Masters of Philosophy in Applied Epidemiology
Australian National University

‘Infectious diseases among marginalised populations’

Dina Raus Saulo
November 2014

Field placement
The Kirby Institute

Field Supervisors
John Kaldor & Tony Butler

Academic Supervisors
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Funded by: Indigenous Offender Health Capacity Building Grant, Justice Health Research Program, Kirby Institute & the Leonard Broome Scholarship
Declaration of Work
This body of work includes multiple discrete projects that were undertaken collaboratively with multiple stakeholders and the author acknowledges the contribution made by each of the stakeholders involved in the projects. Taken as a whole document, the author certifies that this thesis is an original work. None of the work has been previously submitted by me for the purpose of obtaining a degree or diploma in any university or other tertiary education institution. To the author’s best knowledge, this thesis does not contain material previously published by another person, except where due reference is made in the text. The author acknowledges that copyright of published works contained within this thesis resides with the copyright holder(s) of those works.

Dina Raus Saulo

Dated: 17th December, 2015
Abstract

From February 2013 to November 2014 I undertook a field placement at the Kirby Institute for Infection and Immunity in Society (the Kirby Institute), as a part of a Master of Philosophy in Applied Epidemiology (MAE). This bound volume is the product of projects undertaken while at the Kirby Institute in the Justice Health Research Program and the Public Health Interventions Research Group. Within are six chapters which demonstrate work undertaken, lessons learnt, knowledge gained and MAE requirements met.

Due to my placement predominantly in the justice health research program, three out of four major projects have a focus on blood borne viruses and associated risk factors among offender populations. I evaluated the national prison entrant’s blood borne virus and risk behaviour survey (NPEBBVS), the only multi-jurisdictional prison BBV monitoring mechanism nationally. As a data analysis project I explored hepatitis B core antibody and hepatitis C antibody prevalence and associated risk factors among Indigenous and non-Indigenous prison entrants from the NPEBBVS. Findings from this chapter were presented at a number of conferences and events. As an acute public health problem, I had the opportunity to investigate hepatitis C (HCV) incidence cases in a prison facility. We developed a case series study using mixed methods to collect data on the unusual cluster of HCV cases. I conducted both quantitative and qualitative interviews with participating inmates to gather prisoner’s perspective of HCV incidence, understanding routes of transmission in the prison setting and possible strategies in decreasing exposure and risk.

From the start of 2013 I was involved in the ‘vaccine impact in the Indigenous population’ (VIP-I) study with a large group of investigators. The aim of VIP-I was to evaluate the effectiveness of the HPV vaccine among Indigenous women in Australia. My role in the study was as a field coordinator, chapter 5 demonstrates my involvement from the development stage onwards. This chapter is largely methodological, only preliminary results are presented as recruitment is still ongoing.

Teaching experience during the MAE included; lessons from the field and a group teaching session with MAE peers. I worked individually on a project management module for the lesson from the field exercise, my fellow MAE cohort completed this module which touched on interdisciplinary collaboration in research. The group teaching experience was created and conducted with two fellow MAE scholars, we built a framework to distinguish real or artificial rate change when interpreting time series data.

The projects within this thesis contribute to the Kirby Institutes area of work with marginalised at risk populations. I have been fortunate to be a part of a number of projects that have
potential to impact public health policy and programs for both Indigenous and offender populations.
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Acknowledgments

The MAE has been an amazing experience; I can’t recommend it enough to people wanting a solid foundation in field epidemiology. I appreciate the ability to have worked on a diverse range of projects and collaborations throughout my placement at the Kirby Institute.

Firstly, I would like to thank Rebecca Guy and John Kaldor for suggesting I apply for the MAE in 2012 and Tony Butler for the ability to join the Justice Health Research Program under the Indigenous Offender Health Capacity Building Group. I would like to particularly acknowledge my field supervisors: John Kaldor (Head of Program, Public Health Interventions Research Group) and Tony Butler (Head of Program, Justice Health Research Program). Thank you both for your time and support during my placement at the Kirby.

To my academic supervisors Stephanie Davis, Phyll Dance and Emily Fearnley, thank you for your support, encouragement and guidance throughout the MAE. Additionally thank you to Martyn Kirk and other staff of the MAE program at National Centre for Epidemiology and Public Health.

I have acknowledged collaborators and investigators of projects within the bound volume however there are people who I have worked with or had support from along the way who I would like to say a special thank you to; Skye McGregor, Paul Simpson, Michael Levy, Amalie Dyda, Lise Lafferty and Lorraine Yapp.

Kerryn, Pip, Anna, Courtney, Tim, Anita, Jason and Tove: It was a pleasure doing the MAE with you all, I look forward to see where the future takes us all.

Family and friends have been such support during the MAE: Mum, Dad, Johnny and Benson, love you all. Harp, Kristie and Summer thanks for scheduled study breaks and check-ins. And lastly Liam Ridgeway, I wouldn’t have been able to do this without you, thank you for your constant love and support.
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Field placement & summary of core activities
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<th>Abbreviation</th>
<th>Full Form</th>
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<tbody>
<tr>
<td>ANU</td>
<td>Australian National University</td>
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<tr>
<td>BBV</td>
<td>Blood Borne Viruses</td>
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<tr>
<td>HBV</td>
<td>Hepatitis B</td>
</tr>
<tr>
<td>HCV</td>
<td>Hepatitis C</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>HPV</td>
<td>Human papillomavirus</td>
</tr>
<tr>
<td>IOH-CBG</td>
<td>Indigenous Offender Health - Capacity Building Group</td>
</tr>
<tr>
<td>JHRP</td>
<td>Justice Health Research Program</td>
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<tr>
<td>MAE</td>
<td>Masters in Applied Epidemiology</td>
</tr>
<tr>
<td>NCEPH</td>
<td>National Centre for Epidemiology and Public Health</td>
</tr>
<tr>
<td>NCHECR</td>
<td>National Centre for HIV Epidemiology and Clinical Research</td>
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<tr>
<td>NPEBBVS</td>
<td>The national prison entrants blood borne virus survey</td>
</tr>
<tr>
<td>PHIRG</td>
<td>Public Health Interventions Research Group</td>
</tr>
<tr>
<td>STI</td>
<td>Sexually Transmissible Infections</td>
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</table>
1.2 Introduction
Over the past 21 months at the Kirby Institute I have been based in the Justice Health Research Program (JHRP) in the Indigenous Offender Health Capacity Building Group (IOH-CBG) and the Public Health Interventions Research Group (PHIRG) with some overlap into the Aboriginal & Torres Strait Islander Health Program.

During this time I have had the opportunity to undertake a variety of projects including; evaluating the national prison entrants blood borne virus survey (NPEBBVS); analysing Indigenous specific hepatitis C and B data from the NPEBBVS; participate in a prison outbreak investigation; and work with a group of experienced investigators on a larger epidemiological study to evaluate the impact of the human papillomavirus (HPV) vaccine on HPV genotypes among Indigenous women.

1.3 Overview of field placement

1.3.1 The Kirby Institute
The Kirby Institute, formerly known as the National Centre for HIV Epidemiology and Clinical Research (NCHECR), was formed in response to the Human Immunodeficiency Virus (HIV) pandemic in Australia during the mid 1980’s. NCHECR had the purpose of providing research to improve epidemiological evidence, knowledge, prevention and treatment of HIV. HIV was causing increasing panic and fear in the communities experiencing the full impact of a disease, particularly the gay community in Sydney. From its inception, NCHECR worked in partnership with community organisations and still to this day understands the important input communities can offer on issues affecting them.

In 2011, NCHECR was renamed the Kirby Institute for infection and immunity in society. The Kirby Institute is a leader in HIV research and continues to have a large focus on clinical and behavioural research based in Australia and the Asia Pacific region. The change in name encompasses the broadening scope of research taken on over the past 27 years. The Kirby Institute has applied the same principles used during the HIV pandemic to produce comprehensive knowledge around other Blood Borne Viruses (BBV) and Sexually Transmissible Infections (STIs).

The Kirby Institute consists of eleven research programs:

- Aboriginal and Torres Strait Islander Health Program
- Biostatistics and Databases Program
- HIV Epidemiology and Prevention Program
- Immunovirology and Pathogenesis Program
CHAPTER 1 | INTRODUCTION

- Justice Health Research Program
- Public Health Interventions Research Group
- Sexual Health Program
- Surveillance and Evaluation Program for Public Health
- Therapeutic and Vaccine Research Program
- Viral Hepatitis Clinical Research Program
- Viral Hepatitis Epidemiology and Prevention Program

1.3.2 Justice health research program

The Justice Health Research Program (JHRP) is the newest program at the Kirby. Core work can be divided into three categories (Figure 1). Research projects involve adult and juvenile prison populations, as well as those serving community based sentences, ex-prisoners and community.

JHRP researchers have published copious papers within the three categories both collaborating across Kirby Institute programs and with external organisations. The JHRP coordinates a triennial national prison entrants’ blood borne virus and risk behaviour survey. The data from this survey are used to assess prevalence of hepatitis C, B and HIV and risk behaviours among Australian prison entrants. The JHRP is also involved in evaluating and informing national prisoner health indicators. The Sexual Health Attitudes of Australian Prisoners (SHAAP) is another large study the JHRP has coordinated and is currently working towards adapting for the juvenile justice setting. The wide scope of work undertaken within each of the three categories by the JHRP is a reflection of the health of Australian prisoners and the broad range of social, cultural and economic issues affecting them.
**1.3.3 Indigenous Offender Health Capacity Building Group**

Within the JHRP is the Indigenous Offender Health Capacity Building Group (IOH-CBG). Established in 2004, the IOH-CBG collaboration consists of Indigenous and non-Indigenous researchers, mentors and four collaborating centres from NSW, WA, ACT. Central coordination is conducted by the JHRP at the Kirby Institute.

The aims of IOH-CBG are to foster knowledge and skills of Indigenous and non-Indigenous researchers in key areas affecting Indigenous offenders and to develop a national health and criminal justice network.

The key areas affecting Indigenous offenders are:

- Mental health
- Substance use
- Blood borne viruses
- Impact of incarceration on communities
CHAPTER 1 | INTRODUCTION

- Models of care for offenders

The majority of projects I have undertaken have an offender health focus reflecting my placement primarily with the JHRP. Chapter 2, 3 and 4 have an offender and blood borne virus focus. I have fulfilled core MAE requirement. Below is a list of MAE requirements met while placed at the Kirby Institute (Table 1, page 10).

1.4 Summary of MAE requirements

Field projects

Chapter 2: Analysis of a public health dataset: Blood borne virus prevalence and risk behaviours among Indigenous and non-Indigenous prison entrants in four Australian states

Chapter 3: Evaluate a surveillance system or other health information system: Evaluation of the National Prison Entrants Blood Borne Virus and Risk Behaviour Survey (NPEBBVS)

Chapter 4: Outbreak: Incident Hepatitis C cases detected through a custodial HCV treatment program

Chapter 5: Design and conduct an epidemiological study: Impact of Australia’s HPV vaccination program on prevalence of HPV genotypes in Aboriginal and Torres Strait Islander women attending for Pap testing

1.4.1 Teaching requirements

Chapter 6: Lessons from the field - Project management

Interpretation of rate change in time series data

1.4.2 Advanced draft peer review publication

Chapter 2 Appendix 1: “Hepatitis C and hepatitis B prevalence and associated risk factors among Indigenous and non-Indigenous prison entrants in Australia”

1.4.3 Communication for a non-scientific audience

Chapter 1 Appendix 1: Highlighting Aboriginal and Torres Strait Islander Research at the Kirby institute 2013 booklet

Chapter 5 Appendix 2: Patient information sheet – VIP-I study

Chapter 4 Appendix 5: Patient information sheet – Hep C incidence in prison study
1.5 Conference presentations

1. **UNSW fifth annual symposium 2013** – Dreaming up the future of Aboriginal and Torres Strait Islander Public Health, UNSW medical faculty, October 2013. Presentation Title: ‘Development and evaluation of a sexual and reproductive health program for young Aboriginal people in NSW’

2. **The Australasian sexual health conference, Darwin Convention Centre**, October 2013. Presentation title: ‘A funded Sexual and Reproductive Health Worker position at an Aboriginal Community Controlled Health Service improves health service access and sexually transmissible infection testing in Aboriginal youth’ Co-presented with Jackie Milsom from Bulgarr Ngaru Medical Aboriginal Corporation, Grafton

   Presentation title: ‘Blood Borne Virus prevalence among Aboriginal and Torres Strait Islander Prison Entrants in four Australian States’


Presentation title: ‘Evaluating the effectiveness of the HPV vaccine among Indigenous women in Australia’ (Appendix, chapter 5)


1.6 Course Work
I attended all three Course block sessions at ANU and attended online lectures. I presented field reports as required at course blocks, ran a problem solving session titled; ethical considerations when interviewing prisoners: confidentiality and incriminating evidence. As required, I obtained a distinction average across core subjects (first four course work subjects listed below).

Course subjects:

- POPH8316 Outbreak Investigation – Semester 1 2013
- POPH8317 Public Health Surveillance – Semester 1 2013
- POPH8313 Analysis of Public Health Data – Semester 2 2013
- POPH8950F Issues in Applied Epidemiology – Semester 1 2014
Table 1. MAE requirements completed within chapters

<table>
<thead>
<tr>
<th>Chapter 1: Field placement and summary of core activities</th>
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<th>Chapter 3: Blood borne virus prevalence and risk behaviours among Indigenous and non-Indigenous prison entrants in four Australian states</th>
<th>Chapter 4: Incident Hepatitis C cases detected through a custodial HCV treatment program</th>
<th>Chapter 5: Vaccine impact in the Indigenous population (VIP-I)</th>
<th>Chapter 6: Lessons from the field - Project management Interpretation of rate change in time series data</th>
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<tr>
<td>Evaluate a surveillance system</td>
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<tr>
<td>Epidemiological study</td>
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<td>✓ ✓</td>
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<tr>
<td>Literature review</td>
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<td>Non-scientific audience</td>
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<td>Teaching requirements</td>
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Analyse a public health dataset
Evaluate a surveillance system
Epidemiological study
Literature review
Non-scientific audience
Abstract and oral presentation of the project
Teaching requirements
CHAPTER 2 | DATA ANALYSIS

Vaccine Impact on HPV genotypes among Australian Indigenous Women (VIP-I)

Description of the project:
There has been a documented decrease in HPV vaccine genotypes by other studies since the introduction of the Australian HPV vaccine program. These studies have not had a sufficient Indigenous sample size to determine whether there has been a corresponding decrease in Indigenous women.

VIP-I aims to evaluate the effectiveness of the HPV vaccination program among Indigenous women in Australia by:

- Estimating the proportion of Indigenous women who have been vaccinated among a sample of 18-26 years old women attending for Pap testing.
- Estimating and comparing the prevalence of HPV types (including vaccine-specific types 6/11/16/18 and other high risk HPV types) among demographically similar populations of Indigenous women sampled in the post-vaccine era compared to those sampled in the pre-vaccine era.

Expected benefit to the Community:
VIP-I results will provide valuable information on the extent to which the HPV vaccine, administered nationally, has been effective in reducing circulating HPV genotypes in Indigenous communities. This will provide evidence of the impact of the vaccination program in Indigenous communities, which will impact on ongoing public health policy in this area.


Organisations: Kirby Institute and Royal Women’s Hospital, Melbourne

Funding body: Commonwealth Department of Health

Achievements/key findings:
Three sites are currently recruiting participants. The VIP-I project was presented at both the National Indigenous Immunisations Research workshop 2013 and RANZCOG 2014 Indigenous Women’s Health Meeting.

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Appendix 1: Communication to a non-scientific audience
2 Data analysis
Bood borne virus prevalence and risk behaviours among Indigenous and Non-Indigenous Prison Entrants in four Australian States
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## 2.1 Abbreviation list

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<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>ACT</td>
<td>Australian Capital Territory</td>
</tr>
<tr>
<td>Anti-HBc</td>
<td>Anti-hepatitis B core antibody</td>
</tr>
<tr>
<td>aOR</td>
<td>Adjusted odds ratio</td>
</tr>
<tr>
<td>ARIA</td>
<td>Accessibility/remoteness index of Australia</td>
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<tr>
<td>BBV</td>
<td>Blood borne virus</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence Interval</td>
</tr>
<tr>
<td>HB</td>
<td>Hepatitis B virus</td>
</tr>
<tr>
<td>HCV</td>
<td>Hepatitis C virus</td>
</tr>
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<td>HCVAb</td>
<td>Anti-hepatitis C antibody</td>
</tr>
<tr>
<td>HIV</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>IDU</td>
<td>Injecting drug use</td>
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<tr>
<td>IOH-CBG</td>
<td>Indigenous offender health capacity building group</td>
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<td>JHRP</td>
<td>Justice Health Research Program</td>
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<td>MAE</td>
<td>Masters of Applied Epidemiology</td>
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<tr>
<td>NT</td>
<td>Northern Territory</td>
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<tr>
<td>NPEBBVS</td>
<td>National prison entrant blood borne virus and risk behaviour survey</td>
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<td>NSP</td>
<td>Needle and Syringe Programs</td>
</tr>
<tr>
<td>NSW</td>
<td>New South Wales</td>
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<tr>
<td>OR</td>
<td>Odds ratio</td>
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<td>QLD</td>
<td>Queensland</td>
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<tr>
<td>SA</td>
<td>South Australia</td>
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<tr>
<td>STI</td>
<td>Sexually transmissible infections</td>
</tr>
<tr>
<td>TAS</td>
<td>Tasmania</td>
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2.2 Prologue

2.2.1 My role

The Justice Health Research Program (JHRP) at the Kirby Institute coordinates a number of large cross-sectional surveys in adult prisons. Data analysis of a public health data set is a core requirement the Masters of Applied Epidemiology (MAE). I undertook an analysis with the national prison entrant blood borne virus and risk behaviour survey (NPEBBVS) based on Indigenous status to understand the factors associated with blood borne viruses (BBVs) among Indigenous and non-Indigenous prison entrants. As my MAE has been partly funded by the Indigenous Offender Health Capacity Building Group (IOH-CBG) it is a priority of mine to add to Aboriginal and Torres Strait Islander offender health research. Originally, I set out to analyse an Indigenous only prison entrant sample. I developed a data analysis plan and completed analysis based on the original idea and later altered this to include an Indigenous/ non-Indigenous comparison after meeting with supervisors to discuss the analysis and findings.

On 4 October 2013, I attended the annual IOH-CBG meeting in Perth where I presented preliminary demographic and prevalence data to IOH-CBG investigators and field researchers. Attending this meeting gave me an opportunity to see the diversity of projects currently underway in the Indigenous offender health sphere. On 27 November 2013, I presented findings at the national Indigenous health conference in Cairns.

As a requirement of the MAE I also developed this chapter along with colleagues from the JHRP into an advanced draft publication (we are currently waiting for further information on response rates for 2013/2014 survey collection. This was done later during the MAE and has the addition of 2013/2014 NPEBBVS data which this chapter does not include (Appendix 1)).

2.2.2 Lessons learnt

Given this is one of the only projects I have worked on during the MAE with existing data, a major learning I have taken from the analysis is to have a good understanding of the original purpose for the collection of the data. Understanding the aims and objectives of the NPEBBVS provided context to the way in which data were analysed and interpreted. This project has pushed me to examine data with a critical eye, particularly understanding and unpacking how stratification affects data and interpretation of findings.

Because this study focused on a minority population within a larger sample I was challenged with interpreting the validity of smaller sample sizes when exploring trends over time. I was able to understand internal and external validity of findings taking into consideration the prison context and the methodological constraints to working in a rigid system.
Prior to starting the MAE I had no experience using analytical tools such as Stata. In preparation for this project from August - November I organised Stata sessions fortnightly with Kirby Institute based MAE alumni Amalie Dyda. I quickly grasped some of the basic concepts of the program and was able to conduct analysis and build a clear well-ordered Stata do file. A Stata do file is an optional file which allows one to write and save code for running analysis. A clear file allow for code to be run at the press of a button, particularly useful for doing same analysis of subset data.

2.2.3 Acknowledgments
I would like to acknowledge my supervisors Tony Butler, John Kaldor, Stephanie Davis, Phyll Dance and Emily Fearnley in assisting me to develop this chapter. Tony Butler established the NPEBBVS in 2004 and has coordinated the project every survey year since. Logistically this survey is complex to run due to jurisdictional negotiations and the ever changing funding environment; I appreciate the ability to use the NPEBBVS databases. I would also like to thank Amalie Dyda, who gave her time to tutor me on Stata to build up my skills and confidence to eventually use the program as described in this chapter.
CHAPTER 2 | DATA ANALYSIS

2.3 Abstract

2.3.1 Introduction
The justice system is diverse comprising of juvenile and adult, female, male and transgender offenders serving different types and lengths of sentences in a number of settings. Indigenous prison entrants are over represented within this population making up 27% of the national prisoner population but only 3% of the general population. Prisons are recognised as a high risk setting for BBV acquisition. Indigenous people are recognised as a priority population in regards to BBVs. This data analysis aims to determine the prevalence of the hepatitis C virus (HCV), hepatitis B virus (HBV) and associated risk factors among Indigenous and non-Indigenous prison entrants.

2.3.2 Methods
This study utilises data from the NPEBBVS in 2004, 2007 and 2010. Prison entrants were recruited at participating prison reception centres over a set two week period in four states; New South Wales (NSW), Queensland (QLD), Western Australia (WA) and Tasmania (TAS). Participants undertook a demographic and risk behaviour survey and provided blood and urine samples. Disease prevalence was determined by serological markers hepatitis C antibody (HCVAb) and hepatitis B core antibody (anti-HBc). Risk factors and demographics were analysed for associations to disease outcomes of interest. Data were stratified by Indigenous and non-Indigenous status and injecting status. Stata 12 was used to analyse data.

2.3.3 Results
There were 1,752 prison entrants from NSW, QLD, WA and TAS across all survey years. Indigenous prison entrants represented 22% (n=382) of the sample. Both Indigenous (83-88%) and non-Indigenous (90-92%) prison entrants were predominantly male. HCVAb prevalence among Indigenous prison entrants was 37% in 2004, 42% in 2007 and 24% in 2010 and 33%, 30% and 23% respectively in non-Indigenous prison entrants. A history of injecting drug use was significantly associated with HCVAb positivity among both Indigenous (odds ratio (OR) = 29.0, confidence interval (CI) = 9.85-85.20) and non-Indigenous (OR = 48.9, CI = 24.26-97.53) prison entrants. Indigenous prison entrants had a higher burden of disease; anti-HBc prevalence 40% (2004), 29% (2007) and 21% (2010), compared to their non-Indigenous counterparts 17% (2004), 15% (2007) and 16% (2010). Being over 30 years of age was significantly associated to anti-HBc positivity.

2.3.4 Conclusion
To best target resources, public health interventions should take into consideration the similarities and differences between Indigenous and non-Indigenous offenders when developing public health programs, policy and allocating funding.
2.4 Background

Prisons are a focus of blood borne virus (BBV) risk because of the injecting drug use (IDU) histories of many offenders, and lack of harm-reduction strategies available to this population while in prison\(^1, \ 2\). Sharing needles and other injecting equipment has been identified as presenting a higher risk of transmission of BBVs, particularly HCV, but community based harm-reduction initiatives are yet to be introduced into prisons\(^3\).

In 2011, Aboriginal and Torres Strait Islander (referred to in the remainder of the chapter as Indigenous) people were 3% of the Australian population, yet accounted for 27% of the Australian prison population\(^4\). Indigenous people are over-represented in this high risk setting, therefore, Indigenous people in touch with the justice system are recognised as a high priority population within the Commonwealth government’s Third National Aboriginal and Torres Strait Islander Blood Borne Viruses and Sexually Transmissible Infections Strategy 2010-2013\(^5\). This strategy highlights the need to strengthen evidence-based harm reduction approaches to BBVs in the custodial setting. The translation of this strategy into practical and meaningful application within the Australian prison health context requires the support of research, including monitoring and surveillance, to determine resource allocation to establish and evaluate sustainable approaches to infectious disease transmission and harm reduction.

2.4.1 The National Prison Entrants Blood Borne Virus Survey

The NPEBBVS is a triennial cross-sectional survey established in 2004 by Tony Butler at the Centre for Health Research in Criminal Justice (Justice Health NSW) in partnership with the Kirby Institute (formerly known as the National Centre in HIV Epidemiology and Clinical Research). The aim of the NPEBBVS is to monitor prevalence of Human Immunodeficiency Virus (HIV), HCV, HBV, sexually transmissible infections (STIs) and risk behaviours among Australian prison entrants. The NPEBBVS is the only repeated multijurisdictional monitoring/surveillance mechanism across the Australian justice system. In 2004, the survey included four states, NSW, QLD, WA and TAS. Subsequent surveys have included all states and territories.

Each survey year, data are collected over a two week period at centres where prison entrants are received before transfer into the general prison population. The Justice Health Research Program (JHRP) publishes a report after every survey round. In addition, there have been two peer-reviewed publications describing the population and BBV prevalence of prison entrants including 2004-2010 survey data\(^6, \ 7\). There has been no previous analysis of the survey according to Indigenous status.
Cross-sectional surveys like the NPEBBVS provide a snap-shot of disease and risk factors among the most disadvantaged and health poor people in society today. This marginalised group is often overlooked by national BBV surveillance despite carrying a large burden of disease.

