Jobson Dale (Orcid ID: 0000-0002-5918-3484)
Gyorki David E (Orcid ID: 0000-0002-3165-4694)
Soyer H. Peter (Orcid ID: 0000-0002-4770-561X)

Development of Melanoma Clinical Quality Indicators for the Australian Melanoma Clinical Outcomes Registry (MelCOR): a modified Delphi study

Corresponding author:
Associate Professor Victoria Mar
Alfred Hospital
55 Commercial Road, Melbourne 3004
Victoria, Australia
Tel: +61 3 9076 2000
victoria.mar@monash.edu.au

Funding statement
No funding was obtained for this specific publication however the overall MelCOR project is funded by the Melanoma Institute of Australia.

Ethics Statement
This study was approved by the Alfred Hospital Ethics Committee (ref 190/21).

Acknowledgement statement
We would like to thank all the participants, organizations and public who have contributed to the MelCOR project to date.

GVL is supported by NHMRC Practitioner Fellowship and the University of Sydney Medical Foundation.

MS was supported by a Victorian Agency Clinical Fellowship

HPS holds an NHMRC MRFF Next Generation Clinical Researchers Program Practitioner Fellowship (APP1137127).

Conflicts of interest
GVL is consultant advisor for Aduro Biotech Inc, Amgen Inc, Array Biopharma inc, Boehringer Ingelheim International GmbH, Bristol-Myers Squibb, Evaxion Biotech A/S, Hexel AG, Highlight Therapeutics S.L., Merck Sharpe & Dohme, Novartis Pharma AG, OncoSec, Pierre Fabre, QBiotics Group Limited, Regeneron Pharmaceuticals Inc, SkylineDX B.V., Specialised Therapeutics Australia Pty Ltd.

RAS has received fees for professional services from F. Hoffmann-La Roche Ltd, Evaxion, Provectus Biopharmaceuticals Australia, Qbiotics, Novartis, Merck Sharp & Dohme, NeraCare, AMGEN Inc., Bristol-Myers Squibb, Myriad Genetics, GlaxoSmithKline

HPS is a shareholder of MoleMap NZ Limited and e-derm consult GmbH, and undertakes regular teledermatological reporting for both companies. HPS is a Medical Consultant for Canfield Scientific Inc, MoleMap Australia Pty Ltd, Blaze Bioscience Inc, Revenio Research Oy

and a Medical Advisor for First Derm.

CJM, HPS and SS are currently on the AJD Editorial board.

Keywords
clinical quality indicators, melanoma, Australia, clinical registry, delphi

Author details
Dr Dale Jobson
ORCID ID: 0000-0002-5918-3484
email: dalewjobson@gmail.com
Affiliations
Victorian Melanoma Service, Alfred Hospital
School of Public Health and Preventative Medicine, Monash University

Mr Benjamin Roffey
ORCID ID: N/A
email: benjamin.roffey@monash.edu
Affiliations
School of Public Health and Preventative Medicine, Monash University

Mr Christopher Arnold AM
ORCID ID:
email: chris@hodgsonassoc.com.au
Affiliations
Hodgson Associates, Melbourne, Australia
Biogrid Australia, Parkville, Australia

Dr Anthony Azzi
ORCID ID: 0000-0002-5263-5046
Email: tony@newcastleskincheck.com.au
Affiliations
Newcastle Skin Check, Newcastle, Australia
School of Medicine, University of Queensland
Skin Cancer Institute, Singapore
Skin Cancer College Australasia, Auchenflower, Australia
Australian College of Rural and Remote Medicine, Brisbane, Australia

Ms Alison Button-Sloan
ORCID ID:
email: buttonsloan@bigpond.com
Affiliations
Australian Melanoma Consumer Alliance, Melbourne, Australia

Ms Tamara Dawson
ORCID ID:

email: info@mscan.org.au
Affiliations
Melanoma and Skin Cancer Advocacy Network, Carlton, Victoria

Prof Pablo Fernandez-Penas
ORCID ID: 0000-0003-4882-1564
email: pablo.fernandezpenas@sydney.edu.au
Affiliations
Sydney Medical School, The University of Sydney, New South Wales, Australia
Department of Dermatology, Westmead Hospital, Westmead, New South Wales, Australia

A/Prof Paul Fishburn
ORCID ID: 0000-0002-4413-0638
email: drpaulfishburn@ozemail.com.au
Affiliations
Faculty of Medicine, University of Queensland, Brisbane, Australia
Norwest Skin Cancer Centre, Bella Vista, NSW, Australia

A/Prof David E Gyorki
ORCID ID: 0000-0002-3165-4694
email: David.Gyorki@petermac.org
Affiliations
Division of Cancer Surgery, Peter MacCallum Cancer Centre, Melbourne, Australia
Sir Peter MacCallum Department of Oncology, University of Melbourne

Dr. Emma L Hiscutt
ORCID ID:
email: drehiscutt@gmail.com
Affiliations
School of Public Health and Preventative Medicine, Monash University,
Victorian Melanoma Service, Alfred Hospital

Ms Valerie Jakrot
ORCID ID: 0000-0002-8578-5964
email: Valerie.jakrot@melanoma.org.au
Affiliations
Melanoma Institute Australia, Sydney, Australia
The University of Sydney, North Sydney, NSW, Australia

