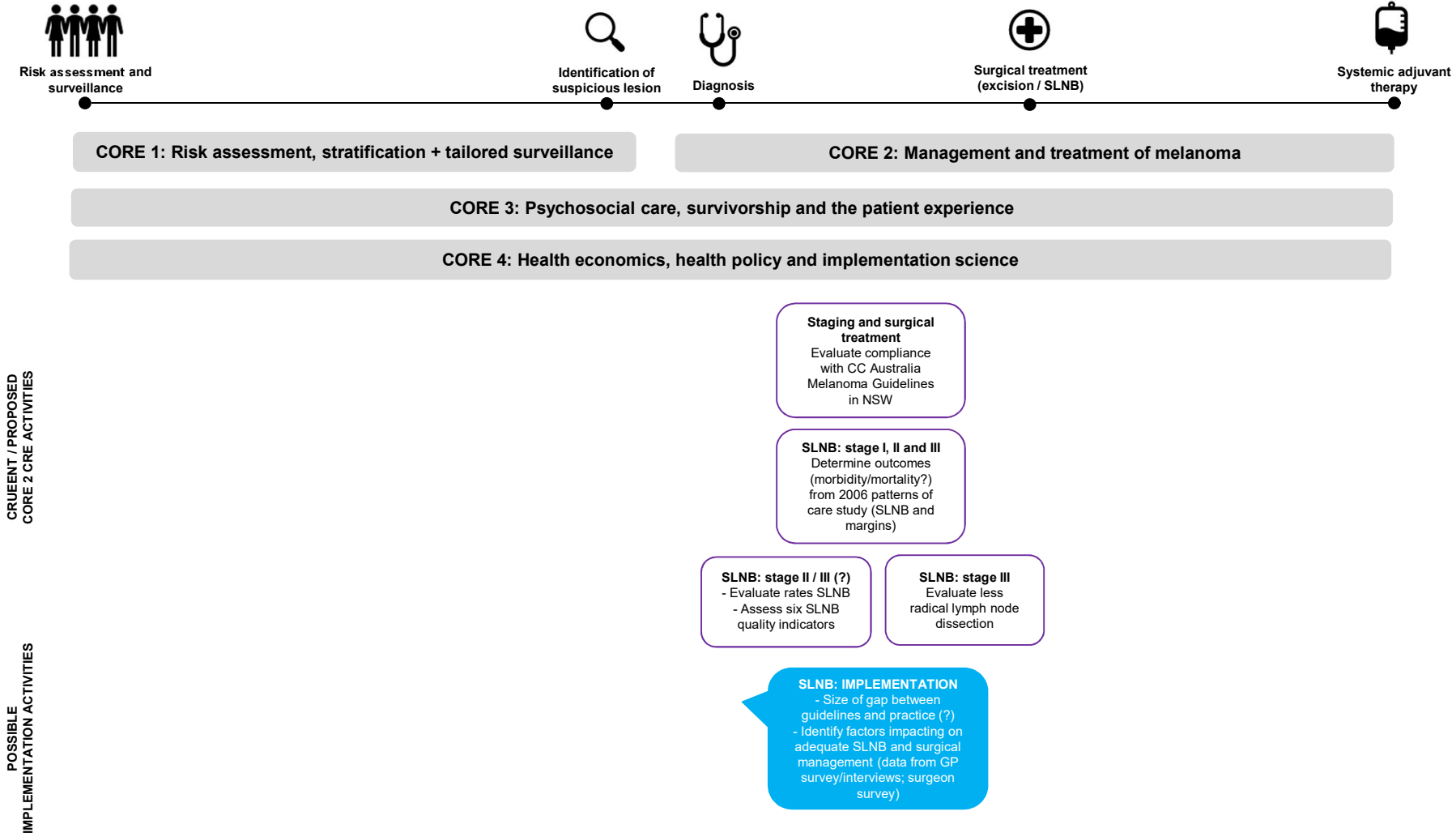


Preliminary mapping exercise: melanoma care continuum / CRE in Melanoma activities



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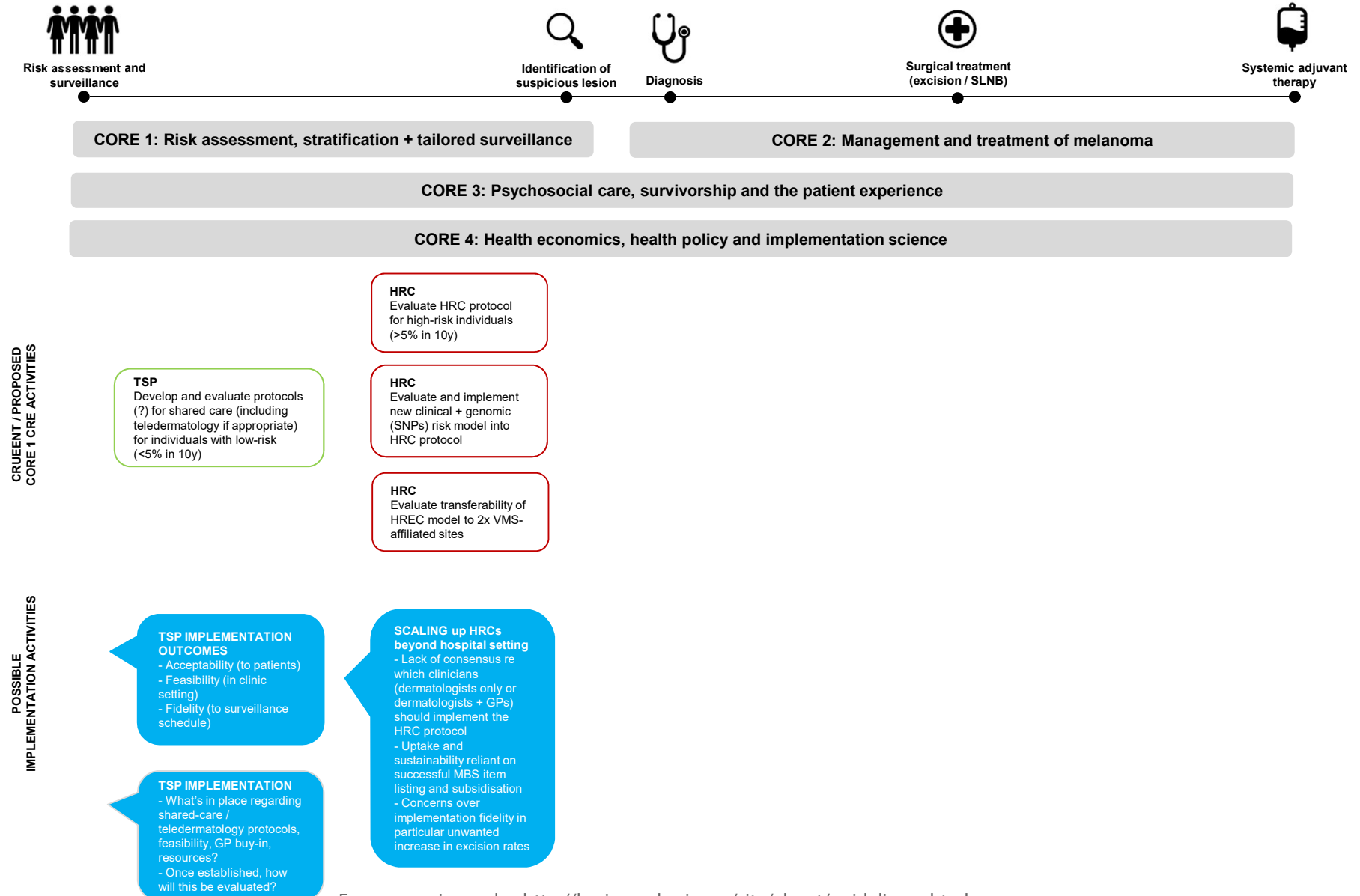
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CRUENT / PROPOSED
CORE 2 CRE ACTIVITIES

POSSIBLE
IMPLEMENTATION ACTIVITIES

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





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

Melanoma management study, GP survey

For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

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8. Have you accessed the recent update of the national clinical practice guidelines for melanoma on the Cancer Council Australia website/Wiki?