### 2.4.2 Hepatitis B and C

In 2012, the overall Australian population prevalence of HCV was 1.4% and for HBV 0.97%. In Australia, there have been six HBV and/or HCV prison based prevalence studies providing an Indigenous and non-Indigenous breakdown\(^6, 8\)\(^{\text{-}12}\), these studies span the period from 1996 to 2010. Variations in methodological approaches, sample size and source population have led to diverse BBV prevalence estimates of offender populations (Table 1). Although diverse estimates, these studies and other prison based cross-sectional surveys demonstrate the high burden of HCV and HBV among offenders compared to the general population\(^7, 13\). HIV is of low prevalence among the Australian prison population, therefore HCV and HBV are the focus of this chapter\(^7, 13\).

HCV and HBV both have a significant public health impact causing morbidity and mortality related to liver disease\(^14, 15\). HBV is a vaccine preventable disease; the vaccine has been available in Australia since 1985 but initially administered \textit{adhoc} and through antenatal screening programs\(^16\). In 2000, the Australia government funded a universal HBV vaccination program targeting infants and school-based adolescents\(^16\). There is no vaccine available for HCV; however treatment for cure is available, unlike HBV which cannot be cured and requires monitoring and in some case lifelong antiviral medication if treatment is necessary\(^15, 17\).

As described above, only six studies were found to provide a breakdown of BBVs by Indigenous status. This is despite the overrepresentation of Indigenous people in prison which makes Indigenous status possible to report in-prison based studies. Providing such a breakdown in epidemiological studies acknowledges the differences between Indigenous and non-Indigenous populations and provides further understanding of infectious diseases among marginalised groups within the offender population. This is important information to assist in effectively planning programs and other preventative activities.
Table 1. Prevalence of Hepatitis B and C among Indigenous and non-Indigenous offenders according to past prevalence studies in Australia

<table>
<thead>
<tr>
<th>Study and study type</th>
<th>Study year</th>
<th>Prison/s location</th>
<th>HCV antibody positive</th>
<th>Anti-HBc positive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Indigenous (%+/tested*)</td>
<td>non-Indigenous (%+/tested)</td>
</tr>
<tr>
<td>Butler et al, 1999†</td>
<td>1996</td>
<td>NSW</td>
<td>36 (82/228)</td>
<td>41 (209/510)</td>
</tr>
<tr>
<td>Cross-sectional survey</td>
<td></td>
<td></td>
<td></td>
<td>54 (124/229)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>27 (139/514)</td>
</tr>
<tr>
<td>Butler et al, 1997†</td>
<td>1994</td>
<td>NSW</td>
<td>37 (15/41)</td>
<td>37 (135/367)</td>
</tr>
<tr>
<td>Cross-sectional survey</td>
<td></td>
<td></td>
<td></td>
<td>29 (12/41)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>31 (113/367)</td>
</tr>
<tr>
<td>Miller et al, 2006‡</td>
<td>2005</td>
<td>SA metropolitian prisons SA northern regional prison</td>
<td>56 (n/a)</td>
<td>41 (n/a)</td>
</tr>
<tr>
<td>Medical record audit</td>
<td></td>
<td></td>
<td></td>
<td>–</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>–</td>
</tr>
<tr>
<td>Butler et al, 2007‡</td>
<td>2004 and 2007</td>
<td>NSW, QLD, WA, TAS</td>
<td>37 (29/102)</td>
<td>34 (125/435)</td>
</tr>
<tr>
<td>Cross-sectional survey</td>
<td></td>
<td></td>
<td></td>
<td>29 (22/102)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>18 (64/435)</td>
</tr>
<tr>
<td>Watkins et al, 2009§</td>
<td>2005-2006</td>
<td>Western Australia</td>
<td>15 (n/a)</td>
<td>38 (n/a)</td>
</tr>
<tr>
<td>Retrospective medical record audit</td>
<td></td>
<td></td>
<td></td>
<td>–</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>–</td>
</tr>
<tr>
<td>Indig et al, 2010§</td>
<td>1996</td>
<td>NSW</td>
<td>30 (61/204)</td>
<td>35 (158/453)</td>
</tr>
<tr>
<td>Cross-sectional survey</td>
<td></td>
<td></td>
<td></td>
<td>53 (108/204)</td>
</tr>
<tr>
<td></td>
<td>2001</td>
<td>Men</td>
<td>42 (95/227)</td>
<td>39 (202/520)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>31 (70/227)</td>
</tr>
<tr>
<td></td>
<td>2009</td>
<td>Men</td>
<td>36 (93/259)</td>
<td>24 (129/538)</td>
</tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>37 (95/259)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Women</td>
<td>72 (22/31)</td>
<td>64 (64/101)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>59 (18/31)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>42 (42/101)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Women</td>
<td>76 (22/29)</td>
<td>61 (84/138)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>45 (13/29)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>28 (38/138)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Women</td>
<td>54 (28/53)</td>
<td>43 (62/146)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>35 (18/53)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>33 (48/146)</td>
</tr>
</tbody>
</table>

*(+/tested) = number of participants positive/number of participants tested. n/a= data not available
CHAPTER 2 | DATA ANALYSIS

2.5 Aims

This data analysis aims to determine the prevalence of HCV and HBV among Indigenous and non-Indigenous prison entrants, identify risk factors for HCV and HBV, identify differences between populations and recommend where public health action could be directed.

2.6 Methods

NPEBBVS data from survey years 2004, 2007 and 2010 were obtained from the databases maintained by the JHRP at the Kirby Institute. NPEBBVS methods have been described in detail in a number of national reports, papers and chapter 3\(^6, 7, 13, 18\). Only states and territories participating in all three survey years were included in the analysis: New South Wales (NSW), Western Australia (WA), Queensland (QLD) and Tasmania (TAS). Twenty survey participants with missing Indigenous status were also excluded from this analysis. NPEBBVS data are collected over a two week period every three years; therefore it was assumed prison entrants across the three time periods are separate individuals.

During survey collection, nurses based at participating prison reception centres were responsible for survey procedures. Procedures included; recruitment of prison entrants, administration of questionnaires and collection of blood and urine samples. Blood and urine samples collected from consenting participants were tested for HCV, HBV, HIV and selected sexually transmitted infections (STIs), namely syphilis, chlamydia and gonorrhoea.

There are a number of serological, virological, biochemical and histological markers to determine HBV status. In this analysis hepatitis B core antibody (Anti-HBc) was used to determine current disease or past exposure and this is present among people who have acute HBV (where it is usually elevated during acute HBV and declines 3-6 months after onset) or patients who have previously been infected with HBV (it is a life-long marker of exposure)\(^15\). Additional markers were used to determine immune status including; Hepatitis B surface antigen (HBsAg) for HBV carrier status; HBV surface antibody (Anti-HBs) levels $\geq$10 mIU/ml to signify vaccine conferred immunity, positive Anti-HBs and Anti-HBc to determine immunity through past exposure and no antibodies present representing no evidence of immunity.

HCV prevalence was determined using the serological marker HCVAb. HCVAb positivity indicates exposure to HCV and can indicate either past or current infection (HCV PCR which indicates current infection is not currently collected as a part of the NPEBBVS).

2.6.1 Data analysis methods

Descriptive analysis involved the calculation by year of the proportion of prison entrants according to Indigenous status, state of origin, gender, age group, sexuality, location of residence before entering prison, number of times incarcerated and risk behaviors such as
tattooing, history of injecting drug use, IDU status in the last month and risk factors associated with injecting including sharing of needles and injecting equipment.

The Accessibility/Remoteness Index of Australia (ARIA), a remoteness measurement tool developed by the Department of Health and Ageing, is used by government in Australia to provide a quantifiable index of remoteness in relation to service provision\(^{19}\). ARIA scores are based on population density by postcode in relation to distance of service provision (Kilometres (km)). Classifications used for this analysis are provided in table 2.

### Table 2. ARIA remoteness classification and definitions

<table>
<thead>
<tr>
<th>Classification</th>
<th>ARIA score (km)</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Highly Accessible</td>
<td>0 - 1.84</td>
<td>Relatively unrestricted accessibility to a wide range of goods and services and opportunities for social interaction.</td>
</tr>
<tr>
<td>Accessible</td>
<td>&gt;1.84 - 3.51</td>
<td>Some restrictions to accessibility of some goods, services and opportunities for social interaction.</td>
</tr>
<tr>
<td>Moderately Accessible</td>
<td>&gt;3.51 - 5.80</td>
<td>Significantly restricted accessibility of goods, services and opportunities for social interaction.</td>
</tr>
<tr>
<td>Remote</td>
<td>&gt;5.80 - 9.08</td>
<td>Very restricted accessibility of goods, services and opportunities for social interaction.</td>
</tr>
<tr>
<td>Very Remote</td>
<td>&gt;9.08 - 12</td>
<td>Very little accessibility of goods, services and opportunities for social interaction.</td>
</tr>
</tbody>
</table>

Source: Information and Research Branch Department of Health and Aged Care. Measuring Remoteness: Accessibility / Remoteness Index of Australia (ARIA), 2001\(^{18}\)

ARIA calculations were based on the prison entrant’s postcode of last residence, to classify participants into the two categories of highly accessible (highly accessible) and non-highly accessible (accessible, moderately accessible, remote, very remote).

Overall HCVAb and anti-HBc prevalence were calculated for each survey year and by Indigenous status. A subgroup analysis of HCVAb and HBCAb prevalence by injecting and Indigenous status was also conducted. The calculations used for these were:
CHAPTER 2 | DATA ANALYSIS

Overall prevalence of HCVAb or HbcAb by survey year and Indigenous status

\[
\text{Prevalence} = \frac{\text{No. of positive results}}{\text{No. Prison entrants tested}} \times 100
\]

Prevalence of HCVAb or HbcAb among prison entrants who have ever injected drugs

\[
\text{Prevalence} = \frac{\text{No. of positive IDU}}{\text{No. IDU tested}} \times 100
\]

Prevalence HCVAb or HbcAb among prison entrants who have never injected drugs

\[
\text{Prevalence} = \frac{\text{No. of positive Non-IDU}}{\text{No. Non-IDU tested}} \times 100
\]

Chi squared test for trends were used to detect significant changes in exposure variables, by Indigenous status, across survey years for all prison entrant participants. Logistic regression was conducted to determine overall risk factors associated with the outcomes of HCV and HBV prevalence, and associated risk factors by Indigenous status. The multivariate models included variables identified in previous prevalence studies as significantly associated with exposure to HCV and HBV. P values <0.05 were considered significant. Statistical analysis was carried out in Stata 12. Graphs and tables were created in Microsoft Excel.

2.7 Results

Overall, 1752 prison entrants from NSW, QLD, WA and TAS participated in the 2004, 2007 and 2010 NPEBBVS. Over the two week survey period prison entrant participation rate in the analysed states was 83% (2004), 74% (2007) and 80% (2010). Indigenous prison entrants represented 22% (n=382) of the overall sample. Table 3 summarises demographic characteristics of Indigenous and non-Indigenous prison entrants by year of survey. Of note, both Indigenous and non-Indigenous entrants were predominantly male and identified as heterosexual.

Of Indigenous prison entrants, 54% were under 30 years of age compared to 47% of non-Indigenous entrants. Indigenous prison entrants had higher representation from areas classified as “non-highly accessible”. There was a significant increase in the proportion of Indigenous people entering prison from non-highly accessible areas, 25% in 2004 and 2007 to 47% in 2010 (p<0.001) (Table 3). Non-Indigenous participants had no significant ARIA change over survey years consistently coming from highly accessible locations (Table 3).

On average, across survey years, those entering prison for the first time accounted for 26% of Indigenous and 34% of non-Indigenous prison entrants. Entrance of first time offenders
significantly increased across survey year among both Indigenous (p 0.004) and non-Indigenous (p<0.001) (Table 3).

Table 3. Characteristics of Indigenous and Non-Indigenous prison entrants by survey year

<table>
<thead>
<tr>
<th></th>
<th>2004</th>
<th>2007</th>
<th>2010</th>
<th>*chi²</th>
<th>p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indigenous</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>82</td>
<td>80</td>
<td>96</td>
<td>85</td>
<td>147</td>
</tr>
<tr>
<td>Female</td>
<td>20</td>
<td>20</td>
<td>17</td>
<td>15</td>
<td>20</td>
</tr>
<tr>
<td>Non-Indigenous</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>446</td>
<td>90</td>
<td>385</td>
<td>91</td>
<td>419</td>
</tr>
<tr>
<td>Female</td>
<td>47</td>
<td>10</td>
<td>39</td>
<td>9</td>
<td>33</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indigenous</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 29 years</td>
<td>49</td>
<td>48</td>
<td>59</td>
<td>52</td>
<td>98</td>
</tr>
<tr>
<td>≥ 30 years</td>
<td>53</td>
<td>52</td>
<td>54</td>
<td>48</td>
<td>69</td>
</tr>
<tr>
<td>Non-Indigenous</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 29 years</td>
<td>234</td>
<td>47</td>
<td>203</td>
<td>48</td>
<td>213</td>
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<tr>
<td>≥ 30 years</td>
<td>260</td>
<td>53</td>
<td>221</td>
<td>52</td>
<td>239</td>
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<tr>
<td>Sexuality</td>
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</tr>
<tr>
<td>Indigenous</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Heterosexual</td>
<td>97</td>
<td>97</td>
<td>106</td>
<td>96</td>
<td>160</td>
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<tr>
<td>Non-heterosexual</td>
<td>3</td>
<td>3</td>
<td>5</td>
<td>4</td>
<td>5</td>
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<tr>
<td>Non-Indigenous</td>
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<tr>
<td>Heterosexual</td>
<td>471</td>
<td>96</td>
<td>412</td>
<td>98</td>
<td>439</td>
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<tr>
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<td>19</td>
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<td>7</td>
<td>2</td>
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<td>ARIA (by post code of last residency)</td>
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<td>76</td>
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<td>24</td>
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<td>354</td>
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<tr>
<td>Number of times in prison</td>
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</tr>
<tr>
<td>First time</td>
<td>18</td>
<td>19</td>
<td>23</td>
<td>22</td>
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<td>Non-Indigenous</td>
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<tr>
<td>First time</td>
<td>131</td>
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<tr>
<td>2+</td>
<td>347</td>
<td>73</td>
<td>264</td>
<td>65</td>
<td>191</td>
</tr>
</tbody>
</table>

*chi² calculation represents proportional change across survey year
Table 4. Risk behaviours of prison entrants by Indigenous status and survey year

<table>
<thead>
<tr>
<th></th>
<th>2004</th>
<th>2007</th>
<th>2010</th>
<th>*chi²</th>
<th><em>p</em>-values</th>
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<tbody>
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<td><strong>Ever injected drugs</strong></td>
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<td></td>
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<td>Indigenous</td>
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<td>64</td>
<td>64</td>
<td>68</td>
<td>75</td>
<td>45</td>
</tr>
<tr>
<td>Non-Indigenous</td>
<td>281</td>
<td>57</td>
<td>224</td>
<td>53</td>
<td>206</td>
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<tr>
<td><strong>Injecting behaviour of those who have ever injected</strong></td>
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</tr>
<tr>
<td>Indigenous</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Injected, in last month</td>
<td>41</td>
<td>64</td>
<td>44</td>
<td>66</td>
<td>45</td>
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<td>Non-Indigenous</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Injected, in last month</td>
<td>181</td>
<td>65</td>
<td>125</td>
<td>57</td>
<td>113</td>
</tr>
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<td><strong>Shared needles in last month</strong></td>
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<td>11</td>
<td>28</td>
<td>15</td>
<td>34</td>
<td>12</td>
</tr>
<tr>
<td>Non-Indigenous</td>
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<td></td>
</tr>
<tr>
<td>Yes</td>
<td>57</td>
<td>31</td>
<td>47</td>
<td>39</td>
<td>25</td>
</tr>
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<td><strong>Shared injecting equipment in last month</strong></td>
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<tr>
<td>Indigenous</td>
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</tr>
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<td>Yes</td>
<td>12</td>
<td>30</td>
<td>19</td>
<td>46</td>
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<td>Non-Indigenous</td>
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<td>49</td>
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<td>44</td>
<td>31</td>
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<tr>
<td><strong>Tattoos</strong></td>
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<td>Indigenous</td>
<td></td>
<td></td>
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</tr>
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<td>62</td>
<td>62</td>
<td>77</td>
<td>68</td>
<td>98</td>
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<tr>
<td>Non-Indigenous</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
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<td>298</td>
<td>61</td>
<td>268</td>
<td>63</td>
<td>304</td>
</tr>
</tbody>
</table>

2.7.1 Injecting drug use and risk behaviours

Table 4 shows risk behaviours of prison entrants. From 2004-2010 there was a decrease in the proportion of prison entrants who had ever injected illicit drugs, 19% (**p**= 0.004) among Indigenous and 11% (**p**=0.001) among non-Indigenous prison entrants (Table 4). Ever acquiring a tattoo remained constant across survey year among both Indigenous and non-Indigenous prison entrants with 60-70% of both groups ever having a tattoo (Table 4).

2.7.2 Hepatitis C prevalence and risk factors

HCVAb prevalence among Indigenous prison entrants was similar to that seen among non-Indigenous prison entrants (Table 5). When stratified by injecting status, both Indigenous and non-Indigenous prison entrants with a history of IDU had consistently high HCVAb prevalence of above 50% across survey years compared to less than 7% among prison entrants with no history of IDU (Figure 1). Risk factor associated with HCVAb positivity among Indigenous and non-Indigenous prison entrants are shown in tables 6 and 7 respectively. Prison entrants who had ever injected were substantially more likely to be HCVAb positive compared to those who had never injected on univariate analysis, and this relationship remained in multivariate analysis (adjusted odds ratio aOR=29, **p**<0.001 for Indigenous prison entrants and aOR=49, **p**<0.001 for non-Indigenous entrants). Other factors significantly associated with HCVAb...
positivity in both Indigenous and non-Indigenous prison entrants included being female, aged 30 years plus and incarceration for a second or subsequent time.

**Table 5. Overall hepatitis C antibody prevalence by Indigenous status and survey year**

<table>
<thead>
<tr>
<th></th>
<th>Indigenous prison entrants</th>
<th>Non-Indigenous prison entrants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number tested</td>
<td>Number positive</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>79</td>
<td>29</td>
</tr>
<tr>
<td>2007</td>
<td>96</td>
<td>40</td>
</tr>
<tr>
<td>2010</td>
<td>149</td>
<td>35</td>
</tr>
<tr>
<td>Total</td>
<td>324</td>
<td>104</td>
</tr>
</tbody>
</table>

Entering prison from a less accessible geographical location was associated with a lower prevalence of HCVAb in both Indigenous and non-Indigenous entrants but the relationship was only statistically significant among Indigenous entrants (aOR=0.14, p<0.001). In univariate analysis, having ever acquired a tattoo was associated with HCVAb positivity among both Indigenous (OR=2.89, p <0.001) and non-Indigenous (OR=2.40, p <0.001) prison entrants. However, having ever acquired a tattoo was only significantly associated with HCVAb among non-Indigenous prison entrants when adjusted in the multivariate model (aOR= 1.53, p= 0.038).

**Figure 1. Hepatitis C antibody (HCVAb) prevalence among Indigenous and non-Indigenous prison entrants by year**

![Figure 1. Hepatitis C antibody (HCVAb) prevalence among Indigenous and non-Indigenous prison entrants by year](image-url)
### Table 6. Factors associated with HCVAb positivity among Indigenous prison entrants

<table>
<thead>
<tr>
<th></th>
<th>Unadjusted</th>
<th>Adjusted*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR 95% CI</td>
<td>P value</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
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</tr>
<tr>
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<td>1</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>3.03 1.55-5.90</td>
<td><strong>0.001</strong></td>
</tr>
<tr>
<td><strong>Year</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>1.22 0.66-2.34</td>
<td>0.526</td>
</tr>
<tr>
<td>2010</td>
<td>0.52 0.29-0.94</td>
<td><strong>0.030</strong></td>
</tr>
<tr>
<td><strong>Age</strong></td>
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<td>1</td>
<td></td>
</tr>
<tr>
<td>≥30</td>
<td>2.5 1.56-4.01</td>
<td>&lt;<strong>0.001</strong></td>
</tr>
<tr>
<td><strong>Ever injected drugs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>40.8 15.92-104.58</td>
<td>&lt;<strong>0.000</strong></td>
</tr>
<tr>
<td><strong>Tattoos</strong></td>
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</tr>
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<td>No</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>2.89 1.67-4.96</td>
<td>&lt;<strong>0.000</strong></td>
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<td><strong>ARIA</strong></td>
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<td></td>
</tr>
<tr>
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<td>&lt;<strong>0.001</strong></td>
</tr>
<tr>
<td><strong>Number of times in prison</strong></td>
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</tr>
<tr>
<td>First time</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2+ time</td>
<td>6.7 3.09-14.53</td>
<td>&lt;<strong>0.000</strong></td>
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</table>

*Adjusted for gender, year, age, IDU, tattoos, ARIA and number of times in prison
Table 7. Factors associated with HCVAb positivity among non-Indigenous prison entrants

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<th></th>
<th>Adjusted*</th>
<th></th>
</tr>
</thead>
<tbody>
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<td></td>
<td>OR</td>
<td>95% CI</td>
<td>P value</td>
<td>OR</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Female</td>
<td>3.03</td>
<td>1.29-3.33</td>
<td><strong>0.002</strong></td>
<td>2.71</td>
</tr>
<tr>
<td>Year</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>1</td>
<td>1</td>
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</tr>
<tr>
<td>2007</td>
<td>0.87</td>
<td>0.64-1.20</td>
<td>0.4</td>
<td>0.8</td>
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<tr>
<td>2010</td>
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<td>0.42-0.80</td>
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<td>0.83</td>
</tr>
<tr>
<td>Age</td>
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<td></td>
</tr>
<tr>
<td>≤29</td>
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<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>≥30</td>
<td>2.03</td>
<td>1.55-2.55</td>
<td>&lt;0.000</td>
<td>2.41</td>
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<tr>
<td>Ever injected drugs</td>
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<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Yes</td>
<td>2.4</td>
<td>1.78-3.22</td>
<td>&lt;0.000</td>
<td>1.53</td>
</tr>
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<tr>
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<td>1</td>
<td></td>
<td>1</td>
</tr>
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<td>0.61</td>
<td>0.38-0.99</td>
<td><strong>0.043</strong></td>
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<tr>
<td>Number of times in prison</td>
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</tr>
<tr>
<td>First time</td>
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<td>1</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>≥2 time</td>
<td>6.05</td>
<td>4.29-8.54</td>
<td>&lt;0.000</td>
<td>3.16</td>
</tr>
</tbody>
</table>

*Adjusted for gender, year, age, IDU, tattoos, ARIA and number of times in prison
2.7.3 Hepatitis B prevalence and risk factors

Across all survey years Indigenous prison entrants had higher Anti-HBc positive prevalence than their non-Indigenous counterparts (Table 8).

Figure 2 shows anti-HBc positivity prevalence among prison entrants by Indigenous status and year, tables 9 and 10 show factors associated with anti-HBc positivity among Indigenous and non-Indigenous prison entrants respectively. For both groups in the univariate analysis, a history of IDU was not significantly associated with anti-HBc positivity (Indigenous OR=1.58, p=0.087, non-Indigenous OR=2.71, p=0.087). However in the multivariate model injecting drug use was significantly associated with anti-HBc positivity among non-Indigenous prison entrants (aOR=2.18, p<0.001).

Age was a common factor associated with anti-HBC positivity among both groups, those prison entrants 30 years and over were more likely to be anti-HBc positive then entrants under 30 years of age. Interestingly, but not significant in either univariate or multivariate analysis, being male was associated with anti-HBc positivity among Indigenous prisoners, but this was reversed among non-Indigenous prison entrants with women twice as likely to be anti-HBc positive than their Indigenous counterparts.

In line with higher prevalence findings, 4% of Indigenous prison entrants were HBV carriers (chronic HBV infection) compared to 2% non-Indigenous (Table 11). Although a high percentage of both non-Indigenous (53%) and Indigenous (30%) prison entrants were not vaccinated, a higher proportion of Indigenous prison entrants were immune through previous exposure to HBV (Table 11).

![Figure 2. Hepatitis B core antibody prevalence among Indigenous and non-Indigenous prison entrants by year and injecting status](image-url)
Table 8. Hepatitis B core antibody prevalence among Indigenous and non-Indigenous prison entrants in NSW, QLD, TAS and WA, by survey year

<table>
<thead>
<tr>
<th></th>
<th>Indigenous prison entrants</th>
<th>Non-Indigenous prison entrants</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number tested</td>
<td>Number positive</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>77</td>
<td>22</td>
</tr>
<tr>
<td>2007</td>
<td>96</td>
<td>38</td>
</tr>
<tr>
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<td>113</td>
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<tr>
<td>Total</td>
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<td>84</td>
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Table 9. Factors associated with hepatitis B core antibody positivity among Indigenous prison entrants

<table>
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<tr>
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<th>Adjusted*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR</td>
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</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
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<td></td>
</tr>
<tr>
<td>Female</td>
<td>0.93</td>
<td>0.43-2.11</td>
</tr>
<tr>
<td>Year</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2004</td>
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<td></td>
</tr>
<tr>
<td>2007</td>
<td>1.64</td>
<td>0.86-3.11</td>
</tr>
<tr>
<td>2010</td>
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<td>0.35-1.32</td>
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<tr>
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<td>Ever injected drugs</td>
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<td></td>
</tr>
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<td>1.58</td>
<td>0.94-2.67</td>
</tr>
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<td>Tattoos</td>
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<td></td>
</tr>
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<td>1.65</td>
<td>0.93 - 2.91</td>
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</tr>
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<td>0.97 - 2.96</td>
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<td>Number of times in prison</td>
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</tr>
<tr>
<td>2+ time</td>
<td>2.88</td>
<td>1.39-5.98</td>
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</tbody>
</table>

*Adjusted for gender, year, age, IDU, tattoos, ARIA and number of times in prison
Table 10. Factors associated with hepatitis B core antibody positivity among non-Indigenous prison entrants

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<tr>
<th></th>
<th>Unadjusted</th>
<th></th>
<th></th>
<th>Adjusted*</th>
<th></th>
<th></th>
</tr>
</thead>
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<td></td>
<td>OR</td>
<td>95% CI</td>
<td>P value</td>
<td>OR</td>
<td>95% CI</td>
<td>P value</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
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<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1.59</td>
<td>0.83-3.03</td>
<td>0.158</td>
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<td>0.75-3.05</td>
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</tr>
<tr>
<td><strong>Year</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2004</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
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</tr>
<tr>
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<td>0.55-1.21</td>
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<td>1.78-5.12</td>
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<td>2.96</td>
<td>2.02-4.35</td>
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</tr>
<tr>
<td><strong>Ever injected drugs</strong></td>
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<td></td>
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</tr>
<tr>
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<td></td>
<td></td>
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</tr>
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<tr>
<td>First time</td>
<td>1</td>
<td></td>
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<td>1</td>
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<td></td>
</tr>
<tr>
<td>2+ time</td>
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<td>1.39-2.94</td>
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*Adjusted for gender, year, age, IDU, tattoos, ARIA and number of times in prison

Table 11. Immunity status of prison entrants tested for hepatitis B serology

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<th>non-Indigenous</th>
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</thead>
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<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td></td>
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<tr>
<td>No evidence of immunity</td>
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<td>30</td>
<td>542</td>
<td>53</td>
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<tr>
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<td>2</td>
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2.8 Discussion
This study shows the high rates of HBV and HCV exposure amongst Australian prisoners and likelihood of higher disease. It also shows an increase over time of prison entrants who are entering prison for their first time. Those being incarcerated for a first or subsequent time are entering an environment of higher HCV and HBV prevalence compared to the general community with reduced harm minimisation options.

