



IDS Study Proposal

Full Skin Examination in screening for cutaneous malignancy: A focus on Concealed Sites. Practices of Australian and International Dermatologists.

Version 1

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Proposed start date: 21/2/21

Proposed end date: 21/6/21

Conflict of interest

Funding Sources

None

Financial or personal interest related to the proposed study

None

Interest in intellectual property rights subject of the study

All ideas are my own and remain my intellectual property

Is a drug, device or other investigational product being used or evaluated?

No

Study design

Study type

Please concisely describe the study type: e.,g. Case registry, Retrospective Cohort, Retrospective Case-Series, Prospective Case-Control, Intervention Trial.

A cross-sectional study, consisting of an online self-administered twelve-question survey.

The questions address six main areas:

1. Demographics of the target audience (age, gender);
2. Prevalence of special site exam relative to the proportion of patients seen per week for high risk FSE;
3. Conduct of special site exam: routine or not, degree of undress, chaperone use, how to introduce exam to patient;
4. Factors that act to influence and deter inclusion of special site exam;
5. Barriers to FSE- physician, patient factors;
6. Risks in not including special site exam in FSE;
7. Opinion regarding whether dermatologists believe it is their responsibility to routinely offer this as part of FSE.

Checklist

If any included, e.g. STROBE, please specify

Study Outline

Please extensively describe the plans for the study. Topics may include:

- Rationale
- Study design
- Study population (with specific inclusion and exclusion criteria)
- Primary and secondary hypotheses

Clinical Question/s

What is the standard practice amongst Australian dermatologists to the full skin examination in screening for cutaneous malignancy, with respect to inclusion of concealed sites; ano-genital, breast, scalp and oral mucosa.

Is the FSE being conducted adequately, with inclusion of concealed sites for the purposes of screening for cutaneous malignancy and if not what are the potential barriers to this?

Background

The Full Skin Examination (FSE), interchangeable with the term Total Body Skin Examination (TBSE), is a method of screening for cutaneous malignancy, which involves thorough surveillance of the skin, with head to toe examination, typically aided by dermoscopy. FSE examinations are routinely conducted annually for most adult Australians and are more frequently recommended for patients at risk for cutaneous malignancy.¹ Pertinent risk factors include a personal or family history of

melanoma, personal history of non-melanoma skin cancer (NMSC), multiple naevi/dysplastic naevi, fair phenotypic characteristics, extensive history of ultraviolet radiation exposure (including solarium use) and immunosuppression.²

FSE is the primary screening mechanism for melanoma and non-melanoma skin cancer in high-risk patients. There is currently no consensus on specific anatomic sites that require inclusion in routine FSE/TBSE. The Australasian College of Dermatology does not have a position statement regarding this practice. The American College of Dermatology, details that TBSE or FSE should include inspection of the scalp, hair, nails and mucous membranes of the mouth, eyes, anus, and genitals.³

Clinicians may face dilemmas about the inclusion of concealed sites into the FSE, for various reasons, including lack of guidelines regarding approach to this common, every day practice, absence of patient concern and the low incidence of pathology at these sites, compounded by the unique nature of concealed sites being both sensitive (ano-genital and breast) and difficult to visualise (hair-covered scalp and oral cavity). Barriers to dermatologists performing routine FSE include practical impediments, such as availability of chaperone and lack of time¹⁴, in addition to fear of being accused of professional misconduct and ensuing medical litigant action.

Additionally patients have varying preferences regarding FSE conduct. Some patients avoid seeking FSE due to embarrassment⁴ or prefer physicians of a particular gender^{4,5}, whereas from clinical experience, we recognise some patients have expectations that concealed sites should be routinely surveyed as part of the FSE.

FSE provides a vital opportunity to detect, cure and treat cutaneous malignancy at an early stage, thereby improving patient outcomes. While skin cancer at concealed sites is rare, patients tend to present at a later stage, which often portends a poor prognosis.⁹⁻¹² One of the reasons melanoma and NMSC is missed at these sites, is omission of inspection.¹³

In conducting the FSE the dermatologist must negotiate individual patient preferences and sensitivities while ensuring adequacy of full skin inspection, as well as balancing the time required for concealed site exam (CSE) with the knowledge that there may be low yield of detection but the chance to diagnose and treat disease at an early and potentially curable stage.

