

# spanc

Study of the Prevention of Anal Cancer

ISSUE 13 FEBRUARY 2018

## SPANC WILL END THIS YEAR

After almost 10 years of research vital for our community, **SPANC** will finish its clinical observations by April this year. For those of you who do have a final clinical visit due, Pat will be calling you soon, but please feel free to give us a ring on 9385.9201 or 1800.477.262 to book. This will be your final opportunity to have an anal health screening in the SPANC study, while also assisting this important research one last time. The non-clinical 'review visits' (where the doctor will discuss your overall study results with you) will continue until August

### IN THIS ISSUE

- Welcome to the new staff who will take us through to the end of the study
- SPANC Information Night
- Some of your questions asked at the SPANC Information Night
- We thank the generous donors of prizes for the SPANC Information Night

### Welcome to new staff taking us through to the end of SPANC



**Amber Ellis**

**Amber** joined our SPANC team at RPA Sexual Health in February last year, extending her sexual health nursing position. Prior to working in sexual health Amber was an emergency department nurse at St Vincent's Hospital. She is enjoying public health research and will commence her Master of Public health and Tropical Medicine in 2018.



**Simon Comben**

**SPANC** also welcomes **Simon Comben** who has taken over from Dan Seeds at our SVH SPANC site. Simon started working on SPANC November 2017 after working for 3 years at Royal Prince Alfred Hospital. There he worked on surgical and medical wards and spent the last year and a half in Intensive Care. Prior to studying nursing he completed a Bachelor of Science in medical microbiology and immunology. He is looking forward to his new role with SPANC as a clinical trials coordinator.

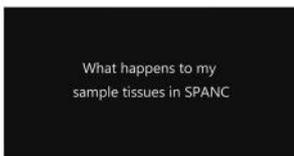
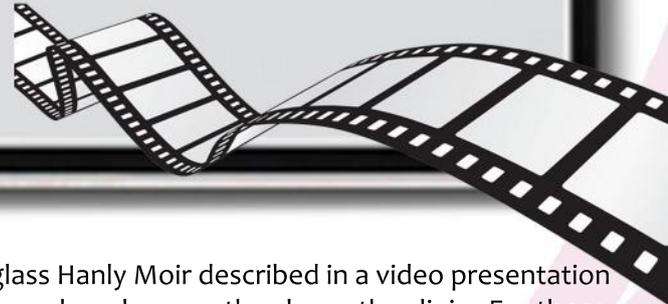
## SPANC Information Night - Video Messages



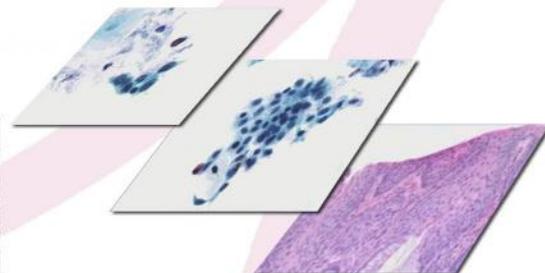
**President and Vice-Chancellor of UNSW Australia Professor Ian Jacobs** acknowledged the support of the participants in the study recognising they sometimes faced some challenging moments at their study visits. He said SPANC participants were not only doing a great job helping gay men's health but also the community's health in general in the fight against anal cancer. He thanked the SPANC participants and wished everyone a great SPANC Information Evening



**The Hon. Michael Kirby** once again sent his greeting from the SPANC 'engine room' (the Research Assistants' office at the Kirby Institute, UNSW) He stated he supports "the work of SPANC and honours the volunteers in contributing to this medical research in the interest of the gay community, Australia and the world where the Kirby Institute is at the cutting edge of research in this area." He thanked everyone sincerely for their volunteer participation.



**Jenny Roberts** - SPANC Pathologist at Douglass Hanly Moir described in a video presentation what happens to your biopsy tissue samples and swabs once they leave the clinic. For those of you interested in watching this fantastic presentation, you'll find the video on the SPANC website [www.spanc.org.au](http://www.spanc.org.au). Just look under 'reports' where all the SPANC newsletters are found. If you're reading this online click [HERE](#) to view the video.





# Speakers at the SPANC Information Night...



## Dare to D.A.R.E



**A/Prof Richard Hillman**, Chief Clinical Investigator of the SPANC study talked about 'Taking care of downunder' and getting to know your bottom from its anatomy to its function. He also gave tips for good anal health: Healthy diet, including fruit and vegetables; Healthy hygiene habits; Healthy sex life etc. He urged participants to become familiar with performing their own D.A.R.Es (Digital Ano Rectal Examination) between visits to a doctor that might also perform these examinations. For more information on performing a D.A.R.E you can visit <https://www.youtube.com/watch?v=KDUcJHdzSk> where Richard explains the procedure in full.