2.8.1 Hepatitis C
The prison entrant population has a higher HCVAb prevalence compared to the general Australian population (1.4% in 2013)\(^{(20)}\). The overall decrease in HCVAb prevalence from 2004 to 2010 shown in this study, may reflect the overall decline of hepatitis C diagnosis per capita in Australia\(^{(20)}\) including reduced HCVAb prevalence among people accessing needle and syringe programs (NSPs) in the general community\(^{(21)}\). However as this decrease was not significant this finding should be interpreted with caution.

The major risk factor associated with HCVAb positivity among prison entrant is a history of IDU. The high prevalence of IDU seen in this study is consistent with rates of IDU among people in touch with the justice system found in other studies, this coupled with lack of harm minimisation available in-prison confirms IDU as a particularly important risk factor in the prison context\(^{(1, 10)}\). Community based interventions such as the needle and syringe program, known to reduce HCV transmission in the general community are currently not available in any Australian prison\(^{(2, 22)}\). Of people entering prison 17% will inject while incarcerated\(^{(12)}\). Inmates (both injecting and non-injecting) will have potential exposure to blood through activities such as tattooing, piercing, fights and sport during incarceration put them at risk of acquiring HCV.

There were similar risk factors associated with HCVAb positivity among both Indigenous and non-Indigenous prison entrants including age, gender, injecting status and numbers of times incarcerated. It would appear similarities in social disadvantage and drug use across Indigenous and non-Indigenous offenders could be a common factor in HCVAb positivity. However this does not imply there should not be a focus on the Indigenous population with regards to service provision, education and harm minimisation. In fact, tailoring public health programs based on Indigenous status and place of residence would allow a more targeted approach to HCV health promotion, education and harm minimisation among Indigenous and non-Indigenous people in both the prison setting and the wider community.
2.8.2 Hepatitis B

Both Indigenous and non-Indigenous prison entrants had a higher HBV prevalence than the general Australian population (less than 1%)\(^{(20)}\). Overall anti-HBc prevalence was higher in Indigenous prison entrants, this probably reflects higher rates of vertical transmission from mother to child among the Indigenous population\(^{(23)}\). Additionally, accessibility to antenatal screening and vaccination due to complex lives of people in touch with the justice system may contribute to lower vaccination rates in both Indigenous and non-Indigenous prison entrants.

Although national notifications of newly acquired HBV have declined over time\(^{(24)}\) there was a slight increase in anti-HBc positivity among prison entrants with no history of IDU. The reasons for continued HBV infections despite a national universal vaccination program (introduced in Australian in 2000) may relate to the high number of Indigenous and non-Indigenous prison entrants missing vaccination through main stream programs. In Australia national notification of newly acquired HBV among people under 30 years of age from 2003 - 2012 declined, demonstrating the impact of the HBV vaccine program\(^{(24, 25)}\). There is some evidence from this study to suggest the universal HBV vaccination program has had some impact among younger prison entrants. However, there are still a large number of Indigenous and non-Indigenous prison entrants who display no HBV immunity through vaccination or previous exposure. Therefore the prison setting provides an opportunity for vaccination of those who have missed mainstream vaccine programs. An accelerated HBV vaccine course would be ideal to provide some coverage while in-prison and when entering back into the community\(^{(26)}\). An accelerated HBV vaccine course consists of 4 doses at 0, 1, 2 and 12 months or 0, 7 days, 21 days and 12 months. Accelerated doses result in recipients attaining seroprotective antibodies in earlier month compared to those receiving normal schedule at 0, 6 and 12 months\(^{(16)}\).

2.8.3 Strengths and limitations

More than 50,000 people are processed through Australian prisons each year\(^{(4)}\). The offender population is age, gender and security classification diverse. Offender populations have complex health needs which further marginalise and categorise them. The NPEBBVS is the only repeated multijurisdictional survey providing point prevalence of BBVs, STIs and risk behaviours among prison entrants. While the NPEBBVS participants represent a small proportion of the overall yearly prison entrant population, data from the NPEBBVS study are comparable to data from other prevalence prison studies\(^{(22)}\) providing evidence for generalisability to prison entrant populations nationally. Additionally the recruitment of men, women, Indigenous, non-Indigenous entrants into the NPEBBVS is representative of the overall proportions of these populations within the justice system\(^{(8)}\). The proportion of men to woman in the NPEBBVS is similar to that of the prison population; however the small female sample
size in the NPEBBVS creates difficulties in interpreting the findings from this group as proportions of various demographic and other factors are unstable by virtue of small numbers. However there is some evidence of the reliability of our findings with regards to female prisoners; female prevalence data from the NPEBBVS is comparable to another large cross sectional survey of prisoners\textsuperscript{[27]}.

There maybe limitations with the generalisability of these findings to specific populations. The Indigenous prison population varies between states and territories. The NPEBBVS findings from NSW, QLD, WA and TAS (current study population) in which Indigenous people make up 22\% of the prison population should be generalised only with caution to other jurisdictions who have different prison entrant demographic characteristics. For example, the NT has larger representation of Indigenous people in prison (86\% in 2013\textsuperscript{[28]}) and large cultural diversity among Indigenous people with many different language groups. A separate analysis for the NT, WA and SA data would be beneficial for these populations. Alternatively, analysis by area remoteness of the overall NPEBBVS sample without looking at trends over time would allow sufficient data for analysis.

HCVAb is an indicator of exposure; this serological marker cannot be used to directly determine level of acute or chronic HCV infection. As a result it is challenging to determine the actual burden of disease. Future surveys should consider testing for HCV PCR to provide a true indication of disease burden, although the test is expensive (\$180).

The strength of the NPEBBVS is in the purpose and uniqueness of the survey and the important contribution the NPEBBVS data provides for understanding BBV and risk factors among this marginalised population. In the absence of a national BBV monitoring mechanism or national screening policy for prison entrants, the NPEBBVS gives the only national BBV prevalence estimates among prison entrants.

### 2.9 Conclusion

The NPEBBVS is a unique mechanism for monitoring BBVs and risk factors among prison entrants. This study shows the high burden of HCV and HBV experienced by offender populations compared to the general community. It indicates a need for tailored and targeted health programs and policy to decrease the prevalence within the offender population.

Factors associated with HCV and HBV are varied, therefore approaches to developing policy, initiatives and programs should be streamlined to take into consideration similarities while targeted to address differences identified between the Indigenous and non-Indigenous populations.
Likewise, when reporting on Indigenous BBV prevalence a break down by location (urban versus, regional and remote) and injecting status can provide context and inform program and policy development.

### 2.10 Implications and recommendations

- The findings of this study provide further evidence the need for harm minimisation in prisons. For a long time, there have been calls to implement NSP’s in Australian prisons without success\(^3\). Dialogue since the 1980’s is in a state of stalemate, new and innovative approaches to advocating for the implementation of NSP’s and other harm minimisation initiatives in this setting could lead to progression.

- Prisons have been identified as high risk settings for HCV and HBV transmission due to both high prevalence among prison entrants and risk behaviours. Access to harm minimisation in the form of vaccination, condoms for those engaged in sexual activity while in-prison, bleach for cleaning injecting equipment, and other surfaces and equipment in contact with blood, opiate management programs and appropriate educational materials for individuals in the justice system could reduce risk of prison transmission.

- HBV is higher among Indigenous prison entrants and vaccination coverage is poor. Prisons may provide a good setting to monitor coverage of the HBV vaccination program or provide a catch up program for those offenders missed in mainstream vaccination programs.

- For a comprehensive understanding of HCV epidemiology, collection of HCV PCR in addition to HCVAb would be ideal to differentiate acute, past and current infection in prison entrants and assist prison medical services to manage cases appropriately.

- The NPEBBVS is the only national prison surveillance system. Further discussion is required regarding the implementation of a passive national surveillance system to monitor infectious disease in prison to understand the epidemiology of infectious disease and provide adequate infection control measures and harm minimisation strategies where necessary.
Future research, other than the NPEBBVS, should look to undertake targeted recruitment of women within the justice system to improve knowledge and understanding of BBV prevalence and associated risk factors among this population.

2.11 References


20. The Kirby Institute. HIV, viral hepatitis and sexually transmissible infections in Australia Annual Surveillance Report 2013. The Kirby Institute, the University of New South Wales, Sydney NSW 2052.


Hepatitis C and hepatitis B prevalence and associated risk factors among Indigenous and non-Indigenous prison entrants in Australia

**Intended Journal:** Australian and New Zealand Journal of Public Health

**Authors:** Dina Saulo¹, Paul Simpson¹, Mary Ellen Harrod¹, Tony Butler¹

1. The Kirby Institute

**Background:** Prisoners and Indigenous people are priority populations. Yet, there remains little Indigenous-specific research on hepatitis C virus (HCV) and hepatitis B virus (HBV) among prisoners. This study aims to compare HCV and HBV antibody prevalence and associated risk factors by Indigenous status.

**Methods:** Data was extracted from a national cross-sectional prison entrant survey collected in 2004, 2007, 2010 and 2013. Descriptive analysis of demographic data and prevalence of HCV and HBV were determined. Logistic regression was used to examine factors associated with HCV and HBV by Indigenous status.

**Results:** Indigenous people accounted for 25.4%(547/2230) of prison entrants. HCV antibody (HCVAb) prevalence in Indigenous entrants was 37%(2004), 42%(2007), 24%(2010), and 42%(2013). Prevalence among non-Indigenous was 33%, 30%, 23%, and 37% respectively. Risk factors associated to HCVAb positivity were similar between groups, injecting drug use (IDU) is the predominate risk factor. HBV core-antibody (anti-HBc) prevalence among Indigenous entrants was higher in 2004, 2007 and 2010. In 2013, anti-HBc prevalence was similar (13-14%). Age was significantly associated with anti-HBc status, injecting was only associated with anti-HBc among non-indigenous entrants.

**Conclusion:** In developing public health programs and policies on HCV and HBV, consideration of the similarities and differences between Indigenous and non-Indigenous offenders is required.

**Background**

Aboriginal and Torres Strait Islander (hereafter Indigenous) people comprise 3.0% of the Australian population but a staggering 27% of the Australian prisoner population³⁰. Indigenous people in contact with the justice system are recognised as a high priority population within the government’s Fourth National Aboriginal and Torres Strait Islander Blood Borne Viruses and Sexually Transmissible Infections Strategy 2014-2017³¹. This strategy
prioritises strengthening evidence-based approaches to harm reduction and increased surveillance and monitoring research for blood borne viruses (BBVs) in the custodial setting. Prisons are a priority setting for BBV risk due to the IDU history of many offenders, the high risk of transmission of BBVs, particularly HCV through sharing equipment, and the limited access to effective harm reduction measures such as needle and syringe program (NSP)\(^{30,31}\).

From 1996-2010, six prison-based HBV and/or HCV prevalence studies have been conducted that provide an Indigenous non-Indigenous breakdown\(^{6, 8-10, 28, 32}\). Breakdown by Indigenous status acknowledges that these populations are not homogenous and assist in effectively plan screening, prevention and treatment activities in a culturally appropriate manner. Prevalence estimates provided by these studies indicate that Indigenous prison entrants have a higher level of HCV and HBV than non-Indigenous prison entrants. However, these studies do not provide an in-depth understanding of these differences.

The aim of this study was to explore prevalence and identify factors associated with HCV and HBV exposure among Indigenous and non-Indigenous prison entrants across a ten-year period.

**Methods**

**Survey**

The National Prison Entrants Blood Borne Virus Survey (NPEBBVS) is a triennial cross-sectional survey established in 2004. It monitors the prevalence of (Human Immunodeficiency Virus) HIV, HCV, HBV, sexually transmissible infections (STIs) and risk behaviours among Australian prison entrants. The NPEBBVS is funded by corrective/justice health from all jurisdictions. NPEBBVS methods are described in detail elsewhere\(^{6, 13, 33}\). Briefly, data are collected over a two week period by identified Public Health Nurses at participating reception prisons. Survey procedures include obtaining informed participant consent, questionnaire administration and collection of a blood and urine sample. Samples are tested for sexually transmissible and blood borne viral infections. Hepatitis B core antibody (anti-HBc) was used in this analysis as a marker for exposure to HBV, and hepatitis C antibody (HCVAb) as a marker for exposure to HCV\(^{34}\).

This analysis includes 2004, 2007, 2010 and 2013 NPEBBVS data from states which participated in all four survey years: New South Wales (NSW), Western Australia (WA), Queensland (QLD) and Tasmania (TAS). Survey participants with Indigenous status not recorded were excluded from analysis.

**Data analysis**
Chi-squared test for trends were used to detect significant changes in descriptive variables by Indigenous status, IDU status and survey year. HCVAb and anti-HBc prevalence were calculated separately for each survey year, and by Indigenous status. Logistic regression was conducted to determine those risk factors associated with HCV and HBV prevalence by Indigenous status. The Accessibility/Remoteness Index of Australia (ARIA) was included as an independent variable. ARIA calculations were based on the prison entrant’s postcode of last residence before prison with entrants classified into the two categories of highly accessible (locations with higher service provision) and non-highly accessible (locations with less service provision). Data analysis was carried out in Stata 12.

Results

Participants

Overall, 2,230 prison entrants from NSW, QLD, WA and TAS participated in the 2004, 2007, 2010 and 2013 NPEBBVS. Participation rate by prison entrants at reception centres over the two week survey period in the four states combined was 83% (2004), 74% (2007), 80% (2010). Indigenous prison entrants accounted for 24.5% of the total sample across all survey years (n=547). The overall sample was primarily male (89%) reflecting the composition of the overall prisoner population in Australia. Indigenous women made up 33% of the overall female prison entrants population and were incarcerated at a higher rate than non-Indigenous women from 2004 – 2010. In 2013, both Indigenous and non-Indigenous woman were incarcerated at a similar rate. There was a high rate of recidivism among Indigenous and non-Indigenous prison entrants where the majority of prison entrants were returning to prison for a subsequent episode. However, from 2004 to 2013 there was an increase in first time offenders among both Indigenous (18.0% (2004) – 22.6% (2013), p 0.844) and non-Indigenous (26.7% (2004) – 36.9% (2010), p 0.001) prison entrants.
Table 1. Demographics and risk behaviour of Indigenous and Non-Indigenous prison entrants by survey year

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<tr>
<th></th>
<th>2004</th>
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<th>2010</th>
<th>2013</th>
<th>*chi²</th>
<th>p-values</th>
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<td>96 85.0%</td>
<td>147 88.0%</td>
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<td>141 87.0%</td>
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<tr>
<td></td>
<td></td>
<td>542 90.5%</td>
<td>484 90.9%</td>
<td>535 91.2%</td>
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<td></td>
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<tr>
<td><strong>Age</strong></td>
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<tr>
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<td>95 57.2%</td>
<td>84 52.2%</td>
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<td>54 47.8%</td>
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<td>77 47.8%</td>
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<td>199 47.0%</td>
<td>207 45.8%</td>
<td>120 38.5%</td>
<td>0.108</td>
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<td>271 55.0%</td>
<td>224 53.0%</td>
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<td>192 61.5%</td>
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<td><strong>ARIA (by post code of last residency)</strong></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
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<td>73 75.3%</td>
<td>76 75.3%</td>
<td>85 53.1%</td>
<td>95 60.1%</td>
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</tr>
<tr>
<td></td>
<td>Not Highly accessible</td>
<td>24 24.7%</td>
<td>25 24.8%</td>
<td>75 46.9%</td>
<td>63 39.9%</td>
<td></td>
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<tr>
<td>Non-Indigenous</td>
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<td>354 88.3%</td>
<td>385 88.1%</td>
<td>251 83.7%</td>
<td>0.043</td>
</tr>
<tr>
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<td>45 9.5%</td>
<td>47 11.7%</td>
<td>52 11.9%</td>
<td>49 16.3%</td>
<td></td>
</tr>
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<td></td>
<td></td>
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<td></td>
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<td>35 21.3%</td>
<td>37 22.6%</td>
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<td>82 82.0%</td>
<td>90 79.6%</td>
<td>129 78.7%</td>
<td>127 77.4%</td>
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<tr>
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<td>First time</td>
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<td>140 33.3%</td>
<td>169 37.8%</td>
<td>113 36.9%</td>
<td>0.001</td>
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<td>360 73.3%</td>
<td>281 66.8%</td>
<td>278 62.2%</td>
<td>193 63.1%</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td>45 39.8%</td>
<td>92 55.1%</td>
<td>75 45.7%</td>
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<td>64 64.0%</td>
<td>68 60.2%</td>
<td>75 44.9%</td>
<td>89 54.3%</td>
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<td>200 47.2%</td>
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<tr>
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<td>281 57.4%</td>
<td>224 52.8%</td>
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<td>154 50.2%</td>
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<tr>
<td>Indigenous</td>
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<td>23 36.0%</td>
<td>23 34.3%</td>
<td>29 39.6%</td>
<td>26 29.6%</td>
<td>0.629</td>
</tr>
<tr>
<td></td>
<td>Injected, in last month</td>
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<td>44 65.7%</td>
<td>45 60.8%</td>
<td>62 70.5%</td>
<td></td>
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<td>Non-Indigenous</td>
<td>Injected, not in last month</td>
<td>97 34.9%</td>
<td>94 42.9%</td>
<td>91 44.6%</td>
<td>45 29.4%</td>
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<tr>
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<td>Injected, in last month</td>
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<td>125 57.1%</td>
<td>113 55.4%</td>
<td>108 70.6%</td>
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<tr>
<td><strong>shared needles in last month</strong></td>
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<td></td>
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<td>No</td>
<td>29 72.5%</td>
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<td>74 61.2%</td>
<td>80 76.2%</td>
<td>75 70.1%</td>
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<td>57 31.3%</td>
<td>47 38.8%</td>
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<td><strong>shared injecting equipment in last month</strong></td>
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<td></td>
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<td>28 70.0%</td>
<td>22 53.7%</td>
<td>26 37.7%</td>
<td>48 80.0%</td>
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<td>19 46.3%</td>
<td>15 62.3%</td>
<td>12 20.0%</td>
<td></td>
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<td>Non-Indigenous</td>
<td>No</td>
<td>133 73.1%</td>
<td>65 56.5%</td>
<td>79 68.1%</td>
<td>88 83.8%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
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<td>49 26.9%</td>
<td>50 43.5%</td>
<td>31 28.2%</td>
<td>17 16.2%</td>
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<td>38 38.0%</td>
<td>36 31.9%</td>
<td>58 37.2%</td>
<td>35 21.5%</td>
<td>0.018</td>
</tr>
<tr>
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<td>62 62.0%</td>
<td>77 68.1%</td>
<td>98 62.8%</td>
<td>128 78.5%</td>
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<tr>
<td>Non-Indigenous</td>
<td>No</td>
<td>192 39.2%</td>
<td>156 36.8%</td>
<td>144 32.1%</td>
<td>80 25.9%</td>
<td>0.001</td>
</tr>
<tr>
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<td>298 60.8%</td>
<td>268 63.2%</td>
<td>304 67.9%</td>
<td>229 74.1%</td>
<td></td>
</tr>
</tbody>
</table>

*chi² calculation represent proportional change across survey year
Chi-squared analysis revealed a significant increase in the proportion of Indigenous people entering prison from non-highly accessible areas across survey years (from 25% in 2004 and 2007 to 47% in 2010 and 40% in 2013 (p<0.001)). P-values for ARIA changed over survey years for non-Indigenous participants (p<0.043).

**Hepatitis C prevalence and risk factors**

From 2004 - 2013 the proportion of people who had ever injected illicit drugs decreased from 58.5% to 51.6%, this decrease was significant for both Indigenous (from 64% (2004), 60% (2007), 45% (2010) and 54% in 2013, p= 0.010) and non-Indigenous entrants (p= 0.004) (Table 1). The majority of both Indigenous and non-Indigenous entrants who had ever injected did so in the month prior to incarceration. There was no significant change across survey years among prison entrants who had shared needles in the month prior to incarceration but there was a significant decrease in sharing injecting equipment in the month prior to incarceration among both Indigenous and non-Indigenous entrants (Table 1) From 2004 – 2013 there was a significant increase in prison entrants ever having a tattoo for both Indigenous (p =0.018) and non-Indigenous entrants (p= 0.001) (Table 1).

HCVAb prevalence among Indigenous prison entrants was 37% in 2004, 42% in 2007, 24% in 2010, and 42% in 2013; and 33%, 30%, 23%, and 37% respectively in non-Indigenous prison entrants (Table 2). When stratified by injecting status, both Indigenous and non-Indigenous prison entrants had a similar HCVAb prevalence. Indigenous people with a history of IDU had an HCVAb prevalence of 56% (2004), 63% (2007), 53% (2010), and 54% (2013). Non-Indigenous prison entrants with a history of IDU had an HCVAb prevalence of 56%, 55%, 51%, and 62%, (Table 2).

<table>
<thead>
<tr>
<th>Year</th>
<th>Number</th>
<th>Number positive</th>
<th>Overall prevalence</th>
<th>95% CI</th>
<th>Number</th>
<th>Number positive</th>
<th>Overall prevalence</th>
<th>95% CI</th>
</tr>
</thead>
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<tr>
<td>2004</td>
<td>79</td>
<td>29</td>
<td>36.7%</td>
<td>0.28 - 0.51</td>
<td>368</td>
<td>243</td>
<td>33.4%</td>
<td>0.30-0.40</td>
</tr>
<tr>
<td>2007</td>
<td>96</td>
<td>40</td>
<td>41.7%</td>
<td>0.33 - 0.54</td>
<td>345</td>
<td>105</td>
<td>30.4%</td>
<td>0.27-0.37</td>
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<tr>
<td>2010</td>
<td>149</td>
<td>35</td>
<td>23.5%</td>
<td>0.18 - 0.32</td>
<td>368</td>
<td>84</td>
<td>22.8%</td>
<td>0.19-0.27</td>
</tr>
<tr>
<td>2013</td>
<td>88</td>
<td>37</td>
<td>42.1%</td>
<td>0.32-0.53</td>
<td>197</td>
<td>72</td>
<td>36.6%</td>
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</table>

**HCVAb prevalence among Indigenous and Non-Indigenous prison entrants**

By injecting status and survey year

<table>
<thead>
<tr>
<th>Year</th>
<th>Non-IDU prevalence</th>
<th>IDU prevalence</th>
<th>Non-IDU prevalence</th>
<th>IDU prevalence</th>
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<tr>
<td>2004</td>
<td>3.57%</td>
<td>0.0009 - 0.18</td>
<td>56.0%</td>
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<tr>
<td>2007</td>
<td>5.56%</td>
<td>0.006 - 0.19</td>
<td>63.3%</td>
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</tr>
<tr>
<td>2010</td>
<td>1.18%</td>
<td>0.0003 - 0.06</td>
<td>53.1%</td>
<td>0.40 - 0.66</td>
</tr>
<tr>
<td>2013</td>
<td>4.55%</td>
<td>0.001 - 0.23</td>
<td>53.9%</td>
<td>0.41-0.66</td>
</tr>
</tbody>
</table>

Table 2. HCVAb prevalence among Indigenous and Non-Indigenous prison entrants in NSW, QLD, Tas and WA, by survey year
Indigenous prison entrants who had ever injected were more likely to be HCVAb positive than those who had not injected drugs (adjusted odds ratio [aOR]=31.0, CI 11.64-82.67, p<0.001) as were non-Indigenous prisoner entrants who had ever injected drugs (aOR=42.5, CI 23.65-76.36, p<0.001) (Table 3).

