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Developing an Australian Melanoma Clinical Outcomes Registry (MelCOR): a protocol paper

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ABSTRACT

Introduction Australia has the highest incidence of melanoma in the world with variable care provided by a diverse range of clinicians. Clinical quality registries aim to identify these variations in care and provide anonymised, benchmarked feedback to clinicians and institutions to improve patient outcomes. The Australian Melanoma Clinical Outcomes Registry (MelCOR) aims to collect population-wide, clinical-level data for the early management of cutaneous melanoma and provide anonymised feedback to healthcare providers.

Methods and analysis A modified Delphi process will be undertaken to identify key clinical quality indicators for inclusion in the MelCOR pilot. MelCOR will prospectively collect data relevant to these quality indicators, initially for all people over the age of 18 years living in Victoria and Queensland with a melanoma diagnosis confirmed by histopathology, via a two-stage recruitment and consent process. In stage 1, existing State-based cancer registries contact the treating clinician and provide an opportunity for them to opt themselves or their patients out of direct contact with MelCOR. After stage 1, re-identifiable clinical data are provided to the MelCOR under a waiver of consent. In stage 2, the State-based cancer registry will approach the patient directly and invite them to opt in to MelCOR and share identifiable data. If a patient elects to opt in, MelCOR will be able to contact patients directly to collect patient-reported outcome measures. Aggregated data will be used to provide benchmarked, comparative feedback to participating institutions/clinicians.

Ethics and dissemination Following the successful collection of pilot data, the feasibility of an Australia-wide roll out will be evaluated. Key quality indicator data will be the core of the MelCOR dataset, with additional data points added later. Annual reports will be issued, first to the relevant stakeholders followed by the public. MelCOR is approved by the Alfred Ethics Committee (58280/127/20).

STRENGTH AND LIMITATIONS OF THIS STUDY

⇒ The Australian Melanoma Clinical Outcomes Registry (MelCOR) will collect population-wide, clinical-level data on the early management of cutaneous melanoma using existing State-based cancer registries.
⇒ Reporting newly diagnosed melanoma to existing State-based cancer registries is currently required by law, thus enabling our data model to capture population-wide data.
⇒ Data collection to State-based cancer registries is currently limited to basic pathology and date of death data.
⇒ MelCOR will use the readily available data by developing clinical quality indicators that can be measured using pathology reports.
⇒ When the MelCOR infrastructure and system have been piloted, we will look to expand the scope of data collected and develop additional quality clinical indicators.

INTRODUCTION

Melanoma in Australia

Melanoma is a common and potentially deadly malignancy diagnosed in over 232 000 patients annually worldwide, with approximately 55 500 deaths.[1] The incidence varies greatly between countries; Australia has the highest incidence of melanoma in the world with 54 cases per 100 000 persons per year making it the third most common cancer in men and fourth in women.[2 3] This high incidence translates to a large economic impact on the Australian healthcare system with an estimated cost of over $A200 million annually.[4]

Localised, thin cutaneous melanoma has an excellent long-term prognosis compared with locally advanced or metastatic disease emphasising the importance of early diagnosis and appropriate treatment.[5] Australian melanoma care is currently provided by a complex mix of community-based clinics, private and public hospitals with a wide range of clinicians involved including general practitioners, dermatologists, general surgeons and plastic surgeons.[6] Australian Clinical Guidelines exist to help clinicians manage melanoma. However, there is currently no national system in place

to systematically monitor clinician and institutional compliance with best practice guidelines or collect clinical data or patient-reported outcome measures (PROMs).[7 8]

Rationale for a melanoma clinical quality registry in Australia

A recent landmark study found many Australians did not receive recommended melanoma treatment according to the Australian Clinical Guidelines.[9] Specifically, the study found that most melanoma lesions were excised with either inadequate or excessive surgical margins.

Clinical quality registries (CQRs) aim to reduce this type of variability in care by providing anonymised, comparative clinical performance data back to health service providers. The implementation of CQRs, particularly in the setting of cancer, has been shown to improve patient outcomes.[10] It is also in keeping with the Australian Commission for Safety and Quality in Health Care recommendations calling for a nationally consistent approach to the collection and reporting of indicators to monitor the safety and quality of care delivery.[5]

Currently, nationally inclusive, systematic and consistent data collection and reporting of quality indicators to monitor melanoma patient outcomes do not exist.[1 3] Rather, data collection occurs across multiple jurisdictional State-based epidemiological cancer registries and institutional databases which are not standardised and do not provide or report sufficient clinical detail to influence practice.