Dr Alister Lilleyman
ORCID ID:
email: amlilley@bigpond.net.au
Affiliations
Skin Cancer College Australasia, Auchenflower, Australia

Australian College of Rural and Remote Medicine, Brisbane, Australia

Dr Alistair Lochhead
ORCID ID:
email: Alistair.Lochhead@southernpath.com.au
Affiliations
Southern IML Pathology, Wollongong, Australia
Department of Anatomical Pathology, Wollongong Hospital, Wollongong, Australia
Graduate School of Medicine, University of Wollongong

Prof Georgina V Long
ORCID ID: 0000-0001-8894-3545
email: georgina.long@sydney.ed.au
Affiliations
Melanoma Institute Australia, The University of Sydney, Sydney, Australia
Faculty of Medicine and Health, The University of Sydney, Sydney, Australia
Department of Medical Oncology, Royal North Shore hospital, Sydney, Australia
Mater Hospital, Sydney, Australia

Ms Sonia Mailer
ORCID ID:
email: sonia.mailer@petermac.org
Affiliations
Melanoma Research Victoria, Melbourne, Victoria 3000, Australia
Peter MacCallum Cancer Centre, Melbourne, Victoria 3000, Australia
Sir Peter MacCallum Department of Oncology, The University of Melbourne, Victoria 3010, Australia

Prof Graham Mann
ORCID ID: 0000-0003-1301-405X
email: graham.mann@anu.edu.au
Affiliations
Melanoma Institute Australia, The University of Sydney, NSW, Australia
The John Curtin School of Medical Research, The John Curtin School of Medical Research, Australian National University, ACT, Australia

A/Prof Christopher J McCormack
ORCID ID:
email: chris@caulfielddermatology.com.au
Affiliations
Department of Surgical Oncology, Peter MacCallum Cancer Centre, Melbourne, Australia

A/Prof Jim Muir
ORCID ID: 0000-0003-3791-161X
email: muirmed@outlook.com
Affiliations
University of Queensland, Brisbane, Australia

Mater Hospital, Brisbane, Australia

Dr George F Pratt
ORCID ID:
email: drgpratt@gmail.com
Affiliations
Plastic and Reconstructive Unit, Monash Health, Dandenong, Australia
Plastic and Reconstructive Surgery, Peninsula Health, Frankston, Australia

Prof Richard A. Scolyer
ORCID ID: 0000-0002-8991-0013
email: Richard.Scolyer@health.nsw.gov.au
Affiliations
Melanoma Institute Australia, The University of Sydney, North Sydney, NSW, Australia
Faculty of Medicine and Health, The University of Sydney, Sydney, NSW, Australia
Tissue Pathology and Diagnostic Oncology, Royal Prince Alfred Hospital and NSW Health Pathology, Sydney, NSW, Australia
Charles Perkins Centre, The University of Sydney, Sydney, NSW, Australia

Prof Mark Shackelton
ORCID ID: 0000-0002-7673-4655
email: Mark.Shackleton@monash.edu
Affiliations
Central Clinical School and School of Public Health and Preventive Medicine, Monash University, Prahran, Australia
Department of Oncology, Alfred Health, Prahran, Australia

A/Prof Stephen Shumack
ORCID ID: 0000-0002-9121-7795
email: sshumack@iinet.net.au
Affiliations
Royal North Shore Hospital, Sydney, Australia

Prof H. Peter Soyer
ORCID ID: 0000-0002-4770-561X
email: p.soyer@uq.edu.au
Affiliations
The University of Queensland Diamantina Institute, The University of Queensland, Dermatology Research Centre, Brisbane, Australia
Dermatology Department, Princess Alexandra Hospital, Brisbane, Australia

Dr Chin-Guan Tan
ORCID ID:
email: Guan.Tan@mps.com.au
Affiliations
Melbourne Pathology, Collingwood, Australia

Dr Angela Webb
ORCID ID: 0000-0002-0659-8029
email: dr.a.webb@gmail.com
Affiliations
Division of Cancer Surgery, Peter MacCallum Cancer Centre, Melbourne, Australia
Sir Peter MacCallum Department of Oncology, University of Melbourne
Skin Health Institute, Carlton, Australia

Prof John Zalcberg
ORCID ID: 0000-0002-6624-0782
email: john.zalcberg@monash.edu
Affiliations; Department of Medical Oncology, Alfred Health and
School of Public Health and Preventative Medicine, Faculty of Medicine, Nursing and Health Sciences, Monash University. Melbourne, Australia

Prof Rachael Morton
ORCID ID: 0000-0001-7834-0572
email: rachael.morton@sydney.edu.au
Affiliations
NHMRC Clinical Trials Centre, University of Sydney, Sydney, Australia
Melanoma Institute Australia, Sydney, Australia

A/Prof Victoria Mar
ORCID ID: 0000-0001-9423-3435
email: victoria.mar@monash.edu
Affiliations
Victorian Melanoma Service, Alfred Hospital
School of Public Health and Preventative Medicine, Monash University

Development of Melanoma Clinical Quality Indicators for the Australian Melanoma Clinical Outcomes Registry (MelCOR): a modified Delphi study

ABSTRACT

Background: Clinical quality registries aim to identify significant variations in care and provide anonymised feedback to institutions to improve patient outcomes. Thirty-six Australian organisations with an interest in melanoma, raised funds through three consecutive Melanoma Marches, organised by Melanoma Institute Australia, to create a national Melanoma Clinical Outcomes Registry (MelCOR). This study aimed to formally develop valid clinical quality indicators for the diagnosis and early management of cutaneous melanoma as an important step in creating the registry.