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- 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): _____

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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 usually 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: _____

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3 17. Would you expect the clinician to whom you refer the patient, to recommend a sentinel lymph node
4 biopsy if they were eligible? **(tick one only)**

- 5 No, never
6 Occasionally
7 Most of the time
8 Yes, always
9

10 18. After a negative sentinel lymph node biopsy, are you wanting to be involved in ongoing patient follow-
11 up? **(tick one only)**

- 12 No
13 Yes, with follow-up managed mainly by myself
14 Yes, with follow-up managed mainly by the specialist
15 Yes, with follow-up managed in a shared care arrangement between the specialist and myself
16
17

18 19. After a positive sentinel lymph node biopsy, are you wanting to be involved in ongoing patient follow-
19 up? **(tick one only)**

- 20 No
21 Yes, with follow-up managed mainly by myself
22 Yes, with follow-up managed mainly by the specialist
23 Yes, with follow-up managed in a shared care arrangement between the specialist and myself
24
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26 20. Are there any tests or scans that you would arrange for patients eligible for sentinel lymph node
27 biopsy? **(tick all that apply)**

- 28 No other tests or scans
29 Ultrasound examination of regional nodes
30 Chest X ray
31 CT Chest/abdomen/pelvis
32 Whole body PET-CT
33 CT or MRI scan of brain
34 Other, please specify: _____
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37 → Please go to question 22
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40 *[Note Question 21 is only for those who selected 'No' at Question 12]*
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43 21. Why would you not usually recommend sentinel lymph node biopsy? **(tick all that apply)**

- 44 Don't know much about it
45 Difficulty in accessing facilities for sentinel lymph node biopsy
46 No confirmed survival benefit
47 Does not add sufficient additional prognostic information
48 Does not impact subsequent management
49 The morbidity of the procedure
50 The morbidity of completion lymphadenectomy if the sentinel node is positive
51 Costs to the patient
52 Other, please specify: _____
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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

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

4 Yes → please enter your email address: _____.

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

6 No
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11 24. Please enter your email address if you would like to go into a lucky draw to win one of three iPads. The
12 draw will take place when recruitment to the study is complete.

13 Email address: _____

14 Your email address will not be linked to your survey responses and will be stored separately.
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18 *You have completed the questionnaire! Thank you very much for your time.*
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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

1 6. How many years have you been practising as a Dermatologist?
2

- 3 <5 years
4 6-10 years
5 11-20 years
6 21-30 years
7 31-40 years
8 >40 years
9

10 7. On a scale of 1 to 5, how familiar are you with the Australian “Clinical Practice Guidelines for the
11 Diagnosis and Management of Melanoma”?
12

13 **(tick ONE only)**

- 14 1 - Very unfamiliar
15 2 - Somewhat unfamiliar
16 3 - A little familiar
17 4 - Quite familiar
18 5 - Very familiar
19

20 8. Have you accessed the recent update of the Australian “Clinical Practice Guidelines for the Diagnosis and
21 Management of Melanoma” on the Cancer Council Australia website/Wiki?
22

- 23 No
24 Yes
25

26 9. Have you read any articles (e.g. in journals, magazines, newsletters) or listened to talks about sentinel
27 lymph node biopsy (SLNB) for melanoma in the last 3 years?
28

- 29 No → go to question 11
30 Yes → **tick ALL that apply**
31 Australasian Journal of Dermatology
32 Medical Journal of Australia (MJA)
33 Journal of the American Academy of Dermatology (JAAD)
34 British Journal of Dermatology (BJD)
35 New England Journal of Medicine (NEJM)
36 Other peer-reviewed journal, please specify: _____
37 Australian Conference
38 International Conference
39 Other, please specify _____
40

41 10. Do you think these articles or presentations have influenced your attitude to sentinel lymph node
42 biopsy for melanoma?
43
44
45
46
47
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- 1 No
2
3 Yes – more likely to recommend SLNB
4
5 Yes – less likely to recommend SLNB
6

7 How have they influenced you? _____
8
9

10 11. Do you think that sentinel lymph node biopsy has an important role in the management of melanoma
11 patients?
12

- 13 No → Why not? _____
14
15 Yes
16
17 Unsure → Why not? _____
18

19
20
21 12. Would you usually discuss and recommend sentinel lymph node biopsy to a patient with a newly
22 diagnosed melanoma, if eligible for sentinel lymph node biopsy?
23

- 24 No → go to question 13
25
26 Yes → go to question 14
27

28
29 **[Note Question 13 is only for those who selected 'NO' at Question 12]**
30

31 13. Why would you not usually recommend sentinel lymph node biopsy?
32

33 **(tick ALL that apply)**
34

- 35 Don't know much about it
36
37 No added value of sentinel lymph node biopsy
38
39 Difficulty in accessing facilities for sentinel lymph node biopsy
40
41 No confirmed overall survival benefit
42
43 Does not add additional prognostic information beyond what is provided by Breslow thickness
44
45 Does not impact subsequent management
46
47 The morbidity of the procedure
48
49 The morbidity of completion lymphadenectomy if the sentinel node is positive
50
51 Costs to the patient
52
53 Other, please specify: _____
54

55 **Continue to Question 23 [page 6]**
56
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1 **[Note Question 14 is only for those who selected 'YES' at Question 12]**

2
3 14. Why do you believe that sentinel lymph node biopsy may be of value for eligible patients?

4
5 **(tick ALL that apply)**

- 6 More accurate staging
- 7
- 8 To provide prognostic information
- 9
- 10 Likely survival benefit
- 11
- 12 Results may influence follow-up plan
- 13
- 14 To assess suitability for adjuvant systemic therapies if found to be sentinel lymph node positive
- 15
- 16 To select patients for completion lymphadenectomy
- 17
- 18 Improved regional control
- 19
- 20 Other (please specify): _____
- 21
- 22

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

25
26 **(tick ALL that apply)**

- 27
- 28 <0.80 mm
- 29
- 30 <0.80 mm with high-risk pathological feature/s
- 31
- 32 0.80 - 1.00 mm
- 33
- 34 0.80 - 1.00 mm with high-risk pathological feature/s
- 35
- 36 1.01 - 2.00 mm
- 37
- 38 2.01 - 4.00 mm
- 39
- 40 >4.00 mm
- 41
- 42 None of the above (I would not refer for SLNB)
- 43
- 44
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1 16. Would any of these factors influence your decision to discuss or recommend sentinel lymph node
2 biopsy to patients?
3

4 **(tick ALL that apply)**

- 5 Breslow thickness
- 6 Presence of ulceration
- 7 Mitotic rate of the melanoma
- 8 Lymphovascular invasion in the melanoma
- 9 Body site of the melanoma
- 10 Wide excision already performed
- 11 Type of wound closure following diagnostic biopsy
- 12 Presence of palpable regional lymph nodes
- 13 Histological subtype, e.g. desmoplastic, nodular, lentigo maligna melanoma
- 14 Age of the patient
- 15 Comorbidities of the patient
- 16 Possible morbidity of the sentinel lymph node biopsy procedure
- 17 Possible morbidity of completion lymphadenectomy
- 18 The likelihood that the results will influence patient management
- 19 Access to services for sentinel lymph node mapping and biopsy
- 20 Distance to services for sentinel lymph node mapping and biopsy
- 21 Costs to the patient
- 22 Patient level of anxiety
- 23 Patient preference
- 24 Other, please specify _____

25 17. For patients for whom sentinel lymph node biopsy would be suitable, who would you usually refer the
26 patient to for definitive management?
27

28 **(tick ONE only)**

- 29 A local general surgeon
- 30 Any surgical oncologist
- 31 A melanoma-trained surgical oncologist
- 32 Any plastic surgeon
- 33 A melanoma-trained plastic surgeon
- 34 A melanoma specialist dermatologist
- 35 A specialist melanoma service where there is a multidisciplinary team
- 36 None of the above (I would not refer for SLNB)

- 1 Other, please specify: _____

2
3 18. Would you expect the clinician to whom you refer the patient to recommend a sentinel lymph node
4 biopsy if they were eligible?

5
6 **(tick ONE only)**

- 7 No, never
8
9 Occasionally
10
11 Most of the time if appropriate for the patient's situation
12
13 Yes, always
14
15 I would not refer to a surgeon who routinely recommends SLNB
16

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

19
20 **(tick ONE only)**

- 21 No
22
23 Yes, with follow-up managed mainly by myself
24
25 Yes, with follow-up managed mainly by the surgeon
26
27 Yes, with follow-up managed in a shared care arrangement between the surgeon and myself
28

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

31
32 **(tick ONE only)**

- 33 No
34
35 Yes, with follow-up managed mainly by myself
36
37 Yes, with follow-up managed mainly by the surgeon or medical oncologist
38
39 Yes, with follow-up managed in a shared care arrangement between the surgeon or medical
40 oncologist and myself
41
42

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

45
46 **(tick ALL that apply)**

- 47 No other tests or scans
48
49 Ultrasound examination of regional nodes
50
51 Chest X ray
52
53 CT chest/abdomen/pelvis
54
55 Whole body PET-CT
56
57 CT or MRI scan of brain
58
59 Other, please specify: _____
60

1 22. Are there any tests or scans that you would arrange for follow-up of patients diagnosed with melanoma
2 >1 mm?
3

4 **(tick ALL that apply)**

- 5 No other tests or scans
6
7 Ultrasound examination of regional nodes
8
9 Chest X ray
10
11 CT chest/abdomen/pelvis
12
13 Whole body PET-CT
14
15 CT or MRI scan of brain
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17 Other, please specify: _____
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1 23. Would you like to receive a summary of the results of this study after it has been completed, in about 1
2 years' time?
3