Digital Ano Rectal Examination



## Potential Implications

**Prof Andrew Grulich**, Chief Investigator of the SPANC study talked about the SPANC data in his presentation, 'Where to from here' He explained the latest findings from SPANC data that went against long held views on anal cancer: High grade lesions frequently clear on their own without the need for treatment; and High grade lesions usually persist in men who have persistent HPV infection.

SPANC finding	Implications
High grade lesions frequently clear on their own without the need for treatment	<ul style="list-style-type: none"> <li>We should not treat all men with high grade lesions</li> <li>We should target treatment to those men who have persistent high grade lesions</li> </ul>
High grade lesions usually persist in men who have persistent HPV infection	We should trial type-specific HPV testing as a screening test
<b>SPANC follow up to 3 years required to confirm these interim conclusions</b>	



## Keep SPANCman happy!



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Study of the Prevention of Anal Cancer



**Dr Carmella Law**, Site Principal Investigator of the SPANC study at St Vincent's Hospital, gave a brief SPANC history explaining how over time SPANC has listened to its participants and implemented steps to address issues like appointment scheduling, addressing pain, a more comfortable chair for undergoing the anal procedures, to the overall well-being of the participant throughout their SPANC visit experience. Some issues weren't resolved straight away but over time these changes were made. It would be true to say that the experience a participant had in SPANC back in 2010 when the study first started is now totally different to what a SPANC participant is used to these days. It is also true to say that Carmella was in the forefront pushing for these improvements.

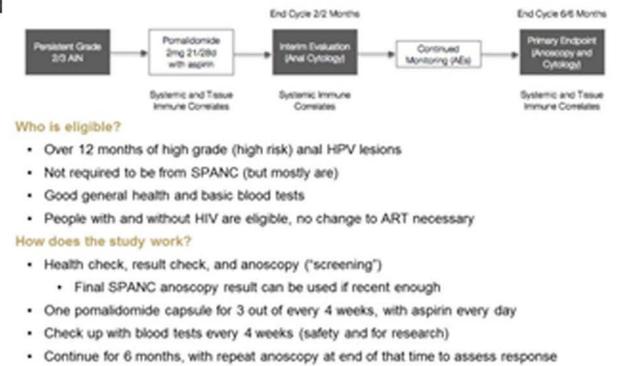
## Speakers at the **SPANC** Information Night...



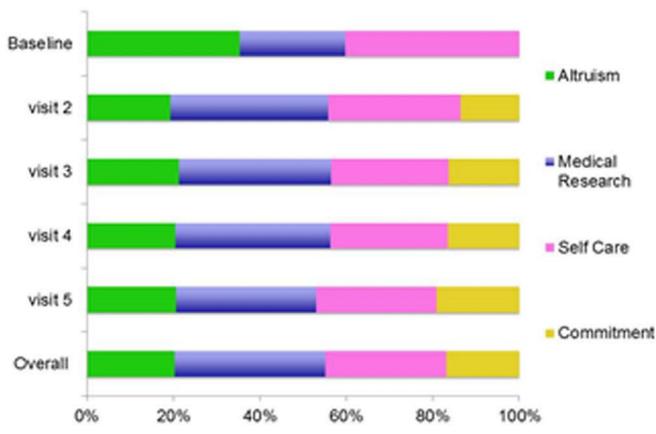
**Dr Mark Polizzotto**, Chief Investigator of the SPACE study talked about the use of a treatment drug to enhance the immune response to the cancer in participants who'd had over 12 months of high grade (high risk) anal HPV lesions. The SPACE study is using the drug Pomalidomide for its treatment. For information about this study please email [mpolizzotto@kirby.unsw.edu.au](mailto:mpolizzotto@kirby.unsw.edu.au)



### SPACE Study Plan



### Changes in SPANC motivation over time



**Patrick McGrath**, Research Assistant in SPANC examined the reasons you gave for joining, and staying in, SPANC (a question asked in your survey at each visit) He pointed out a shift in motivation over time, from altruism and self-care at Baseline, to assisting medical research at later visits. When he asked, 'Who feels they know more about their anal health today than before they joined the Study?', every hand in the room went up, a powerful and gratifying result for a study that has had to focus on clinical data for analysis, but through its study machinery (a consultative process with clinicians, regular Newsletters, Info Nights, annual presence at Fairday, and always-open communication lines), has generated wide community knowledge about anal health, and specifically anal cancer.