Methods: Potential clinical quality indicators were identified by examining the literature, including Australian and international melanoma guidelines, and by consulting with key melanoma and registry opinion leaders. A modified two-round Delphi survey method was used, with participants invited from relevant health professions routinely managing melanoma as well as relevant consumer organisations.

Results: Nineteen participants completed at least one round of the Delphi process. 12 of 13 proposed clinical quality indictors met the validity criteria. The clinical quality indicators included acceptable biopsy method, appropriate excision margins, standardised pathology reporting, indications for sentinel lymph node biopsy, and involvement of multidisciplinary care and referrals.

Conclusion: This study provides a multi-stakeholder consensus for important clinical quality indicators that define optimal practice that will now be used in the Australian Melanoma Clinical Outcomes Registry (MelCOR).

Keywords

clinical quality indicators, melanoma, Australia, clinical registry, delphi

Introduction

International studies have shown many patients do not receive medical care consistent with clinical guidelines (1, 2). This is also true for Australians with melanoma, with a landmark study finding many did not receive recommended treatment (3).

Clinical quality registries (CQRs) are an effective means to determine the extent of variation in care and the impact of that variation on clinical and patient outcomes. CQRs aim to provide anonymised, comparative clinical performance data back to health service providers to help them address any significant variations in care. The implementation of CQRs, particularly in the setting of cancer, has been shown to improve patient outcomes (4). The Australian Commission for Safety and Quality in Health Care recommended a nationally consistent approach to the collection and reporting of indicators to monitor the safety and quality of health care delivery (5).

Despite Australia having the highest rate of melanoma in the world, a standardised and systematic approach to data collection and the subsequent reporting of quality indicators to monitor patient outcomes does not exist (6, 7). Whilst, some data is collected by multiple jurisdictional epidemiological-based cancer registries and individual institutional databases, these datasets are currently not standardized and do not provide sufficient clinical detail to monitor quality of care or influence practice. In 2018, thirty-six Australian organisations with an interest in melanoma set out to create a national Melanoma Clinical Outcomes Registry (MelCOR) for the diagnosis and early management of melanoma. The Melanoma Institute Australia oversaw public fundraising efforts to enable the creation and pilot operations of MelCOR.

Before a registry can be created, stakeholders must identify and agree which clinical quality indicators reflect optimal, evidence-based practice within real world settings. Quality indicators need to be objective, measurable and feasible to collect, and have traditionally been classified into three distinct domains (8):

1. Structural - denotes the attributes of the settings in which care occurs (for example, facilities, qualifications of personnel or clinical volume);

2. Processes - denotes what is actually being done in giving and receiving care (for example, recommended diagnostic techniques or treatment);
3. Outcomes - denotes the effects of care on the health status of patients or populations (for example, monitoring local or distant disease recurrence).

We aimed to develop a set of clinical quality indicators for the diagnosis and early management of cutaneous melanoma as an important step in creating a national melanoma clinical outcomes registry.

Methods

Process to develop and validate clinical quality indicators

A modified two-round RAND/University of California Los Angeles Appropriateness Method (RAM) was used to select and validate clinical quality indicators (9). This is a well described method that combines high quality scientific evidence with the collective judgement of experts to yield a consensus statement. In this case, we sought to elucidate appropriate and feasible clinical quality indicators for the diagnosis and early management of cutaneous melanoma.

Clinical quality indicator development

Proposed indicators were developed by a panel of melanoma and registry experts from a comprehensive literature review, review of national and international melanoma clinical practice guidelines, and international melanoma quality indicator development studies (10-17). All proposed indicators were consistent with the Australian Clinical Practice Melanoma Guidelines recommendations, based on evidence derived from published research studies (10). Clinical quality indicators were divided into distinct components: numerators (target events), denominators (populations of interest), and exclusions (members of the population who should not be included) (Table 1). The clinical quality indicators proposed covered two domains: structure and process (8). Outcome domains were not proposed because of the limited feasibility for collecting information about recurrence or metastasis at this stage as events can take years to occur and patient follow up can be highly variable across the country.

Table 1. Example of a proposed clinical quality indicator for cutaneous melanoma.

Quality Indicator	Detail	Exclusions
All critical data points are reported on the pathology report	Numerator: Completed synoptic pathology report Denominator: All pathology reports	*In situ* melanoma

Participants

Participation was open to all relevant stakeholders. Relevant national organisations with both expertise and involvement in melanoma care were identified and invited to participate in the process to ensure a diversity of viewpoints. Each individual participant was also encouraged to invite additional qualified colleagues.

Clinical quality indicator validation

A modified two round Delphi process was conducted (Supplementary Figure 1). The first round asked participants to independently rate each of the proposed clinical quality indicators for appropriateness and feasibility. Appropriateness was defined as the degree to which an indicator was objective, measurable, and reflective of best practice within real world settings, particularly given the need to collect data from pathology reports which are mandated by legislation to be provided to each of the State/Territory epidemiological (population-wide) registries.