With Australia having the highest rate of melanoma in the world and significant variations in treatment across a diverse range of care providers, Australians with a new diagnosis of melanoma can only benefit from the introduction of the Melanoma Clinical Outcomes Registry (MelCOR).

Melanoma Clinical Outcomes Registry aims and objectives

The MelCOR project aims to monitor the quality of care provided to patients with cutaneous melanoma by establishing a clinical outcomes registry.

Before we embark on implementing a national registry, a pilot feasibility study will determine the following:

1. If a collaborative national MelCOR can be established using the State-based cancer registries as a federated data source.
2. The data universally available in each State-based cancer registry that can be used for assessment.
3. The clinical quality indicators that can be used to assess quality of care based on the above data source(s).
4. The best feedback model to provide quality of care reports to stakeholders.
5. Ongoing funding requirements for the roll out and maintenance of a national MelCOR.

Here, we describe the protocol for the MelCOR pilot study in Queensland and Victoria with the goal of expanding data collection to other Australian States and territories in the near future.

METHODS AND ANALYSIS

Study design

MelCOR will be a non-interventional, multicentre, prospective melanoma registry maintained in accordance with all the relevant ethical, legislative, financial and governance controls for each jurisdiction. The MelCOR pilot commenced in 2021 and will continue until the feasibility of an Australian-wide melanoma registry can be established, we anticipate the pilot to be completed by 2023.

Establishment of MelCOR and governance

In 2018, 36 Australian organisations with an interest in melanoma set out to create the MelCOR for the early management of cutaneous melanoma. The Melanoma Institute Australia, an independent non-profit organisation, oversaw public fundraising efforts to enable the creation and pilot operations of MelCOR. An expert panel of investigators, clinicians, melanoma researchers, consumers and other professionals were assembled into a Steering Committee to oversee and operate MelCOR. Overall governance and the responsibility for MelCOR rests with the Steering Committee with a subset of this committee appointed as an Executive Committee which is tasked to monitor operations. An operational team was then established within the Monash University Cancer Research Programme and is responsible for the day-to-day operations of the pilot project.

Enrolment criteria

All Australian patients with melanoma will be eligible for inclusion in MelCOR if they meet the following two criteria:

1. Diagnosed with cutaneous melanoma (including in situ disease) after data collection has started in the treating State.
2. Eighteen years or older at the time of data extraction from the State-based cancer registry.

Patient identification and data requested

MelCOR will use existing State-based cancer registries to identify patients recently diagnosed with melanoma. Currently, new cancer diagnoses are required by law to be reported to the relevant State-based cancer registries. Demographic and pathology data collected by the State-based cancer registry will be classified into three distinct types:

1. Identifiable—patient's personal details linked to medical data.
2. Re-identifiable—medical data with a coded identifier substituted for the patients' personal details. Only entities with access to the linkage codes (eg, State-based cancer registry) will be able to convert the re-identifiable data back into identified data. MelCOR will not hold re-identification linkage codes.
3. De-identifiable—medical data with all identifiable data removed, and all potentially identifiable data (eg, age, postcode) aggregated to ensure it remains anonymous.