Rationale and Significance

The practice of FSE by dermatologists, specifically with respect to site-specific inclusion, namely concealed sites, is not well defined. Further, no guidelines exist detailing how examination of concealed sites should be addressed or conducted by the physician. As a result it is likely that the inclusion and approach to CSE differs greatly. Little is known about the prevalence, influencing factors, barriers and attitudes of dermatologist specifically to the CSE.

CSE also falls under the scope of practice of other health professionals, creating grey areas about who is responsible for screening these sites, e.g. breast, cervical and prostate cancer screening by GPs/specialists and oral examination by dentists. A study examining genital area screening demonstrated that dermatologists examine the vulva in 4% of cases, compared with 94% by gynaecologists. The dermatologists

in this study were also less clear about their role in screening for genital malignancy than gynaecologists, despite dermatologists having greater confidence in their skills to diagnose lesions at this site.¹⁵

A key element of medical negligence claims is whether a physician has deviated from standard of care/common peer practice.¹⁶ When standard of care and responsibilities are undefined, fulfilment versus breach of duty is not clear.

Our study will characterise what the standard practices of dermatologists are with regards to inclusion of CSE in FSE. This may then assist in the establishment of a collective approach to CSE as a profession and importantly what constitutes accepted practice and thereby standard of care. This is necessary to set benchmarks of expected patient care, delineate roles and responsibilities of the dermatologist in regards to CSE and to protect the profession medico-legally.

Aim

1. To provide a snapshot of current peer practice amongst dermatologist in relation to the CSE
2. To provide a platform for possible future development of a standardised approach, in the form of guidelines, to this common exam as a profession and medico-legally

Objectives

1. To ascertain the prevalence, method of conduct, influencing factors, barriers and attitudes to the CSE in an Australian Dermatologist cohort.
2. To compare current practice in Australia and internationally

Hypotheses

1. The prevalence of CSE in FSE is low
2. The conduct of the CSE differs widely
3. Demographic differences may predict outcomes.
4. Australian and International practices will differ

Study Population

Fellows of the Australasian College of Dermatologists
International Dermatologists, recruited via the International Dermoscopy Society membership list.

The only exclusion criteria are survey responses in which demographic information is not answered or less than 80% of the questionnaire is attempted.

Setting:

The Australasian College of Dermatology membership platform, in affiliation with the Melanoma Institute Australia, a non for profit specialist melanoma referral centre, which is itself affiliated with The University of Sydney. The international comparative study will take place in concert with the International Dermoscopy Society.

Recruitment Plan:

The Australasian College of Dermatology weekly email newsletter to Fellows of the college.

The International Dermoscopy Society membership emails to International Dermatologists from across the world, which captures 168 countries and includes 18,331 society members.

Outcome Measures:

Primary: Physician reported frequency, practice and attitudes regarding inclusion of special site exam.

Secondary Outcomes: Differences between Australian and international dermatologists

Survey Procedure

The survey was designed using Google Forms, a free online Google tool, via Gmail account and stored on the G Drive server. The survey was also tested in Survey Monkey for design modifications. To reflect affiliation with the MIA and The University of Sydney, the official MIA and USYD logo was incorporated into the survey layout, including the invitation and reminder to participate.

The survey was pre-tested on a number of dermatologists and a clinical epidemiologist and refined accordingly.

Fellows will be invited to complete the survey via an announcement and web link as part of the weekly Australasian College of Dermatology newsletter.

Informed consent is implied in the member choosing to fill out the survey.

Participants will not need to login to Gmail to complete the survey, ensuring total anonymity.

Participants will be advised to fill out the survey once only and encouraged to complete the questionnaire in one sitting, as it will not be saved. The questionnaire is expected to take less than 2 minutes to complete. There will be unlimited time to answer and responses may be changed before completion of the form.

The principal and coordinating investigator will have access to the final data.

Overseas colleagues will be given the option to use the questionnaire to sample local dermatologist groups, pending ethics approval at their local institutions.

Further we may recruit medicolegal advice and input regarding the nature of our study, specifically what constitutes common peer practice nationally and internationally and how are findings may influence the formulation of practice guidelines.

Timeline

- 6 week duration:
 - Week 1: Invitation email with survey link
 - Week 2 and 4: Reminder email
 - Week 6: Survey close

Recorded data

E.g. Dermatoscopic images, annotations, surveys, biological specimens, etc.