4 Yes → please enter your email address: _____
5

6 *Your email address will not be linked to your survey responses and will be stored separately.*
7

8 No
9

10 24. Would like to go into a lucky draw to win one of three iPads? The draw will take place when recruitment
11 to the study is complete.
12

13 Yes → please enter your email address: _____
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15 *Your email address will not be linked to your survey responses and will be stored separately.*
16

17 No
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19 25. Would you be willing to be contacted by the research team for a 20-minute confidential interview to
20 discuss risk factors, diagnosis and management of patients with melanoma by dermatologists? We would
21 reimburse your time with a \$100 Coles/Myer gift voucher.
22

23 Yes → Please enter your contact details below and ask the research team for a Participant
24 Information Sheet and Consent form for the interview study. Your contact details will be stored
25 separately to your survey and interview data.
26

27 No
28

29
30 Your Name: _____
31

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33
34 Best contact phone number: _____
35

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38 Email address: _____
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42 Best time and/or day of the week: _____
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45 ***You have completed the questionnaire! Thank you very much for your time.***
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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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2019-032636.R1
Article Type:	Protocol
Date Submitted by the Author:	24-Dec-2019
Complete List of Authors:	Rapport, Frances ; Macquarie University, Australian Institute of Health Innovation Smith, Andrea; Macquarie University, Australian Institute of Health Innovation Cust, Anne; The University of Sydney, Sydney Medical School Mann, Graham; University of Sydney, Western Clinical School, Westmead Millenium Institute Watts, Caroline; University of Sydney, Sydney School of Public Health Gyorki, David; Peter MacCallum Cancer Centre Henderson, Michael; Peter MacCallum Cancer Institute, Cancer Surgery Hong, Angela; Melanoma Institute Australia Kelly, John; Alfred Health, Victorian Melanoma Service Long, Georgina; Melanoma Institute Australia Mar, Victoria; Alfred Health, Victorian Melanoma Service Morton, Rachael; NHMRC Clinical Trials Centre Saw, Robyn; Melanoma Institute Australia Scolyer, Richard; University of Sydney, Sydney Medical School Spillane, Andrew; Melanoma Institute Australia Thompson, John ; Melanoma Institute Australia Braithwaite, Jeffrey; Macquarie University, Australian Institute of Health Innovation
Primary Subject Heading:	Oncology
Secondary Subject Heading:	Dermatology
Keywords:	QUALITATIVE RESEARCH, melanoma, sentinel lymph node biopsy, implementation science, systemic adjuvant therapy, Dermatological tumours < ONCOLOGY

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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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Journal: BMJ Open

Word count 3498 (excluding Abstract, Article Summary, tables and boxes, acknowledgements and references)

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

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60

1 **ABSTRACT**

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

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

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

32 **Strengths and limitations of this study**

33 The mixed-method design, comprising cross-sectional questionnaires, in-depth interviews and
34 documentary analysis, will generate rich data about the determinants of SLNB guideline
35 implementation.

36 The TICD Checklist will be used to identify the determinants of implementation (that is, the barriers
37 and enablers of implementation).

38 The TICD Checklist will also help to inform possible implementation strategies that could be used to
39 address some of these barriers to implementation of the SLNB guidelines.

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

42 **INTRODUCTION**

43 *Centre of Research Excellence in Melanoma*

44 The Centre of Research Excellence (CRE) in Melanoma is an Australian collaboration of clinicians,
45 researchers and implementation scientists from melanoma centres and universities in New South
46 Wales (Melanoma Institute Australia; The University of Sydney; and the Australian Institute of Health
47 Innovation, Macquarie University) and Victoria (Peter MacCallum Cancer Centre; Victorian
48 Melanoma Service Alfred Hospital; The University of Melbourne; Monash University and the Skin
49 and Cancer Foundation), Australia, and is funded by the Australian National Health and Medical
50 Research Council (NHMRC). The Melanoma CRE, like all Australian government-funded CREs, is
51 tasked with three primary objectives: pursuing collaborative research; developing capacity; and
52 promoting translation of research outcomes into policy and practice. This third objective is the focus
53 of the mixed-methods study outlined in this protocol paper, in particular to understand the
54 structural, contextual and cultural factors affecting implementation of the recently updated national
55 clinical practice guidelines for SLNB for melanoma patients in Australia.

56 *Prioritisation of SLNB uptake as a key implementation goal*

57 One of the rationales behind embedding implementation science expertise within the Melanoma
58 CRE is to support the transfer of evidence-based, effective and efficient patient-centred care across
59 and beyond the Melanoma CRE research sites so that all melanoma patients, regardless of location
60 in Australia, can benefit from its generation of knowledge. A necessary first step in the
61 implementation process is to identify and prioritise interventions with the greatest potential to

62 impact positively on the quality of care for patients with melanoma. Between December 2018 and
 63 February 2019, meetings of Melanoma CRE members systematically mapped CRE projects across the
 64 melanoma care continuum (Supplementary file 1) and identified two in which implementation
 65 science had the greatest potential to identify pathways to practice change. One of these, 'SLNB for
 66 patients with melanoma', is outlined in this protocol paper.

67 *Melanoma diagnosis and staging*

68 Melanoma is the fourth most common cancer diagnosis in Australia.¹ In 2019, it is estimated that
 69 15,229 people will be diagnosed with invasive melanoma and that 1,725 people will die from it.¹
 70 Between 2011 and 2015, an individual diagnosed with melanoma had a 91% chance of surviving for
 71 5 years.¹ Survival is influenced by the stage of the melanoma at diagnosis. Staging takes into account
 72 tumour thickness and ulceration and whether the melanoma has spread regionally (to the lymph
 73 nodes) or more distantly (to other parts of the body) (Table 1).^{2,3} Accurate staging is a fundamental
 74 prerequisite for optimal melanoma management. From the perspective of the individual patient,
 75 staging provides important prognostic information, guides management and clinical decision-
 76 making, including whether a patient may benefit from adjuvant systemic therapy, shapes
 77 communication between the patient, their clinician, and the patient's family and may determine the
 78 patient's eligibility for clinical trials.⁴ From a public health perspective, staging also facilitates
 79 standardised reporting, centralised cancer registry reporting, the design and conduct of clinical trials,
 80 and the analysis of clinical trial data.²

81 **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 <i>in situ</i> 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: <ul style="list-style-type: none"> • ≤ 2mm in thickness <u>without</u> ulceration • ≤ 1mm in thickness <u>with</u> ulceration
Stage II	The melanoma has not spread beyond the primary site (i.e. no metastases or lymph node involvement); the melanoma is: <ul style="list-style-type: none"> • > 2mm in thickness <u>without</u> ulceration • > 1mm in thickness <u>with</u> 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

82 Adapted from AJCC 8th edition staging guidelines^{2,3}

83 *SLNB*

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

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

98 SLNB avoided this unnecessary morbidity by using nuclear medicine and vital blue dyes to
99 identify the SLN, that is, the lymph node receiving direct lymphatic drainage from the primary
100 melanoma site.⁵ The rationale (which Morton referred to as the incubator hypothesis or step-wise
101 model of disease progression) was that the most likely site of early metastases, the SLN, could then
102 be removed and tested pathologically for clinically occult melanoma cells and, if found, a completion
103 lymph node dissection performed. Conversely, if the SLN was clear of metastatic disease, then it was
104 reasoned that it was unlikely that other, more distant nodes would be diseased, thereby saving the
105 patient from an unnecessary lymph node dissection. In this context, SLNB has been reported to be
106 cost-effective for the management of intermediate-thickness melanoma.⁷

107 *Contemporary melanoma management*

108 Based on the results of two recent randomised controlled trials,^{8,9} it is now widely accepted that a
109 completion lymph node dissection in patients who are SLN-positive does not provide an overall
110 survival benefit. Consequently, the role SLNB plays in contemporary melanoma management is

1
2
3 111 changing. In Australia and in many other countries, in addition to providing staging and prognostic
4 112 information, SLNB is now being used to identify patients who might benefit from adjuvant systemic
5 113 therapy. Adjuvant systemic therapies, such as immunotherapies (in which the patient's own immune
6 114 system is activated to target cancer cells) and BRAF-directed targeted molecular therapies (which
7 115 block the growth and spread of cancer by interfering with specific abnormal molecules within the
8 116 tumour cells themselves), have been developed on the basis of recent advances in our
9 117 understanding of the molecular and immune biology of melanoma. These adjuvant systemic
10 118 therapies have been shown to significantly prolong survival in patients with unresectable stage III
11 119 and stage IV melanoma¹⁰ and have also been shown to improve recurrence-free survival when
12 120 administered as adjuvant therapy in patients with resected stage III melanoma.¹¹⁻¹³ However, they
13 121 are not yet publicly funded in the adjuvant melanoma setting in Australia. Consequently, access is
14 122 often restricted to clinical trials, eligibility for which requires staging via SLNB, and compassionate
15 123 access schemes.