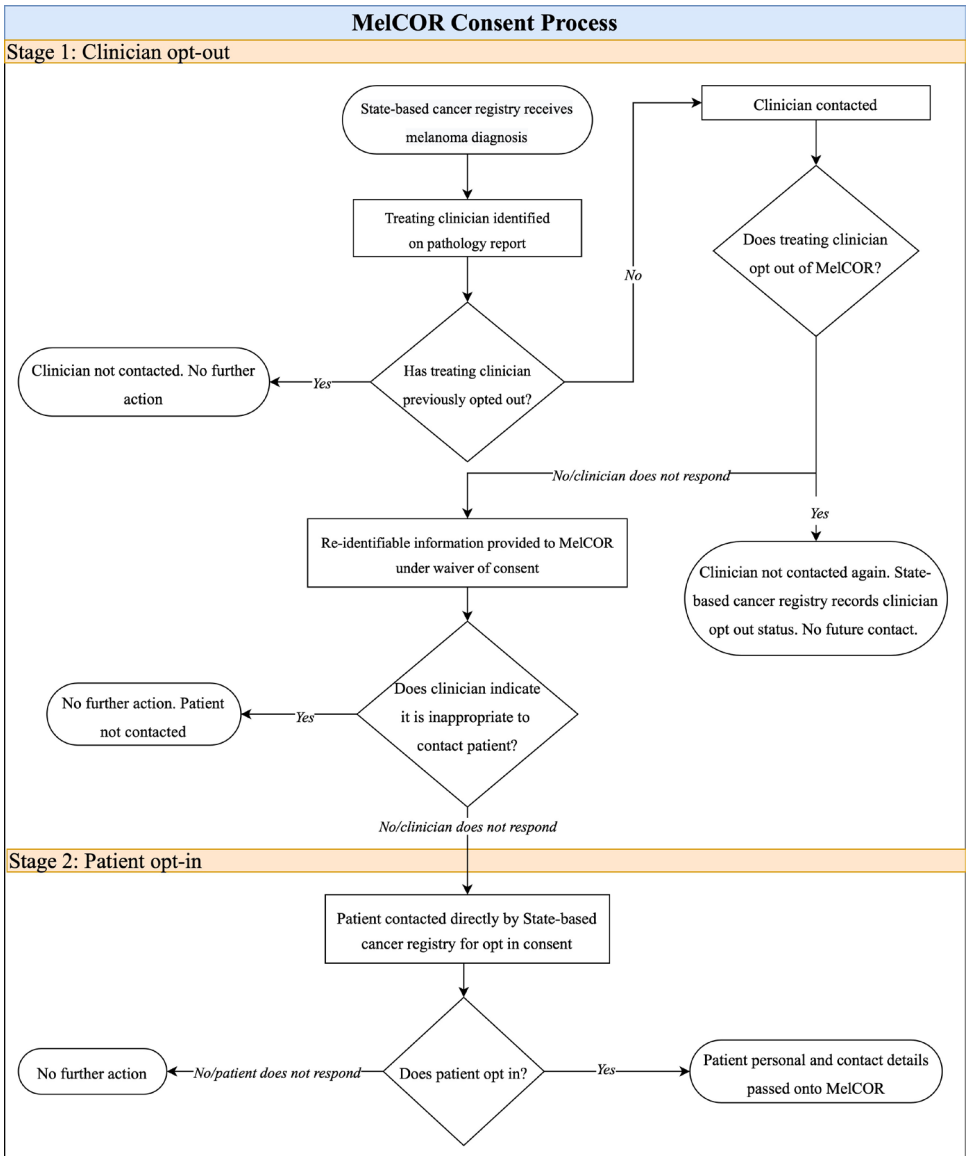

Figure 1 Melanoma Clinical Outcomes Registry (MelCOR) consent process for State-based cancer registry.

To prevent the dissemination of sensitive information, it is intended that all initial clinician contact and patient consent processes will be performed by the relevant State-based registry on behalf of MelCOR, with specific consent to release data to MelCOR sought by the relevant State-based cancer registry.

Patient recruitment, consent and data transfer

Patient recruitment, consent and data transfer from existing cancer registries to MelCOR will follow a two-stage process (figure 1).

Stage 1: clinician opt out

In stage 1, the treating clinician will be contacted by the State-based registry via postal mail to ensure the clinician is aware of the MelCOR project and confirm that the recruitment of the patient is appropriate.

Once contact is established, the treating clinician will have the following options:

1. Not respond. If the clinician does not respond to the information sent by the State-based registry, a waiver of consent will be applied, and re-identifiable data will be passed from the State-based cancer registry to MelCOR. The consent process will then progress to stage 2.
2. Request that a specific patient is not contacted. For example, the clinician advises that contacting the patient is inappropriate (eg, non-English speaker). In this situation, re-identifiable data will be passed from the State-based cancer registry to MelCOR under a waiver of consent. The patient will not be contacted by MelCOR or the State-based cancer registry as part of the stage 2 consent process.

   Note: the reasons why patients should not be contacted will be collected and passed on to MelCOR in an aggregated format (eg, 20 patients were not contacted due to translator requirements).

3. Opt out of MelCOR entirely. A clinician may elect to opt out all their current and future patients from MelCOR. If they chose this option, they will not receive further correspondence from MelCOR. However, a waiver of consent will be applied, and re-identifiable data will be passed from the State-based cancer registry to MelCOR.

Stage 2: patient opt in

In stage 2, all patients not 'opted out' by their treating clinician will be contacted by the State-based cancer registry with information about MelCOR. The patient can then opt in, and their identifiable data will be provided to MelCOR. Patients will be given sufficient time from initial contact (4 weeks from estimated postal delivery) to perform the opt-in process. If no opt-in consent is provided at the end of this time, identifiable data will not be given to MelCOR but the core re-identifiable data from stage 1 will be transferred to MelCOR. Patients may still opt in after this time, and the additional data will then be sent to MelCOR in the next scheduled data transfer.

If a patient opts in and permits identifiable data to be provided to MelCOR, they will be contacted directly by MelCOR (via email or SMS) for collection of PROMs when this component of MelCOR is activated after the completion of the pilot programme. A patient or clinician may withdraw consent or request no future contact with MelCOR at any time.

