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Future directions
in cervical screening

Compass Trial

Information for Practitioners and Clinics

V5

08/12/2014

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On behalf of VCS Inc. thank you for agreeing to participate in the Compass Trial.

The Trial has been approved by Bellberry Ethics Committee and is being conducted in accordance with strict protocols.

In order to participate in the Trial you will be required to comply with the terms set out below. If you are unable to meet the requirements for the Trial detailed below, please notify a VCS Pathology Liaison Physician on 03 9250 0300 immediately and do not commence recruitment of Trial participants.

Please note that the following enclosures form part of the Trial details:

A. A Medical Practitioner Information Sheet setting out the background to the Compass Trial.
B. Insurance information for Practitioners
C. A sample Participant Information Sheet explaining the nature of the Trial, which is to be provided to each woman prior to seeking her consent to participate.
D. A sample Cytology Request Form/ Participant Consent Form to be completed and signed by each woman prior to enrolling her in the Trial.
E. The Adverse Events Form.
F. Protocol for the collection of cervical screening samples for the Compass Trial

Yours sincerely

A/Prof Marion Saville, co-Principal Investigator
On behalf of Victorian Cytology Service Inc.

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Role and Responsibilities

Your participation in the Compass Trial should be readily accommodated as part of the regular cervical screening service that you provide. However, the investigators acknowledge that additional steps will be required for the purposes of the Trial. These are:

1. To determine whether individual women are eligible for the Trial; that is, **does she meet all of the following criteria:**

    a) Women aged between 25-69;
    b) Attending for routine cervical screening;
    c) Resident of Australia; and

2. To provide the patient with a ***Participant Information Sheet*** (enclosure C). The woman should be given an opportunity to **read the information and ask questions**.

3. To obtain patient consent the patient must sign the ***Participant Consent Form*** (enclosure D) in order to document the consent.

    Prior to signing, please ensure that the woman is fully aware that her participation in the Trial is entirely voluntary, and that declining to participate will not have any impact on the cervical screening or any subsequent medical care that she receives. If she is unsure about taking part in the Trial, she should not be enrolled as a participant.

4. The cervical sample should be obtained as usual (with plastic cervical sampling instruments) and the entire sample should be placed into a **ThinPrep PreservCyt vial**. No conventional Pap smear slide should be prepared.

5. At the conclusion of the consultation:

    a) Mark the sample as “Compass” using the provided yellow Compass stickers; and
    b) Return the sample and Cytology Request Form/ Participant Consent Form (to be completed and signed by each woman prior to enrolling her in the Trial) to VCS Pathology.

Once the steps above have been completed, your responsibilities with respect to that patient’s recruitment in the Compass Trial are completed.

Adverse reactions and events

In the unlikely event of an adverse reaction or event arising from the taking of a sample or the use of the LBC collection kit, you will be required to complete the Adverse Events Form (enclosure D). Please complete this form and return it to Victorian Cytology Service, 265 Faraday Street Carlton, VIC 3053, marked to the attention of Associate Professor Marion Saville.

Test Reports and Trial Data

Once the sample has been taken and received by VCS Pathology, randomisation will occur and the sample will be tested according to the Trial protocol.

The laboratory reports which will be issued to you will specify the recommended management of screening intervals for the patient which will be:

- Women with **negative (normal)** results in the image-read **cytology** screening arm – **2.5 years**; and
- Women with **negative (normal)** results in the **primary HPV** testing arm – **5 years**, unless the woman has been selected for repeat testing at **2.5 years** as part of safety monitoring.

At the bottom of the trial report issued to practitioners there will be a tear off result slip for the woman. The tear off slip contains important information about when the woman is due for her next cervical screening and has a peel off card for her to keep. This card advises the woman when her next test is due. The back of the card also provides information for any practitioner the woman may see in the future with regard to cervical screening.

It is very important that the woman receives this card, except in the case where there is a need for referral to colposcopy where we understand that you will need to see her in person to explain her results and organize referral to a specialist. If your practice does not currently receive hard copy trial reports, or you do not wish to send the tear off slips, then please let VCS Pathology know and we can send these to women on your behalf.

The trial report will be accompanied by a brochure for the woman providing more information about her test results and the trial.

Health Practitioners will continue to receive reports from VCS Pathology and the Victorian Cervical Cytology Registry with respect to patients enrolled in the Trial, on the same basis as patients who are not enrolled in the Trial, except that the reports will be modified to meet the requirements of clinical care within the context of the Trial. All cervical samples collected for Compass participants should be collected using a **ThinPrep Preservcyt vial.**

All other research data, material and information arising from the Trial will be held and owned by UNSW Australia and Victorian Cytology Service as the researchers responsible for the conduct of the Compass Trial. Although Health Practitioners will not have access to such Trial material, results will be published in a series of scientific papers.

Insurance

It is a **condition** of your participation in the Trial that:

1. You, or the practice or clinic of which you are a member, are a current financial member of a Medical Defence Organisation (MDO) and have a **clinical trial level of cover** or otherwise have professional indemnity insurance which covers your medical practice.

2. You have notified your MDO or other insurer of your intent to participate in the Trial and that the applicable MDO or insurer has agreed that your insurance cover will apply to your participation in the Trial.

3. You comply with and maintain the applicable insurance cover for the duration of your participation in the Trial.

Note: Details of this Trial have been provided to a number of MDOs, which should facilitate the confirmation of insurance cover, as required above. In most cases, upon providing notice to your MDO, insurance cover will be automatically extended (at no additional cost) with respect to your participation in this Trial, as the Trial has been approved by ***Bellberry Ethics Committee*** *(which are registered with the NHMRC).*

It is recommended that you ***make your own enquiries*** *and* ***ensure that you are able to comply with these insurance provisions prior to recruiting participants for the Trial.***

Detailed information about insurance requirements can be found in ***Attachment B***

Liability Issues

The insurance cover which you are required to obtain, as detailed above, is expected to cover the collection of the LBC samples from participants which is a standard part of Health Practitioners' work.

With respect to the analysis of the samples, Victorian Cytology Service's insurance will cover any claims or losses which may arise (as is the case with any samples analysed).

To the extent that any claim or loss arises in relation to the conduct of the Compass Trial with relation to the Scientific Protocol (as distinct from the collection and analysis of the samples), the Clinical Trial Insurance cover obtained by the UNSW Australia and Victorian Cytology Service will apply.

Variation to Trial Procedures

It may be necessary, from time to time, for aspects of the Trial procedures to be modified or varied. Should this become necessary, you will be promptly informed of the required changes and will be supported in their implementation.

Compensation

Health Practitioners and Trial participants will not receive any payment or compensation for their involvement in the Trial.

Completion of Trial Recruitment

The aim of the Trial is to recruit 121,000 women. The VCS Pathology Liaison Physicians will keep you informed of the progress with recruitment and notify you when the target figure has been reached; following which no further patients will be eligible to participate. We anticipate that recruitment will occur over 18 months.

QI&CPD

As a participant in the Compass Trial, you are eligible to take part in the Active Learning Module and earn 40 category 1 QI&CPD points. Further details may be obtained from the VCS Pathology Liaison Physicians on, 03 9250 0300.

Further Queries

If you have any further queries in relation to the Compass Trial, please contact: Dr. Stella Heley, VCS Pathology Liaison Physician on 03 9250 0365

We thank you for your participation in the Compass Trial, and for contributing towards the development of a much improved cervical screening method for women in Australia.

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Attachments

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B. **Insurance information** for Practitioners
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