124 *International (AJCC staging system) and national (Australian) guidelines for SLNB*

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

135 *Rates of SLNB in Australia and internationally*

136 The limited data that exist for rates of SLNB for melanoma in Australia indicate that these rates may
137 be lower than expected.^a A population-based study in Queensland between 2010 and 2014 reported
138 rates of SLNB of 33% (261 of 787 study patients) for stage 1b and stage 2 melanoma patients.¹⁶ The
139 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 > 1 mm thick provided they can be done in the context of a controlled clinical trial and by surgeons trained in these procedures'; the 2008 guidelines stated 'Patients with a melanoma > 1.0 mm in thickness should be given the opportunity to discuss sentinel lymph node biopsy to provide staging and prognostic information'.

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2
3 140 of patients diagnosed with a melanoma >0.75mm thick.¹⁷ SLNB rates in Australia are roughly
4
5 141 comparable to rates reported internationally. Data from the US Surveillance Epidemiology and End
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7 142 Results (SEER) database for 2004-2006 indicate that 53% of eligible patients received a SLNB,¹⁸ while
8
9 143 data from a population-based study in the northeast of France indicated that 34% of patients with a
10
11 144 melanoma >1mm in thickness received a SLNB.¹⁹ Factors associated with having a SLNB included
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13 145 patient age <50 years,¹⁷ primary tumour on upper limb,¹⁷ treatment in an urban setting,^{17,19-23} and
14
15 146 hospital size (>50 beds)²⁴ Recent international data indicate that rates of SLNB are increasing: in the
16
17 147 Netherlands the SLNB rate increased from 39.0% in 2003 to 47.8% in 2014.²⁵ The authors suggested
18
19 148 that changes in rates of SLNB may be related to evolving views on SLNB as a staging or therapeutic
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21 149 procedure, changes to the AJCC staging system, and less acceptance of the step-wise model of
22
23 150 disease progression.

22 151 *Challenges relating to implementation of clinical practice guidelines*

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25 152 Clinical practice guidelines synthesise and summarise complex research evidence into easily
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27 153 understandable recommendations. Clinical practice guidelines were initially heralded as a means of
28
29 154 overcoming the knowledge gaps perceived to be behind observed variations in clinical practice.²⁶
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31 155 However, even guidelines that are based on rigorous evidence rarely penetrate medical practice as
32
33 156 intended.²⁶ It is now accepted that the distillation and summary of evidence into clinical practice
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35 157 guidelines, although a necessary step, is not in and of itself sufficient for the translation of research
36
37 158 evidence into routine clinical practice.²⁶

37 159 Successful adoption and implementation of guidelines requires an understanding of the
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39 160 technical, social, political, economic, cultural, structural and psychological barriers to the use of
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41 161 research evidence.²⁷ As Greenhalgh and colleagues noted in 2004, clinicians are not passive
42
43 162 recipients of innovations (such as guidelines).²⁸ Instead they 'seek innovations, experiment with
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45 163 them, evaluate them, find (or fail to find) meaning in them, develop feelings (positive or negative)
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47 164 about them, challenge them, worry about them, complain about them, "work around" them, gain
48
49 165 experience with them, modify them to fit particular tasks, and try to improve or re-design them—
50
51 166 often through dialogue with other users.' In addition, as Ferlie and colleagues noted in 2001, the
52
53 167 research evidence for a particular practice is often ambiguous and contested.²⁹ Consequently, the
54
55 168 evidence base, 'must be continually interpreted and reframed in accordance with the local context, a
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57 169 process that often involves power struggles among various professional groups'.²⁹ For their
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59 170 widespread acceptance, guidelines need to be perceived as authoritative, credible and professional
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171 documents that help healthcare professionals improve their practice, traits closely tied to the
172
provenance of the guidelines.²⁶

173 *Theoretical framework*

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

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

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

197 **METHODS AND ANALYSIS**

198 **Study design**

199 This protocol outlines the research design for a mixed-methods study informed by the TICD
200 Checklist.³⁰ Cross-sectional questionnaires and in-depth semi-structured interviews with GPs and
201 dermatologists, and in-depth semi-structured interviews with other healthcare professionals and
202 stakeholders in melanoma care in Australia will be complemented by data collected through
203 documentary analysis of material such as editorials, organisational and institutional reports, books
204 and brochures relating to SLNB in Australia, including policy documentation (Table 2). Data collection

205 for GP questionnaires and interviews commenced in December 2018; and for other healthcare
 206 professionals and stakeholders in May 2019. The study runs until 2023. The credibility of the study's
 207 findings will be enhanced through the use of multiple sources of information, different methods of
 208 data collection and the involvement of researchers with diverse areas of expertise (e.g. in clinical
 209 practice, melanoma, implementation science, complexity science, behaviour change science and
 210 public health). This triangulation of methods, data sources and investigator expertise will ensure that
 211 the findings are data-rich and comprehensive.³² The reporting of the study design as outlined in this
 212 protocol is informed by the consolidated Criteria for Reporting Qualitative Research (COREQ)
 213 checklist and the Strengthening the Reporting of Observational studies in Epidemiology (STROBE)
 214 guidelines.^{33,34}

215 **Study aim and objectives**

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

219 **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	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
	Provide an account of factors that have contributed to this discourse	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)
	Contextualise data collected in the interviews with other documentation	Documentary analysis of printed and electronic material

<p>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23</p>	<p>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</p> <p>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</p>	<p>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)</p>
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221 **Sample and setting**

222 *Participants*

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

232 **Box 1 Inclusion and exclusion criteria**

233 Questionnaires and interviews (GPs and dermatologists)

- 234 • Must have worked as a general practitioner or dermatologist in Australia in the previous
 235 12 months.

236 Interviews (other healthcare professionals)

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

238 Interviews (stakeholders)

- 239 • Current or prior experience of managing patients with melanoma in Australia; or
 240 • Current or prior experience of working for an organisation or institution that could have
 241 influenced healthcare practitioners', policymakers' or patients' views on SLNB in Australia.

242 Documentary analysis

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

245 *Sampling and recruitment: questionnaires*

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

249 *Sampling and recruitment: interviews*

250 Sampling will be driven by a number of purposive sampling strategies, including stratified purposive
 251 sampling and maximum variation sampling (to gain as wide a range of perspectives as possible from
 252 individuals with different professional backgrounds and responsibilities), key informant sampling (to
 253 ensure important informants are included) and snowball sampling (to ensure sampling is not
 254 restricted to key informants already known to the CRE in Melanoma members).³⁵ Sampling will be
 255 iterative, with decisions informed by the ongoing data analysis.³⁶ Recruitment strategies will include:
 256 (1) recruitment of healthcare professionals at relevant conferences and professional development
 257 activities; (2) identification of key stakeholders by members of the CRE in Melanoma; and (3)
 258 identification of additional key stakeholders by participants. The overarching recruitment strategy
 259 will be to select for interview individuals from around Australia whose experiences and professional
 260 roles within melanoma healthcare put them in a position to provide rich and relevant data.
 261 Recruitment will cease once data analysis indicates thematic saturation has been reached, this being
 262 the point at which our analysis allows us to provide a comprehensive and credible account of the
 263 structural, contextual and cultural factors impacting on implementation of the national clinical
 264 practice guidelines for SLNB in patients with melanoma in Australia. It is anticipated that between 50
 265 and 65 participants will be recruited in order to ensure a variety of perspectives and experiences
 266 from all relevant sectors in Australian melanoma care (20-25 GPs; 10-15 dermatologists; 20-25 other
 267 healthcare professionals and stakeholders).

268 *Sampling: documentary analysis*

269 Documentary materials relevant to the development and use of the national SLNB guidelines will be
 270 purposively sampled and included, based on their potential to provide background and contextual
 271 information relevant to study's aims (Box 1). Relevant documentary materials (such as
 272 commentaries and editorials, journal articles and white papers, books and brochures, event
 273 programs, newspapers, press releases, program proposals, summaries, organisational and
 274 institutional reports, questionnaire data, and public records) will be used to uncover meaning,
 275 develop understanding and discover insights relevant to the study's aim.

276 **Data collection**

277 *Questionnaires*

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

284 *Interviews*

285 Semi-structured interview guides have been developed for healthcare professionals and
 286 stakeholders based on a review of literature and through consultation with melanoma healthcare
 287 professionals (Table 3). The interview guides outline the major topics that will be discussed in the
 288 interviews and include a range of questions and prompts. Interviews will be face-to-face or by
 289 telephone (depending on participant preference) and will be audio-recorded and professionally
 290 transcribed. Field notes written up immediately after each interview will further inform and enrich
 291 data analysis.

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

Topics	Example questions
<i>Melanoma healthcare professionals</i>	
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?