Feasibility was defined as the degree to which an indicator was easily and objectively measurable from pathology reports, without requiring additional information from clinicians or patients. Each indicator was rated via an online survey using a nine-point Likert scale with 1 – 3 described as 'Not Appropriate/Feasible', 4 – 6 as 'Uncertain' and 7 – 9 as 'Appropriate/Feasible'. Summary statistics were calculated from the first round and sent to all participants.

Following the first round, participants were invited to an online video meeting (face to face meetings were not possible because of the COVID-19 pandemic restrictions) co-chaired by a

dermatologist and a registry expert to discuss and amend each indicator. Participants were given an opportunity to propose new indicators or alter the wording of proposed indicators. A second survey with the amended and new indicators was then sent to all participants for another round of rating via an online survey. Indicators were deemed valid if more than 75% of participants rated it 7 – 9 (Appropriate/Feasible), and the mean score of all participants fell within that same band. Summary statistics were calculated and indicators that met validity criteria on the second round were deemed to be valid. Statistical methods used were consistent with other Delphi processes encountered in the literature review (15-17).

Results

Out of the thirty-six Australian organisations who set out to create MelCOR, twenty-three were identified as having the relevant expertise and were invited to participate in the Delphi study (Supplementary Table 1). Seventeen of the twenty three invited organisations had members present with a diverse range of specialities represented including dermatologists, pathologists, general practitioners, surgeons, oncologists, nurses, consumers, authors of the Australian Melanoma Guidelines (10), and members of the MelCOR steering committee (Table 2). All organisations had also contributed to the development of the Australian Melanoma Clinical Guidelines (10). Nineteen participants completed at least one round of the process. Fourteen participants rated clinical quality indicators in the first round, 14 attended the online discussion and 19 participants rated the amended and newly proposed clinical quality indicators in the final round.

Table 2. Specialties represented in the development of the MelCOR quality indicators.

Specialities Represented	Participants (n)
Dermatology	5
Pathology	3
Surgery	3
General Practice	3
Consumer	2
Nursing	2
Medical Oncology	1

During the first round, 2 of 12 proposed clinical quality indicators met validity criteria for both appropriateness and feasibility. Panel discussion resulted in the amendment of the remaining 10 clinical quality indicators and the proposal of one additional clinical quality indicator. Participants attending the online discussion included dermatologists (n=5), oncologists (n=2), pathologists (n=2), nurses (n=2), a surgeon (n=1), a general practitioner (n=1) and a consumer representative (n=1). In the final round, 12 of 13 of the amended and newly proposed clinical quality indictors met the validity criteria for both appropriateness and feasibility (Table 3 & 4).

Table 3. Twelve Melanoma Quality Indicators rated as valid.

Quality Indicator	Detail	Exclusions	Domain
Complete excisional biopsy (punch or ellipse) is used for initial diagnostic biopsy	Numerator: Pathology report where either biopsy type is stated as ellipse or biopsy type is stated as punch and margins are clear	Lentigo maligna	Process
	Denominator: All diagnostic biopsy reports		
Shave biopsy technique should only be used for the diagnosis of clinically suspected in situ melanoma	Numerator: Histopathology reported as melanoma in situ or <0.5mm Breslow thickness	No exclusions	Process
	Denominator: All histopathology biopsy reports where biopsy type is shave		
Radial margin is not involved in initial diagnostic biopsy	Numerator: Number of initial diagnostic biopsy reports where the radial margin is clear of tumour	Lentigo maligna	Process
	Denominator: All diagnostic biopsies		
Deep margin of initial diagnostic biopsy is clear of tumour	Numerator: Initial diagnostic biopsy where the deep margin is reported as clear of tumour	No exclusions	Process
	Denominator: All diagnostic biopsies		
All critical data points are reported on the pathology report	Numerator: Completed synoptic pathology report	In situ melanoma	Process
	Denominator: All pathology reports		
Wide local excision for invasive melanoma has been performed	Numerator: Reports of 'wide local excision' for invasive melanoma in which there is (at least) no residual melanoma at the margin	No exclusions	Process
	Denominator: All cases of invasive melanoma		

Sentinel lymph node biopsy is performed when Breslow thickness >1mm	Numerator: Tumours with a Breslow thickness > 1mm with evidence of a SLNB being performed	No exclusions	Process
	Denominator: All tumours with a Breslow thickness > 1.00mm		
Sentinel lymph node biopsy is performed when Breslow Thickness is between 0.8mm-1mm with other prognostic features (ulceration and/or mitotic index > 1 per mm^2)	Numerator: Tumours with a Breslow thickness between 0.8mm-1mm with other poor prognosis features (ulceration and/or mitotic index > 1 per mm^2) with evidence of a SLNB being performed	No exclusions	Process
	Denominator: Number of tumours with a Breslow thickness between 0.8mm-1mm with ulceration and/or mitotic index > $1mm^2$		
Radiological scans should not be performed on asymptomatic patients with stage 0 - II disease	Numerator: Patients with stage 0-II melanoma who do not have a radiological scan	No exclusions	Process
	Denominator: All patients with stage 0-II melanoma		
Patients with a positive sentinel lymph node biopsy are referred to a medical oncologist	Numerator: Patients with positive sentinel lymph node referred to a medical oncologist	No exclusions	Structure
	Denominator: All patients with a positive sentinel lymph node		
Completion lymph node dissection should not be performed following a positive sentinel lymph node biopsy	Numerator: Patients without a reported complete lymph node dissection	No exclusions	Process
	Denominator: All patients with a positive sentinel node biopsy		
Patients with stage III or IV melanoma should be discussed by a multidisciplinary melanoma team to plan management	Numerator: Stage III or IV patients discussed by multidisciplinary melanoma team	No exclusions	Structure
	Denominator: All patients diagnosed with stage III or stage IV melanoma		

Table 4. One Melanoma Quality Indicator that did not meet validity criteria.