**A/Prof Dave Templeton**, Site Principal Investigator of the SPANC study at RPA Sexual Health gave an update of the findings in SPANC so far and an outline of the SPANC publications currently available. We'll endeavor to keep the SPANC website up to date with these [www.spanc.org.au/reports](http://www.spanc.org.au/reports)



### In conclusion....

- Early SPANC results show great promise in:
  - better understanding the natural history of anal HSIL
  - identifying a minimally invasive screening test for persistent HSIL (& thus GBM at highest risk of future anal cancer)
- In men with HSIL at baseline
  - >50% persisted and >20% cleared at 12 month visit
- Persistence strongly related to HRHPV/HPV
  - Repeat HRHPV/HPV16 positivity: **almost no likelihood of clearance**
  - Two HPV tests, separated by at least 6 months, may identify men with chronic HRHPV infection at risk of anal cancer
- We need more anoscopists...

# Q & A

## The panel at the Information Night give some answers



What percentage of gay men get HPV?



**Andrew:** A great majority of gay men get HPV. In fact a great majority of heterosexuals get HPV, and science still can't predict in whom HPV will go away on its own, and in whom it will persist. Testing on SPANC specimens will help advance this science, by comparing men who get HPV and clear the infection, to men who get HPV with high grade disease that does not go away. Immunological and genetic factors may be important, and we also know that smoking increases the risk of getting anal cancer.



A/Prof Richard Hillman



**Richard:** Immunologically, there are clearly defined risk factors that Andrew's just highlighted, but as a clinician working in the field I see a different perspective clinically, and it's seems to be random sometimes. Some guys who have a busy sex life, and who you may think would be in contact with the virus more, may never develop any symptoms from HPV. In contrast some guys with very few partners may have the HPV virus which develops into cancer. So, whilst the immunological factors are incredibly important, they're by no means the whole answer; whether it's genetics or whether it's random, we need to find out as we start looking at screening tests.



Prof Andrew Grulich



I'm HIV positive and have been diagnosed with high-grade anal disease, what can I do to stop it going to anal cancer?



**Richard:** Look after yourself in terms of diet, nutrition, non-smoking. Beyond that we don't have any magical pills to stop it at the moment.



Dr Carmella Law



When I give myself my self-administered **DARE** (digital ano/rectal examination) test, what am I looking for?

*[at this point, for demonstration purposes, Richard drew attention to some rubber artificial anuses he'd brought in, noting that each one had a different name plus a tracking device inserted just in case they went missing .... to much amusement from the audience]*



**Richard:** Essentially you're looking for a lump. We now know from studies in the US that people can detect a lump as small as 3mm diameter. A really well-trained finger can detect something the size of a grain of rice, or just a change in smoothness of the lining of the anal canal. Practise makes perfect, I mean that - just as women learn to detect abnormalities in their breast which has made a significant impact on their health, I'd like gay men, if they're comfortable, to do that with their anuses. It would be good for gay men to learn the same skills and find abnormalities in their anal canal at a very early stage.



A/Prof Dave Templeton



Dr Mark Polizzotto

# Q & A

*...the panel at the Information Night give some answers*



Is it obvious, when doing the finger test (DARE) what the difference is between the start of anal cancer, and, say, a haemorrhoid?



**Richard:** Haemorrhoids are incredibly common; they're almost a natural, physiological, event. A haemorrhoid is basically a bag of blood which occurs because we stand upright. We evolved two-three million years ago to stand upright and that caused hydrostatic pressure to lead to ballooning of some of the blood vessels. You see varicose veins in people's legs - haemorrhoids are basically varicose vein in the arse. In the early stages they can be compressed or collapsed because they're only a bag of blood, but if they become thrombosed (clotted) they will become solid and you can detect them. If you find any new abnormality, or symptoms change, then you should get a health care professional to have a look at it. This is most important. It may well turn out to be insignificant, but at least you'll know.



Regarding the issue of keeping our anus clean, saunas have chlorine in the jacuzzi, and at home I use glycerine soap. Years ago a doctor told me not to use soap on my bum. Can you comment?



**Richard:** Your anus is a very special part of your body. There are a huge number of nerve endings. The skin there is more delicate than the skin on your feet or hands, and second only in sensitivity to the skin of the head of the penis. When soap manufacturers make their soaps, they optimise them for the general skin condition. They don't optimise for the most sensitive parts of our body, the anus and under the foreskin in uncircumcised men. So, in soaps and shower gels, there are chemicals that in most cases don't affect people, but can cause problems in some people. Soaps can dry out the natural oils of the skin, change the eco-system of the natural, healthy skin bugs, and deposit a number of different chemicals which can cause eczema-type conditions. Toilet paper can have a very abrasive impact on the anus. If people are overzealous with its use it can cause trauma to the area, and potentially this could introduce allergens into your system. Do not use soap unless you really need to - you really just need to remove the loose materials from the area. Our bodies have evolved over millions of years in the absence of soap, and our immune systems are amazing in the anal canal region, they're phenomenally effective in dealing with infections. Do not use things like Dettol, bleach or baby wipes on your bottom, as you will do more damage than good.