294 SLNB: sentinel lymph node biopsy.

295 *Documentary analysis*

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

300 **Data analysis**

301 *Questionnaires*

302 Postcode will be classified using the Accessibility/Remoteness Index of Australia (ARIA), and Socio-
303 Economic Indexes for Areas (SEIFA) classifications.^{38,39} Descriptive analyses and multivariable
304 regression models will be used to examine factors related to SLNB practices and attitudes, and
305 familiarity with the Australian clinical practice guidelines for melanoma management, estimated
306 using probability ratios and 95% confidence intervals (CIs). Potential predictors that will be assessed
307 in the regression models include age, sex, type of practice, years of practice, number of invasive
308 melanomas diagnosed in a year, location of practice and GPs' exposure to information relating to
309 SLNB. All analyses will be conducted using SAS version 9.4 (SAS Institute Inc).

310 *Interviews*

311 The interview data will be analysed using thematic analysis and this analysis will initially be inductive
312 and data driven.^{40,41} The analysis will be informed by, but not necessarily limited to, the TICD
313 Checklist's seven domains: guideline factors; individual health professional factors; patient factors;
314 professional interactions; incentives and resources; capacity for organisational change; and social,

1
2
3 315 political, and legal factors.³⁰ The de-identified transcripts will be read by two members of the
4
5 316 research team. Data will be compared within and across interviews in order to identify
6
7 317 commonalities, differences and patterns in the data. Transcripts will be coded by two researchers
8
9 318 and a list of themes and categories relevant to the study's aim generated. These themes will then be
10
11 319 discussed with other members of the research team and refined until agreement is reached on those
12
13 320 most relevant to the study's aim. A thematic map will be developed and the data recoded to these
14
15 321 themes. Analytic memos will be written throughout the data analysis process.

16 322 *Documentary materials*

17
18 323 The analysis process will commence by assessing the authenticity and usefulness of each document,
19
20 324 taking into account the document's relevance to the study's aim, the original purpose of the
21
22 325 document, the context in which it was produced, and the intended audience.⁴² As with the interview
23
24 326 data, the documentary data will be analysed using thematic analysis.⁴¹

25 327 **Indirect Patient and Public Involvement**

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27
28 328 We did not directly include PPI in the design of this study, but the melanoma guidelines used in the
29
30 329 study were developed and updated by a committee that includes patient representatives.

31
32 330

33 331 **ETHICS AND DISSEMINATION**

34 332 **Ethics**

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36
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38 333 Ethical approval for the study has been granted by the University of Sydney Human Research Ethics
39
40 334 Committee (HREC), project numbers 2018/713 and 2019/308. Data collection and analysis will be
41
42 335 conducted in accordance with the Australian National Health and Medical Research Council National
43
44 336 Statement.⁴³ All participants will provide informed consent prior to taking part in the study.

45 337 **Data storage and protection**

46
47
48 338 Participant privacy and confidentiality will be maintained by removing all identifying information
49
50 339 from the transcripts, by assigning pseudonyms to participants, and by storing study data securely on
51
52 340 password-protected computers or in locked filing cabinets within university premises, to which only
53
54 341 named researchers from the research team will have access. Deidentified interview transcripts will
55
56 342 be stored separately from the file containing participant identifiers. All data will be destroyed 7 years
57
58 343 after completion of the study in accordance with standard ethical guidelines around storage of study
59
60 344 data.

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3 345 **Dissemination of study findings**
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5 346 Study findings will be disseminated via peer-reviewed journal publications, generalist publications,
6
7 347 presentations to the public, academics, clinicians, policymakers, melanoma consumers, and at
8
9 348 scientific conferences.

10
11 349 **SIGNIFICANCE AND IMPACT OF STUDY**
12

13 350 This is the first multi-methods study to investigate the structural, contextual and cultural factors
14
15 351 impacting the implementation of national SLNB guidelines in Australia. The study will bring to light
16
17 352 the range of professional perspectives on SLNB, document the discourse surrounding SLNB in
18
19 353 Australia and report on how these may be affecting uptake of SLNB in patients with melanoma. The
20
21 354 knowledge generated by this project will be used to inform future efforts to support effective and
22
23 355 widespread melanoma guideline implementation in Australia and internationally. A greater
24
25 356 awareness of the guidelines, and the patients with melanoma to whom they apply, should in turn
26
27 357 lead to improved melanoma management and outcomes for patients, including more accurate
28
29 358 information about prognosis and access to adjuvant systemic therapies such as immunotherapy or
30
31 359 BRAF-directed targeted molecular therapy for eligible melanoma patients. And finally, the
32
33 360 knowledge generated in this study will focus attention on the role of SLNB as a diagnostic and
34
35 361 prognostic tool in melanoma, the role it has to play in accurate melanoma staging and cancer
36
37 362 registry reporting, and the role SLNB plays in the design and conduct of melanoma clinical trials both
38
39 363 now and in the future.

37 364 **Author statement**
38

39 365 **Acknowledgements** We thank Sam Robinson for help in preparing the ethics application.
40

41
42 366 **Funding** This work was funded by the Melanoma Centre of Research Excellence grant (1135285)
43
44 367 from the Australian National Health and Medical Research Council. RLM received funding from an
45
46 368 NHMRC Translating Research into Practice (TRIP) Fellowship (1150989). AEC received a NHMRC
47
48 369 Career Development Fellowship (1147843) and Cancer Institute NSW Career Development
49
50 370 Fellowship (15/CDF/1-14).

51 371 **Competing interests** JFT has received honoraria for advisory board participation from BMS Australia,
52
53 372 MSD Australia, GSK and Provectus Inc, and travel support from GSK and Provectus Inc.

54
55 373 **Contributorship statement** FR, ALS, AEC, GJM, CGW, DEG, MH, AMH, JWK, GVL, VJM, RLM, RPMS,
56
57 374 RAS, AJS, JFT and JB were involved in the conception of the work; AEC, GJM, RAS, JB, JWK, RLM, AJS,
58
59 375 RPMS, MH were involved in acquisition of the funding; ALS, FR, JB, AEC were involved in the design
60

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3 376 of the work; ALS drafted the manuscript; FR, ALS, AEC, GJM, CGW, DEG, MH, AMH, JWK, GVL, VJM,
4
5 377 RLM, RPMS, RAS, AJS, JFT and JB were involved in critically revising the manuscript.
6

7
8 378 **Ethics approval** University of Sydney Human Research Ethics Committee, project numbers 2018/713
9
10 379 and 2019/308.

