S D a l Cancer Study of the Prevention of Anal Cancer

ISSUE 1 MAY 2011

Welcome to the first SPANC (Study of the Prevention of Anal Cancer) newsletter.

Thank you to all of you who have joined SPANC so far. Your participation has played an important role in helping the study understand what works and what doesn't and we're constantly reviewing scheduling and procedures to improve your overall experience during your SPANC participation.

WHERE IS SPANC SO FAR?

SPANC started recruitment in September 2010 and has enrolled over 95 participants to date.

We are currently limited by space and staffing resources but hope in 2011 to employ a further two anoscopists and obtain more space for the study procedures to operate more efficiently and minimise the time needed to participate in the study.

Those of you returning for your first follow-up appointment will notice how much quicker the overall procedure will be. There will be no need to consent you again and the questionnaire has been reduced to around 10 minutes.

YOUR FEEDBACK – WHAT HAVE WE DONE TO IMPROVE SPANC SO FAR?

We appreciate your feedback and try to act on your suggestions wherever we can. Some of you have mentioned that logging into the SPANC website to complete your questionnaire in a public space can prove a little uncomfortable due to the SPANC logo on every page. We now offer you the option of logging directly into the questionnaire, bypassing the SPANC website and its logo.

We have also asked many of you if you would mind having a female anoscopist if we employed one in the future. Most of you said that you didn't mind however we would always give you the option if/when we did employ a female anoscopist.

FAIR DAY 2011

SPANC had its first stall at Fair Day this year. More than 160 people gave us their names for follow up and hopefully eventual enrolment into the study. It seems that gay guys are concerned about the growing increase in anal cancer and are keen to be involved in a study that is striving to promote regular anal screening for gay men.



SPANC would like to thank **Auscreen** and **Ego** who generously donated thousands of sunscreen samples for distribution at the Fair.

MAG MEETING 12 APR 2011

A group of SPANC team members attended the April meeting of MAG (Mature Aged Gays) held at ACON to give a presentation on the SPANC study. The meeting was well attended by about 120 people with around 30 people showing interest in joining the study. We were all impressed by the warmth and hospitality shown by the group.



WHAT DO WE KNOW ABOUT ANAL CANCER SO FAR?

The great majority of cases of anal cancer are caused by infection with human papilloma virus (HPV). HPV is the virus that is known to cause cervical cancer in women. There are more than 100 types of HPV. Some types cause genital warts and other types cause more than 90% of anal cancer. HPV is a very common sexually transmitted infection that most gay men get at some stage in their lives. Most gay men with HPV do not develop anal cancer.

Risk factors for anal cancer include the following:

- Being older: over 45 years old if HIVor over 35 years old if HIV+.
- Having many sexual partners and having receptive anal sex (these reflect the risk of anal HPV infection).
- · Smoking cigarettes.

It is not know what causes a small minority of those men with anal HPV infection to develop anal cancer.

The treatment of cancer of the anus usually involves radiotherapy and chemotherapy. Cancers that arise outside of the anus in the skin are termed perianal skin cancers or anal margin cancers. These are treated as skin cancers and not as true anal cancers.

WHY SPANC?

SPANC is a study of anal HPV infection and related anal disease in gay men.

Gay men are more than 20 times more likely than other men to develop anal cancer. This study will provide information to guide the possible future introduction of anal cancer screening programs for gay men. We also hope to find out more about the anal changes caused by HPV. The aim of SPANC is to determine whether regular anal testing should be introduced to prevent anal cancer.

66 As this is our first newsletter we thought we'd include a more detailed background on SPANC, the motivation behind the study and a little about the SPANC team 99

WHO PERFORMS THE HIGH RESOLUTION ANOSCOPY?

Currently we have two doctors who will perform the High Resolution Anoscopies (HRAs). They are Richard Hillman and Dave Templeton. We are training more doctors to enable the further expansion of the study.



<u>RICHARD</u> HILLMAN

is one of the co-investigators for the SPANC study and is the main anoscopist

performing the High Resolution Anoscopies (HRAs). Following specialist training in HIV medicine and sexual health, Richard ran a large HIV unit in London, before moving back to Scotland. Since arriving in Australia in 2001, he has been Course Coordinator and initiated a major redevelopment and expansion of the University of Sydney Masters of Medicine (STD/HIV) Program.