Other factors significantly associated with HCVAb in both Indigenous and non-Indigenous prison entrants were age, subsequent imprisonment and residing in a highly accessible location before prison. Indigenous and non-Indigenous prison entrants aged over 30 were more likely to be HCVAb positive compared to those aged 29 and under (Indigenous aOR=3.57, CI 1.99-6.38, p<0.001 and non-Indigenous aOR=2.67, CI 1.89-3.65, p<0.001). Being incarcerated for the second or subsequent time was associated with HCVAb in both Indigenous prison entrants (aOR=4.30, CI 1.71-10.76, p<0.002) and non-Indigenous prison entrants (aOR=3.92, CI 2.52-6.10, p<0.001). Entering prison from a less accessible geographical location was associated with a lower prevalence of HCVAb in both Indigenous and non-Indigenous entrants. Having ever acquired a tattoo was not significantly associated with HCVAb among either Indigenous or non-Indigenous prison entrants.
<table>
<thead>
<tr>
<th></th>
<th>Indigenous</th>
<th></th>
<th></th>
<th>Non-Indigenous</th>
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</tr>
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<tr>
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</tr>
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<td>2+ time</td>
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<td>1.71-10.76</td>
<td>0.002</td>
<td>3.92</td>
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</table>
Hepatitis B prevalence and risk factors
From 2004-2010, anti-HBc prevalence among Indigenous prison entrants was 40% (2004), 29% (2007), 21% (2010), higher than their non-Indigenous counterparts 17% (2004), 15% (2007), and 16% (2010). In 2013, the prevalence was similar in Indigenous (13.3%) and non-Indigenous (14.4%) entrants (Table 4). Overall, from 2004-2010 anti-HBc has decreased among Indigenous prisoners and remained stable among non-Indigenous prison entrants.

When stratified by injecting status, anti-HBc prevalence among Indigenous prison entrants who had ever injected drugs was 38% (2004), 45% (2007), 16% (2010) and 13% (2013) compared to 24% (2004), 23% (2007), 19.4% (2010) and 18% (2013) among non-Indigenous prison entrants who had never injected. IDU was significantly associated with anti-HBc in non-Indigenous prison entrants only (aOR=2.2, CI 1.52-3.25, p <0.001).

Being 30 years of age or older was the only factor to be significantly associated with anti-HBc positivity in both Indigenous (aOR= 2.81, CI 1.61-4.91, p<0.001) and non-Indigenous (aOR= 2.90, CI 2.02-4.17, p <0.001) (Table 5). Unlike HCVAb among Indigenous entrants, anti-HB is more likely to be of higher prevalence among those prison entrants not from a highly assessable area prior to prison (aOR=2.00, CI 1.05-4.91, p0.034).
Table 5. Factors associated with HBV core antibody (HBcAb) positivity among Indigenous and non-Indigenous prison entrants

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<td>0.56</td>
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<td>First time</td>
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<td></td>
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</tr>
<tr>
<td>2+ time</td>
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<td>1.04-15.98</td>
<td>0.082</td>
<td>1.37</td>
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</tbody>
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Discussion

This study showed that the prison entrant population has a much higher HCVAb and anti-HBc prevalence compared to the general community which in 2013 was 1.4% for HCV and 0.97% for HBV\(^{15}\). Findings revealed equally high HCVAb prevalence among Indigenous and non-Indigenous prison entrants. Although anti-HBc prevalence rates were high in both Indigenous and non-Indigenous groups, the former exhibited higher and more variable rates that non-Indigenous entrants across survey years.

Despite the high prevalence of HCVAb there was a declining trend among prison entrants across survey years. Decreases in HCVAb prevalence among prison entrants may be due to a number of factors such as a decrease in those inmates who have ever injected. However, during this time period there was an overall decline of hepatitis C diagnosis per capita in
Australia\textsuperscript{(24)} reflected in a reduced HCVAb prevalence among people accessing NSPs in the community\textsuperscript{(36)}.

The high burden of HCVAb among prison entrants in this study was significantly associated with a history of IDU which is consistent with previous studies. The prevalence of having ever injected drugs was 44-65% among prison entrants, consistent with the prevalence of IDU among those in contact with the justice system in other studies indicating IDU as an important risk factor in the prison context\textsuperscript{(1-10)}. Non-Indigenous female prison entrants were more likely to be HCVAb positive than their male counterparts. Higher HCVAb prevalence has been noted among female (including Indigenous female) offenders in previous studies as well as community based IDU studies\textsuperscript{(27, 37)}. This could be attributed to gender roles and power dynamics between female and male injecting partners and groups\textsuperscript{(27)}, leading to women being more likely to be exposed to sharing behaviours. However, a limitation to understanding prevalence among women in the NPEBBVS is the relatively small female sample.

Overall, Indigenous and non-Indigenous prison entrants had similar risk factors for HCVAb. This suggests that Indigenous status is not a predominant factor associated with HCV. Rather, findings indicate that age (being over 30 years), gender (female), injecting status and number of times incarcerated (2+ times) were risk factors associated with HCVAb. It would appear similarities in social disadvantage and drug use across Indigenous and non-Indigenous offenders could be a common factor in HCVAb positivity.

This does not imply there should not be a focus on the Indigenous population in regards to service provision, education and harm-minimisation. Tailoring public health programs based on both Indigenous status and ARIA would allow a more targeted approach to HCV health promotion, education and harm-minimisation. Indigenous prison entrants were significantly more likely to be HCV antibody positive if they resided in a more highly serviced area, whereas coming from a non-highly accessible area was associated with lower risk, largely reflecting the differences in patterns of drug use between metropolitan and non-metropolitan areas\textsuperscript{(38)}. Little is known about Indigenous injectors from remote communities, further research is required.

Overall, anti-HBc prevalence was higher in Indigenous prison entrants compared to non-Indigenous prison entrants. Anti-HBc prevalence was related to age in both populations and injecting drug use in non-Indigenous prisoners only. Hepatitis B risk factors include: household contacts and vertical transmission with the higher prevalence in Indigenous entrants reflecting high exposure to hepatitis B in the general Indigenous population\textsuperscript{(23, 25, 39)}. Although national notifications of newly acquired hepatitis B have declined over time\textsuperscript{(24)} there was a slight
increase in anti-HBc among prison entrants with no history of injecting. Like hepatitis C, there is a cumulative lifetime risk of HBV acquisition and being aged 30 years or older was associated with anti-HBc positivity in both Indigenous and non-Indigenous prison entrants. People aged over 30 years have not participated in either the universal infant HBV vaccination program introduced in 2000 or the adolescent catch-up program that commenced in 1997. These programs have demonstrated decline in newly acquired HBV notifications in people aged under 30 as well as evidence of decreased prevalence\(^{(25)}\) and increased immunity in younger people\(^{(24, 39)}\). The prison setting provides an ideal opportunity to prevent HBV acquisition through vaccination to this at-risk population through either standard or accelerated HBV vaccine schedules\(^{(26)}\).

Further research on HBV among offenders and the wider Indigenous population is needed to understand hepatitis B vaccine coverage rates. Additionally, in-prison initiatives to ensure prison entrants have adequate immunity including incentives to be vaccinated and rapid vaccination schedules could be explored.

The interpretation of the findings should be qualified by study limitations. The Indigenous sample from the NPEBBVS for each state and territory is relatively small, and data were only collected over a two week window period. The proportion of men to woman is similar to that of the prison population; low representation of women in the sample makes it difficult for the overall findings to be transferable to the wider female offender population. However, prevalence data from the NPEBBVS is comparable to other studies of female prisoners\(^{(12, 28)}\). Further, the Indigenous population varies between states and territories and so does the Indigenous population in each prison. This difference means the analysis of each individual state or territory data would be beneficial but sample sizes would need to be larger to draw more reliable conclusions.

HCVAb and HBCAb are both indicators of exposure, but these serological markers cannot be used to directly determine levels of acute or chronic infection with HCV or HBV. As current national strategies prioritise this population, there is justification to resource the NPEBBVS to provide an ongoing consecutive snapshot of BBV and risk behaviour among Indigenous and non-Indigenous prison entrants.

The NPEBBVS is the only repeated multi-jurisdictional survey among prison entrants, and provides a snapshot of BBVs, STIs and risk behaviours in this population. The NPEBBVS prevalence data are comparable to other prevalence studies\(^{(27, 28, 36)}\). In the absence of a national prison BBV monitoring mechanism or a national screening policy for prison entrants, the NPEBBVS provides the only national BBV prevalence among prison entrants.
Conclusion

The NPEBBVS is a unique mechanism for monitoring BBVs and risk factors among prison entrants in Australia. Indigenous people are over-represented among this group and, therefore, this dataset provides understanding of disease burden among a marginalised population absent from national reporting. This study shows the high burden of HCV and HBV experienced by offender populations compared to the general community as well as similarities and disparities in associated HCV and HBV risk factors between Indigenous and non-Indigenous entrants. Factors associated with HCV and HBV acquisition vary, and approaches to developing policy, initiatives and programs should consider this. These could be streamlined to take into consideration similarities among both Indigenous and non Indigenous populations while targeted to address differences among these populations.

Acknowledgment: The NPEBBVS was established and is coordinated by Prof. Tony Butler (The Kirby Institute). This analysis was completed by Dina Saulo as a part of a Masters of Philosophy in Applied Epidemiology (MAE), Australian National University (ANU). Work was undertaken while placed in the field at the Kirby institute. Dina Saulo is funded by the Indigenous offender health - capacity building group (IOH-CBG) and the Leonard Broome scholarship and under the supervision of; Dr Phyll Dance (National Centre for Epidemiology and Public Health (NCEPH), ANU); Dr Emily Fearnley (NCEPH, ANU); Prof. John Kaldor (The Kirby Institute) and Prof. Tony Butler (The Kirby Institute). Thank you for all your support and encouragement.

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3 Evaluation of a surveillance system
The National Prison Entrant Blood Borne Virus Survey
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3.1 Abbreviations list

ACT  Australian Capital Territory

AIHW  Australian Institute of Health and Welfare

BBV  Blood borne virus

CDC  Centre for Disease Control and Prevention

HBV  Hepatitis B

HCV  Hepatitis C

HIV  Human Immunodeficiency virus

IDU  Injecting drug use

JHRP  Justice Health Research Program

NPEBBVS  National prison entrant blood borne virus survey

NPHDC  National Prisoner Health Data Collection

NPHIC  National Prisoner Health Information Committee

NSW  New South Wales

NT  Northern Territory

QLD  Queensland

SA  South Australia

STI  Sexually Transmissible Infection

TAS  Tasmania

VIC  Victoria

WA  Western Australia
3.2 Prologue

Being placed in the Justice Health Research Program (JHRP) for the majority of my time at the Kirby Institute has given me a new understanding of the issues affecting offender populations. During my field placement I had an opportunity to analyse national prison entrant blood borne virus survey (NPEBBVS) data (Chapter 2). I looked at hepatitis B (HBV) and hepatitis C (HCV) prevalence and associated risk factors among Indigenous and non-Indigenous prison entrants. A requirement of the Masters of Philosophy in Applied Epidemiology is to evaluate a surveillance system so it was fitting to conduct the evaluation on the NPEBBVS. The survey runs every three years, and 2013 was a survey year (some jurisdictions were only able to participant in early 2014 for reasons discussed within) so it was a good opportunity to consult stakeholders on the operation and processes of the survey while it was fresh in their mind.

My role in the evaluation included:

- Assessing the NPEBBV surveillance system attributes as outlined in the Centre for Disease Control and Prevention (CDC) “Updated Guidelines for Evaluating Public Health Surveillance Systems” via an interview guide for stakeholder consultation that I developed (Appendix 2).

- Obtaining ethics approval from both University of New South Wales (NSW) and Australian National University human ethics committees (Appendix 1: participant information sheet and consent form).

- Conducting phone interviews with stakeholders. I obtained consent to audio record interviews then transcribed them for analysis.

- Analysing NPEBBVS data to examine survey variables for data quality and representativeness.

- Feedback of findings to stakeholders in a condensed report, currently in development to be distributed to stakeholders, December 2014.

I also had the opportunity to be exposed to other surveillance systems throughout my field placement. This included a two week secondment to the NSW Department of Health, Health Protection Branch to assist in chasing up missing data fields from the previous quarter’s HIV notifications. The epidemiological project I have worked on during the MAE (chapter 5) has
now moved into a surveillance phase. A pilot study has been developed to assess surveillance methodology and sampling techniques to ensure a targeted sample of Indigenous women and men for ongoing national HPV surveillance, and to test the acceptability and feasibility of self collected sampling.

3.2.1 Lessons learnt
During stakeholder interviews I listened to people talk about the complex needs of prison populations, the transmission of blood borne viruses (BBV) and prison setting aspects to disease among this population. An active surveillance system, like the NPEBBVS that also collects risk behaviour and demographic data, is valuable for understanding disease in context over time. A passive surveillance system that electronically captures disease notifications from prisons nationally would be beneficial, but there would still need to be an active system to monitor risk behaviours. Through using the CDC surveillance evaluation framework attributes, I have developed and gained more knowledge not only on how to evaluate a surveillance system, but I have a better understanding of how surveillance systems work and how the environment that they operate in influences performance.

3.2.2 Public health implications
The NPEBBVS produces influential data, which are used within national strategies, policy, planning and have cross disciplinary application. Stakeholders involved with this evaluation did not know the extent to which the NPEBBVS has influenced national or jurisdictional strategies and actions. From this evaluation, I will prepare a condensed report for stakeholders before the end of 2014. This report will share the achievements of the NPEBBVS nationally, and will demonstrate how jurisdictional collaboration through the NPEBBVS has benefited prison health. It would be ideal to have a communication channel for the ongoing dissemination of NPEBBVS work and to encourage more cross jurisdictional collaboration. It was evident that each state and territory justice or corrective health service was fragmented from others. There are some recommendations within this document that are based around resourcing and communication that could improve the operation of future NPEBBVSs.
3.3 Abstract
The NPEBBVS was established in 2004 to monitor the prevalence of blood borne viruses and risk behaviours among prison entrants and to build national research capacity in the prison health sector. The survey has been undertaken every three years for the last decade and provides a valuable insight into a priority population. The NPEBBVS has not been formally evaluated. The aim of this evaluation is to assess whether the NPEBBVS is meeting its objectives effectively.

3.3.1 Methods
The Centre for Disease Control and Prevention (CDC) “Updated Guidelines for Evaluating Public Health Surveillance Systems” was used to systematically assess key attributes of the NPEBBVS. Information for the evaluation has been gathered through stakeholder interviews, document review and NPEBBVS data analysis.

3.3.2 Results
The NPEBBVS effectively gathers a unique dataset to enhance understanding of the prison population. It has been successful in raising the profile and advocating for prisoner health nationally, as demonstrated through its use at local and national levels. The NPEBBVS represents a small proportion of the overall prisoner population, however the longitudinal prevalence of prison entrant blood borne viruses (BBV), sexually transmissible infections (STIs) and risk behaviours are similar to other published studies. During interviews, stakeholders identified operational systems, resources and the complex needs of the prison entrant population as barriers to the simplicity and acceptability of the NPEBBVS. The NPEBBVS demonstrated flexibility to adapt in a sometimes unpredictable environment to meet the system objectives. NPEBBVS stability and longevity is reliant on external funding sources and resourcing.

3.3.3 Conclusions
The NPEBBVS is effective in influencing practice, policy and resources nationally and within jurisdictions. Whilst the effectiveness of the NPEBBVS to meet its objectives has produced great results from a data gathering perspective, it faces significant challenges in terms of stability. In the absence of other national data sets of BBVs and STIs for prison populations, the NPEBBVS monitors and provides context and input into national surveillance systems, and the data collected informs national prison health indicators. Ongoing collection with adequate funding to operate is recommended.
3.4 Introduction

In 2013, the Australian prisoner population was 30,775, including sentenced and un-sentenced inmates in 123 prison facilities across the country\(^2\). Men accounted for 92% and women 8% of the prison population. Overall the Australian imprisonment rate increased from 157 per 100,000 in 2003 to 170 per 100,000 in 2013\(^2\). Recidivism was common, where 58% of the prison population had been incarcerated before their current episode\(^2\).

Most prisoners come from a low socioeconomic background, drawn from the most disadvantaged and marginalised groups in the community who are health poor, with 34% having education levels below year 10\(^3\). The four predominant health issues among prisoners are mental health\(^4\), chronic illness, communicable diseases and substance use\(^3\). Mental health has emerged as a key issue for this population. A large mental health study conducted in New South Wales (NSW) found a 12-month prevalence of any psychiatric disorder among prisoners was 74% compared to 22% in the general population, this burden could not be attributed only to alcohol and other drug use\(^4\).

Reported among prisoners in Australia or internationally are high rates of STIs such as syphilis, human immunodeficiency virus (HIV), hepatitis B (HBV), and herpes simplex virus type-2\(^5\). Around 44% of prisoners will use an illicit drug while incarcerated\(^16\). People who inject drugs while in prison are at risk of BBV infections such as HIV, hepatitis C (HCV) and HBV, largely due to sharing contaminated injecting equipment\(^6\). Even though possession of needles is illegal in prison, inmates do continue to inject during incarceration, albeit less frequently than in the community, and sharing equipment among inmates is common\(^7\). When they do inject they are at an increased risk of acquiring infection\(^7, 8\). Tattooing, sharing razors, and other blood contact (e.g. during fights or sport) also put prisoners at risk of exposure to BBVs\(^8\).

Nationally there are no surveillance mechanisms that identify BBV notifications from prisons, and no monitoring of STIs such as chlamydia, gonorrhoea, herpes and syphilis among this population. Previously, routine HIV testing among prison entrants occurred and was included in national monitoring for HIV infection\(^9\). Nationally, the proportion of inmates tested at entry to prison decreased between 1997 and 2009, and testing varied across jurisdictions\(^9\). For example, some states had a blanket test policy while others had a test at risk policy\(^10\). Due to inconsistencies across jurisdictions and low prevalence, the collection of these data has ceased. Currently HIV, HBV, HCV and STI notifications from the prison population are not identifiable in the national notifiable disease surveillance system. National epidemiology of these infections in this high risk population is still unclear. Several *ad hoc* prevalence studies have been conducted in some states and territories to bridge this knowledge gap\(^11-14\) including the NSW prisoner health survey, a large comprehensive cross-sectional inmate study.
conducted every five years\textsuperscript{[15, 16]}. However, there is a lack of a national effort and co-ordination to monitor this at risk population.

Each state and territory prison system operates differently and this is the case for prisoner health also. For example, Western Australian (WA) prison health is operated by corrective services with no direct reporting to WA Health (the state health department), compared to other jurisdictions which are connected to state or territory health departments\textsuperscript{[17]}. There are also private prisons in some jurisdictions, including privately run health services\textsuperscript{[17]}. This diversity may indicate why a national effort for monitoring disease notifications from prisons has not been established. In lieu of national government based monitoring, the NPEBBVS aims to monitor the prevalence of HCV, HBV, HIV and risk behaviour information among a consecutive sample of prison entrants. The NPEBBVS has not been formally evaluated previously. Evaluation of surveillance systems is important to ensure capturing and monitoring of conditions of public health importance are effective and meet surveillance system objectives.

### 3.5 Purpose of Evaluation

- Describe the systems and processes of the NPEBBVS
- Identify the extent to which the NPEBBVS meets its objectives
- Provide recommendations for future NPEBBVS

### 3.6 Evaluation methods

To assess the effectiveness of the NPEBBVS in meeting its objectives the United States Department of Health, Centre for Disease Control and Prevention (CDC) “Updated Guidelines for Evaluating Public Health Surveillance Systems”\textsuperscript{[1]} was utilised to provide a framework to systematically evaluate the NPEBBVS. The CDC guidelines identify ten attributes to evaluate. For the purpose of this evaluation, the following eight system attributes were assessed:

1) Usefulness
2) Simplicity
3) Flexibility
4) Data Quality
5) Acceptability
6) Representativeness
7) Timeliness
8) Stability
CHAPTER 3 | EVALUATION OF A SURVEILLANCE SYSTEM
Sensitivity and predictive value positive are attributes of the CDC evaluation framework, but due to the type of diagnostic data collected for the NPEBBVS these calculations were not possible. Three data collection activities were undertaken to assess the selected system attributes: 1) Literature review, 2) Analysis of NPEBBVS data and 3) Stakeholder interviews (Table 1 outlines which method informed each attribute).

3.6.1 Literature review
Medline, Web of Science and Google Scholar (for grey literature) were used to search for NPEBBVS citations and mentions in publications, reports and policy documents.

3.6.2 NPEBBVS data analysis
NPEBBVS data from survey years 2004, 2007, 2010 and 2013 were analysed to assess data quality with a focus on variables relating to system objectives, representativeness and possible application of NPEBBVS data.

3.6.3 Stakeholder interviews
To assess the effectiveness of the NPEBBVS to meet its objectives, NPEBBVS stakeholders from all jurisdictions were invited to participate in 30 minute phone interviews (Appendix 1. Participant information and consent form). Stakeholders were invited by email from the central coordinator of the NPEBBVS to participate in the evaluation. Invitations were sent to: prison public health and medical service staff (directors, managers, doctors and public health nurses), staff that administered surveys, policy makers, NPEBBVS national and jurisdictional coordinators. All stakeholders invited were involved in the NPEBBVS at some level and gave feedback based on their own involvement and experience whether that was from a coordination, management, survey and sample collection or policy perspective. All attributes were explored through stakeholder interviews (see Table 1 for attributes explored and Appendix 2. Stakeholder interview guide).
Table 1. Data collection methods used to inform system attributes

<table>
<thead>
<tr>
<th>System Attribute</th>
<th>Literature review</th>
<th>Descriptive data analysis</th>
<th>Stakeholder consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Usefulness</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Simplicity</td>
<td>-</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Flexibility</td>
<td>-</td>
<td>-</td>
<td>✓</td>
</tr>
<tr>
<td>Data quality</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Acceptability</td>
<td>-</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Representativeness</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Timeliness</td>
<td>-</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Stability</td>
<td>-</td>
<td>-</td>
<td>✓</td>
</tr>
</tbody>
</table>

✓ = yes  - = no

3.6.4 Ethics
Ethics approval was granted by the University of New South Wales Human Research Ethics Committee and the Australian National University Human Research Ethics Committee.

3.7 Results
Six stakeholders each participated in 30 minute interviews and represented five different states and territories. Stakeholders who participated included a prison medical director (1), public health nurses (2), people that administered the surveys (2) and a state government BBV program coordinator (1).

3.8 System and processes of the NPEBBVS
In early 2000 there was a notable gap in prison health data nationally\(^{[18]}\). At this time, two national prison health related data sources existed: (i) the HIV notification system and (ii) deaths in custody\(^{[19]}\). By 2009 the prison HIV notification system ceased operation due to \emph{ad hoc} testing by jurisdictions and low prevalence leading to poor data quality\(^{[20, 21]}\). There was a
noticeable absence of prison populations from national disease surveillance. Without a national effort to monitor BBVs, STIs and risk behaviours among offender populations, Professor Tony Butler (Kirby Institute) established the NPEBBVS in 2004 whilst at Justice Health NSW. The NPEBBVS was modelled on the consecutive community national needle and syringe program (NSP) survey which commenced in 1995 and continues to provide a rich consecutive dataset collected over a two week period every year at NSPs around Australia\(^{22}\).

### 3.8.1 NPEBBVS aims and objectives
The NPEBBVS aims to collect BBV, STI and risk behaviour prevalence among a consecutive sample of prisoner entrants. NPEBBVS objectives are to:

1) Monitor HBV, HCV, HIV, and STI (syphilis, chlamydia and gonorrhoea) prevalence among prison entrants.

2) Collect ongoing information on risk behaviours such as drug use, high risk injecting practices, sexual risk behaviours, tattooing, and tobacco smoking among prison entrants.

3) Monitor BBVs, STIs and associated risk behaviours in Indigenous and non-Indigenous prison entrants.

4) Examine trends in BBVs, STIs, and risk behaviours among prison entrants.

5) Monitor HBV vaccination coverage in an at-risk (prisoners) population.

6) Provide a snapshot of BBVs and risk behaviours in a national sample of non-injectors who are at risk of exposure to BBVs.

### 3.8.2 NPEBBVS Study design
The NPEBBVS is a cross sectional survey of consecutive prison entrants collected every three years over a two week period at selected prison reception centres (selected by jurisdictions). Data collection has occurred in 2004, 2007, 2010 and 2013/2014. In 2004, four jurisdictions participated, successive surveys have increased participation and in 2010 and 2013/2014 all jurisdictions participated (Table 2. NPEBBVS jurisdictions and prison entrants response rate at reception by survey year).
### Table 2. NPEBBVS jurisdictions and prison entrants response rate at reception by survey year

<table>
<thead>
<tr>
<th>Survey year</th>
<th>Participating states and territories</th>
<th>Response rate</th>
</tr>
</thead>
</table>
| 2004        | 1. NSW  
              2. WA  
              3. TAS  
              4. QLD       | 612/739 (83%) |
| 2007        | 1. NSW  
              2. WA  
              3. TAS  
              4. QLD  
              5. ACT  
              6. SA  
              7. VIC       | 740/992 (75%) |
| 2010        | 1. NSW  
              2. WA  
              3. TAS  
              4. QLD  
              5. ACT  
              6. SA  
              7. VIC  
              8. NT       | 873/1154 (76%) |
| 2013/2014   | 1. NSW  
              2. WA  
              3. TAS  
              4. QLD  
              5. ACT  
              6. SA  
              7. VIC  
              8. NT       | Response rate not currently available |

NSW = New South Wales, WA = Western Australia, TAS = Tasmania, QLD = Queensland, ACT = Australian Capital Territory, SA = South Australia, VIC = Victoria & NT = Northern Territory

### 3.8.3 NPEBBVS Study Population and recruitment

There are around 20 prison reception centres across Australia; these centres process all prison entrants prior to transfer into the general prison population. Processing of prisoners includes screening and assessment by reception nurses, psychologists and welfare. During assessment prison entrants are asked to participate in the NPEBBVS. Written consent is obtained by identified public health nurses at participating prison reception centres.
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All adult prison entrants (male and female) processed through reception centres during the two week survey period are eligible to participate in the NPEBBVS. Those prison entrants moving between prisons or court are excluded.