11
12 380 **Provenance and peer review** Not commissioned; externally peer reviewed.
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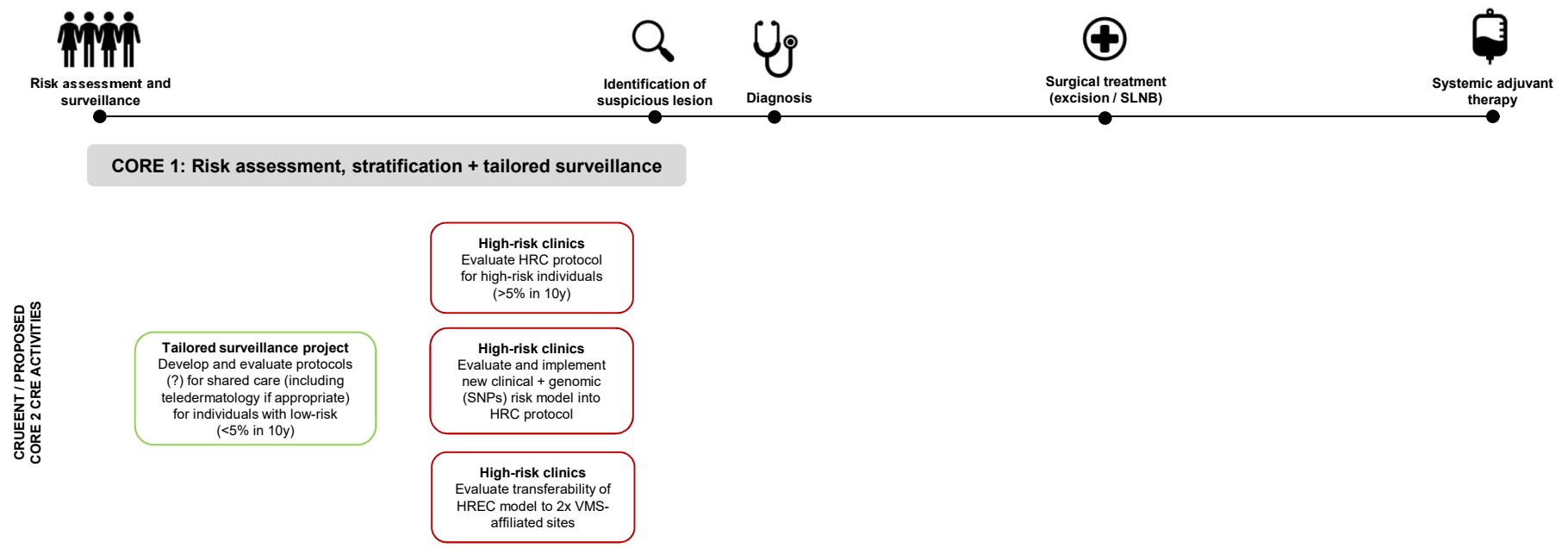
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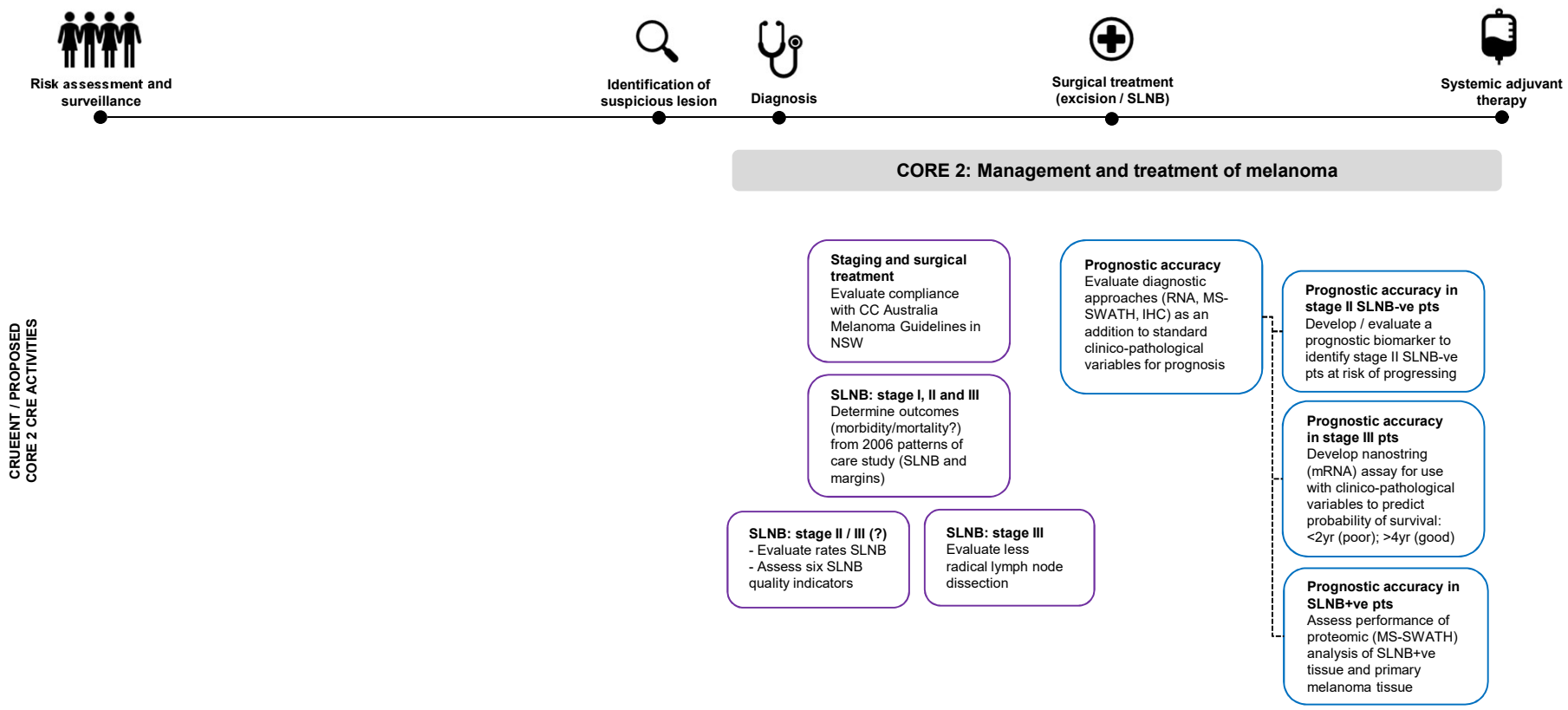
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Preliminary mapping exercise: melanoma care continuum / CRE in Melanoma activities

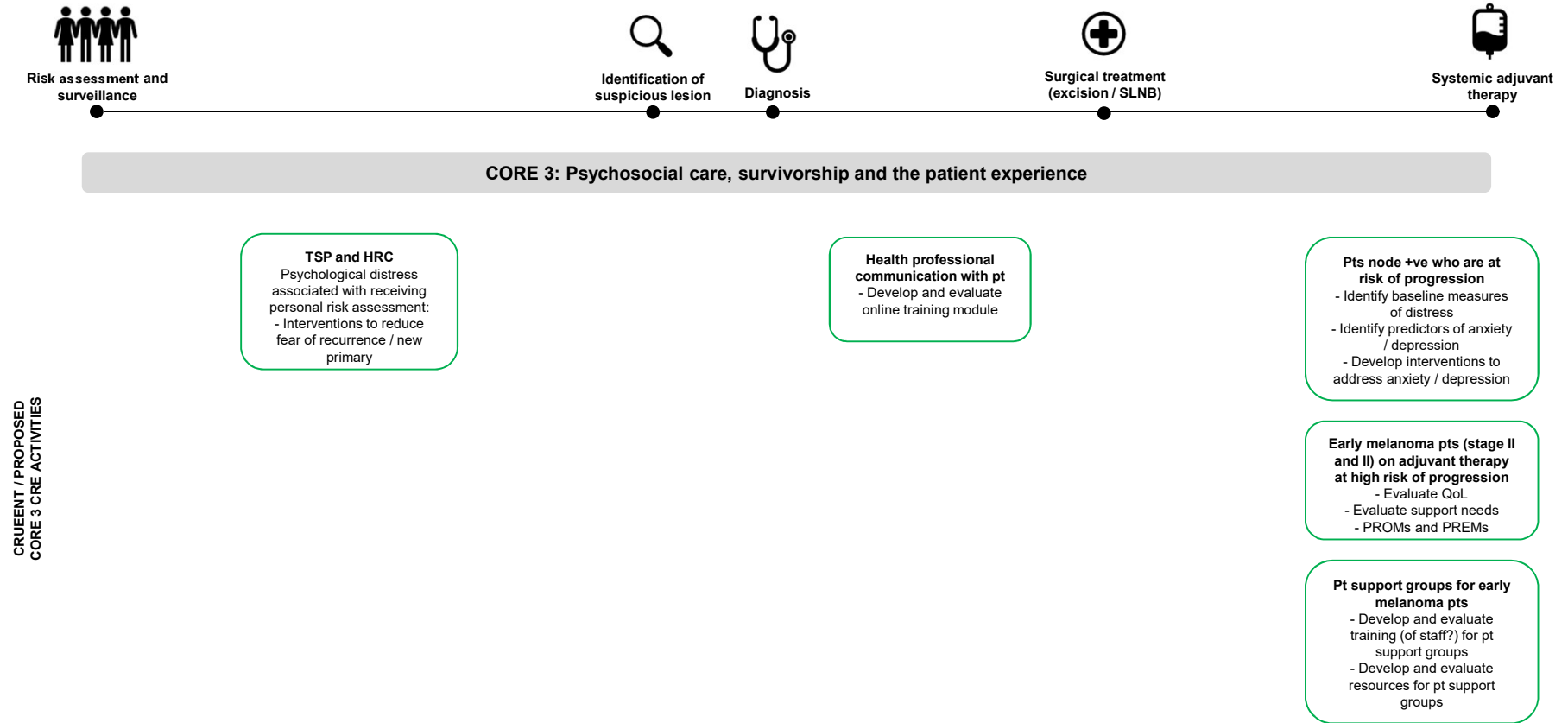


Preliminary mapping exercise: melanoma care continuum / CRE in Melanoma activities