Quality Indicator	Detail	Exclusion	Area
Patients should be referred to a genetic testing service if they are high risk (defined as having 3 or more first or second-degree family members with melanoma where predictive features are present: multiple primary melanomas, early age of onset, or pancreatic cancer)	Numerator: High risk patients	No exclusions	Process
	Denominator: All patients		

Discussion

We developed 12 clinical quality indicators that reflect optimal practice for the early management of cutaneous melanoma and are thought to be feasible to collect, predominantly from pathology reports of resected tumours. This is an important step in creating a National Melanoma Clinical Outcomes Registry and improving outcomes for melanoma patients in Australia.

Melanoma is the third most common cancer in Australia with approximately 16,000 new invasive and over 23,000 *in situ* melanomas diagnosed each year with approximately 1,300 deaths annually (18). Early diagnosis and appropriate management of cutaneous melanoma is associated with excellent patient outcomes (19). Comprehensive Australian clinical guidelines were first introduced by the Australian Cancer Network in 1999 to improve the consistency and quality of care delivered to patients and have been continually updated since that time to reflect best practice (10, 20). A large prospective cohort study reported poor adherence to Australian clinical guidelines for surgical margins (one third of patients), with over-treatment in just under half of patients, and under-treatment in one fifth of patients resulting in increased locoregional recurrence rates (3). This highlights the need to develop clinical quality indicators to allow institutions and practices to benchmark outcomes of service provision.

The development of clinical quality indicators for melanoma using a modified Delphi process has been performed in the USA, Italy and Germany (15-17). Traditionally an expert panel is selected, however we opted to use an 'open invitation' model to encourage diverse stakeholder participation. The scope of our quality indicators focused on clinical aspects of melanoma care including pathology reporting, biopsy technique, surgical margins, sentinel lymph node biopsy indicators and multidisciplinary care. These were similar to clinical measures used by other groups which have developed quality indicators (15-17). We ensured that all the validated clinical quality indicators were consistent with both national and international melanoma clinical practice guidelines (10, 13). We deliberately focused on clinical aspects of care that have been shown to impact patient outcomes and can be feasibly collected using existing data rather than requiring a manual extraction of electronic records at multiple health services (including primary care, hospital, and specialist

practices). In the future, we plan to collect additional melanoma quality indicators, including patient reported outcome measures (21). These patient outcome measurements are currently being collected in more mature melanoma national databases such the Canadian Melanoma Research Network (22).

Ultimately, we aim to collect data pertinent to our consensus clinical quality indicators from public and private health services and provide anonymous feedback to each participating centre or practice. This feedback will inform variations from agreed best practice (as defined by the quality indicators) and, in due course, guide change to processes that seek to improve outcomes for Australians with melanoma. We are not aware of data that examines the impact of melanoma clinical quality registries on patient outcomes; however, such registries have been attributed to improved outcomes in other cancers (4, 23). For example, the implementation of quality indicators in the Danish Lung Cancer Registry and Manchester Polyposis Registry for colorectal cancer were associated with an improvement in patient survival (24, 25).

While our clinical quality indicators were rated as feasible to collect, collecting the required data from the many relevant entities involved will be a challenge, compounded by the disparate locations and medical workforce involved in treating primary cutaneous melanoma in Australia including independent primary care clinics. To address this, we have increased the feasibility of data collection by designing quality indicators that will mostly be collected from pathology reports. Our quality indicators will undergo further evaluation once the feasibility is established in real world pilot testing of data collection. Given rapid advances in the field, particularly with respect to adjuvant therapies, we expect best practice and management guidelines to evolve as trial data in this space matures. As such, clinical quality indicators need to evolve to reflect emerging knowledge and new indicators may be defined for future inclusion in the registry.

Our melanoma clinical quality indicators are limited to the diagnosis and early management of cutaneous melanoma, as this was identified by stakeholders as the most critical need with perceived problems of deviation from recommended practice and hence defined the initial scope of the registry. In addition, while participation in the development of quality

indicators was open to all individuals from invited organizations, we only had a total of 19 participants, albeit from diverse backgrounds with representation from nearly all invited organisations, disciplines, and consumer groups. While representative, this is a small sample of all the clinicians and stakeholders involved in early melanoma care in Australia and thus our list of indicators may not reflect all stakeholder viewpoints. Before MelCOR formally adopts the indicators proposed by the Delphi process, public comment will be invited from all relevant stakeholders.

Using a modified Delphi process, we identified twelve clinical quality indicators that were deemed appropriate, feasible and consistent with best practice Australian guidelines for early management of melanoma. This study marks an important step in the creation of the Australian Melanoma Clinical Outcomes Registry (MelCOR).