Methodology of data collection

E.g. Online Database (e.g. RedCap), printed CRF with provided template attached, Online questionnaire

Data will be collected via google forms, secure, password protected and only accessible by PI and SI.

Electronic data Considerations:

1. Ensuring anonymity

The survey link will only be sent to Fellows of the Australasian College of Dermatology via private email contact list, which is not available to the principle and coordinating investigator. No login or password will be required to access the survey, ensuring complete anonymity. No details of the participants over and beyond the survey questions will be collected. The identity of respondents will not be known and all data will be non-identifiable.

2. Ensuring Privacy and security of Data

The investigators plan to use an online web based survey programme such as Google Forms or Survey Monkey. Pending design considerations other platforms may be considered.

a. Google forms:

Information collected with Google Forms is stored on a spread sheet in the Google Drive which can be downloaded as a file.

This form is as secure as a Gmail account. Both investigators (each with completely private passwords) have access to survey data via login to Google account. The information from the survey can only be accessed by a third party if either investigator allows documents to be shared with new collaborators.

Data is stored and used as outlined in the Google Terms and Conditions:

- Google Terms of Service <https://www.google.com/policies/terms/> (Last updated Oct 27, 2017) and
- Google Privacy Policy: <https://www.google.com/policies/privacy/> (Last updated Dec 18, 2017)

3. Data Retention

At the completion of the study, data will be downloaded and deleted from the drive.

The data retention period will be in line with the Australian Code for the Responsible Conduct of Research.

Statistical evaluation plan

Note details on the planned analyses such as specific hypotheses, used tests, and correction for multiple testing if applicable. Please include corresponding power calculation for primary hypothesis. If power calculation is not included, please indicate the reason.

Statistical considerations

- Pending further statistical advice, the following will be planned:
 - Descriptive statistics (frequency and percent) will be collated for each survey response.
 - Differences between the responses, will be assessed using the Student's *t* test for continuous variables (e.g. age group, number of high risk skin exams per week) and Chi squared test for categorical variables (e.g. gender, exam conduct)
 - Logistic regression will be used to investigate the relationship between categorical variables (binary, ordinal and nominal) and the outcome variable, e.g., to determine factors predictive of a dermatologist including CSE.

- Aim for at least 65% response rate.

- Risk of non-response bias will be reduced through the following means:
 - Pre-testing the survey in terms of wording, formatting and length.
 - 6 week survey duration
 - reminder emails
 - ensuring confidentiality
 - emphasise benefit of participation: the need for a collective approach to this practice as a profession and medico-legally
 - Survey participation counts towards CME/CPD points: Category 3 Level 1 – GBM. (1 point).

Ethics

Central ethics review already in place?

Please note the respective institutional review board. Studies without a central ethics review will only be accepted for special reasons upon request.

Ethics approval by St Vincent and Mater Hospitals Sydney Australia, Melanoma Institute Australia, University of Sydney Australia.

Informed Consent Form

Written / Waived / Other. Based on recommendation from corresponding Central Ethic Committee/Institutional Review Board.

NA, consent implied with participation in the survey

Ethics and Data security considerations

Note any potential ethical issues of the study. Please lay out how data will be secured and transferred, especially in regard to data protection regulations.

Nil specific – please see above.

Authorship and compensation

Criteria for co-authorship

E.g. providing at least 10 cases

Significant contribution to the roll out of the study internationally. Contribution to write up of the international paper and journal submission. The work has been done in terms of ethics, q'aire design and the analysis of data is straightforward. Open to discussion.

Criteria for named contribution

Assisting in executing survey dissemination to IDS members, international Dermatologist

Other compensations planned

Any potential financial compensations for participants or patients

No, as per response rate in Australia, not necessary.

Completion of the survey in Australia contributed to continuing professional education points, potentially IDS could offer similar.

Accessibility of results

Please note how you will make your results available to the community and the IDS, and whether you plan to publish in an Open-Access journal.

Aiming for an international Dermatology journal, not necessarily open access. For IDS community happy to provide a free link (pending acceptance/journal requirements).

Data availability after publication

Please lay out if and how data will be available for other research groups after conclusion of the study

No specific plans for this.

Resources

Requested resources from the IDS

Please note which resources, like the mailing list, or linking from the IDS Website are needed, and why.

Mailing list- IDS membership

Administration to orchestrate initial, reminder and followup emails.

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