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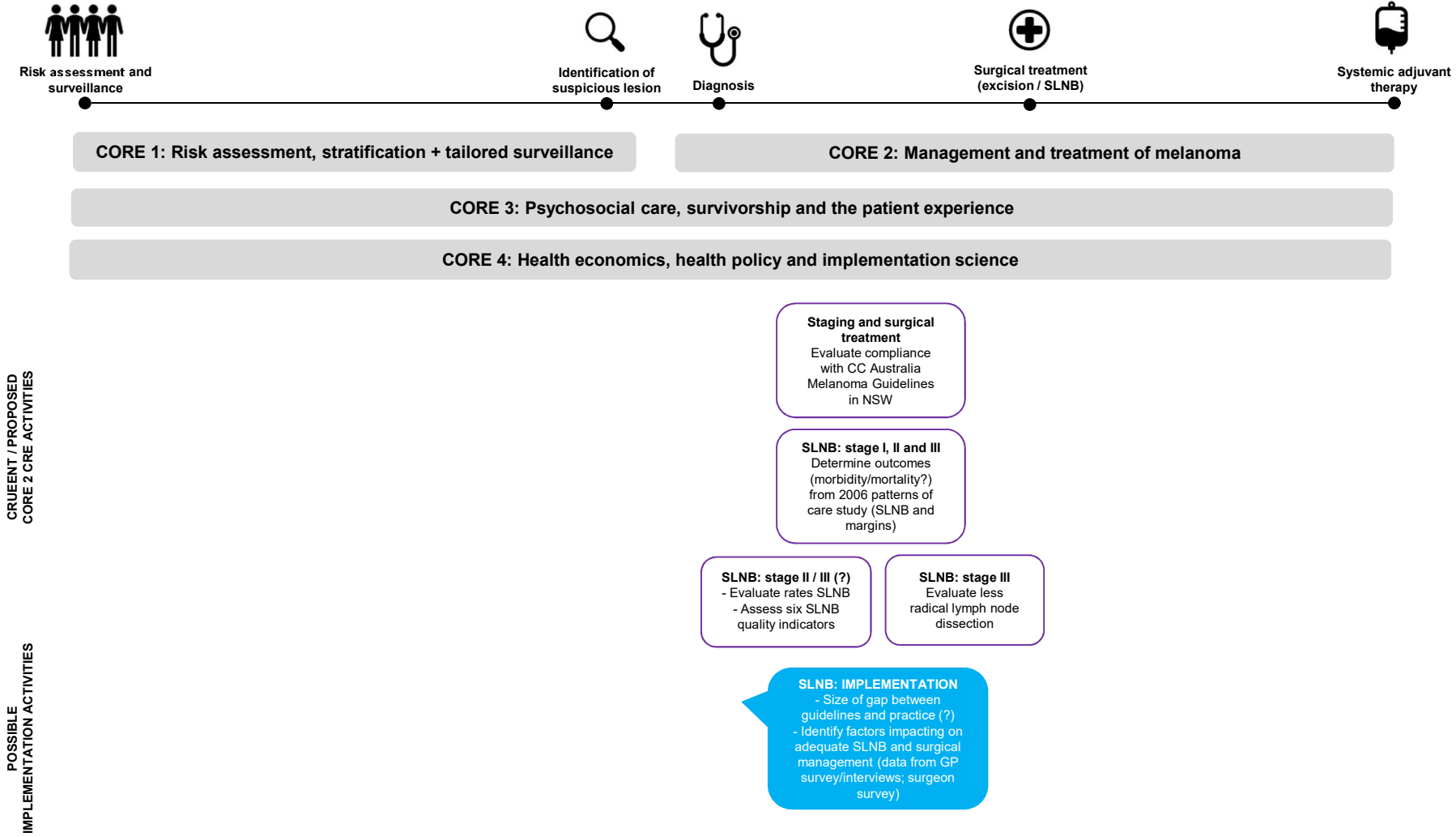
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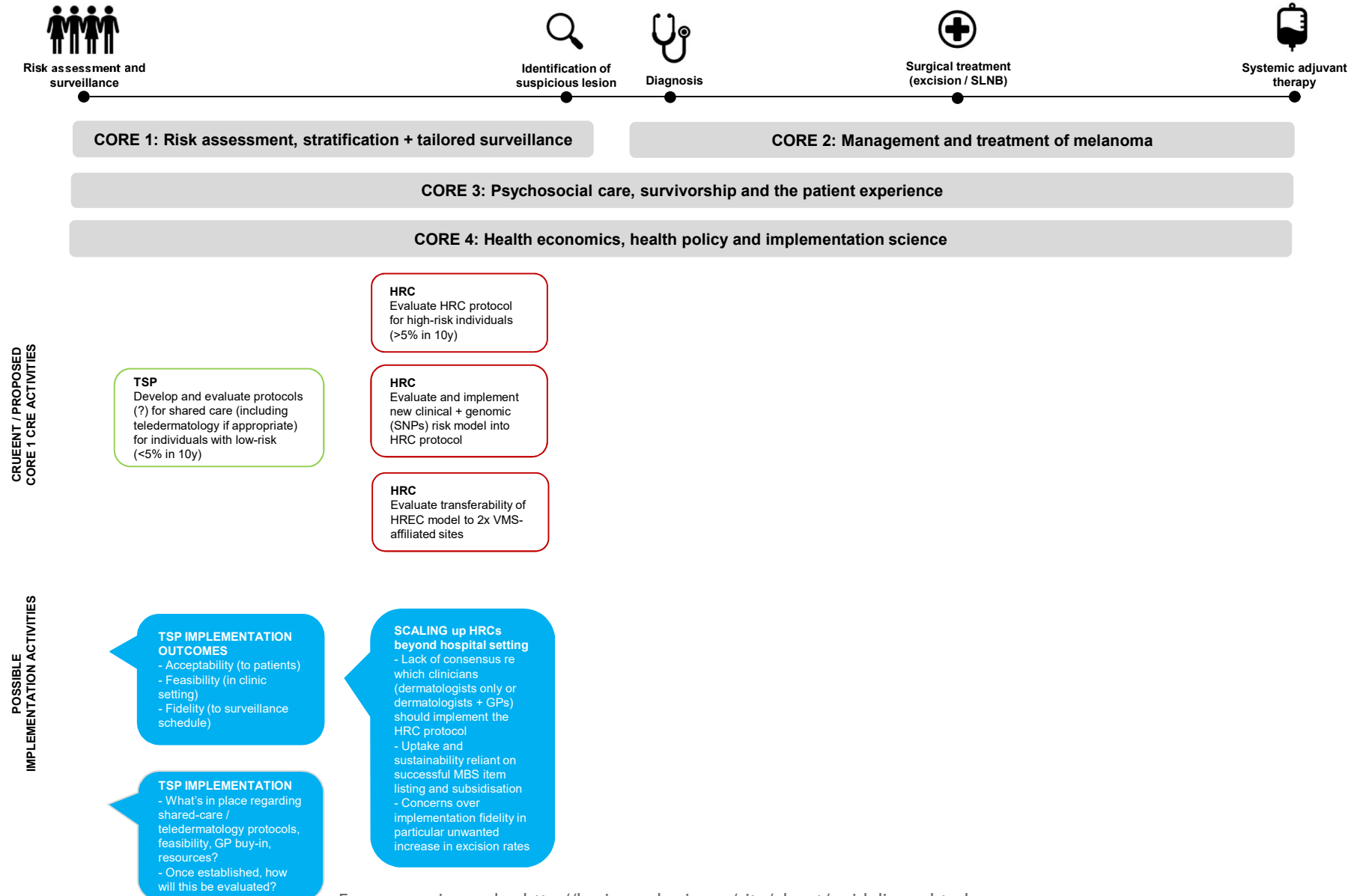
CRUJENT / PROPOSED
CORE 3 CRE ACTIVITIES

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



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





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

Melanoma management study, GP survey

For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

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8. Have you accessed the recent update of the national clinical practice guidelines for melanoma on the Cancer Council Australia website/Wiki?

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- 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): _____

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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 usually 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: _____

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3 17. Would you expect the clinician to whom you refer the patient, to recommend a sentinel lymph node
4 biopsy if they were eligible? **(tick one only)**

- 5 No, never
6 Occasionally
7 Most of the time
8 Yes, always
9

10 18. After a negative sentinel lymph node biopsy, are you wanting to be involved in ongoing patient follow-
11 up? **(tick one only)**

- 12 No
13 Yes, with follow-up managed mainly by myself
14 Yes, with follow-up managed mainly by the specialist
15 Yes, with follow-up managed in a shared care arrangement between the specialist and myself
16
17

18 19. After a positive sentinel lymph node biopsy, are you wanting to be involved in ongoing patient follow-
19 up? **(tick one only)**

- 20 No
21 Yes, with follow-up managed mainly by myself
22 Yes, with follow-up managed mainly by the specialist
23 Yes, with follow-up managed in a shared care arrangement between the specialist and myself
24
25

26 20. Are there any tests or scans that you would arrange for patients eligible for sentinel lymph node
27 biopsy? **(tick all that apply)**

- 28 No other tests or scans
29 Ultrasound examination of regional nodes
30 Chest X ray
31 CT Chest/abdomen/pelvis
32 Whole body PET-CT
33 CT or MRI scan of brain
34 Other, please specify: _____
35
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37 → Please go to question 22
38
39

40 *[Note Question 21 is only for those who selected 'No' at Question 12]*
41
42

43 21. Why would you not usually recommend sentinel lymph node biopsy? **(tick all that apply)**

- 44 Don't know much about it
45 Difficulty in accessing facilities for sentinel lymph node biopsy
46 No confirmed survival benefit
47 Does not add sufficient additional prognostic information
48 Does not impact subsequent management
49 The morbidity of the procedure
50 The morbidity of completion lymphadenectomy if the sentinel node is positive
51 Costs to the patient
52 Other, please specify: _____
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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

For peer review only

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

4 Yes → please enter your email address: _____.

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

6 No
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11 24. Please enter your email address if you would like to go into a lucky draw to win one of three iPads. The
12 draw will take place when recruitment to the study is complete.