References

1. McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, et al. The quality of health care delivered to adults in the United States. New England Journal of Medicine. 2003;348(26):2635-45.
2. Hillner BE, Smith TJ. The quality of cancer care: does the literature support the rhetoric? Institute of Medicine Background Paper, USA. 1999.
3. Varey AH, Madronio CM, Cust AE, Goumas C, Mann GJ, Armstrong BK, et al. Poor adherence to national clinical management guidelines: a population-based, cross-sectional study of the surgical management of melanoma in New South Wales, Australia. Annals of Surgical Oncology. 2017;24(8):2080-8.
4. Hoque DME, Kumari V, Hoque M, Ruseckaite R, Romero L, Evans SM. Impact of clinical registries on quality of patient care and clinical outcomes: a systematic review. PLOS One. 2017;12(9):e0183667.
5. Austalian Commission of Safety Quality in Health Care. Prioritised List of Clinical Domains for Clinical Quality Registry Development. ACSQHC Sydney; 2016.
6. Ferlay J, Soerjomataram I, Dikshit R, Eser S, Mathers C, Rebelo M, et al. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. International Journal of Cancer. 2015;136(5):E359-E86.
7. Aitken JF, Youlden DR, Baade PD, Soyer HP, Green AC, Smithers BM. Generational shift in melanoma incidence and mortality in Queensland, Australia, 1995–2014. International Journal of Cancer. 2018;142(8):1528-35.
8. Donabedian A. The quality of care: how can it be assessed? JAMA. 1988;260(12):1743-8.
9. Fitch K, Bernstein SJ, Aguilar MD, Burnand B, LaCalle JR. The RAND/UCLA appropriateness method user's manual. Rand Corp Santa Monica CA; 2001.
10. Cancer Council Australia Melanoma Guidelines Working Party. Clinical practice guidelines for the diagnosis and management of melanoma. Sydney: Melanoma Institute Australia. [Version URL: https://wiki.cancer.org.au/australiawiki/index.php?oldid=215123, cited 2021 Sep 14]. Available from: https://wiki.cancer.org.au/australia/Guidelines:Melanoma
11. Dummer R, Hauschild A, Lindenblatt N, Pentheroudakis G, Keilholz U. Cutaneous melanoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Annals of Oncology. 2015;26:126-32.
12. Pflugfelder A, Kochs C, Blum A, Capellaro M, Czeschik C, Dettenborn T, et al. Malignant melanoma S3-guideline "diagnosis, therapy and follow-up of melanoma". JDDG: Journal der Deutschen Dermatologischen Gesellschaft. 2013;11(s6):1-116.
13. National Institute for Health and Care Excellence. Melanoma: assessment and management. United Kindgom. Cited 2021 Sep 14. Available from: https://www.nice.org.uk/guidance/ng14
14. Berrocal A, Espinosa E, Marín S, Malvehy J, Moreno D, Lozano MD, et al. Spanish Multidisciplinary Melanoma Group (GEM) guidelines for the management of patients with advanced melanoma. European Journal of Dermatology. 2015;25(5):392-403.
15. Follmann M, Eigentler T, Adam H, Wenzel G, Langer T, Wesselmann S. Quality assurance in melanoma care: guideline-based quality indicators for melanoma–implementation, evaluation and update process. JDDG: Journal der Deutschen Dermatologischen Gesellschaft. 2020;18(8):848-57.

16. Bilimoria KY, Raval MV, Bentrem DJ, Wayne JD, Balch CM, Ko CY. National assessment of melanoma care using formally developed quality indicators. Journal of Clinical Oncology. 2009;27(32):5445.
17. Sommariva A, Clemente C, Rossi C. Standardization and quality control of surgical treatment of cutaneous melanoma: looking for consensus of the Italian melanoma intergroup. European Journal of Surgical Oncology (EJSO). 2015;41(1):148-56.
18. Australian Institute of Health and Welfare. Cancer data in Australia. Canberra, Australia. Cited 2021 Sep 14. Available from: https://www.aihw.gov.au/reports/cancer/cancer-data-in-australia/contents/summary
19. Voss RK, Woods TN, Cromwell KD, Nelson KC, Cormier JN. Improving outcomes in patients with melanoma: strategies to ensure an early diagnosis. Patient related outcome measures. 2015;6:229.
20. Thompson J. Clinical practice guidelines for the diagnosis and management of melanoma: Foreword Cancer Council Australia 2008 [Available from: https://wiki.cancer.org.au/australia/Guidelines:Melanoma/Foreword.
21. Blood Z, Tran A, Caleo L, Saw R, Dieng M, Shackleton M, et al. Implementation of patient-reported outcome measures and patient-reported experience measures in melanoma clinical quality registries: a systematic review. BMJ open. 2021;11(2):e040751.
22. Gwadry-Sridhar F, McConkey H, Teng X, Ernst DS. The national melanoma research registry: A fundamental for disease disease characterization and epidemiology. Annals of Oncology. 2019,29(8): 1228.
23. Sommariva A, Forsea A-M, Agius D, Ascierto PA, Bastiaannet E, Borgognoni L, et al. Quality assurance in melanoma care: The EU-MELACARE study. European Journal of Surgical Oncology. 2018;44(11):1773-8.
24. Mallinson E, Newton K, Bowen J, Lalloo F, Clancy T, Hill J, et al. The impact of screening and genetic registration on mortality and colorectal cancer incidence in familial adenomatous polyposis. Gut. 2010;59(10):1378-82.
25. Jakobsen E, Green A, Oesterlind K, Rasmussen TR, Iachina M, Palshof T. Nationwide quality improvement in lung cancer care: the role of the Danish Lung Cancer Group and Registry. Journal of Thoracic Oncology. 2013;8(10):1238-47.