3.8.4 Conditions under surveillance

Conditions under surveillance include HBV, HCV, HIV, syphilis, chlamydia and gonorrhoea. Table 3 includes diseases monitored, test type and disease markers used in the NPEBBVS. Blood and urine samples are collected at admission or within the first 72 hours of an inmates’ prison stay. Screening for sexually transmitted infections only began in 2010.

Table 3. NPEBBVS sample type and disease markers

<table>
<thead>
<tr>
<th>Sample</th>
<th>Disease</th>
<th>Marker</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood</td>
<td>Hepatitis B</td>
<td>Hepatitis B surface-antibody</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hepatitis B surface-antigen</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hepatitis B e-antigen and e-antibody</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hepatitis B (IgM &amp; IgG) core-antibody</td>
</tr>
<tr>
<td></td>
<td>Hepatitis C</td>
<td>Hepatitis C antibody</td>
</tr>
<tr>
<td></td>
<td>HIV</td>
<td>HIV antibody</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HIV antigen</td>
</tr>
<tr>
<td></td>
<td>Syphilis</td>
<td>Treponema pallidum (syphilis) antibody</td>
</tr>
<tr>
<td>Urine</td>
<td>Chlamydia</td>
<td>Chlamydiatrachomatis DNA</td>
</tr>
<tr>
<td></td>
<td>Gonorrhoea</td>
<td>Neisseria gonorrhoea DNA</td>
</tr>
</tbody>
</table>

IgG=Immunoglobulin G  IgM=Immunoglobulin M  DNA=Deoxyribonucleic Acid

Risk behaviours associated with conditions under surveillance are collected via a paper-based questionnaire administered by a NPEBBVS nurse at reception. The questionnaire includes basic demographic and criminological information, risk behaviours associated with diseases under surveillance including drug use, risky injecting practices, sexual risk behaviours, tattooing, piercing and tobacco smoking (Appendix 3. NPEBBVS data collection tool).

3.8.5 Sample collection and pathology

The NPEBBVS offers an enhanced screening period at participating reception centres. Reception nurses are integral to the NPEBBVS process; as they recruit prison entrants, administer the questionnaires and collect biological samples. Public health nurses involved in the survey have venepuncture and pre and post-test counselling experience. Blood and urine samples are ideally collected on the same day at prison entry and survey completion (however due to time constraints and limited resources samples can be collected within the first 72
hours after entering prison). Samples are sent to the prison medical service’s usual local public health laboratory for testing. Results are fed back to participants according to prison medical service policy and procedures, providing appropriate post-test counselling, education and clinical management. If participants have left prison before results are returned, public health nurses are required to follow up with the participant in the community. Laboratory and medical notifications of reportable diseases are provided to the appropriate jurisdictional health department as per usual notification procedures. For the NPEBBVS, test results are retrieved from medical records by a designated NPEBBVS public health nurse and compiled with their corresponding completed NPEBBVS questionnaires and sent to the Kirby Institute (paper based). The Kirby Institute receives positive, negative, equivocal and not tested information for each NPEBBVS participant who has been screened.

3.8.6 Data management
The NPEBBVS coordinator in each jurisdiction sends complete questionnaires and test results to the Kirby Institute. A data entry person is employed at the Kirby Institute to enter survey data from paper based surveys into a database. Data are cleaned and coded for analysis. Reports include comprehensive national, state and territory data and are distributed to stakeholders such as prison public health and medical staff, health departments, peak BBV and STI organisations and policy makers. Data for all survey years are stored at the Kirby Institute according to National Health and Medical Research Centre (NHMRC) guidelines. See Figure 1 for system process and data flow.
1. Person enters prison at a reception centre
2. Public health nurse recruits entrant at prison reception centre, and if participant consents will complete:
   a. Survey collection – NPEBBVS tool
   b. Sample collection – blood and urine sample
3. Sample is sent to laboratory as per prison medical service usual procedure. Results are returned from the laboratory to the prison medical service,
4. The public health nurse documents laboratory results with corresponding surveys and follows up results with participants in prison and in the community if person has been released back to the community. Surveys are stored securely at the prison medical service.
5. When complete, surveys with laboratory results are sent from the medical service to the Kirby Institute for:
   a. Data entry
   b. Data cleaning
   c. Analysis
6. Reporting is conducted by the Kirby Institute
3.9 Surveillance system performance

NPEBBVS performance was measured by exploring surveillance system attributes.

3.9.1 Usefulness

Usefulness of a surveillance system is demonstrated through its contribution to prevent, control and improve understanding of health events and ability to influence\(^1\).

**Document review**

The survey data have influenced clinical practice, program implementation and contributed to resourcing in a number of jurisdictions. NPEBBVS outputs include survey reports and publications; the following outputs were identified in this evaluation:

1) National Prison Entrants Blood borne Virus Survey, 2004\(^{23}\)
2) National Prison Entrants Blood borne virus and risk behaviour survey report 2004 and 2007\(^{24}\)
5) The 2004 Australian prison entrants blood-borne virus and risk behaviour survey\(^{25}\)

Two of the above mentioned peer-review publications (5 & 6) have collectively been cited 30 times. Other publications planned include an Indigenous and non-Indigenous HBV and HCV prevalence comparison (see Chapter 2, Appendix 1), among others. Presentations of NPEBBVS data have been conducted by Tony Butler (Kirby Institute) to provide feedback to jurisdictions, national committees and various other groups with a prison health agenda.

The first NPEBBVS and three other key prison based surveys collectively informed the establishment of the National Prisoner Health Information Committee (NPHIC) with the role of reporting national prisoner health indicators\(^{27}\). In 2009, the NPHIC led the establishment of the National Prisoner Health Data Collection (NPHDC) in which data were also collected over a two week period at Australian prisons. The Australian Institute of Health and Welfare (AIHW) use NPHDC data along with national and jurisdictional prison data sets to produce the “Health of Australian Prisoners” report\(^3\). NPHDC is the only national prison data set to collect comprehensive health data, however, it is self-reported and not diagnostic. For this reason,
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data for the reporting of communicable diseases in the AIHW ‘Health of Australian prisoners’ report are obtained directly from the NPEBBVS.

People in custodial settings continue to be a priority population in all current National BBV and STI strategies.\(^{28-31}\) The incorporation of prisoners as a priority population is the result of a number of bodies of work and advocacy including the NPEBBVS. The first national hepatitis C strategy 2005-2008 identified no nationally standardised data on hepatitis C from prisons\(^{32, 33}\). In the third strategy\(^{32}\), the NPEBBVS provided the only national BBV and STI snapshot. Providing the only diagnostic national dataset, the NPEBBVS could be a tool for measuring national indicators, particularly for the HCV strategy.

In recent years the NPEBBVS has become more recognised for its drug related data collected as a part of risk behaviour section of the survey. The National Drug Strategy 2010-2015\(^{34}\) identified the need to focus on prison drug supply and demand. The NPEBBVS has application in this area and could potentially be utilised in national drug related monitoring, particularly for understanding demographic and criminological factors, and the use of drugs before entering prison. Another example of the NPEBBVS cross sectoral application is the use of smoking data. Prisoners smoke tobacco at extremely high rates (85\%)\(^{24}\). This finding from the NPEBBVS resulted in prisoners being identified as a key group in the National Preventative Health Taskforce Report and has resulted in the development of a national summit on tobacco smoking in prisons\(^{35}\).

Stakeholder Interviews

NPEBBVS stakeholders discussed how the NPEBBVS was used in their jurisdiction. Responses included:

- As an advocacy tool to raise the profile of prisoner health.
- Providing evidence to obtain funding to increase or implement on site specialty health services.
- To negotiate collaboration with external health providers.
- As an advocacy tool for the development of BBV programs and educational resources.
- As evidence to increase treatment provision within prisons.

One of the larger jurisdictions (NSW) conducts a comprehensive inmate health survey\(^{16, 36}\) every five years. The impact of the NPEBBVS is reduced for this jurisdiction as they often use their health survey data as an advocacy tool rather than the NPEBBVS. From interviews with
stakeholders, no other jurisdiction had a survey like the ongoing inmate health survey. Participation in the NPEBBVS for a majority of jurisdictions was seen as a chance to:

1. Receive a snapshot of disease burden and risk factors in their jurisdictions.
2. Raise the profile of prison health services at national and state level for both advocacy and public health practice purposes.

3.9.2 Simplicity

Simplicity is the ease at which a surveillance system operates\(^1\).

**Stakeholder interviews**

There are around 126 prisons around the country and processing of persons through prison reception centres before entry to prisons is a common practice across all jurisdictions. By focusing on the prison entrant population, operation of the NPEBBVS is narrowed to about 20 prison reception centres around the country creating a common collection point for all prison entrants over a two week period. Data collection at prison entry is designed to minimise prison health service disruption. However, despite this process, difficulties to collect blood and urine samples at admission occur due to time constraints, workload and priority of high risk patients requiring health assessments on entry. While stakeholders recognised NPEBBVS collection at reception centres as the easiest, most systematic and consistent sampling method, there were a number of barriers complicating NPEBBVS collection identified, including:

- Prison entrants in a state of withdrawal from substances.
- Current lengthy jurisdictional entry assessments; another survey is a burden.
- The high volume of prisoner movements (entry, release, transfer between prisons, court and external medical appointments) through the system increasing workload of already over stretched prison health service.
- Competing priorities of high risk entrants (mental health or other health issues) requiring immediate attention.
- Staffing issues – reduced number of staff, increasing imprisonment rate and reduced capacity to take on other work.

One stakeholder reflected on difficulties of screening entrants as follows:

“A lot of patients have mental health issues ... they are at risk of self-harm, or they are violent or they are detoxing so we can’t actually access them to conduct the survey. So that can be quite difficult, and I understand why it is...
focused on new receptions, but it can be difficult in terms of actually being able to access those patients.”

During interviews, stakeholders identified the need for a dedicated public health nurse with venepuncture and pre-/post-test counselling experience assigned during the NPEBBVS recruitment period. In the absence of ongoing funding to assist jurisdictions over the two week period, the issues related to simplicity have somewhat been relieved by the flexibility of the NPEBBVS to adapt to jurisdictional needs (see 3.8.3 flexibility).

Within six months of survey collection, stakeholders receive the NPEBBVS report. Reports include overall data by survey year, a comparison to previous years and a breakdown by each jurisdiction. There is no one place online where all NPEBBVS reports can be found, the most recent can be downloaded from the Kirby Institute’s website and only one of three NPEBBVS reports appeared during literature searches on Medline, PubMed and Web of Science. NPEBBVS reports are extensive, while all stakeholders found the reports useful, they also thought they could be simplified. During interviews three stakeholders suggested condensing the report. Stakeholders also suggested a two page document summarising key findings, such a document would be useful for jurisdictions to share with their stakeholders as an advocacy tool.

3.9.3 Flexibility

Flexibility is the ability of a surveillance system to accommodate change and adapt appropriately[3].

Stakeholder interview and document review

Survey tool flexibility

Being a longitudinal cross sectional survey, a set methodology with core questions is necessary, and this has been achieved with the NPEBBVS. However, over time there has been additional survey questions included. Some jurisdictions have seen the NPEBBVS as an opportunity to add jurisdiction specific questions, and nationally a number of questions have been added or adjusted over time to collect relevant information. For example, a government funded National Human Papillomavirus (HPV) vaccine program was implemented in 2007 in schools and the community for women under the age of 28 years[37]. An additional question about HPV vaccination was added to the NPEBBVS in 2010.

In 2010, following consultation with sexual health researchers and clinicians, sexual risk behaviour questions were changed from risk behaviours in the last month to focus on risk behaviours in the last three months. The change aligned NPEBBVS sexual risk behaviour
questions to other general population risk behaviour surveys for future comparison purposes. Another change in 2010 saw the inclusion of a demographic question about homelessness. In 2013, a question about willingness to undertake HCV treatment was included.

In the future there is potential to include alcohol and mental health questions. Considering the existing constraints of time and staffing, broadening of questions and survey scope could impact timeliness and in turn acceptability. For consistency and focus, it will be important for the NPEBBVS not to move away from its original objectives.

**Operational flexibility**

The NPEBBVS is collected during the same two week period as the community based national NSP survey to decrease overlap of clients. However, overtime, particularly in 2013, some jurisdictions participating in the NPEBBVS were unable to participate during the set collection period. Jurisdictions negotiated a two week survey collection period to accommodate their reduced capacity. The inclusion of all jurisdictions in all NPEBBVS moving forward is far more valuable than ensuring strict collection periods and demonstrates the flexibility of the NPEBBVS to accommodate jurisdictional needs. From 2007-2013, only 5-6% of NPEBBVS participants had reported ever having taken part in the NSP survey[5].

One stakeholder described the flexibility of the NPEBBVS to accommodate jurisdictional capacity:

“The capacity for us to select our own two weeks was a God-send. We would just not be able to have done it on the planned days because our HR [human resource] capacity wouldn’t have allowed for it.”

Due to lengthy jurisdictional entry assessments, substance use withdrawal and prison system operations, some jurisdictions have had difficulties collecting blood and urine samples at entry. To accommodate these identified issues jurisdictions can collect a sample within the first 72 hours after entry. It is acknowledged that resources and jurisdictional operational issues provide challenges for the NPEBBVS. The NPEBBVS has proved to be flexible by adapting and modifying its content and timelines to accommodate national, state and territory needs without jeopardising the ability to meet its core objective.

**3.9.4 Data quality**

Data quality refers to completeness and validity of information gathered by the surveillance system[6].

*Data analysis and stakeholder interviews*
Jurisdictionally, the quantity of data varies due to the overall population size and weekly offender intake (Table 4. Prison entrant participation per jurisdiction (% distribution) by survey year). The ACT and TAS have a smaller prison population size and therefore have a smaller NPEBBVS sample. However, the inclusion of these jurisdictions in the overall data provides completeness to national reporting. In stakeholder interviews, smaller jurisdictions saw the value in participating and the ability to use national data when advocating, planning and developing policy for prison health services. Past NPEBBVS have had a 70-80% response rate of entrants over the two week survey period. In stakeholder interviews, it was evident that public health nurses were trying to balance tensions between collecting survey data and duty of care. Public health nurses were dealing with patients with complex health needs. This affected the number of prison entrants they could recruit and the time spent with each individual entrant.

Table 4. Prison entrant participation per jurisdiction (% distribution) by survey year

<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>NSW</td>
<td>308 (51%)</td>
<td>244 (33%)</td>
<td>254 (31%)</td>
<td>69 (9%)</td>
</tr>
<tr>
<td>QLD</td>
<td>140 (23%)</td>
<td>157 (21%)</td>
<td>211 (26%)</td>
<td>282 (36%)</td>
</tr>
<tr>
<td>WA</td>
<td>117 (19%)</td>
<td>98 (13%)</td>
<td>122 (15%)</td>
<td>97 (13%)</td>
</tr>
<tr>
<td>Tas</td>
<td>43 (7%)</td>
<td>46 (6%)</td>
<td>32 (4%)</td>
<td>35 (4%)</td>
</tr>
<tr>
<td>NT</td>
<td>-</td>
<td>-</td>
<td>75 (9%)</td>
<td>60 (8%)</td>
</tr>
<tr>
<td>SA</td>
<td>-</td>
<td>27 (4%)</td>
<td>56 (7%)</td>
<td>50 (6%)</td>
</tr>
<tr>
<td>ACT</td>
<td>-</td>
<td>4 (1%)</td>
<td>13 (2%)</td>
<td>27 (3%)</td>
</tr>
<tr>
<td>VIC</td>
<td>-</td>
<td>161 (22%)</td>
<td>48 (6%)</td>
<td>173 (22%)</td>
</tr>
<tr>
<td>Total</td>
<td>608</td>
<td>737</td>
<td>811</td>
<td>793</td>
</tr>
</tbody>
</table>

-= Did not participate

In states and territories where there are many prisons, movement of prisoners is common. Movements do not always coincide with health staff work hours, meaning some entrants will be lost to follow up in the NPEBBVS or they will have questionnaires collected but not blood and urine samples. One stakeholder explains:

“... a lot of patients get received into the system, say in one afternoon, and then next morning before the nurses start work they are already on a truck to another centre or in a truck back to court. So it is difficult to get actual representative data because they are on the move so much.”

Prisoner movements, time constraints and resource issues such as under staffing or absence of a dedicated public health nurse at reception centres in combination cause potential selection biases and was leading to loss to follow up. This translates to less testing of participants who have completed questionnaires (20-30% of participants each survey year have no samples
collected), and missed opportunities to strengthen the NPEBBVS data set. Systemic issues of increasing imprisonment rate, high prisoner movements and under resourcing at reception centres were common across jurisdictions. The NPEBBVS operates in a regimented and rigid environment, issues like the above stated are ongoing particularly for larger states and territories with a high number of prisoner movements daily.

Data analysis and stakeholder interviews

Data completion and quality were examined through analysis of NPEBBVS data in regards to the system objectives listed below.

**NPEBBVS objective 1**: Monitor BBV (HBV, HCV, HIV), and STI (syphilis, chlamydia and gonorrhoea) prevalence among prison entrants.

**NPEBBVS objective 4**: Examine trends in BBVs, STIs, and risk behaviours among prison entrants.

Table 5 depicts BBV status and the number of survey participants not tested, ranging from 19% to 49% for different tests over the eleven year period of the surveys. This is a reflection of the prison system and the operational boundaries of the system, and not necessarily the ability for the surveillance mechanism to capture these data. Over the two weeks of collection, each jurisdiction is conducting enhanced screening of prison entrants; this is a stretch on the prison health system’s usual operation. In 2013, sample testing data were poor due to resourcing issues, and participants not tested ranged from 29% to 49% across different BBVs (Table 5. Number and percentage of NPEBBVS participants tested for BBVs).

Key themes identified as putting pressure on resources within the prison system and therefore impacting the NPEBBVS function include:

- Increasing prison population.
- Poor health and complex needs of those entering prison needing immediate attention
- Lack of public health nurses within the prison system.
- Funding constraints.
- Competing issues and political environment within and outside of prisons.

STI testing was introduced in 2010. Testing rates were considerably different between 2010 and 2013, with higher rates of participants ‘not tested’ in 2013 for all STIs (Table 6. Frequency of NPEBBV STI testing). Stakeholder interviews revealed some reluctance around sexual health questions by survey administrators and cultural issues when asking sexual health questions in
some jurisdictions. Risk factor questions are particularly affected by the survey administrators or the participants’ acceptability and comfort to ask and answer.

| Table 5. Number and percentage of NPEBBVS participants tested for BBVs |
|-----------------------------|-----------|-----------|-----------|-----------|
|                            | 2004 n=608 (%) | 2007 n=737 (%) | 2010 n=811 (%) | 2013 n=793 (%) |
| **Hepatitis C antibody**   |            |            |            |            |
| Negative                   | 299 (49)   | 380 (52)   | 510 (63)   | 393 (50)   |
| Positive                   | 155 (26)   | 207 (28)   | 141 (17)   | 168 (21)   |
| Equivocal                  | 3 (<1)     | 4 (<1)     | 1 (<1)     | 2 (<1)     |
| Not tested                 | 151 (25)   | 146 (20)   | 159 (20)   | 226 (29)   |
| **Hepatitis B core antibody** |            |            |            |            |
| Negative                   | 360 (59)   | 445 (60)   | 426 (53)   | 374 (48)   |
| Positive                   | 87 (14)    | 120 (16)   | 101 (13)   | 82 (10)    |
| Equivocal                  | 3(<1)      | 2 (<1)     | 0          | 1 (<1)     |
| Not tested                 | 158 (26)   | 170 (23)   | 284 (35)   | 329 (42)   |
| **Hepatitis B surface antigen** |           |            |            |            |
| Negative                   | 440 (72)   | 571 (78)   | 596 (74)   | 389 (49)   |
| Positive                   | 13 (2)     | 14 (2)     | 13 (2)     | 13 (2)     |
| Equivocal                  | 0          | 0          | 0          | 1 (<1)     |
| Not tested                 | 155 (26)   | 152 (21)   | 202 (25)   | 384 (49)   |
| **HIV**                    |            |            |            |            |
| Negative                   | 447 (74)   | 580 (79)   | 661 (82)   | 501 (64)   |
| Positive                   | 3 (1)      | 4 (1)      | 0          | 0          |
| Equivocal                  | 0          | 2 (<1)     | 0          | 0          |
| Not tested                 | 158 (26)   | 151 (21)   | 150 (19)   | 286 (36)   |

There were good response rates for number of partners in the last three months, 14-18% of participants did not respond to condom use questions however it is not known if this is due to not being asked or the invasiveness nature of the question (Table 7. NPEBBVS sexual behaviour and risk). Condom use in the last three months with both female and male partners was introduced to the NPEBBVS in 2010. This question appeared to be causing confusion at a data collection and/or data cleaning point. Review of this question to better understand findings for both male and female participants would be beneficial, and may require specific training at point of collection or understanding at a data cleaning phase for conformity (Table 7. NPEBBVS sexual behaviour and risk).
### Table 7. NPEBBVS sexual behaviour and risk

<table>
<thead>
<tr>
<th>Survey year (n=number of surveys completed)</th>
<th>2004 (n=608 (%))</th>
<th>2007 (n=737 (%))</th>
<th>2010 (n=811 (%))</th>
<th>2013 (n=793 (%))</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number and gender of sexual partners in the last 3 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No sex in last 3 months</td>
<td>121 (15)</td>
<td>108 (14%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-5 partners</td>
<td>628 (77)</td>
<td>605 (79)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6-10 partners</td>
<td>28 (5)</td>
<td>33 (4)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10+ partners</td>
<td>19 (2)</td>
<td>11 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>15 (2)</td>
<td>36 (5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>1 or more female sexual partners in last 3 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male entrants</td>
<td>104 (84)</td>
<td>536 (86)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female entrants</td>
<td>8 (57)</td>
<td>14 (17)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>1 or more male sexual partners in last 3 months</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male entrants</td>
<td>15 (54)</td>
<td>5 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female entrants</td>
<td>60 (83)</td>
<td>77 (75)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Condom use at last sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>155 (26)</td>
<td>169 (23)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>443 (73)</td>
<td>563 (76)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>10 (2)</td>
<td>5 (&lt;1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Condom use with regular female sex partner</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>325 (40)</td>
<td>338 (43)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Always</td>
<td>73 (9)</td>
<td>43 (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sometimes</td>
<td>73 (9)</td>
<td>82 (11)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not applicable</td>
<td>201 (25)</td>
<td>178 (23)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>139 (17)</td>
<td>140 (18)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Condom use with casual female sex partner</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>96 (12)</td>
<td>110 (14)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Always</td>
<td>66 (9)</td>
<td>44 (6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sometimes</td>
<td>53 (7)</td>
<td>66 (9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not applicable</td>
<td>488 (60)</td>
<td>447 (57)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>107 (14)</td>
<td>114 (14)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Condom use with regular male sex partner</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>48 (6)</td>
<td>15 (2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Always</td>
<td>9 (1)</td>
<td>15 (2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sometimes</td>
<td>9 (1)</td>
<td>37 (5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not applicable</td>
<td>29 (4)</td>
<td>506 (65)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>716 (88)</td>
<td>182 (23)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Condom use with casual male sex partner</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>12 (2)</td>
<td>7 (&lt;1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Always</td>
<td>5 (&lt;1)</td>
<td>9 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sometimes</td>
<td>4 (&lt;1)</td>
<td>7 (1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not applicable</td>
<td>72 (9)</td>
<td>542 (69)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>718 (89)</td>
<td>216 (28)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 7 continued. NPEBBVS sexual behaviour and risk

<table>
<thead>
<tr>
<th></th>
<th>2004 n=608 (%)</th>
<th>2007 n=737 (%)</th>
<th>2010 n=811 (%)</th>
<th>2013 n=793 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ever paid for sex in the last month</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>8 (1)</td>
<td>14 (2)</td>
<td>20 (3)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>586 (96)</td>
<td>713 (97)</td>
<td>735 (93)</td>
<td></td>
</tr>
<tr>
<td>missing</td>
<td>14 (2)</td>
<td>10 (1%)</td>
<td>38 (5)</td>
<td></td>
</tr>
<tr>
<td>If yes, did you use a condom</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4 (50)</td>
<td>6 (43)</td>
<td>7 (35)</td>
<td></td>
</tr>
<tr>
<td>no</td>
<td>3 (38)</td>
<td>5 (36)</td>
<td>5 (25)</td>
<td></td>
</tr>
<tr>
<td>missing</td>
<td>1 (13)</td>
<td>3 (21)</td>
<td>8 (40)</td>
<td></td>
</tr>
</tbody>
</table>

Table 6. Frequency of NPEBBV STI testing

<table>
<thead>
<tr>
<th></th>
<th>Survey year</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2010 n=811 (%)</td>
<td>2013 n=793 (%)</td>
</tr>
<tr>
<td>Chlamydia</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>461 (75)</td>
<td>470 (59)</td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>26 (4)</td>
<td>23 (3)</td>
<td></td>
</tr>
<tr>
<td>Equivocal</td>
<td>0</td>
<td>2 (&lt;1)</td>
<td></td>
</tr>
<tr>
<td>Not tested</td>
<td>132 (21)</td>
<td>228 (38)</td>
<td></td>
</tr>
<tr>
<td>Gonorrhoea</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>473 (76)</td>
<td>490 (62)</td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>3 (1)</td>
<td>1 (&lt;1)</td>
<td></td>
</tr>
<tr>
<td>Equivocal</td>
<td>0</td>
<td>2 (&lt;1)</td>
<td></td>
</tr>
<tr>
<td>Not tested</td>
<td>143 (23)</td>
<td>230 (38)</td>
<td></td>
</tr>
<tr>
<td>Syphilis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>471 (76)</td>
<td>505 (64)</td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>23 (4)</td>
<td>7 (1)</td>
<td></td>
</tr>
<tr>
<td>Equivocal</td>
<td>1 (&lt;1)</td>
<td>1 (&lt;1)</td>
<td></td>
</tr>
<tr>
<td>Not tested</td>
<td>124 (20)</td>
<td>280 (35)</td>
<td></td>
</tr>
</tbody>
</table>

**NPEBBVS Objective 2:** Collect ongoing information on risk behaviours such as drug use, high risk injecting practices, sexual risk behaviours, tattooing, and tobacco smoking among prison entrants.