13 Email address: _____

14 Your email address will not be linked to your survey responses and will be stored separately.
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18 *You have completed the questionnaire! Thank you very much for your time.*
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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

1 6. How many years have you been practising as a Dermatologist?
2

- 3 <5 years
4 6-10 years
5 11-20 years
6 21-30 years
7 31-40 years
8 >40 years
9

10 7. On a scale of 1 to 5, how familiar are you with the Australian “Clinical Practice Guidelines for the
11 Diagnosis and Management of Melanoma”?
12

13 **(tick ONE only)**

- 14 1 - Very unfamiliar
15 2 - Somewhat unfamiliar
16 3 - A little familiar
17 4 - Quite familiar
18 5 - Very familiar
19

20 8. Have you accessed the recent update of the Australian “Clinical Practice Guidelines for the Diagnosis and
21 Management of Melanoma” on the Cancer Council Australia website/Wiki?
22

- 23 No
24 Yes
25

26 9. Have you read any articles (e.g. in journals, magazines, newsletters) or listened to talks about sentinel
27 lymph node biopsy (SLNB) for melanoma in the last 3 years?
28

- 29 No → go to question 11
30 Yes → **tick ALL that apply**
31 Australasian Journal of Dermatology
32 Medical Journal of Australia (MJA)
33 Journal of the American Academy of Dermatology (JAAD)
34 British Journal of Dermatology (BJD)
35 New England Journal of Medicine (NEJM)
36 Other peer-reviewed journal, please specify: _____
37 Australian Conference
38 International Conference
39 Other, please specify _____
40

41 10. Do you think these articles or presentations have influenced your attitude to sentinel lymph node
42 biopsy for melanoma?
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- 1 No
2
3 Yes – more likely to recommend SLNB
4
5 Yes – less likely to recommend SLNB
6

7 How have they influenced you? _____
8
9

10 11. Do you think that sentinel lymph node biopsy has an important role in the management of melanoma
11 patients?
12

- 13 No → Why not? _____
14
15 Yes
16
17 Unsure → Why not? _____
18

19
20
21 12. Would you usually discuss and recommend sentinel lymph node biopsy to a patient with a newly
22 diagnosed melanoma, if eligible for sentinel lymph node biopsy?
23

- 24 No → go to question 13
25
26 Yes → go to question 14
27

28
29 **[Note Question 13 is only for those who selected 'NO' at Question 12]**
30

31 13. Why would you not usually recommend sentinel lymph node biopsy?
32

33 **(tick ALL that apply)**
34

- 35 Don't know much about it
36
37 No added value of sentinel lymph node biopsy
38
39 Difficulty in accessing facilities for sentinel lymph node biopsy
40
41 No confirmed overall survival benefit
42
43 Does not add additional prognostic information beyond what is provided by Breslow thickness
44
45 Does not impact subsequent management
46
47 The morbidity of the procedure
48
49 The morbidity of completion lymphadenectomy if the sentinel node is positive
50
51 Costs to the patient
52
53 Other, please specify: _____
54

55 **Continue to Question 23 [page 6]**
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1 **[Note Question 14 is only for those who selected 'YES' at Question 12]**

2
3 14. Why do you believe that sentinel lymph node biopsy may be of value for eligible patients?

4
5 **(tick ALL that apply)**

- 6 More accurate staging
- 7
- 8 To provide prognostic information
- 9
- 10 Likely survival benefit
- 11
- 12 Results may influence follow-up plan
- 13
- 14 To assess suitability for adjuvant systemic therapies if found to be sentinel lymph node positive
- 15
- 16 To select patients for completion lymphadenectomy
- 17
- 18 Improved regional control
- 19
- 20 Other (please specify): _____
- 21
- 22

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

25
26 **(tick ALL that apply)**

- 27
- 28 <0.80 mm
- 29
- 30 <0.80 mm with high-risk pathological feature/s
- 31
- 32 0.80 - 1.00 mm
- 33
- 34 0.80 - 1.00 mm with high-risk pathological feature/s
- 35
- 36 1.01 - 2.00 mm
- 37
- 38 2.01 - 4.00 mm
- 39
- 40 >4.00 mm
- 41
- 42 None of the above (I would not refer for SLNB)
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1 16. Would any of these factors influence your decision to discuss or recommend sentinel lymph node
2 biopsy to patients?
3

4 **(tick ALL that apply)**

- 5 Breslow thickness
- 6 Presence of ulceration
- 7 Mitotic rate of the melanoma
- 8 Lymphovascular invasion in the melanoma
- 9 Body site of the melanoma
- 10 Wide excision already performed
- 11 Type of wound closure following diagnostic biopsy
- 12 Presence of palpable regional lymph nodes
- 13 Histological subtype, e.g. desmoplastic, nodular, lentigo maligna melanoma
- 14 Age of the patient
- 15 Comorbidities of the patient
- 16 Possible morbidity of the sentinel lymph node biopsy procedure
- 17 Possible morbidity of completion lymphadenectomy
- 18 The likelihood that the results will influence patient management
- 19 Access to services for sentinel lymph node mapping and biopsy
- 20 Distance to services for sentinel lymph node mapping and biopsy
- 21 Costs to the patient
- 22 Patient level of anxiety
- 23 Patient preference
- 24 Other, please specify _____

25 17. For patients for whom sentinel lymph node biopsy would be suitable, who would you usually refer the
26 patient to for definitive management?
27

28 **(tick ONE only)**

- 29 A local general surgeon
- 30 Any surgical oncologist
- 31 A melanoma-trained surgical oncologist
- 32 Any plastic surgeon
- 33 A melanoma-trained plastic surgeon
- 34 A melanoma specialist dermatologist
- 35 A specialist melanoma service where there is a multidisciplinary team
- 36 None of the above (I would not refer for SLNB)

- 1 Other, please specify: _____

2
3 18. Would you expect the clinician to whom you refer the patient to recommend a sentinel lymph node
4 biopsy if they were eligible?

5
6 **(tick ONE only)**

- 7 No, never
8
9 Occasionally
10
11 Most of the time if appropriate for the patient's situation
12
13 Yes, always
14
15 I would not refer to a surgeon who routinely recommends SLNB
16

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

19
20 **(tick ONE only)**

- 21 No
22
23 Yes, with follow-up managed mainly by myself
24
25 Yes, with follow-up managed mainly by the surgeon
26
27 Yes, with follow-up managed in a shared care arrangement between the surgeon and myself
28

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

31
32 **(tick ONE only)**

- 33 No
34
35 Yes, with follow-up managed mainly by myself
36
37 Yes, with follow-up managed mainly by the surgeon or medical oncologist
38
39 Yes, with follow-up managed in a shared care arrangement between the surgeon or medical
40 oncologist and myself
41
42

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

45
46 **(tick ALL that apply)**

- 47 No other tests or scans
48
49 Ultrasound examination of regional nodes
50
51 Chest X ray
52
53 CT chest/abdomen/pelvis
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55 Whole body PET-CT
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57 CT or MRI scan of brain
58
59 Other, please specify: _____
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1 22. Are there any tests or scans that you would arrange for follow-up of patients diagnosed with melanoma
2 >1 mm?
3

4 **(tick ALL that apply)**

- 5 No other tests or scans
6
7 Ultrasound examination of regional nodes
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9 Chest X ray
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11 CT chest/abdomen/pelvis
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13 Whole body PET-CT
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15 CT or MRI scan of brain
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Continue to next page

For peer review only

ID number: _____

1 23. Would you like to receive a summary of the results of this study after it has been completed, in about 1
2 years' time?
3

4 Yes → please enter your email address: _____
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6 *Your email address will not be linked to your survey responses and will be stored separately.*
7

8 No
9

10 24. Would like to go into a lucky draw to win one of three iPads? The draw will take place when recruitment
11 to the study is complete.
12

13 Yes → please enter your email address: _____
14

15 *Your email address will not be linked to your survey responses and will be stored separately.*
16

17 No
18

19 25. Would you be willing to be contacted by the research team for a 20-minute confidential interview to
20 discuss risk factors, diagnosis and management of patients with melanoma by dermatologists? We would
21 reimburse your time with a \$100 Coles/Myer gift voucher.
22

23 Yes → Please enter your contact details below and ask the research team for a Participant
24 Information Sheet and Consent form for the interview study. Your contact details will be stored
25 separately to your survey and interview data.
26

27 No
28
29

30 Your Name: _____
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33 Best contact phone number: _____
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36 Email address: _____
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39 Best time and/or day of the week: _____
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45 ***You have completed the questionnaire! Thank you very much for your time.***
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