Development of Melanoma Clinical Quality Indicators for the Australian Melanoma Clinical Outcomes Registry (MelCOR): a modified Delphi study

Corresponding author:
Associate Professor Victoria Mar
Alfred Hospital
55 Commercial Road, Melbourne 3004
Victoria, Australia
Tel: +61 3 9076 2000
victoria.mar@monash.edu.au

Funding statement
No funding was obtained for this specific publication however the overall MelCOR project is funded by the Melanoma Institute of Australia.

Ethics Statement
This study was approved by the Alfred Hospital Ethics Committee (ref 190/21).

Acknowledgement statement
We would like to thank all the participants, organizations and public who have contributed to the MelCOR project to date.

GVL is supported by NHMRC Practitioner Fellowship and the University of Sydney Medical Foundation.

MS was supported by a Victorian Agency Clinical Fellowship

HPS holds an NHMRC MRFF Next Generation Clinical Researchers Program Practitioner Fellowship (APP1137127).

Conflicts of interest
GVL is consultant advisor for Aduro Biotech Inc, Amgen Inc, Array Biopharma inc, Boehringer Ingelheim International GmbH, Bristol-Myers Squibb, Evaxion Biotech A/S, Hexel AG, Highlight Therapeutics S.L., Merck Sharpe & Dohme, Novartis Pharma AG, OncoSec, Pierre Fabre, QBiotics Group Limited, Regeneron Pharmaceuticals Inc, SkylineDX B.V., Specialised Therapeutics Australia Pty Ltd.

RAS has received fees for professional services from F. Hoffmann-La Roche Ltd, Evaxion, Provectus Biopharmaceuticals Australia, Qbiotics, Novartis, Merck Sharp & Dohme, NeraCare, AMGEN Inc., Bristol-Myers Squibb, Myriad Genetics, GlaxoSmithKline

HPS is a shareholder of MoleMap NZ Limited and e-derm consult GmbH, and undertakes regular teledermatological reporting for both companies. HPS is a Medical Consultant for Canfield Scientific Inc, MoleMap Australia Pty Ltd, Blaze Bioscience Inc, Revenio Research Oy and a Medical Advisor for First Derm.

CJM, HPS and SS are currently on the AJD Editorial board.

Keywords
clinical quality indicators, melanoma, Australia, clinical registry, delphi

Author details
Dr Dale Jobson
ORCID ID: 0000-0002-5918-3484
email: dalewjobson@gmail.com
Affiliations
Victorian Melanoma Service, Alfred Hospital
School of Public Health and Preventative Medicine, Monash University

Mr Benjamin Roffey
ORCID ID: N/A
email: benjamin.roffey@monash.edu
Affiliations
School of Public Health and Preventative Medicine, Monash University

Mr Christopher Arnold AM
ORCID ID:
email: chris@hodgsonassoc.com.au
Affiliations
Hodgson Associates, Melbourne, Australia
Biogrid Australia, Parkville, Australia

Dr Anthony Azzi
ORCID ID: 0000-0002-5263-5046
Email: tony@newcastleskincheck.com.au
Affiliations
Newcastle Skin Check, Newcastle, Australia
School of Medicine, University of Queensland
Skin Cancer Institute, Singapore
Skin Cancer College Australasia, Auchenflower, Australia
Australian College of Rural and Remote Medicine, Brisbane, Australia

Ms Alison Button-Sloan
ORCID ID:
email: buttonsloan@bigpond.com
Affiliations
Australian Melanoma Consumer Alliance, Melbourne, Australia

Ms Tamara Dawson
ORCID ID:
email: info@mscan.org.au
Affiliations

Melanoma and Skin Cancer Advocacy Network, Carlton, Victoria

Prof Pablo Fernandez-Penas
ORCID ID: 0000-0003-4882-1564
email: pablo.fernandezpenas@sydney.edu.au
Affiliations
Sydney Medical School, The University of Sydney, New South Wales, Australia
Department of Dermatology, Westmead Hospital, Westmead, New South Wales, Australia

A/Prof Paul Fishburn
ORCID ID: 0000-0002-4413-0638
email: drpaulfishburn@ozemail.com.au
Affiliations
Faculty of Medicine, University of Queensland, Brisbane, Australia
Norwest Skin Cancer Centre, Bella Vista, NSW, Australia

A/Prof David E Gyorki
ORCID ID: 0000-0002-3165-4694
email: David.Gyorki@petermac.org
Affiliations
Division of Cancer Surgery, Peter MacCallum Cancer Centre, Melbourne, Australia
Sir Peter MacCallum Department of Oncology, University of Melbourne

Dr. Emma L Hiscutt
ORCID ID:
email: drehiscutt@gmail.com
Affiliations
School of Public Health and Preventative Medicine, Monash University,
Victorian Melanoma Service, Alfred Hospital