**NPEBBVS Objective 6:** Provide a snapshot of BBVs and risk behaviours in a national sample of non-injectors who are at risk of exposure to BBVs.

Prison entrants who had history of injecting drug use (IDU) in the last month was consistent over time between 25-38% and data completeness for this variable was good. For this variable only 19 out of 2634 instances of incompleteness occurred over the four survey years, however we must consider the fact that illicit drug use particularly on entry to prison may not be
accurately reported (Table 8). Analysis of risk behaviours such as frequency of injecting, sharing of needles and syringes, and injecting equipment are only calculated among those who have injected in the last month. Completeness of variables corresponds with the number of people who injected in the last month.

Table 8. NPEBBVS frequency of risk factors over survey year

<table>
<thead>
<tr>
<th></th>
<th>2004 n=608 (%)</th>
<th>2007 n=737 (%)</th>
<th>2010 n=811 (%)</th>
<th>2013 n=793 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequency of injecting in the last month</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never injected</td>
<td>247 (41)</td>
<td>333 (46)</td>
<td>458 (57)</td>
<td>398 (55)</td>
</tr>
<tr>
<td>Injected in last month</td>
<td>225 (38)</td>
<td>247 (34)</td>
<td>199 (25)</td>
<td>215 (30)</td>
</tr>
<tr>
<td>Did not inject in the last month</td>
<td>125 (21)</td>
<td>151 (21)</td>
<td>150 (19)</td>
<td>102 (14)</td>
</tr>
<tr>
<td>Missing</td>
<td>11 (2)</td>
<td>6 (&lt;1)</td>
<td>4 (&lt;1)</td>
<td>3 (&lt;1)</td>
</tr>
<tr>
<td><strong>Frequency of sharing needle and syringe in last month</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not share</td>
<td>157 (70)</td>
<td>162 (67)</td>
<td>137 (73)</td>
<td>174 (81)</td>
</tr>
<tr>
<td>Shared</td>
<td>68 (30)</td>
<td>80 (33)</td>
<td>52 (28)</td>
<td>41 (19)</td>
</tr>
<tr>
<td><strong>Ever sharing injecting equipment in the last month</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did not share</td>
<td>164 (73)</td>
<td>136 (59)</td>
<td>127 (67)</td>
<td>52 (25)</td>
</tr>
<tr>
<td>Shared</td>
<td>61 (27)</td>
<td>96 (41)</td>
<td>62 (33)</td>
<td>158 (75)</td>
</tr>
<tr>
<td><strong>Any tattoos</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>368 (61)</td>
<td>456 (62)</td>
<td>484 (60)</td>
<td>532 (67)</td>
</tr>
<tr>
<td>No</td>
<td>232 (38)</td>
<td>280 (38)</td>
<td>310 (38)</td>
<td>232 (29)</td>
</tr>
<tr>
<td>Missing</td>
<td>8 (1)</td>
<td>1 (&lt;1)</td>
<td>17 (2)</td>
<td>29 (4)</td>
</tr>
<tr>
<td><strong>Any tattoo in the last month</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>69 (19)</td>
<td>135 (30)</td>
<td>148 (31)</td>
<td>168 (32)</td>
</tr>
<tr>
<td>No</td>
<td>295 (80)</td>
<td>319 (70)</td>
<td>329 (68)</td>
<td>360 (68)</td>
</tr>
<tr>
<td>Missing</td>
<td>4 (&lt;1)</td>
<td>2 (&lt;1)</td>
<td>7 (1)</td>
<td>4 (&lt;1)</td>
</tr>
<tr>
<td><strong>Ever smoked cigarettes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>679 (92)</td>
<td>759 (94)</td>
<td>699 (88)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>58 (8)</td>
<td>51 (6)</td>
<td>67 (9)</td>
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</tr>
<tr>
<td>Missing</td>
<td>0</td>
<td>1 (&lt;1)</td>
<td>27 (4)</td>
<td></td>
</tr>
<tr>
<td><strong>Current smoker</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>626 (92)</td>
<td>690 (85)</td>
<td>629 (79)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>52 (8)</td>
<td>119 (15)</td>
<td>63 (8)</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>1 (&lt;1)</td>
<td>2 (&lt;1)</td>
<td>7 (&lt;1)</td>
<td></td>
</tr>
</tbody>
</table>

NPEBBVS objective 3: Monitor BBVs, STIs and associated risk behaviours in Indigenous and non-Indigenous prison entrants.

Completeness of Indigenous status is very good. From 2004 to 2013 only 25 out of 2639 records have not included Indigenous status (Table 9). Survey reports include Indigenous and non-Indigenous breakdown, and there is currently a BBV Indigenous, non-Indigenous comparison paper being prepared for publication (Chapter 2, Appendix 1).
The Indigenous entrant numbers allow for analysis among complete variables like injecting drug use, but when looking at risk factors among people who inject by Indigenous status, these numbers are too small to compare by year. Women prison entrants account for a smaller percentage of survey participants, only up to 14% of the NPEBBVS survey sample each year, this creates difficulties in understanding BBVs, STIs and risk factors among female prison entrants (Table 10. NPEBBVS Gender frequency by survey year).

Table 10. NPEBBVS Gender frequency by survey year

<table>
<thead>
<tr>
<th>Gender</th>
<th>2004 n=608 (%)</th>
<th>2007 n=737 (%)</th>
<th>2010 n=811 (%)</th>
<th>2013 n=793 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>538 (89)</td>
<td>666 (90)</td>
<td>734 (90)</td>
<td>684 (86)</td>
</tr>
<tr>
<td>Female</td>
<td>69 (11)</td>
<td>71 (10)</td>
<td>77 (10)</td>
<td>109 (14)</td>
</tr>
<tr>
<td>Transgender</td>
<td>1 (&lt;1)</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Data completeness for variables relating directly to NPEBBVS objectives were relatively complete. Issues in data completeness were related to sample collection for diagnostic testing. A closer look at the process of sample collection (blood and urine) for future survey iterations may improve testing rates. Again, it comes back to resourcing, including having a dedicated public health nurse without other duties to focus on recruiting and collecting survey information. Sexual health questions are relatively complete, but not tests, and lower prevalence of STI infections makes drawing conclusions based on sexual risk behaviours difficult.

### 3.9.5 Acceptability

Acceptability includes both participant and the organisational willingness to be involved or contribute to the surveillance system\(^{(1)}\). **Stakeholder interviews**

Stakeholder interviews revealed that acceptability by jurisdictions was highly dependent on resources. Most jurisdictions discussed reduced capacity to take on other work and the impact of increasing imprisonment rates on health service staff, capacity and budget.
Allocating staff to dedicate time to NPEBBVS collection over the survey period put a burden on usual prison health service operations. Most jurisdictions noted the survey time frame of two weeks as acceptable, as longer time frames would create issues relating to rostering and health service operation.

The NPEBBVS does not have ongoing funding. The national survey coordinator based at the Kirby Institute negotiates with state and territory health departments and corrective/justice health services to provide funding and resources during the survey period. Jurisdictions are asked to provide a core amount of money for the central coordinator based on the size of the prisoner population. In the current funding model jurisdictions pay for extra pathology costs and other in-kind expenses such as state coordinator, additional health services staff and public health nurses. This is a long negotiation process undertaken well in advance of each survey collection period. The willingness of state and territory health departments and prison health services to provide both funding and resources demonstrate jurisdictional support for the NPEBBVS and acceptability for the aims, objectives and outputs of the NPEBBVS.

Reception is a relatively acceptable place to conduct the NPEBBVS although this varied across jurisdictions. Gaining access to patients at reception seemed the best vantage point in terms of information gathering as this operation is consistent across jurisdictions. Every prison entrant is processed through a reception centre regardless of jurisdiction, but exit surveys have found inconsistencies in the ability to monitor all prisoners exiting the system\(^3\). During stakeholder interviews, nurses administering surveys said the survey was easy to navigate and most questions were acceptable to participants. Training was provided to public health nurses by the central coordinator based at the Kirby Institute or coordinator based at jurisdictions with NPEBBVS experience. People administering the survey may benefit from receiving educational material around asking sensitive questions. More buy-in from nurses at the stage of writing publications and analysing the data may also assist in gathering more complete data sets and promoting the usefulness of the survey outcomes to individual and organisational practice.

Response rates of people entering participating prison reception centres have been consistent over survey years at 83% in 2004, 75% in 2007 and 76% in 2010. (Further information not yet available from reception centres is required to calculate 2013/2014 response rate). Stakeholders who have collected data for the NPEBBVS said prison entrants were relatively keen to participate; one stakeholder said the staff emphasize to entrants that the survey is national and entrants like the idea of being a part of a national survey. One stakeholder talked about environmental pressures and volatilities on both participants and survey administrators:
they [prison entrants] have been bombarded with questions plus geographically dislocated from their life, the questions are invasive and environmentally you have to have somewhere they feel safe to answer the questions and that can’t always be afforded during a reception and particularly if we don’t know a client that is our highest risk, for any prison it’s the highest risk period of time, volatilities can present themselves”

Due to logistical reasons, people entering prison and participating in the NPEBBVS were not interviewed for the purposes of this evaluation. Being able to understand acceptability from the prison entrant perspective would provide greater understanding of acceptability.

3.9.6 Representativeness
Representativeness encompasses accuracy to describe the population (person and place) over time.\(^{(1)}\).

Stakeholder interviews, data analysis and document review

In 2013, the Australian prison population reached over 30 000 people for the first time.\(^{(2)}\) The NPEBBVS sample represents 3% of the overall prison population. Never-the-less, both prison and community based prevalence studies from different jurisdictions are consistent with NPEBBVS findings,\(^{(12,16,38)}\) externally validating NPEBBVS HCV, HBV and injecting prevalence results. The NPEBBVS has been collected four times over the last 12 years. With continuation, it has the potential to be much like the ongoing NSP survey which has provided a valuable longitudinal dataset of BBV prevalence, injecting drug use and risk behaviours in the general community.\(^{(38)}\)

Two jurisdictions raised the issues of population, geographic and service provision variation within their state or territory. Both jurisdictions noted a two week period doesn’t allow for an adequate representation of the overall prison population. This included remote and non-metropolitan comparisons which would be beneficial, but under the current methodology would be difficult to capture. Two stakeholders mentioned the value in targeted sampling for specific populations (women and remote entrants); however, increasing time of collection would have resource implications. One stakeholder discussed implications of the underrepresentation of women in their jurisdictional sample:

“Female prison population is much smaller than the male population. The numbers for females ... was 9 or 10 and none of them came up with hep C positivity and that sort of gives a false representation when we know the numbers in female prisoners [with HCV] is generally higher”
Gathering a representative sample is a juggling act of epidemiological rigour, resources, prison setting constraints, prison population issues and meeting the objectives of the surveillance system.

### 3.9.7 Timeliness

Timeliness incorporates timeframes of all steps within the surveillance system\(^1\).

*Interviews*

The NPEBBVS is collected over a two week period every three years but from start to finish, the survey takes around 18 months to plan, implement and conclude, leaving a 12 month downtime period before repeating the process. The central coordinator begins negotiation with jurisdictions regarding funding and ethics approval 12 months prior to survey collection. The coordinator provides one day of NPEBBVS training for prison medical staff in each jurisdiction before surveys are collected. Laboratory results are received by prison medical services as per usual practice. Once laboratory results are received by prison medical services, a public health nurse compiles results with corresponding surveys. All documents are then sent to the central coordinator at the Kirby Institute. Prison health services provide funding for survey pathology costs therefore timeframes related to laboratory aspects of the survey were out of the scope of this evaluation. Altogether, public health nurses could be engaged in study activities for up to a month depending on their availability to compile results with surveys. The time from data entry and cleaning to producing a printed report can take up to six months. The central coordinator of the NPEBBVS is not a funded role and therefore the NPEBBVS is not a primary focus of work, extending the timeline of some survey steps. Additionally lack of funding for a dedicated data manager delayed the time between survey collection and distribution of findings.

NPEBBVS collection every three years was acceptable to all jurisdictions and related mainly to resource availability. The three year time period was adequate for allowing jurisdictions time to use the findings to generate outcomes for their service provision. One stakeholder reflected on the time frame:

> “I definitely wouldn’t recommend it sooner, particularly because of the stress that it does put on the public health nurses. I think the main focus in terms of time should be how long it takes for each organisation to absorb their information and timing to changing service planning appropriately.”

At admission to prison, the interview process can take up to 25 minutes. This is additional time on top of other assessments required by prison protocols (protocols and entrant assessment
vary by jurisdiction). Multiple jurisdictions collect samples within the first 72 hours of entrants’ incarceration. One jurisdiction opted to do next day survey collection due to time constraints, entry protocols and its impact on entrants:

“We have a forty-five minute health induction. I can’t tack a twenty-five minute BBV survey on the end of that, particularly when for our cohort, most of them have spent the night in custody, had a police questionnaire, been to court, come to prison, had the prison questionnaire then come to health and had the health questionnaire then fronting another questionnaire. It’s just not going to happen. It becomes problematic in a lot of ways, but that is our current practice. But they were all caught the following day if they were still in custody.”

Timeliness and a number of the attributes ended up being discussions related to resourcing of prisons to cope with the increasing incarceration rate and the specific issues unique to the prison setting such as, prisoner’s complex needs, movement of prisoners in short timeframes and nursing roster hours.

3.9.8 Stability
Stability of a surveillance system assesses the reliability of the system to operate without failure\(^1\).

Stakeholder interviews

It was evident from stakeholder interviews that the NPEBBVS was driven by champions in jurisdictions. Some identified the potential for the survey to lose momentum if champions were to leave prison health services. Stakeholders recognised the importance of gaining prison medical director’s support in conducting the survey. Currently the survey is housed at the Kirby Institute, however it has moved to different organisations with the originator of the survey and national coordinator, Tony Butler. Gaining ongoing funding for the NPEBBVS would allow for the survey to be based at one organisation and not be so reliant on an individual driver. Ongoing funding would allow for a dedicated central coordinator, leading to improved communication with stakeholders. Dedicated resources could assist with translation of the NPEBBVS into actionable state and territory strategies and cultivate ongoing collaboration across jurisdictions. One participant reflected on possibilities if properly funded:

“The key to more sustainability is having more buy-in from jurisdictions, but it is really hard without a central budget to have ongoing teleconferences and having someone in the background writing papers and engaging people.”
Stability is very much reliant on funding and resources. The current model of funding is far from ideal. The outcomes and uses of the NPEBBVS warrant improved stability.

### 3.10 Limitations of the evaluation

There are a number of limitations to this evaluation. Inability to interview people (prison entrants) who have participated in the survey is an obvious limitation to understanding acceptability from all perspectives. It would have been beneficial to do a cost benefit analysis, but due to time constraints this was not possible, but this may be of benefit in the future to advocate for an ongoing funding source. A number of jurisdictions did not participate in the stakeholder interviews as part of the evaluation. As jurisdictions are diverse, full participation would provide more comprehensive evaluation findings. Operation and governance in each state and territory are different, and each has its own unique barriers and strengths. Jurisdictions’ practices influenced the process of collecting the NPEBBVS in each jurisdiction, so evaluating processes of the survey were sometimes difficult to compare between jurisdictions.

### 3.11 Conclusions

In the absence of a national prison BBV and STI surveillance scheme, the NPEBBVS provides the only national prison based BBV and STI snapshot and trend analysis over time.

The data collected as a part of the NPEBBVS are used to describe BBVs, STIs and risk behaviours to meet the objectives of the NPEBBVS, which is demonstrated in a number of outputs.\(^\text{5,23-26}\)

The NPEBBVS achieves its purpose and objectives; from a data gathering perspective it has proven to be effective through its many applications in policies and guidelines. Despite being a smaller snapshot of the wider offender population, NPEBBVS data are consistent with other jurisdictional cross sectional BBV prevalence studies. Overall, the main issue affecting all attributes, jurisdictions and the operation of the NPEBBVS in general, is limited resources. Commonwealth funding (ongoing) would enable smoother operation and increase data quality by improving biological sample collection, by supporting jurisdictions to employ dedicated public health nurses during survey collection and a central coordinator position.

At a national level it is evident that it has been challenging to get all jurisdictions involved, and long negotiation periods are required for participation in the NPEBBVS. Champions at each of the prisons need to be increasingly supported to advocate for the NPEBBVS. Ongoing commitment from jurisdictions could be formalised to ensure the continuation of the NPEBBVS, creating more stability and reducing the risk of the NPEBBVS losing momentum when champions leave.
CHAPTER 3 | EVALUATION OF A SURVEILLANCE SYSTEM

3.12 Recommendations

- The main recommendation from this evaluation is the absolute need for the ongoing collection of the NPEBBVS. There are areas that could improve, but overall the survey meets its objectives.

- A central coordinator is needed to provide consistent communication between all stakeholders on an ongoing basis and facilitate research translation and collaboration.

3.12.1 Report and data

- Simplification of reporting jurisdictional data would be beneficial, particularly a two page summary report for jurisdictions to share with their stakeholders and management.

- Targeting women’s prison reception centers for a longer duration (four weeks) would allow for a larger female sample, and ability to understand the female offender population would be beneficial in terms of planning and resourcing these centers.

- Achieving more buy-in from prison nurses or other prison staff to be a part of the reporting phase of NPEBBVS, for example through publication, could increase prison sector research capacity.

3.12.2 Funding

The current funding model is not ideal and ongoing Commonwealth funding would allow for stability through:

- All jurisdictional involvement in every survey year moving forward.
- Dedicated public health nurses to focus on collecting surveys and samples over the two week collection period.
- Cost coverage of pathology (currently paid by jurisdictions).
- A dedicated person to coordinate from start to finish, stay in contact with stakeholders and develop output during the 12 months in between surveys.

3.13 References


Appendix 1. Participant Information and consent form

HREC Approval No: 2014-7-30
THE UNIVERSITY OF NEW SOUTH WALES AND THE KIRBY INSTITUTE

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM
Evaluation of the National Prison Entrant Blood Borne Virus Survey

Investigator: Dina Saulo

Introduction
You are invited to take part in the Evaluation of the National Prison Entrant Blood Borne Virus Survey (NPEBBVS). You have been invited because of your involvement as a stakeholder of the NPEBBVS, your contact details were obtained as a result of your involvement.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the processes involved with taking part. Knowing what is involved will help you decide if you want to take part in the research.

What is the purpose of this research?
The purpose of this research project is to formally evaluate the NPEBBVS, an evaluation is important to ensure the capturing and monitoring of conditions of public health importance is effective, efficient and meeting the NPEBBVS objectives. The evaluation will consist of stakeholder interviews with people involved at all different levels of the NPEBBVS system.

Why have I been invited to participate in this research?
You have been invited to participate in a consultative interview because you are a stakeholder of the NPEBBVS. Your involvement in the NPEBBVS, whether it be at a management or reception center level at participating prison facilities or policy, data and reporting level, your knowledge and insight into the NPEBBVS survey processes or data as a stakeholder is greatly valued.

Description of study procedures and risks
If you decide to participate:

Consent
You will be asked to provide written consent to take part in a one-on-one interview with the investigator. This may be by phone or face to face depending on logistics. Consent to audio record will also be asked of participants, you may refuse to be audio recorded in which case the investigator will scribe notes during the interview process.

Interview process
You will be asked to participate in a semi-structured interview about the NPEBBVS in relation to the following attributes: Simplicity, flexibility, data quality, acceptability, representativeness, timeliness and stability. Interviews will take 30-60 minutes.

The information you provide will be confidential. The interview will be recorded for the purpose of transcribing; after the interview is transcribed the audio recording will be erased. Only the investigator will have access to interview data. The investigator will ensure participants organisational association and individual identity are not identifiable in any research outputs. On obtaining consent from participants a number and involvement in the system will be assigned, for example; “Stakeholder 1,
What are the possible benefits of taking part?

Your involvement could potentially inform improvements in the NPEBBVS system in the future. We cannot and do not guarantee or promise that you will receive any benefits from this study.

What are the alternatives to participation?

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. Your decision not to participate will not affect your future relations with the University of New South Wales or the Kirby Institute.

Confidentiality and disclosure of information

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission, except as required by law. If you give us your permission by signing this document, we plan to publish the results in the form of a short report for NPEBBVS coordinators and stakeholders. Additionally, Dina Saulo will be publishing data on the evaluation of the NPEBBVS as in a surveillance evaluation chapter of her Master of Applied Epidemiology thesis as a part of an Australian National University degree. Information published will be in relation to the above stated attributes and recommendations for future survey rollout. In any publication, information will be provided in such a way that you cannot be identified. Information provided will be stored securely for 7 years after the interviews in compliance with ethics guidelines.

Recompense to participants

There will be no remuneration or additional cost attached to participating in this study and you may not directly benefit from participation in the study.

Complaints

Complaints may be directed to the relevant Ethics Secretariat, details of which are provided below. Any complaint you make will be investigated promptly and you will be informed of the outcome.

University of New South Wales HREC
02 9385 4234 or humanethics@unsw.edu.au
Application ID: 2014-7-30

Australian National University HREC
02 6125 3427 or human.ethics.officer@anu.edu.au
Application ID: 2014/555

Feedback to participants

If you would like to receive a summary report of the evaluation please indicate to the investigator during the interview process.

Your consent

If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time; you can do this by filling out the revocation consent form below and returning to Dina Saulo. You do not need to provide a reason and will not prejudice future relations with the University of NSW or the Kirby Institute. Once withdrawn, information from interviews conducted with you will not be included in any publication.

If you have any questions, please direct them to Dina Saulo:
You will be given a copy of this form to keep.
PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM (continued)

Evaluation of the National Prison Entrant Blood Borne Virus Survey

Investigator: Dina Saulo

Declaration by Participant

- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future care.
- I understand that I will be given a signed copy of this document to keep.

........................................................................................................
Signature of Research Participant
........................................................................................................
Signature of Witness

........................................................................................................
(Please PRINT name)
........................................................................................................
(Please PRINT name)

........................................................................................................
Date
........................................................................................................
Nature of Witness
REVOCATION OF CONSENT

Evaluation of the National Prison Entrant Blood Borne Virus Survey

Investigator: Dina Saulo

I hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with The University of New South Wales, and the Kirby Institute.

Signature................................................................................................................................. Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to:

Dina Saulo
Master of Applied Epidemiology student, Kirby Institute
Justice Health Research Program | The Kirby Institute

Wallace Wurth Building, Sydney NSW 2052

T: +61 (0)2 9385 9002

E: dsaulo@kirby.unsw.edu.au
Appendix 2. Stakeholder interview guide

Questions will be asked about usefulness, Simplicity, data quality, representativeness, flexibility, acceptability, timeliness and stability. All questions are not relevant to every stakeholder; themes for direction of questioning are provided below along with sample questions that could be asked during interviews, dependant on stakeholder involvement in the NPEBBVS.