I was diagnosed with ITP (Idiopathic thrombocytopenic purpura) 10 years ago. I'm OK now and my platelet levels are back up to 175 to 180. I've been asked to go on the SPACE study. Will that affect my immune system in any way?



**Mark:** In general the SPACE study is set up to keep a close eye on safety during the study, including regular blood tests. I would recommend a one-on-one consultation discussing your particular circumstance and medical history with ITP, to give you a definite answer to your question.

# Q & A

*...the panel at the Information Night give some answers*



The participants seem to consist of more mature men. Was that by design or was that who signed up? Is there a reason there isn't a broader spectrum of ages?



**Andrew:** The main reason we aimed at recruiting guys from 35 years and up is that anal cancer is very rare in younger men under 35. Although we know that HPV infection starts from when people begin to become sexually active, we felt that the intervention program should commence closer to an age when people are going to be at risk of anal cancer, particularly when we were asking as much from our participants in terms of procedures and discomfort as we did.



There don't appear to be younger guys here tonight in the audience. Did you get a pretty good spread in ages when recruiting?



**Andrew:** Yes, we got quite a good spread in ages; the average age was about 50. Perhaps guys more at retirement ages have more time to come to events like this?



I have 2 questions. First, as when I go to my doctor for my regular prostate exam, can I assume that he will automatically check for anal cancer at the same time, or do I have to ask specifically for this to be done? Would they be knowledgeable enough to pick up anything abnormal during a normal prostate exam procedure? Secondly, you mentioned tonight a 100% cure rate for anal cancers under 1cm, but less so if it was picked up at 3cm. From 1cm to 3 cm, does that take a long time? Is it a quick growing or slow growing tumour, generally speaking?



**Dave:** To answer the first part of your question: I think the key thing is that a lot of people specialised in the area will not be looking for anything else but obvious abnormalities or the shape of your prostate. They aren't really trained or experienced in looking for anal cancers. So I would suggest going to a gay-friendly GP or sexual health clinic where doctors know what they are looking and feeling for, and who have had the experience of doing this on a regular basis. To answer your second question: the growth rate of cancers can vary quite a lot. Some grow really slowly over years and others a lot sooner. There are numerous factors associated with this. However even self-examining you are definitely going to feel a growth of 1cm. As Richard said, go along to a doctor who knows what he's looking for and get yourself checked out.



You said earlier to avoid using soaps on the anal area. I use less invasive washes like Dermaveen soap-free liquid. Is this ok?



**Richard:** There's a huge variation amongst users – some people can tolerate all sorts of products on their skin, others can't. If you find using this product doesn't irritate you, then that's fine, but we do see under the microscope a lot of disturbed skin from overzealous washing. So try to just use water if possible, and see how you go.

# Q & A

*...the panel at the Information Night give some answers*



Are the various creams and oral medications used when treating HPV tested on animals?



**Mark:** There's a very long testing process in safety testing before a product is approved for human use that generally includes testing on animals at the earliest stage. That often gives signals as to safety, and many agents never get past that stage. The focus in the first stage studies in humans is also safety, ensuring the agent is also safe in humans, and then we move on to studies of efficacy: whether it works for particular conditions. That progression of safety and efficacy is built into studies like the ANTIVA Study and the SPACE study.



Given that HIV is a disease where coagulation is increased even in treated people, and the risk of sclerosis and stroke is increased, I'm interested in the therapy that you mentioned about taking it with aspirin and also the fact that that therapy increases immune activation. Are there risks that we do not know and might there be unforeseen consequences to that treatment?



**Mark:** We did do a lot of work earlier with this medication treating people with HIV and monitoring, for example, their levels of inflammation and levels of their HIV drugs which is of major concern, as HIV drugs affect other medications in a number of ways and vice versa. In that earlier study we were reasonably confident that with a short exposure to the drug we weren't doing anything that was untoward. Regarding the blood clotting question: these drugs were developed for people with advanced cancers, and we know that people with cancer are at very high risk of blood clots, far more than people with treated HIV. It's not clear that in a healthy individual with treated HIV there's an increase in blood clots, but we included the aspirin to be on the safer side.