Richard has broad research interests in sexual health, including clinical aspects of HIV, the diagnosis of sexually transmitted infections and vulnerable populations. His doctorate was in the molecular epidemiology of Human Papillomaviruses. His research output includes more than 30 peer reviewed articles, nine letters, six review articles, two books, two book chapters, and more than 60 presentations at local and international meetings. He currently has a number of ongoing projects including in areas as diverse as anal cancer, sex workers and sexual health teaching.



<u>DAVE</u> TEMPLETON

is a Sexual Health Physician who has been specialising in management of HIV

and other STIs for over 10 years. Dave is currently a NHMRC postdoctoral researcher and Clinical Anoscopist for the SPANC study at St Vincent's Hospital, having trained in Anoscopy in San Francisco and Sydney. Dave is also Manager and Staff Specialist at RPA Sexual Health in Sydney's inner west, and Senior Lecturer at the National Centre in HIV Epidemiology and Clinical Research. Dave completed his PhD in 2008 at the Kirby Institute (formerly NCHECR) on STIs and HIV in the Health in Men study. He has published almost 50 papers in the scientific literature, mostly regarding STIs and HIV in gay men.

WHO ELSE IS INVOLVED IN SPANC?

The SPANC team is made up of a large number of organisations that include investigators, community members, doctors, clinical and research staff and laboratory clinicians. Here are a few of the people that you may be in contact with as a participant in the SPANC study. All the members of the SPANC team are listed at the end of this newsletter.

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TARA MAHER

CLINICAL TRIALS NURSE

Tara has worked at St Vincent's Hospital on the SPANC study

since September 2010. Prior to her appointment at SVH she worked in the HIV/GUM Clinical Trials Department at the Royal Sussex County Hospital in Brighton UK since April 2003. Tara has over 15 years experience in the field of HIV medicine and has worked on many studies including large International studies and smaller Investigator led projects.

Prior to her arrival in Australia Tara was involved in a large European teaching programme for the initiation of a new drug for the treatment of neuropathic pain and has taught at training sessions in both the UK and Ireland and provided support to clinicians using the product for the first time.

On a personal note Tara arrived in Australia in July 2010 with her partner and two small dogs and as well as her commitment to Clinical Trials Nursing she also has a passion for the welfare of animals.



<u>BRIAN</u> ACRAMAN

SPANC RESEARCH

Brian has worked with the SPANC study since

April 2010 assisting in the questionnaire development and implementation. He began work with the Kirby Institute in 2001 and has worked on other cohort studies such as the Health in Men Study (HIM) and Positive Health (pH).



PATRICK MCGRATH

SPANC RESEARCH ASSISTANT

Patrick joined NCHECR in 2001 as an interviewer

with the HIM (Health in Men) and pH (Positive Health) Studies. He takes enquiries from men interested in joining the SPANC Study and liaises with enrolled participants and clinical staff.



ALI SEVEHON

CLINICAL TRIALS NURSE

Ali has worked on the SPANC study since it began in September

2010 and has worked at SVH since 1996 in various roles as a registered nurse. She has been working with Richard Hillman assisting in HRA clinics for the past two years. She has worked predominantly with HIV and cancer patients since 1990 but for the past three years have been working in immunology ambulatory services in IBAC, targeting service at patients with HIV, Hepatitis C viral infection, and non-HIV immunological disorders.

THE CLINICAL SUB-COMMITTEE

This committee meets fortnightly at the moment to review any clinical issues raised for discussion.

from left: Richard Hillman, Richard Norris, Dave Templeton, Dorothy Machalek, Ali Sevehon, Winnie Tong, Tara Maher, Patrick McGrath, Mary Poynten, Brian Acraman, Jeff Jin, Andrew Grulich.



WHAT ARE THE KEY COMPONENTS OF SPANC?

RECRUITMENT

Recruitment to SPANC is currently via Facebook advertisements, advertising banners on the ACON and Positive Life websites, word of mouth and community events such as Fair Day.

CONSENT

At your first visit the study doctor or nurse will review the consent forms with you and answer any questions before you are asked to sign.

INTERVIEW

This is an Audio Computer Assisted Self Interview (ACASI) questionnaire which you complete in private and at your own pace on a touch-screen computer. The first interview normally takes around ½ hour to an hour to complete. At follow-up visits, it is much shorter (about 10 minutes).