The pilot programme will recruit patients with melanoma in situ and invasive cutaneous melanoma in Victoria, however in Queensland, only patients with invasive melanoma will be recruited. Queensland patients with melanoma in situ will have re-identifiable data shared with MelCOR, but these patients will not be contacted for recruitment.

Waiver of consent for receiving re-identifiable data and data storage

The re-identifiable data passed from State-based cancer registries to MelCOR will form the core national MelCOR dataset (figure 2). It will be stored in secure servers located at Monash University. These re-identifiable data will have immediately identifiable data (eg, patient name, date of birth, residential address) removed by the State-based cancer registry and replaced with a unique reference to allow subsequent data linkage. The information required to re-identify individuals will not be provided or managed by MelCOR. This will ensure individual's privacy whose consent is waived is not placed at risk in the event of MelCOR suffering a data breach.

The re-identifiable reference will serve two purposes in the database:

1. Allow linkage of re-identifiable data to identifiable data in patients who have opted in to the PROMs collection.
2. Allow linkage of alternate datasets to the MelCOR database. This linkage will be performed by external entities (eg, the State-based cancer registry), as MelCOR will not receive any identifiable patient information during the process unless the patient specifically opts in to the MelCOR database during stage 2 of the consent process.

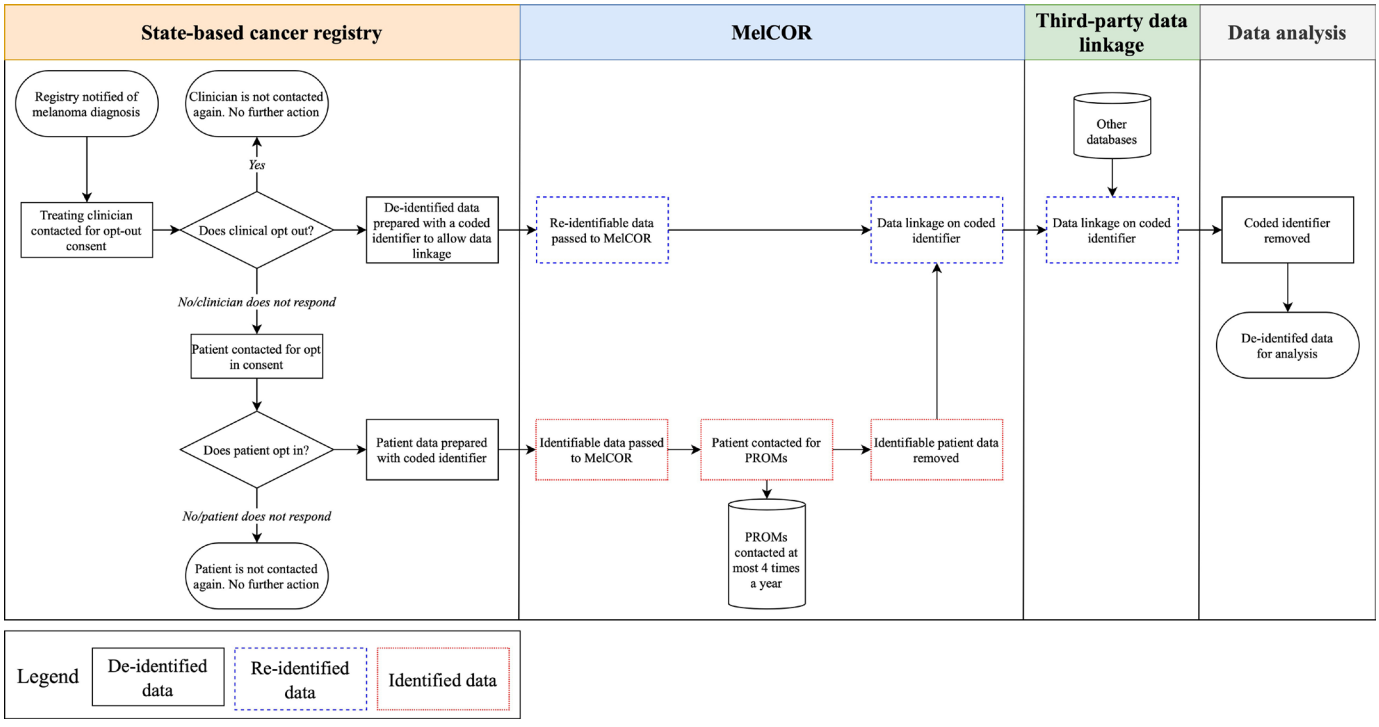

Figure 2 Data flow through the Melanoma Clinical Outcomes Registry (MelCOR) and different levels of data identity. PROM, patient-reported outcome measure.

