

# General Practice Skin Cancer Study

## Receptionist and Nurse Info

### Summary

- Early detection of skin cancer is problematic.
- GP's have a low diagnostic accuracy rate for skin cancer.
- Dermoscopy helps increase diagnostic accuracy in specialist hands.
- It is not known if dermoscopy helps GP's improve diagnostic accuracy.
- The 3 Point Check List is a simplified algorithm to help those inexperienced with dermoscopy.
- **This study wants to determine if skin cancer diagnosis is improved using the 3 Point Check List in a GP setting.**
  
- This is a pivotal study and may have a huge impact on how GP's assess skin lesions. Your participation is needed and greatly appreciated. This study has been designed to minimize the impact on your time by using your PMS to gather and send the data to the study database.

### Background to the study

You are no doubt aware that New Zealand has one of the highest rates of skin cancers in the World<sup>1,2</sup> with the melanoma rate being the highest at 40-50: 100,000. This compares to 7:100,000 in the US and Europe. With the addition of epithelial cell carcinoma (BCC's and SCC's), New Zealanders have a 2 in 3 lifetime chance of developing a skin cancer. It is clear that early diagnosis and treatment can be instrumental in affording a complete cure<sup>2</sup>. This goal is hampered however, as early diagnosis in the general practice setting can be problematic.

GP's are usually the "first port of call" in New Zealand for someone concerned about a skin lesion. GP's and Practice Nurses are in a prime position to check skin lesions opportunistically, eg while checking a shoulder injury or heart or chest examination, taking a BP or treating lesions with liquid nitrogen. Skin lesions can be difficult to assess with the naked eye as benign lesions can be indistinguishable from skin cancers and studies suggest GP's "get it right" only 60% of the time<sup>3</sup>.

Dermoscopy may well be the tool that helps GP's improve their diagnostic rate and therefore detect cancers earlier. There have been suggestions however that dermoscopy should not be used in a general practice setting<sup>4</sup> because of the intense training required before benefits of increased diagnostic accuracy are gained. Concern was also expressed in the same review that diagnostic accuracy could deteriorate using dermoscopy without intense training. These concerns however have not been borne out in recent studies<sup>3,5,6</sup>.

**So what is dermoscopy?** It is the use of a hand held skin microscope that shows skin morphology not able to be seen with the naked eye. The dermoscopic morphological features of common benign skin lesions and skin cancers are now well described and have been correlated with their histopathological findings<sup>7</sup>. Menzies<sup>8</sup> has calculated the sensitivity and specificity of dermoscopic features of invasive melanoma. Diagnostic accuracy is greatly enhanced using this method in trained hands, i.e. dermatologists<sup>8,9-14</sup>. It is not clear if dermoscopy is useful in General Practice. Dermoscopy training unfortunately can be difficult and

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time consuming to learn. Simplified algorithms to aid learning have been developed<sup>15-17</sup>. These have been shown to improve diagnostic accuracy in “nonexperts”<sup>18-19</sup>. The most recent is the Three-point checklist<sup>12</sup>. A short training session (3-4 hours) has been designed to teach medical doctors basic dermatological features. An initial study in Italy and Spain with Primary Care Physicians<sup>5</sup> demonstrated that diagnostic accuracy could be greatly enhanced in this group with dermoscopy.

### **Study Design**

GP's will be randomly assigned to the Dermoscopy Arm or the Control Arm.

For those GP's in the **Control Arm** they continue assessing and treating skin cancers as per the current best practice. Histology results will be collected and the clinical diagnosis and the histopathological diagnosis will be compared.

The **Dermoscopy Arm** will be given an approximately 4 hour Internet or CD based dermoscopy training session in the use of the 3 Point Check List. They will be provided with a hand held dermoscope ( 3-Gen Dermlite DL100). All skin lesions will be assessed with the dermoscope using the 3 Point Check List. Any lesion that scores 2 points or more will then be treated for skin cancer. Again the clinical/ dermoscopic diagnosis and the histopathological diagnosis will be compared.

## **Your Clinic's Participation**

Your clinic's participation in this study will help to determine if this training and method of skin assessment will allow GP's to detect more skin cancers and “weed out” benign lesions than the current “naked eye” assessment. If this is confirmed it will have huge impact on how General Practitioners assess skin lesions in the future. Your practice has been randomised to the **CONTROL ARM**. Your GP(s) will continue to provide current best practice.

**Receptionists role:** You will be provided with study patient information sheets. These should be offered to patients who request to be seen regarding a skin lesion or mole. Ideally this should be provided prior to the appointment so it can be read before the see the doctor. The doctor will determine if the lesion needs to be removed or biopsied – if so the doctor will ask the patient to read the consent form and give consent. The consent form can be given to the patient consent is recorded electronically via the advanced form.

**Nurses role:** This will vary from practice to practice. Nurses are encouraged to make patients aware of the study and again provide study information sheets to those who have a suspicious lesion(s). A GP appointment would need to be arranged.

**Does the patient have to pay for the consultation if they consent to taking part in the study?** Yes, normal charging for GP or Nursing consultations and services still apply.

**Who should be invited to take part in the study?** Any patient that presents with a skin lesion or mole they or you are concerned about.

**Who can take part in the study?** Any patient with a lesion the GP determines needs to be biopsied or excised.

**Is there an age limit?** No.

**How do I access more Patient Information sheets ?** You can either fax the green cover sheet (in the plastic study folder) and these will be posted out to you or you can print copies directly from the PDF or WORD files on the CD.

**What are the green and orange sticky labels for ?** These need to be cut into individual labels and send with any specialist referral letter (the label should be attached to the referral letter with the protective backing left on). The purpose is so the specialist can attach this label to their lab form if the lesion is biopsied or excised thereby advising the lab to forward a copy of results to the study centre.

**How do we send patient information to you ?** This is done automatically via the advanced form . Data entered into the form is sent directly to South Link Healths EDI (electronic mailbox) . If you are not using the advanced form – paper copies should be forwarded in the envelopes provided about once a month.

**Who do we contact if there are any problems?** You can either email me directly - [mark@elanzclinic.co.nz](mailto:mark@elanzclinic.co.nz) or call 03 578 1665. If it is a technical problem with the advanced form or your server set up we may refer you to the IT team at Southlink Health.

**Our website** will have all the forms and most of the information that has been sent to you – so if you mislay any thing this is a good first port of call... [www.theskinclinic.co.nz](http://www.theskinclinic.co.nz) then click on the “GP Dermoscopy Study” tab

### **Histopathology specimens.**

Tissue for histopathology will be collected and delivered to that GP’s Lab service as per their current practice. The Laboratory staff will be blinded – i.e. they will not know which GP’s are in the dermoscopy or control arms.

Lab results will be sent electronically to the GP and a copy will be forwarded to the Study Data Base via HealthLink.

### **Duration of Study**

The study will run for approximately 12 to 18 months. This will depend on the number of GP’s and therefore lab specimens received. The current estimate is approximately 100 melanoma’s will be need to be detected in each arm to give the study sufficient statistical power to demonstrate emphatically if the 3 Point Check List is beneficial.

### **Results**

At the completion of the study all GP participants will receive a summary and the conclusions of the study. Dr Giuseppe Argenziano, a co-author of the paper published on the use of the 3 Point Check List and author of the Italian Primary Care Physicians study, is involved in the planning and analysis of the study.

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**Conflict of Interest** There is no conflict of interest to declare.

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