<table>
<thead>
<tr>
<th>Attributes and themes</th>
<th>Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Usefulness</strong></td>
<td>How are you involved in the NPEBBVS?</td>
</tr>
<tr>
<td><strong>Outputs</strong></td>
<td>1. How useful is the NPEBBVS for you and your organisation? (Probe: use, application of findings, work or funding as a result of findings, how could you use it?)</td>
</tr>
<tr>
<td><strong>application</strong></td>
<td>2. What outputs from the NPEBBVS are you aware of?</td>
</tr>
<tr>
<td><strong>Simplicity</strong></td>
<td>3. The survey has a large focus on injecting, is this appropriate for this population; can you see other applications for the data?</td>
</tr>
<tr>
<td><strong>process</strong></td>
<td>The system</td>
</tr>
<tr>
<td><strong>impact</strong></td>
<td>4. What is the process of maintaining the NPEBBVS system every 3 years? (Probe: time and resources, running and maintaining, process of coordination, training required)</td>
</tr>
<tr>
<td><strong>Data quality</strong></td>
<td>The survey</td>
</tr>
<tr>
<td><strong>completeness</strong></td>
<td>5. Explain the recruitment process</td>
</tr>
<tr>
<td><strong>Validity</strong></td>
<td>6. Does the survey have an impact on the usual operation of the reception centre? If so, how</td>
</tr>
<tr>
<td><strong>Relevance</strong></td>
<td>7. Is the structure of the survey easy to follow?</td>
</tr>
<tr>
<td></td>
<td>8. Are paper based surveys the best way of collecting in this setting</td>
</tr>
<tr>
<td></td>
<td>The report</td>
</tr>
<tr>
<td></td>
<td>9. How is the NPEBBVS reported?</td>
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<tr>
<td></td>
<td>10. Is the report easy to understand and use? (probe: positive and negative aspects of the report)</td>
</tr>
<tr>
<td></td>
<td>11. How would you improve reporting of the NPEBBVS?</td>
</tr>
<tr>
<td></td>
<td>12. Do you consider the NPEBBVS a valid and necessary undertaking? (probe: why, why not, in terms of surveillance use)</td>
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<tr>
<td></td>
<td>13. Validity of data (Probe: sample size, conclusions, trend over time survey collected over a two week period every three years)</td>
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<tr>
<td></td>
<td>14. What are the ramifications of jurisdictions not participating in all</td>
</tr>
<tr>
<td>Representativeness</td>
<td>survey years? (probe: application of data, surveillance)</td>
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<tr>
<td>--------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>Sample frame</td>
<td>15. Is it worth having a sexual health component? (in relation to data completeness of sexual health questions)</td>
</tr>
<tr>
<td>Sample size trends</td>
<td>16. Is the data from NPEBBVS relevance in the current environment and for organisations that might use the data?</td>
</tr>
<tr>
<td></td>
<td>17. Do you think the NPEBBVS is representative of the wider prison entrant population? Or prison population</td>
</tr>
<tr>
<td></td>
<td>18. Does a sample collected over two weeks reflect the wider prison entrant population? (probe: Can NPEBBVS data be used as a yearly prevalence for prison entrants)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flexibility</th>
<th>19. Is the NPEBBVS survey tool easy to modify (probe: ease of change, limitation and ability to modify in the future)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modification</td>
<td>20. Is the survey easy to collect? (Probe: layout of survey, design, difficulty asking questions, workload, extra steps, dynamic of setting, retrieving lab results)</td>
</tr>
<tr>
<td></td>
<td>21. On recruitment, what reactions do participants have to the NPEBBVS? (collection of specimens, survey questions, extra steps)</td>
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<td></td>
<td>22. Would there be a problem with running the survey longer at your reception centre?</td>
</tr>
<tr>
<td></td>
<td>23. Are the timeframes of the system adequate (probe: just the time frames on the aspects you are involved in, rollout of survey, collection, analysis and reporting)</td>
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<tr>
<td></td>
<td>24. From enrolment to finish how long does it take to recruit, collect survey information and collect bloods and urines?</td>
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<td></td>
<td>25. After the survey how long until you receive the report?</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Acceptability</th>
<th>26. Do you know who funds the NPEBBVS? (probe: how funding is acquired)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health staff</td>
<td>27. Do you think it is sustainable to run a national survey every 3 years in prison reception centres?</td>
</tr>
<tr>
<td>Participant</td>
<td>28. What do you think would be a more sustainable way or running the survey?</td>
</tr>
<tr>
<td></td>
<td>29. What time, resources and organisational support are needed to maintain system?</td>
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<td></td>
<td>30. How do you see the survey working in the future</td>
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</table>

<table>
<thead>
<tr>
<th>Stability</th>
<th>Is there anything else you would like to tell me about the NPEBBVS?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding Sustainability</td>
<td>How would you improve the survey NPEBBVS?</td>
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</tbody>
</table>
4 Outbreak

Incident hepatitis C cases detected through a custodial HCV treatment program
4.1 Abbreviation list

HCVAb  Hepatitis C antibody
4.2 Prologue
In March of 2013, I was informed by a field supervisor of an in-prison hepatitis C virus (HCV) outbreak. I was aware this was a non-traditional outbreak; it was slow moving, where incident cases were identified over a two year period in a test and treatment in-prison program, a number of different HCV strains had been identified and there were potential constraints
including permission to conduct the study, implementation and recruitment restrictions. Nevertheless, this project would cover key competencies required to investigate an acute public health problem. Primary information about cases of HCV was obtained and a group of investigators came together to develop a plan of action.

I was a part of a core team including Associate Professor Stuart Kinner, Melbourne University, the prison Medical Director, Ms Kathryn Snow, Melbourne University and Professor Tony Butler, Justice Health Research Program (JHRP), Program Head, Kirby Institute. Our first meeting took place in early 2013 to discuss possible approaches to investigate the outbreak and roles within the team. It was established that the emphasis of the investigation would be for the purposes of research to determine if identified cases were in-prison HCV incidence, to understand the extent to which HCV transmission was happening in the facility, and to provide recommendations to improve strategies, interventions and possibly lead to reduction in HCV exposure among participants.

My role and participation in the team included:

- Development of a patient information sheet (Appendix 1)
- Adaptation of a quantitative survey and development of a qualitative interview tool (Appendix 2)
- Input into the ethics application on how I would be conducting interviews, obtaining consent and analysing data
- Ethics was submitted to three Human Research Ethics Committees (HRECs). I prepared and submitted one of these ethics applications to a relevant jurisdiction HREC.
- Attending prison security training
- Recruiting participants and obtaining signed consent
- Conducting quantitative and semi-structured qualitative interviews
- Transcribing and coding semi-structured interviews
- Entering quantitative data into an Epi Info database
- Analysing quantitative and qualitative data

4.2.1 Lessons Learned
Investigating an acute public health problem or outbreak can take on many different forms depending on the context. I learnt that an outbreak investigation can have different aims, in this case an emphasis on investigation for the purpose of research to inform or improve control measures within a prison facility. Responses to the identified problem can be very different. The common steps in investigating an acute public health problem (outbreak
CHAPTER 4 | OUTBREAK

investigation ten steps) are transferable and flexible across different scenarios. Combining qualitative interviews with a case series study validated quantitative findings in this investigation. For me this highlighted the important skill of interviewing people as part of an outbreak investigation to truly understand the intricacies of the agent (HCV), host (study participant) and environment (impact and challenges presented by the prison setting).

4.2.2 Public health impact

This mixed methods approach using outbreak investigation principles had not been documented in the custodial setting before. The findings from this study have application to harm minimisation strategies in this prison facility. There is potential to generalise these findings across other prison facilities as risk factors identified among study participants have been documented in prison based studies in other jurisdictions\(^1\). Prisons in other jurisdictions should be encouraged to adopt this facility’s approach by making available a range of harm minimisation strategies to reduce HCV incidence rates. The findings from this study strongly support the growing body of evidence for Needle and Syringe Program (NSP) introduction in this prison facility.

Cases were identified as a result of an HCV treatment program, and it is clear that harm minimisation is a priority for the medical services at this facility. The findings of this study might assist in improving current strategies. Findings could assist in the improved screening for HCV treatment candidates and targeted education materials could be of benefit if targeted at a lower literacy level. Also at risk subgroups, such as younger non-injecting drug users, who might be more likely to use drugs while incarcerated or be influenced by older inmates, could benefit from targeted education.

This study combined both quantitative and qualitative methods to give prisoners’ perspectives of HCV incidence. HCV is a prison issue and therefore prisoners should be given the opportunity to be directly involved in the decision making on issues that affect them. Mixed method approaches can assist in giving a voice and context to accompany quantitative data.

4.2.3 Acknowledgments

Firstly, I would like to acknowledge the men who participated in the study for sharing their experiences. Thanks to the prison medical director, Stuart Kinner and Tony Butler for identifying this study as a potential MAE outbreak project and allowing me to run with it. Special thanks to Emily Fearnley for designing the Epi Info database. Further thanks to Phyll Dance, Emily Fearnley, Tony Butler and John Kaldor for your attention and support during survey collection, analysis and write up.
4.3 Abstract

4.3.1 Background
As a result of increased testing through a prison HCV treatment program there was an increase of in-prison incident cases from March 2009 (when this prison opened) to May 2013. HCV test results and time of imprisonment provided suggestive evidence that 30 cases were possibly acquired in custody. The aim of study was to describe and assess the strength of evidence for in-prison HCV incidence among 22 people still in custody and better characterise HCV transmission in a prison setting to identify effective control measures.
4.3.2 Methods
A mixed methods approach was taken, including both quantitative and qualitative interviews. Interviews were conducted at the prison facility with identified participants. Interviews were to determine risk behaviour and imprisonment timeframes related to blood exposure between time of last HCV negative blood test and HCV positive test during the 50 month period, March 2009 to May 2013. Descriptive analysis of demographic and risk factor data from quantitative surveys were conducted and qualitative interviews were manually coded to extract key themes relating to participant experience of HCV.

4.3.3 Results
Seven out of 22 potential participants consented to take part in the study. Six of the seven participants were classified as HCV in-prison incident cases. It was determined that all in-prison incident cases were not notifiable to public health units under the current national newly acquired HCV case definition. All six identified cases had a common history of injecting drug use and one or more episodes of sharing injecting equipment while in prison. Other exposure to blood while in-prison included; hair clippers, tattoos, fights, sport and penile implant. Qualitative interviews shed light on prisoner perspectives of HCV; drug use while in prison; sharing of equipment and knowledge; and inmate perceptions of HCV results, treatment and health.

4.3.4 Conclusion
This was an unusual cluster of HCV infection in a prison and the study provides evidence of in prison HCV incidence. This finding would imply current harm minimisation and reduction strategies are not adequately meeting the needs of a subsection of high risk prisoners. The findings of this investigation add to a body of evidence pointing to the need to implement NSPs in Australian prisons to complement current strategies.

4.4 Background
4.4.1 Hepatitis C
Estimated globally, 184 million people were living with HCV in 2005 and in Australia an estimated 210,000 people were living with HCV in 2001. HCV can cause liver cirrhosis, liver failure and Hepatocellular Carcinoma (HCC). Of those who acquire HCV (acute HCV is characterised as HCV within 6 months of infection) around 15-45% will spontaneously clear the virus, 55-85% will develop chronic HCV, 16% of whom will develop cirrhosis of the liver within 20 years of infection and an estimated 1-3% will progress to HCC after 30 years. There are a number of HCV genotypes and subtypes which vary geographically. In Australia HCV genotype 1 (54%) and 3 (39%) are most common, the remaining 7% genotype prevalence can be attributed to genotype 2, 4, 5 and 6.
HCV is a blood borne virus (BBV) transmitted through blood to blood contact with a HCV positive person. Risk factors have been identified in a number of studies, the most common being injecting drug use and sharing of injecting equipment; transmission routes also include unsterile tattooing or piercing equipment, sharing of toothbrushes, razors, and sexual contact (1, 9). People are often asymptomatic and may not know they have HCV due to slow disease progression.

HCV antibodies are present in blood 8-12 weeks after acute HCV infection, elevated alanine transaminase (ALT) may also be indicative of acute HCV with jaundice and bilirubin in urine detectable in some patients(10). HCV antibody positivity is indicative of past or present infection. The Polymerase Chain Reaction (PCR) test detects presence of HCV ribonucleic acid (RNA), determining current or no infection. PCR RNA can be detected within two weeks of acute infection. Additional tests are required for genotype and viral load(11).

Prisoners are at risk of blood borne viruses while incarcerated(12, 13) with evidence to support in prison transmission of HCV(14-16). In Australia, research on HCV in prisons is predominately through cross sectional surveys determining demographic characteristics, risk factors and behaviours associated with HCV prevalence among offenders. The Hepatitis C Incidence and Transmission Study (HITS), a large prospective cohort study has been conducted since 2005. HITS actively sought and reported on HCV incidence rates of inmates in 13 New South Wales prisons(17-19). Australia is at the forefront of understanding HCV incidence rates, associated demographic characteristics, risk factors and related treatment issues. Additionally, Australian researchers conducted early work on understanding HCV DNA and genotype effects within the prison setting.

HCV treatment is available for individuals over 18 years of age who are HCV PCR positive. Treatment can clear (cure) the HCV virus but does not provide immunity against re-infection(20). Treatment type and duration is based on HCV genotype, disease stage and response to treatment. Duration of treatment for genotypes 1 or 4 is 48 weeks(10). The treatment course includes weekly pegylated interferon injections, twice daily ribaviron and daily Simeprevir tablets for 12 weeks. Then an additional 12-36 week course of dual therapy weekly pegylated interferon injection plus twice daily ribaviron tablets. HCV treatment for genotypes 2 or 3 has a shorter duration of about 24 weeks with interferon and ribaviron. Therapeutic drugs are not limited to the above mentioned; the world of HCV treatment is advancing with a new wave of superior drugs becoming available(21).
Greater than 20% of patients who commence HCV treatment will experience side effects such as, but not limited to: fatigue, headaches, fever, muscle pain and/or cramping, insomnia, hair loss, joint pain, irritability, anorexia, weight loss, depression and injection site inflammation/reaction\textsuperscript{22}. Side effects of earlier and continuing HCV treatment therapeutics are a particular obstacle for treatment uptake and compliance. The prison setting provides a unique opportunity for treatment due to health care availability, however a number of barriers, both actual and perceived exist\textsuperscript{23}. The next wave of improved treatment and combination therapies promise fewer side effects and reduced course duration\textsuperscript{24}.

### 4.4.2 Detecting incident cases

Incidence is an important measure to describe the number of new cases of a disease. Incidence data can be translated into risk of disease, provide projections of disease outcomes, assist in cost effectiveness or mathematical modelling and impact on health policy focus and funding. HCV is a notifiable disease in Australia, if a patient’s blood tests HCV PCR positive this is reportable to jurisdictional public health units by the doctor or laboratory. Reporting a HCV case as “newly acquired” (i.e an incident case) requires a HCV PCR positive blood test result and clinical evidence as defined by the current Australian national notifiable disease case definition, stated by the Department of Health, Communicable Diseases Network Australia (CDNA) (Table 1)\textsuperscript{25}. The definition does not identify new acquisition of a different HCV genotype as a newly acquired infection or an antibody positive, PCR negative individual who becomes PCR positive. The definition relies heavily on an antibody negative status before a PCR positive test result.

<table>
<thead>
<tr>
<th>Table 1. Australian national notifiable diseases case definitions - hepatitis C (newly acquired)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reporting</strong> - Only confirmed cases should be notified.</td>
</tr>
<tr>
<td><strong>Confirmed case</strong></td>
</tr>
<tr>
<td>A confirmed case requires either:</td>
</tr>
<tr>
<td>1. Laboratory definitive evidence</td>
</tr>
<tr>
<td>OR</td>
</tr>
<tr>
<td>2. Laboratory suggestive evidence AND clinical evidence.</td>
</tr>
</tbody>
</table>
Laboratory definitive evidence

1. Detection of anti-hepatitis C antibody from a person who has had a negative anti-hepatitis C antibody test recorded within the past 24 months

OR

2. Detection of hepatitis C virus by nucleic acid testing from a person who has had a negative anti-hepatitis C antibody test result within the past 24 months

OR

3. Detection of anti-hepatitis C antibody from a child aged 18 to 24 months

OR

4. Detection of hepatitis C virus by nucleic acid testing in a child aged 1 to 24 months.

Laboratory suggestive evidence

Detection of anti-hepatitis C antibody, or hepatitis C virus by nucleic acid testing.

Clinical evidence

Clinical hepatitis within the past 24 months (where other causes of acute hepatitis have been excluded) defined as

1. Jaundice

OR

2. Bilirubin in urine

OR

3. Alanine transaminase (ALT) seven times the upper limit of normal.

Source: Department of Health, CDNA, Australian National Notifiable disease case definitions (25).

Among a high risk group this definition fails to identify true incidence. People engaged in risk behaviour may be HCVAb positive due to the frequency of risk behaviours yet HCV PCR negative, and individuals who are PCR positive are at risk of dual infection with other HCV genotypes (18). Re-infection or infection by an alternate genotype could be considered as newly acquired HCV. The definition does not acknowledge the availability of therapeutic treatment options in which a patient may clear HCV and achieve Sustained Viral Response (SVR) (patients who achieve SVR will still be HCVAb positive but PCR negative). The Australian diagnostic strategy of the Hepatitis C testing guidelines state genotype testing is a predictor of treatment dose, therapy and response; but does not touch on genotype testing for diagnosis of re-infection or co-infection (26). Currently this means patients clearing HCV while on treatment who become reinfected will only be considered newly acquired cases (notifiable) if there is
clinical evidence accompanying, however, most cases of HCV are asymptomatic. Identification of serological ALT seven times the upper limit of normal is not possible in all acute HCV cases.

Taking into consideration the limitations of the current case definition for newly acquired HCV, we developed incidence criteria for this study to determine in-prison incidence. In-prison HCV incidence was determined if patients met criteria one, two or three set out in Table 2.

<table>
<thead>
<tr>
<th>Table 2. In-prison HCV incidence criteria</th>
<th>HCVAb</th>
<th>PCR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. On entry to prison</td>
<td>−/+</td>
<td>−</td>
</tr>
<tr>
<td>1. Up to 12 weeks in prison</td>
<td>−/+</td>
<td>−</td>
</tr>
<tr>
<td>1. More than 13 weeks in prison</td>
<td>−/+</td>
<td>+</td>
</tr>
<tr>
<td>2. In-prison HCV treatment – Sustained Virological Response (SVR)</td>
<td>−/+</td>
<td>−</td>
</tr>
<tr>
<td>2. Re-infection while in prison (preferred different genotype)</td>
<td>−/+</td>
<td>+</td>
</tr>
<tr>
<td>3. In-prison spontaneous HCV clearance</td>
<td>−/+</td>
<td>−</td>
</tr>
<tr>
<td>3. Re-infection (preferred different genotype)</td>
<td>−/+</td>
<td>+</td>
</tr>
</tbody>
</table>

4.4.3 Study context, setting and preliminary observations
Following the expansion of a HCV treatment program at a prison facility in an eastern state of Australia, there was an increase in uptake and frequency of HCV testing among people incarcerated. As a result of increased testing, 30 prisoners were identified as possible in-prison incident cases from March 2009 to May 2013. On further examination of HCV test results and time of imprisonment, of these 30 HCV infections there was suggestive evidence that 22 of the cases may have been acquired in custody. The preliminary laboratory evidence suggested that it was not a point source outbreak as cases in these prison residents were of different genotypes.

The identification of 22 cases of HCV in a single prison facility provided an opportunity to better characterise HCV transmission in a prison setting, and to identify potential effective control measures. In order to do this we undertook a mixed methods approach including both quantitative data collection and qualitative interviews to provide inmate perspective, to determine and describe in-prison HCV transmission and incidence.

4.5 Aims
The aims of this study were to:

1. Describe an in-prison case series of newly acquired HCV infection.
2. Determine the strength of evidence for in-prison HCV transmission for each suspected incident case.
3. Identify possible modes of transmission for each suspected incident case, in order to inform preventive efforts.

4.6 Methods

4.6.1 Study type
This study is a mixed methods case series of HCV infection in a prison setting. Semi-structured interviews were undertaken to understand demographic and risk factors. For confidentiality reasons all participant and prison facility identifying data has been removed from this report.

4.6.2 Study population
At the agreed time of interviews, from the 21st to the 24th July 2014, 16 out of 22 potential participants were currently detained at the prison facility.

4.6.3 Participant selection and recruitment
The potential sixteen participants were placed in a line list created by the prison medical director. The line list was analysed by the medical director, medical service reception and correctional staff at the prison for non-associations (people not allowed to associate with each other), visiting time schedule and logistical issues (prison guard to prisoner ratio, ability to move prisoner from housed area to medical service, times of lock-in or muster and least disruption to medical services operation). A timetable of estimated day and time to move potential participants from housed areas to the prison medical service for interviews was established. Letters were sent to all 16 current detainees on the line list. Letters were personally addressed to potential participants from the prison medical director and sent via internal mail. The letter described the study and invited individuals to participate in a one-on-one, survey and semi-structured interview regarding potential risk factors and exposures for infection. Included with the letter was a participant information and consent sheet (Appendix 1). The letter reiterated confidentiality and individuals who chose not to take part in the study were asked to dispose of the letter and not discuss the study. The investigator interviewing only had a de-identified list of possible participants. During the interview week, possible participants whom letters were sent to were further contacted by medical service reception staff and asked if they would like to participate in the study.

4.6.4 Consent process
Once possible participants had expressed interest in participating they were moved at earliest mutual convenience to the medical service and introduced to the interviewer. The interviewer
went through study details as found on the participant information sheet and consent form (Appendix 1). Participants were asked to give written consent before interviews.

4.6.5 Survey and Interview tools

1. Demographic and risk factor survey

The survey used in this study (Appendix 2) was an adaptation of the HITS interview tool\(^{(27)}\). HITS is a large ongoing custodial incidence prospective cohort study including a survey tool for both pre and post HCV infection. For this study both HITS pre and post survey tools were adapted to develop one survey tool for an outbreak scenario. When adapting the survey the following were taken into consideration, time frame of outbreak, demographics and risk factors between time of last HCV negative blood test and HCV positive test during the time period March 2009 to May 2013.

2. Semi-structured interview

Semi-structured qualitative interview topics were established including perception and diagnosis of HCV, prison network and peer education, stigma, injecting, tattooing and treatment. A list of questions was designed as a guide (Appendix 2).

4.6.6 Interview process

Interviews were conducted in a prison medical service consult room to provide a level of confidentiality to the study. The interview room was in view of the medical service prison guard station and a duress alarm was worn by the interviewer for further safety precaution as per prison protocol. Each participant took part in an interview process consisting of both a demographic and risk factor quantitative and semi-structured qualitative interview. Audio recording of interviews was approved at an ethics committee level, but audio recording was ruled out at a service provision level. Confidentiality of the participant was of upmost importance, therefore interviews were conducted by one investigator and qualitative interviews were scribed during interviews by the investigator. The research team decided one investigator interviewing and scribing would be more appropriate for the participants due to the content of the interviews. For safety reasons a doctor not associated with the research was present in the interview room or other medical staff in an adjoining room.

It was ideal to begin interviews with qualitative interviews to understand each participant’s personal experience of HCV testing, diagnosis and treatment within the prison setting before moving onto the quantitative survey. In some instances, due to time constraints such as muster or lock-in, interviews were conducted with quantitative collection first and the
remaining time was used to interview participants about personal perspectives through the qualitative component.

4.6.7 Analysis
Demographic, risk factor and exposure survey data were entered into an Epi Info database to conduct simple descriptive analysis. Qualitative semi-structured interview data were transcribed, thematic analysis of interviews was undertaken by first coding of key words. Secondly, key words were grouped into themes, and thirdly themes were allowed to emerge independently as key words were then analysed into major themes to shed light on the ethnographic concepts of HCV incidence among people while in prison. Triangulations of quantitative and qualitative findings were integrated to provide an in-depth understanding of HCV incidence in prison.

4.6.8 Ethics
Ethics approval was obtained from three relevant jurisdictional HRECs.

4.7 Results
Seven out of sixteen potential participants consented to take part in the study. The reason for refusal was not documented. One potential participant refused at the interview room door because he did not want to talk to someone he did not know. The full combined quantitative and qualitative interview process took around 60 minutes per participant, however due to the constraints of the setting, two interviews were cut short by 30 minutes.

All seven participants were male, heterosexual, with a mean age of 30 years (range 23 to 40 years). One participant had an education level above Year 10. All participants were born in Australia and one identified as Aboriginal. Four out of seven had been detained in juvenile detention centres more than once in their life (recall on number of times in juvenile detention was variable, therefore no range reported) and recidivism was high with all seven participants incarcerated in adult prisons three or more times in their lives (ranging from three to ten times).

Six out of seven participants reported a history of mental illness, all of whom singled out a history of depression during the quantitative survey. However, during qualitative interview the individual who reported not having a history of mental illness talked about a state of depression when hearing about his HCV diagnosis. This was a common reaction for most participants when first diagnosed or when they received news of re-infection. Words used by participants to describe this feeling included “sad”, “depressed” and “upset.”
4.7.1 Risk factors

Participants were asked to recall in-prison risk factors potentially leading to blood exposure between their last negative HCV test and positive HCV test. Risk factors identified included: injecting drug use, haircuts where the scalp or skin was cut, tattoos, undergoing a penile implant, sport and fights in which another inmate’s blood came into contact with their eyes, mouth or open wound (table 3). Six out of seven participants reported multiple in-prison risk factors (table 3).

Table 3. Risk factors exposing participants to another inmates blood by incident case between last negative and positive HCV test while in prison

<table>
<thead>
<tr>
<th>Participant</th>
<th>Injecting</th>
<th>Haircut</th>
<th>Tattoos</th>
<th>Fights</th>
<th>Sports</th>
<th>Penile implant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 1</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Case 2</td>
<td>✓</td>
<td>✓</td>
<td>-</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Case 3</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Case 4</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>-</td>
<td>✓</td>
<td>-</td>
</tr>
<tr>
<td>Case 5</td>
<td>✓</td>
<td>✓</td>
<td>-</td>
<td>✓</td>
<td>✓</td>
<td>-</td>
</tr>
<tr>
<td>Case 6</td>
<td>✓</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Case 7</td>
<td>✓</td>
<td>-</td>
<td>✓</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

4.7.2 Drug use

All participants had a history of illicit drug use. Six participants reported injecting drugs and one participant reported only smoking or taking drugs orally prior to incarceration. All six participants whom reported injecting prior to prison had access to and used clean injecting equipment from needle and syringe programs (NSPs). One participant who reported injecting on the outside noted primarily smoking heroin, rarely injecting and only if he had clean injecting equipment. Between the time of last negative and positive HCV test results, all seven participants reported injecting drugs while in prison (Table 3).

Of those who injected on the outside, five reported injecting drug use decreasing during their sentence in which they became HCV positive (Table 4). One participant explained the decrease in injecting behaviour was due to availability and expense of drugs. Two participants discussed
the need to change the way drugs were taken to essentially get their money’s worth, one of whom said:

“Well you would have to be a millionaire in here to use the same as outside. You definitely wouldn’t smoke drugs it is too expensive.”

The other person explained:

“Before coming inside I never injected drugs, I used to smoke them or eat them. I learnt different ways of taking drugs when I came in here.”

Two participants reported an increase in injecting drug use while incarcerated (Table 4). When contextualised by qualitative data, only one participant had a real increase in injecting drug use. The other inmate who reported an increase was actually initiated to injecting drug use during his prison sentence and did not inject drugs on the outside. Initiation to injecting drugs, initiation to sharing injecting equipment and picking up a “habit” was something a number of participants made reference to during qualitative interviews.

Six out of seven participants reported poly-drug use while in prison (table 4). One participant, who didn’t report poly-drug use, recalled only one incident of injecting at the start of imprisonment when withdrawing and an inability to access the methadone treatment program during this time. The participant did mention this was under older policies and he thought access to methadone treatment on entry had changed to take into consideration this transitional period.