First a comment: In reference to Carmella's management innovations, I think the changes where the participant saw the same clinician and nurses at each visit, constant and familiar, and then being able to see the doctor for a quick catch-up before the procedure, were really good changes and made the participant feel more comfortable. So thank you for that Carmella! Q: In the survey there's lots of focus on sexual practises, lubricants used etc. Has there been any correlation between use of lubricants and condoms and the development of anal cancer?



**Andrew:** I just want to make one comment about behaviour and becoming HPV positive in the anus. I think it's a fairly common misconception that bottoms are much more likely to get anal HPV than tops, and I thought we'd find this our data. In fact we found that tops were equally likely to have anal HPV. This surprised me. We think that's because HPV isn't like catching gonorrhoea, or HIV for that matter, where you have to be exposed to semen or blood. HPV lives on the skin and research studies have found a correlation in men with HPV on their penis and HPV on their hands and under finger nails, so if the anus gets touched or it gets a finger in it then transmission is quite possible. So that's something that men should be aware of. As far as lubricants are concerned I don't think there's any evidence of correlation with anal cancer. HPV is a virus, and anal cancer is a virally-related cancer, and you'd have to hypothesize that the lubricant had some influence on the virus and I don't think that's the case.



**Richard:** other earlier studies have looked at men with existing cancers, and worked backwards at trying to figure out what factors led to its development, and those findings are of poor quality because of observer bias etc. SPANC is what's called a 'prospective' study. We started with research participants and then followed them over 3 years. In that way we've been able to provide some absolutely high quality data. Thank you for spending hours doing those endless questionnaires, and providing that high quality data, which I don't think previous studies have been able to provide.

# Q & A

*...the panel at the Information Night give some answers*



If you go down the self-examination route, how often do you recommend doing it?



**Richard:** If you are an HIV positive gay man, the minimum would be annually but that's a minimum. It's important to become comfortable with the process, so probably once a month is a good idea. If you are an HIV negative gay man then the current guidelines suggest once every 2 to 5 years. There is no hard evidence behind these recommendations at present; it's just that researchers with a knowledge of the disease processes think that this is a reasonable idea. We need to learn from you guys what it's like to do, and what's acceptable to you. There's been very little data looking at this DARE procedure so we're at the forefront of research in this area.



Andrew was just saying that HPV can be transmitted from the hand so would you recommend that when you're doing these anal examinations we should wear a glove, or would that make our finger less sensitive?



**Richard:** We would normally recommend you do this with a glove as HPV is incredibly easy to transmit. It's pointless worrying about it in terms of your sexual practice, because you'll probably get exposed to it. HPV is a necessary, but not sufficient, cause of the development of cancer and pre-cancer. The only way to reliably prevent getting HPV is to get vaccinated before you are sexually active, or never have sex.



About Gardasil: there's a planned vaccination of teenagers next year. While I'm no longer a teenager, can we access a similar vaccination through SPANC or some other means? And what protection would it give SPANC participants?



**Richard:** Gardasil is available now to everyone, it's just that it is only provided free to school age students. The evidence indicates that it works if you are under the age of 26 years. There are no good data for older men, although we do know that it produces a good immune response, including in people with HIV. "Gardasil 9" is the new version that is coming out in 2018. It targets an additional 5 types of HPV, and so provides a wider protection. Unfortunately the same age recommendations are also likely to apply where older people will require 3 shots of the vaccine instead of 2 as is the case for people under 26.



Re self-examinations: it's hard to feel around using the front of your finger, you can only twist it so far. What's the best technique and is there any literature, or videos etc, to show how?



**Richard:** Good question. We are still experimenting with that! If you are right handed, then (if you are reasonably flexible) you can feel the left hand side, front and back of the anal canal. You will find it easier to use the index finger on your left hand to for examining the right hand side of the anus. You may find the following resources helpful: <https://www.youtube.com/watch?v=KDUcJHdz-Sk>  
<https://svhs.org.au/home/our-services/list-of-services/HIV-Immunology-Infectious-Disease/Dysplasia-and-Anal-Cancer-Services>



If you discover a wart, should it be treated if small, or should you wait?



**Richard:** A simple wart is essentially a cosmetic problem. Many people do not treat them, and they occasionally go away of their own accord. If you are worried, seek the advice of a trained healthcare professional, such as your GP or at a Sexual Health clinic. Always seek help if they change in appearance or start bleeding.



*With  
Many Thanks  
to the wonderful  
organisations and individuals  
who donated so generously to the*

# SPANC Information Night



SPANC is funded through the Australian Government's chief medical research agency, the National Health and Medical Research Council and the Cancer Council of NSW. The total through these two sources is over \$3 million.



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