Ms Valerie Jakrot
ORCID ID: 0000-0002-8578-5964
email: Valerie.jakrot@melanoma.org.au
Affiliations
Melanoma Institute Australia, Sydney, Australia
The University of Sydney, North Sydney, NSW, Australia

Dr Alister Lilleyman
ORCID ID:
email: amlilley@bigpond.net.au
Affiliations
Skin Cancer College Australasia, Auchenflower, Australia
Australian College of Rural and Remote Medicine, Brisbane, Australia

Dr Alistair Lochhead
ORCID ID:
email: Alistair.Lochhead@southernpath.com.au
Affiliations
Southern IML Pathology, Wollongong, Australia
Department of Anatomical Pathology, Wollongong Hospital, Wollongong, Australia
Graduate School of Medicine, University of Wollongong

Prof Georgina V Long
ORCID ID: 0000-0001-8894-3545
email: georgina.long@sydney.ed.au
Affiliations
Melanoma Institute Australia, The University of Sydney, Sydney, Australia
Faculty of Medicine and Health, The University of Sydney, Sydney, Australia
Department of Medical Oncology, Royal North Shore hospital, Sydney, Australia
Mater Hospital, Sydney, Australia

Ms Sonia Mailer
ORCID ID:
email: sonia.mailer@petermac.org
Affiliations
Melanoma Research Victoria, Melbourne, Victoria 3000, Australia
Peter MacCallum Cancer Centre, Melbourne, Victoria 3000, Australia
Sir Peter MacCallum Department of Oncology, The University of Melbourne, Victoria 3010, Australia

Prof Graham Mann
ORCID ID: 0000-0003-1301-405X
email: graham.mann@anu.edu.au
Affiliations
Melanoma Institute Australia, The University of Sydney, NSW, Australia
The John Curtin School of Medical Research, The John Curtin School of Medical Research, Australian National University, ACT, Australia

A/Prof Christopher J McCormack
ORCID ID:
email: chris@caulfielddermatology.com.au
Affiliations
Department of Surgical Oncology, Peter MacCallum Cancer Centre, Melbourne, Australia

A/Prof Jim Muir
ORCID ID: 0000-0003-3791-161X
email: muirmed@outlook.com
Affiliations
University of Queensland, Brisbane, Australia
Mater Hospital, Brisbane, Australia

Dr George F Pratt
ORCID ID:
email: drgpratt@gmail.com
Affiliations
Plastic and Reconstructive Unit, Monash Health, Dandenong, Australia
Plastic and Reconstructive Surgery, Peninsula Health, Frankston, Australia

Prof Richard A. Scolyer
ORCID ID: 0000-0002-8991-0013
email: Richard.Scolyer@health.nsw.gov.au
Affiliations
Melanoma Institute Australia, The University of Sydney, North Sydney, NSW, Australia
Faculty of Medicine and Health, The University of Sydney, Sydney, NSW, Australia
Tissue Pathology and Diagnostic Oncology, Royal Prince Alfred Hospital and NSW Health Pathology, Sydney, NSW, Australia
Charles Perkins Centre, The University of Sydney, Sydney, NSW, Australia

Prof Mark Shackelton
ORCID ID: 0000-0002-7673-4655
email: Mark.Shackleton@monash.edu
Affiliations
Central Clinical School and School of Public Health and Preventive Medicine, Monash University, Prahran, Australia
Department of Oncology, Alfred Health, Prahran, Australia

A/Prof Stephen Shumack
ORCID ID: 0000-0002-9121-7795
email: sshumack@iinet.net.au
Affiliations
Royal North Shore Hospital, Sydney, Australia

Prof H. Peter Soyer
ORCID ID: 0000-0002-4770-561X
email: p.soyer@uq.edu.au
Affiliations
The University of Queensland Diamantina Institute, The University of Queensland, Dermatology Research Centre, Brisbane, Australia
Dermatology Department, Princess Alexandra Hospital, Brisbane, Australia

Dr Chin-Guan Tan
ORCID ID:
email: Guan.Tan@mps.com.au
Affiliations
Melbourne Pathology, Collingwood, Australia

Dr Angela Webb
ORCID ID: 0000-0002-0659-8029

email: dr.a.webb@gmail.com
Affiliations
Division of Cancer Surgery, Peter MacCallum Cancer Centre, Melbourne, Australia
Sir Peter MacCallum Department of Oncology, University of Melbourne
Skin Health Institute, Carlton, Australia

Prof John Zalcberg
ORCID ID: 0000-0002-6624-0782
email: john.zalcberg@monash.edu
Affiliations; Department of Medical Oncology, Alfred Health and
School of Public Health and Preventative Medicine, Faculty of Medicine, Nursing and Health Sciences, Monash University. Melbourne, Australia

Prof Rachael Morton
ORCID ID: 0000-0001-7834-0572
email: rachael.morton@sydney.edu.au
Affiliations
NHMRC Clinical Trials Centre, University of Sydney, Sydney, Australia
Melanoma Institute Australia, Sydney, Australia

A/Prof Victoria Mar
ORCID ID: 0000-0001-9423-3435
email: victoria.mar@monash.edu
Affiliations
Victorian Melanoma Service, Alfred Hospital
School of Public Health and Preventative Medicine, Monash University