Once the required linkage activity (eg, linkage to PROMs data or external databases) is complete, the re-identifiable reference will be removed. This will de-identify the data before analysis and reporting. At no point during the process will MelCOR have the means to identify patients who have waived consent. Similarly, all data analysis and third-party access (eg, requests, reporting) will only have access to fully de-identified data. All data released under the waiver of consent will comply with the *Privacy Act 1988 (Cth)* and relevant State legislation.[11]

Clinical quality indicators

Clinical quality indictors measure the extent to which a target has been achieved.[12] Before a registry can provide anonymised, comparative clinical performance data back to health service providers, stakeholders must identify and agree which clinical quality indicators reflect best practice within real-world settings. Quality indicators need to be objective, measurable and feasible to collect. Potential clinical quality indicators will be identified by examining the literature, including Australian and international melanoma guidelines and consulting with melanoma and registry experts.

A modified two-round Delphi survey method will be used to develop the MelCOR clinical quality indicators. Participants will be consulted from a wide range of disciplines including dermatology, pathology, general practice, medical oncology, surgery, nursing and consumers. Through this process, clinical quality indicators will be developed that reflect optimal practice and are thought to be feasible to collect (predominantly from pathology reports of resected tumours) for the early management of cutaneous melanoma.

Reporting

MelCOR will use the developed quality indicators to provide benchmarked, comparative reports back to clinicians and health service providers. Both re-identifiable and identifiable data will be collated and de-identified before being used for reporting. Individuals and practices will only be able to view their own performance against a benchmarked comparison. An umbrella entity (eg, hospital, clinic, dermatology practice) may request a copy of periodic reports with their name and all practising clinicians operating under the umbrella entity unredacted for internal dissemination. Individual clinicians will also be able to request their own individual report. Annual reports will be issued, first to the relevant stakeholders followed by the public. Each annual report will be reviewed and approved by the MelCOR Steering Committee before it is publicly released.

Patient and public involvement

MelCOR has consulted melanoma consumer group leaders in the design and development of the clinical registry protocol. MelCOR will disseminate annual reports to the public, which will be accessible online to all Australian patients with melanoma.

DISCUSSION

We describe a protocol to create a national MelCOR and improve patient outcomes by providing anonymised feedback to the diverse range of clinical providers managing cutaneous melanoma in Australia. Given the high incidence of melanoma in Australia, this registry has the potential to improve early melanoma care for many Australians.

Several other countries have introduced national melanoma-specific cancer registries including Canada, Italy and The Netherlands.[13–16] These registries rely on participating centres inputting data into a centralised database whereas our registry will use data from multiple existing State-based cancer registries to create a national registry. The challenging Australian context of melanoma care being provided by a complex mix of private and public clinics/hospitals means that a centralised opt-in database model is less feasible and would not capture the broader melanoma population.

Cancer reporting and data collection is a legal requirement for clinicians and healthcare providers in Australia. Thus, our data model will ensure that nearly all the newly diagnosed cutaneous melanoma population is identified and included. Once identified, MelCOR will help create standardised national datasets as well as ultimately directly contact patients who opt in to collection of PROMs.

Strengths and limitations

The proposed MelCOR is limited to collecting data for the early management of cutaneous melanoma, rather than widespread metastatic disease. This focus on early management of melanoma is driven by the need to target limited resources to the area of greatest need. Early management of melanoma is far more common than later management of metastatic disease and there is evidence demonstrating variability in care being provided in Australia.[5 9] Our registry model using existing State-based cancer registries is limited by the amount of detailed data that can be collected as these registries predominantly collect basic pathology and date of death data. Advanced melanoma data collection would require detailed data on imaging, treatment and recurrence, which is not uniformly collected across providers or available. We have attempted to use the readily available data by developing clinical quality indicators that can be measured using pathology reports. Currently, insufficient pathology data are routinely collected in Queensland and we are undertaking manual extraction of pathology reports for the MelCOR pilot. In the future, we will look to trial artificial intelligence tools to automatically extract data. This basic, but core pathology data (in addition to demographic data), will form the 'spine' of the MelCOR dataset and allow MelCOR to fulfil its primary function of providing feedback to healthcare providers. When the MelCOR infrastructure and system have been piloted, we will look to add 'ribs' to the dataset by working with existing State-based cancer registries and patients to expand the scope

of data collected and develop additional quality clinical indicators such as recurrence outcomes.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the 'Methods' section for further details.

Patient consent for publication Not applicable.

Ethics approval Not applicable.

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