FULL STI TESTING AND HRA WITH/WITHOUT BIOPSIES

The nurse will perform standard STI testing using venepuncture (blood tests urine samples and anal and throat swabs. The HRA is performed last. After this is completed, you're free to leave or to rest a moment in the waiting room or at the St Vincents coffee shop where you can use a \$10 refreshment voucher provided by the nurse.

TWO WEEKLY AND THREE MONTHLY FOLLOW-UP QUESTIONNAIRES

At two weeks, and again at three months, after you receive your test results we will ask you to complete a brief 10 minute questionnaire online via our website. The purpose of these questionnaires is to help assess your wellbeing after the HRA procedure and receiving your test results. This is also a good opportunity for particpants to tell us what worked well with the procedure and/or where we could improve things to make the procedures more comfortable and informative.

SIX-MONTHLY FOLLOW-UP VISITS

These follow-up visits (approximately every six months over the three years of the, Study), will help provide further important information on the way the human papillomavirus affects anal health. They will also assist in keeping participants informed of any changes to their anal health.

SPANC TIMELINE

- 2009–10 Planning and setting up of the study before approval sought by St Vincent's ethics committee and the University of New South Wales' ethics committee.
- 2010–11 Approval granted by St Vincent's and the University of New South Wales' ethics committees. Study begins recruitment in September 2010.
 - 2011 Recruitment of new participants continues through the year. Six monthly follow-ups begin.
 - 2012 Six monthly follow-ups continue.
 - 2013 Six monthly follow-ups continue.
 - 2014 Six monthly follow-ups continue.
 - 2015 Final data analysis commences.







WHAT MORE CAN YOU DO TO HELP?

If you are reading this e-newsletter, you will probably have already enrolled in the study. If not and you feel you'd like to be a part of this important project, simply complete the registration page on the SPANC website and we'll get back to you and answer any questions before making an appointment for you. And don't forget to encourage your friends to check out the SPANC website and hopefully join in this important study as well.

THE SPANC TEAM

The Kirby Institute (formerly the National Centre in HIV Epidemiology and Clinical Research)

Principal Investigator

Professor Andrew Grulich

Co-Investigator

Associate Professor Garrett Prestage

Co-Investigators

Dr Mary Poynten
Professor Matthew Law
Dr Dave Templeton
Dr Jeff Jin

Associate Professor Richard Hillman

Research Assistants

Patrick McGrath Brian Acraman

St Vincent's Hospital, Sydney

Co-Investigator

Professor Andrew Carr

Clinical Research Manager

Mr Richard Norris

Anoscopist

Associate Professor Richard Hillman Dr Dave Templeton Dr Winnie Tong

Research Nurses

Tara Maher Ali Sevehon

Research Assistant

Brian Acraman

Sexually Transmitted Infections Research Centre (STIRC) Westmead

Co-Investigator

Associate Professor Richard Hillman
Dr Jeff Jin

Melbourne Sexual Health Centre and the University of Melbourne

Co-Investigator

Professor Christopher Fairley

Royal Women's Hospital Melbourne and the University of Melbourne

Co-Investigator

Professor Suzanne Garland

Dept of Microbiology, Royal Women's Hospital, Melbourne

Co-Investigator

Associate Professor Sepehr Tabrizi

Douglass Hanly Moir Pathology

Co-Investigators

Professor Annabelle Farnsworth Dr Jennifer Roberts Ms Adele Richards

School of Public Health, University of Sydney

Co-Investigators

Dr Kirsten McCaffery Dr Kirsten Howard

Positive Life

Community Representatives

Dr Kathy Triffitt Mr Rob Lake

ACON

Mr Ian Walker

Data Safety Management Board

A data safety monitoring board (DSMB) meets every 6 months to review study recruitment, any adverse or serious events and ethics concerns. This board is currently made up of:

Professor Andrew Grulich Associate Professor Richard Hillman Professor Andrew Carr Dr Kathy Petoumenos Dr Kirsten McCaffery Mr Ian Walker



SPANC is funded through the Australian Government's chief medical research agency, the National Health and Medical Research Council. Over the life of SPANC, more than \$1.5 million will be invested in anal cancer prevention.