4.7.3 Sharing of injecting equipment in prison

Injecting drug use, access to injecting equipment and sharing were predominant factors in HCV in-prison incidence. All seven participants believed they became HCV positive while in custody, six singled out injecting drug use combined with sharing as the reason for seroconversion in custody.

Table 4. Prison injecting drug use by incident case between last negative and positive HCV test result
<table>
<thead>
<tr>
<th>Participant Case</th>
<th>Frequency of injecting drug use</th>
<th>Injecting frequency during imprisonment compared to rest of life</th>
<th>Heroin</th>
<th>Buprenorphine (Subutex)</th>
<th>Ice (crystal meth/amphetamines)</th>
<th>GHB/GBH/Liquid e/fantasy</th>
<th>Cocaine/Coke</th>
<th>Benzodiazepines/Benzos</th>
<th>Anabolic/ Steroids</th>
<th>Other opiates/codeine/pethidine/opium/omnopon</th>
<th>Hallucinogens/LSD/acid/magic/Mushies/Daitura</th>
<th>Ecstasy/E/MDA/MDMA</th>
<th>Ketamine/special K</th>
<th>Oxycodeone eg. Oxycontin, Endone</th>
<th>Methadone</th>
<th>Morphine</th>
<th>Speed/base or other methamphetamines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 1</td>
<td>Monthly or more often</td>
<td>↓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Case 2</td>
<td>Daily</td>
<td>↑</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Case 3</td>
<td>Monthly or more often</td>
<td>↓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Case 4</td>
<td>Monthly or more often</td>
<td>↑</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Case 5</td>
<td>Less than monthly</td>
<td>↓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Case 6</td>
<td>Less than monthly</td>
<td>↓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Case 7</td>
<td>Less than monthly</td>
<td>↓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

4.7.4 **Access to injecting equipment outside and inside prison**

Participants had access to clean and sterile injecting equipment on the outside and actively sought it. All participants, with the exception of one younger participant whose initiation to
injecting was during his current sentence, reported collecting clean injecting equipment to use from a NSP “every time I needed” and one participant reported “most times I needed.” One person said:

“Anywhere you go you can get a clean fit or buy them for two dollars from a vending machine, so much on the outside [in] every satellite area fits are easy to get.”

There was a sense of frustration and no control over the lack of access to clean sterile injecting equipment while in prison. All participants knew they were at risk of HCV through sharing injecting equipment, yet had felt they had no choice apart from cleaning injecting equipment with bleach. The quotes from four people below exemplify frustrations and the complications of moving from an environment with abundant access to clean injecting equipment to an in-prison environment which provides no access to clean injecting equipment:

“It’s not by choice that I share.”

“The whole fact that jail doesn’t have clean fits doesn’t change injecting, it does change the rate of infection. No clean fits doesn’t change how people use. It only changes the rate among clean people.”

“I didn’t really inject much until custody in two thousand and five, I know there was a risk and what it does to you [HCV], I didn’t share outside. When I first used in prison, first time to use sharing was inside. I was fresh off the streets and withdrawing. Clean fits are really available in Sydney, everywhere, really available, so I wasn’t used to it.”

“I never shared needles before. I had no control over the situation, it was someone else’s fit and I was really sick so I just shared it. I have never shared on the outside and I had to share, I’ve seen lots of people do that. I was hanging out, I haven’t injected much and would smoke [heroin], usually I would only inject if the fit was clean.”

Policy difference between inside and outside environments forced people who inject drugs while in prison to engage in high risk behaviour that put them at risk of BBVs.
4.7.5 How people are sharing and sourcing injecting equipment

All seven participants had shared injecting equipment while incarcerated. The quotes below from three people shed some light on the circumstances where sharing injecting equipment might occur:

“Usually there is more than one, like one between two to three people. I only really shared since at the [current housed area]. I use with the same three to five people.”

“I have a fit I share between two to three people but if someone has drugs and asks for it I give it to them but only two to three regulars using the fit.”

“Every second person has their own equipment I’ve seen one fit used between forty blokes, no bleach, no nothing just a quick clean of water.”

It would appear from interviews that needles and syringes were being made using any available material.

“I’ve seen people use chicken bones and pens.”

There was some confusion around proper cleaning processes for injecting equipment and almost no talk about processes for cleaning other equipment such as hair clippers. The lack of access to clean injecting equipment meant people were resourceful and creative in making their own and sharing equipment. (Described in more detail under heading 4.7.12 Resourcefulness and creativity attached to minimising harm)

4.7.6 Hair clippers

Five out of seven participants had a haircut while in prison where their scalp or skin was cut in the period between last negative HCV test and positive HCV test. Two participants identified the following concerns around use of hair clippers and exposure to blood in prison:

- Sharing of hair clippers among many inmates;
- Popularity of using clippers on closest possible cut setting (zero);
- Lack of knowledge around blood clean up;
- Lack of available cleaning products for clippers after haircuts.
One participant said:

“All the time, clippers braise [participants own language] us all the time. We don’t have anything to clean them with. We just use little alcohol wipes sometimes but it’s not meant for that. With the clippers, I have hep C so I use a number one instead of a zero. A lot of inmates like to use zero.”

The second participant provided similar information:

“One set of clippers is between about fifty to sixty people. Most people use zero to cut hair. Not long ago someone cut them self and there was blood all over it, to sterile equipment, to clean them up, if there is blood on the clippers just wipe off and rinse under water. He was hep C positive. There is no other way of cutting hair.”

4.7.7 Tattooing

Three participants indicated that tattooing in this particular facility was not too common. This was expressed by one person as “… not as much as other jails”. Yet four out of seven participants had in-prison tattoos between their last negative and positive HCV test. Tattooing equipment usually consisted of a motor, pen as a barrel and needle. Ink used by inmates consisted of charcoal, soot, mixture of soot and toothpaste, pen ink and, if available, tattoo ink. Two out of four people who acquired in-prison tattoos said they supplied clean equipment (new motor - a device that allows for the rotating motion needed to tattoo effectively, needle and/or pen). However, a participant who was both doing other inmates’ tattoos and his own said the process was “dirty”:

“Pretty much it’s dirty. Might use water and change other parts like the motor and needle … I try to change parts between inmates but it was up to them to have clean parts.”

Two inmates receiving tattoos sourced clean parts for their own tattoos, evidently aware of and trying to reduce their risk of acquiring HCV.

“You can’t really catch anything just hep C, just need a new needle and pen each time. I had a tattoo every time I’m in, always with clean equipment”

“I was just trying to get hold of my own gear and clean it. I clean just with water and bleach.”
4.7.8 Other blood to blood contact
Additional behaviours exposing participants to blood while incarcerated included: fighting, sport and penile implants. Three out of seven participants reported a fight in which blood from another person came into contact with their mouth, eyes or an open wound. Three out of seven participants reported having another person’s blood on them while playing sport. Both football and fighting were identified as sports in which contact with someone else’s blood occurred. Fighting as a sport would imply inmates organising fights as opposed to a disagreement leading to a fight, but more information was not sought to differentiate these.

One participant had a penile implant between his last negative and positive HCV test. He recalls there was “Only a little bit of blood involved” adding:

“Yeah I have had that twice. Usually like glass shaved down. Mine were smashed microwave plate. I ground it down on the concrete in the yard, where everyone walks. I bleached it and then boiled it, it’s not sterile. I’ve seen it go bad.”

No participants reported sharing razors or toothbrushes, sexual contact with another inmate, needle stick injury or stabbing.

4.8 Different concepts of shared and cleaned
Participants had different ideas of what was clean and sterile. Each participant explained different ways of cleaning injecting equipment. Participants put a large emphasis on bleaching and cleaning injecting equipment. Yet blood in other situations was not thought of or treated in the same way by everyone. This was evident when discrepancies arose between quantitative and qualitative interviews. For example, one participant indicated always used clean and sterile equipment when injecting in the quantitative component of the data collection, yet discussed sharing equipment with more than 20 people during qualitative data collection. His idea of clean and sterile was bleaching and washing equipment before using. Another participant said he did not share with anyone but he used someone else’s equipment. It seemed sharing was a concept when physically in the presence of others using injecting equipment, but not when using an unsterile fit individually as indicated by one person in the following comment:

“What do you mean by sharing, like straight after someone or just having your own fit? I have a fit I share between two to three people but if someone has drugs and asks for it I give it to them but only two to three regulars using the fit.”
When participants were asked if they bleach or fincol (a hospital grade disinfectant used in some prisons) their injecting equipment properly, most participants immediately said “yes”. But when the recommended process was explained (two flushes of water, two flushes of bleach or fincol, and a 30 second soak of the equipment in bleach or fincol and then two flushes of water) participants went on to change their answers to “sometimes” or “never.” Some participants explained different processes. One said:

“Sharing needles in here, I try to bleach out every time. You are meant to soak overnight it’s the best way. I bleach out six to eight times, suck in and out and rinse with water. I haven’t seen anyone soak overnight.”

4.9 Normalisation and ignoring Hepatitis C

When asked if there was stigma around HCV or if inmates with HCV were perceived differently in prison, six out of seven participants described a culture of HCV normalisation with little stigma attached to HCV infection, or injecting inside. Below five people discuss their view of HCV in prison:

“It’s just normal, no one really cares about it, so many people have it.”

“Compared to the sentence I’m doing, it doesn’t really matter.”

“People don’t really talk about hep C or health, if someone is asked they admit it but no one just talks about it ... majority of people in here have it, if you are going to start treating people differently you will make it difficult for yourself.”

“Main worry isn’t hep C no one really cares about hep C same sort of thing, bleach every time, should be alright.”

“Hep C is pretty acceptable and normal. If people have AIDS then that is a thing but hep C not really.”

One participant however described it in a different way:

“The culture is people try to ignore it, it’s easier to deal with, ignore it.”

HCV was seen as acceptable and normal by participants, yet people inside didn’t really talk about it they “ignored it”. There was, however a culture of learning and teaching strategies to reduce risk, and in doing so, consciousness to protect self and others from becoming infected.
4.10 Ideas and behaviours observed, learnt and taught

Inmates were getting input and piecing together a puzzle about hepatitis C transmission and infection control from a number of different sources: 1) themselves (learnt ideas and behaviours) 2) other inmates (taught and observed ideas and behaviours) and 3) prison medical staff and educational materials. Four participants talked about receiving HCV information from medical staff and material around the facility such as the bleach protocol or “hep C review” (a monthly magazine produced by Hepatitis Australia).

For some participants preconceived ideas and behaviours surrounding HCV developed on the outside were continued even though they were inside, living in a high risk environment. Some participants changed the way they used inside, influenced by other inmates to use drugs, learning new techniques of taking drugs or learning how to clean equipment or strategies to reduce risk of blood to blood contact. One person who was initiated to injecting while in prison recalls older inmates teaching techniques:

“The older blokes taught me how to inject. I never experienced needles before here. They taught me how to shoot up.”

Another person commented on the information received from medical staff at the prison facility but discussed a lack of conveying that learnt information to other inmates. There was a sense of trying to do this, but maybe not knowing quite how to convey the message in the way a peer educator would.

“Had pretty good information from medical staff, inmates don’t really talk about it, some people tell others not to do things, I try to tell others not to do things but it’s up to them to do it or not.”

Taught and learnt ideas and behaviours were evident through language and actions. Language used by participants demonstrated a level of understanding about HCV, transmission routes, risk of HCV, genotype, treatment options (current and future options), infection rate and statistics. Participants described actions of implementing their own harm reduction techniques and consciousness of protecting others in situations where risk arose.

Medical staff provided education to participants; some participants understood discussions with medical staff but confusion about aspects of their diagnosis was evident. There were misunderstandings or misconceptions about HCV, transmission, risk, diagnosis and harm reduction. One person demonstrated misunderstanding of diagnosis:

“When I had the test again my body had antibodies to beat it but must not had too much cos I had it again.”
A misunderstanding about ability to access treatment was demonstrated by a different participant:

“\[\text{participant}^\text{,} \text{``I would like to do treatment again but not sure if I can, might only get one chance.``} \text{\}i\]”

Participants had different processes for bleaching injecting equipment, not always in line with the recommended guidelines.

### 4.11 Resourcefulness and creativity attached to minimising harm

While there was an overpowering undertone among participants to not talk about health or HCV, there was a number of self-developed harm minimisation and reduction strategies that inmates tried to practice to decrease their risk of HCV infection while incarcerated. These included:

- Bleaching, washing and cleaning equipment
- Using among the same small group of people to reduce the pool of infectivity
- Having/making their own injecting equipment to reduce their need to share, and if sharing takes place, ability to dictate who uses it
- Allowing those without HCV to use equipment first
- Using the methadone program to reduce their need to inject more frequently.

These were a number of taught and learnt strategies used by participants who reported always having access to and using clean safe injecting equipment on the outside.

### 4.12 Chasing a high

All participants knew the risk of contracting HCV; they identified behaviours that put them or others at risk of contracting HCV, but this was overridden by the high. Four out of seven participants described a mentality of chasing a high which lead to an increased level of risk related to injecting in prison. The ramifications of sharing equipment and HCV became secondary to the high as explained by the following three quotes from different participants:

- “\[\text{participant}^\text{,} \text{``The want to get high is higher than worry about hep C, it’s pretty sad really.``} \text{\}i\]”
- “\[\text{participant}^\text{,} \text{``No not a care factor, just want to get high.``} \text{\}i\]”
- “\[\text{participant}^\text{,} \text{``People that are getting high or stoned are not really concerned about anything else.``} \text{\}i\]”

Two participants talked about coming into custody and being in a state of withdrawal and needing to use. One of these participants said
“It’s a bit hard when you are really sick. You don’t think about hep C you just think about getting high.”

4.13 HCV diagnosis, treatment and re-infection
Misunderstanding the risk of re-infection after HCV treatment was a reoccurring factor. Five out of seven participants had been on HCV treatment while in prison and all five had been reinfected with the same or different genotypes after clearing the virus or while on treatment. Attached to the initial diagnosis, treatment and re-infection, was a collective emotion of upset and anger which played out differently for each individual. Most felt depressed, some started using again. Five people provided some insight into their experience of HCV treatment in prison and related issues:

“I was on treatment in two thousand ten [in prison] when I left [when released] I stopped taking the ribavirin tablets, they made me feel like shit, depressed. I thought I was clean, I didn’t use on the outside because I thought I was clean.”

“This time I’ve been in since two thousand ten, at the start of this sentence in two thousand ten I started six months of treatment. I cleared it but then I was told I had it again, it’s pretty shit.”

“In two thousand seven I found out [I was HCV positive]. I had a blood check. At first I was really apprehensive; I didn’t want to hear the results, I felt guilty. [While in prison] I went on treatment and cleared it in a month but started using again, next blood test I got a different genotype, treatment was extended for another six months. I retested in a month and was surprised to hear I had genotype one. When I had the test again my body had antibodies to beat it but must not had too much cos I had it again.”

“In two thousand and six in prison I did treatment for genotype one A and in two thousand and twelve in prison treatment for genotype three A.”

Diagnosis or re-infection while in prison added another layer of complexity for inmates with already compound histories of mental illness, drug use, crime and institutionalisation. While all participants had an innate adaptability and survival mentality there were glimpses of a struggle to cope with aspects of their diagnosis, re-infection and treatment while in the prison environment.
4.14 Experience and perception of HCV treatment in-prison

The notion of sickness as a weakness and vulnerability was highlighted, relating to the nature of the prison environment and the need to stay alert. Two participants who had not been on HCV treatment described treatment side effects observed while inside and their perception of treatment:

“I won’t do it, it makes you vulnerable, it makes you sick, your strength’s not there and you need that. If you look sick it makes you weak and vulnerable.”

“I really want to do treatment; it’s just shit how sick it makes you. I seen it make people lose weight, get really sick. They say they can give you stuff for it. But the last thing I want to be is curled up on the floor. I’ve got to be on the ball.”

Five participants who had been on HCV treatment in-prison (treatment undertaken in current or previous sentences) experienced different emotional and physical side effects. Each individual was in a different mind frame about treatment when asked about their experience and if they thought treatment was an option in the future. Most said it would be an option but conditionally, if they were healthy, in the right mental state, while others recognised they would be using drugs and did not want to be reinfected. Below four different participants offered their insight into treatment and side effects in-prison:

“It’s not something I’m thinking about right now, I’m gonna get treatment again one day. The medicine put my body through a lot, it fucked me up and I would want to use.”

“When I was doing interferon I lost ten to fifteen kilograms, it was mentally and physically draining. I would want to get myself to a place where I was healthy to do treatment; I’m waiting for new treatment to be available.”

“Not while I’m in here. Not the right time I need to be in the right mental thinking. I’m going to use again. I don’t want to get reinfected. I want to be healthy and be able to deal with it.”

“Treatment was Ribavirin and Pegasus for twelve months of treatment, nine months I did in segregation because I was losing it.”

One participant mentioned if he could do treatment again he would have done it in the last six months of his sentence. Two participants with longer sentences talked about the want to progress through the system and the need to change behaviours at the later end of their
sentence with the motives of behaviour change and parole. For one participant it was a matter of using less and not letting the drugs affect him as much, “it’s a bit like roulette.” For another it was totally isolating himself from people and activities to stop using and progress through the system.

4.15 Health is a priority
While there was a culture of not talking about health or HCV (as discussed above), as being healthy and strong was important for participants. Even though most were long term drug users and injected while in prison. Five participants discussed their desire to be healthy in different contexts; to be healthy while inside prison to reduce vulnerability, health in general (eating and exercising), wanting to stop using drugs and wanting to protect family from illness on the outside. Four out of seven participants talked about changing their lifestyle to not take drugs. Of those four, one tried rehabilitation (not specified if in or out of prison) and three implemented their own strategies to try and stop taking drugs at different times during sentences, including isolation, going “cold turkey” and focusing on exercise and eating better.

4.16 “We need safe equipment”
Three out of seven participants specifically talked about a need for access to clean and safe injecting equipment in prison. These were unprompted discussions, two people when asked if they would like to say anything else at the end of the interview process and one person during a discussion about perception of people with HCV. Their want for clean injecting equipment was more a concern for other people coming into the prison system, particularly for people coming into prison “clean” (HCV negative) and leaving the prison system with “hep C” and a “habit”. One person explained:

“I tell you what, we need a needle exchange here so we can exchange used fits. I know people who have come in clean and left with a JR and hep C.”

When asked what the term JR meant the participant explained:

“A jack rabbit is a habit, once you are down the burrow you are stuck in the hole.”

In reflection of his own story of HCV acquisition and knowing others in the same situation another person expressed the need for an NSP:

“We need safe equipment, stats show most people come in without and contract hep C. It’s disturbing the same situation happened to me, off the street feeling sick and withdrawing, not worried about using or hep C.”
One participant offered the following quote during the interview process in relation to a question about perception of people with hepatitis C.

“A needle exchange would be good. If they could think about a needle exchange because there are heaps of guys I know who come in and have only smoked marijuana and other drugs and inject for the first time.”

The following quote was expressed by a person who was frustrated by constant talk of possibilities of NSP’s in prison with no outcome. The language he used was a little different in that he spoke about an “injecting room” for safe use and disposal.

“They worry about the safety of prison guards, inmates using needles as weapons things like that, it hasn’t happened though. If they had an injecting room, people could use safely dispose safely it wouldn’t be an issue.”

4.17 In-prison incidence
Using the study criteria developed to define in-prison incidence, six out of seven cases of HCV could be classified as in-prison newly acquired HCV cases. The exception was case six whose drug use outside prison was predominantly through smoking and who recalled sharing injecting equipment for the first time on entry into the prison system. This case is without a doubt a new incident case of HCV, but there is contention as to whether HCV acquisition was in or outside of prison. Due to the transition period into prison, testing results and study criteria, this case has been excluded as in-prison incidence. See Table 5 for each case’s incarceration periods, test and HCV status across the study timeline (Note: Table 5 includes primary data obtained for each case at the beginning of the investigation).

All identified in-prison incident cases believe they had contracted HCV while in prison. All six identified their HCV in-prison diagnosis was as a result of injecting drugs in the context of sharing needles. Interestingly, recalled scenarios of how participants believe they contracted HCV collected during qualitative interviews, were consistent with timeline testing and diagnosis data.

Of the six in-prison incident cases, four acquired HCV genotype 3a, one participant acquired HCV genotype 1 and one participant acquired genotype 1a. Cases one, two and three had genotype change and/or dual infections. Four participants had undergone HCV treatment during current or previous sentences. Three cases were re-infection after SVR to treatment and one case was either relapse or re-infection after SVR.
Only two participants (cases four and six) would be considered notifiable as newly acquired HCV cases according to the national case definition.
### Table 5. HCV testing, results and treatment timeline of cases

<table>
<thead>
<tr>
<th>Year</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
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<tr>
<td>Month</td>
<td>1 2 3 4 5 6 7 8 9 10 11 12</td>
<td>1 2 3 4 5 6 7 8 9 10 11 12</td>
<td>1 2 3 4 5 6 7 8 9 10 11 12</td>
<td>1 2 3 4 5 6 7 8 9 10 11 12</td>
<td>1 2 3 4 5 6 7 8 9 10 11 12</td>
<td>1 2 3 4 5 6 7 8 9 10 11 12</td>
</tr>
<tr>
<td>Case 1</td>
<td>SI</td>
<td>previous test 7/07 - 1a &amp; 1b</td>
<td>1a &amp; 1b</td>
<td>PCR neg</td>
<td>3a</td>
<td></td>
</tr>
<tr>
<td>Case 2</td>
<td>SI</td>
<td>3a</td>
<td></td>
<td>PCR neg</td>
<td>PCR pos 1a</td>
<td></td>
</tr>
<tr>
<td>Case 3</td>
<td>SI</td>
<td>3a</td>
<td>3a</td>
<td>PCR neg</td>
<td>PCR neg</td>
<td>PCR pos 1a &amp; 3a</td>
</tr>
<tr>
<td>Case 4</td>
<td>PHI SI</td>
<td>HCV Ab neg</td>
<td></td>
<td>PCR pos 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case 5</td>
<td>SI</td>
<td></td>
<td>PCR neg</td>
<td>PCR neg</td>
<td>HCV Ab Pos</td>
<td>PCR pos 3a</td>
</tr>
<tr>
<td>Case 6</td>
<td>PHI</td>
<td>HCV Ab neg</td>
<td>3a</td>
<td>PCR pos 3a</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Case 7</td>
<td>PHI SI</td>
<td></td>
<td></td>
<td></td>
<td>PCR neg</td>
<td>PCR pos 3a</td>
</tr>
</tbody>
</table>

- PCV Ab positive or positive, HCV PCR negative
- PCV Ab positive and HCV PCR positive
- Incarceration period
- Blood test
- Acute hepatitis (elevated LFT)
- Study incidence
- SI  Study incidence
- PHI  Public health incidence
- HCV treatment
4.18 Discussion

In line with findings from previous in-prison HCV incidence studies, participants in this case series were all born in Australia, predominantly had an education level equal to or less than year 10, had a history of recidivism, a history of injecting drug use and a history of injecting in prison\(^{12, 17, 19}\). Exposure to blood while incarcerated and multiple risk factors placed study participants at high risk for HCV in-prison incidence and demonstrated the considerable risk of exposure to blood for people residing in the custodial setting. In this study multiple exposures to blood while in prison, between negative and positive HCV test, occurred through injecting drug use, hair clippers, tattooing, fights, sport and penile implants.

Injecting drug use and sharing of injecting equipment while incarcerated was a common risk factor among all participants in this study. All in-prison incident cases said seroconversion was as a result of injecting or sharing of injecting equipment. Around 22% of people with a history of injecting drug use will inject drugs while in prison\(^{28}\), although a national community based study of ex-prisoners reported 42% injected while incarcerated\(^{29}\). This study reflects demographic and behavioural factors associated with HCV transmission among a high risk group of people who inject drugs while in prison.

This prison facility is providing a number of harm minimisation strategies to reduce HCV incidence. These include bleach provision, condom availability, opioid substitution programmes, a HCV treatment program and educational materials. The prison facility in which all study cases resided provided all of the above mentioned strategies, however, in Australia these strategies are not consistently available across all jurisdictions and prisons\(^{30}\). In addition to facility led initiatives, participants were employing their own harm minimisation tactics by reducing injecting drug intake, reducing sharing of equipment, reducing the pool of infectivity in which to share and implementing cleaning strategies. This study provides evidence of in-prison incidence occurrence despite availability of harm reduction strategies. This finding would imply current harm minimisation strategies are not adequately meeting the needs of this subsection of high risk prisoners.

There was a culture of invention/creativity, learning, teaching and taking on different practices and ideas. This was not always best practice, as notable misconceptions and myths about HCV, HCV treatment and harm reduction was demonstrated by participants. Peer education could be an angle of myth breaking and education in the future to decrease transmission, improve outcomes of disease, support treatment and also improve prison health services for people at risk of acquiring HCV\(^{31, 32}\).
Despite best efforts to reduce risk by both participants and corrections, the predominant factor in HCV transmission in prison continues to be the sharing of injecting equipment. This study describes the ongoing sharing within prison facilities and resourcefulness of inmates in finding ways to use drugs while incarcerated. With no availability of clean injecting equipment, inmates who use while incarcerated or inmates who are initiated to injecting while incarcerated will continually be at high risk of acquiring HCV.

Five out of six incident cases had undergone HCV treatment during current or previous prison sentences. As demonstrated, this high risk group of people is likely to become reinfected by the same, different or multiple HCV genotypes while incarcerated due to risk factors. Treatment may decrease the presence of co-infection among this group but little is known about the effects of treatment on circulating HCV genotype immune response. A longitudinal study found the ability of a dominant HCV strain (in a co-infection situation) to suppress and clear a less virulent HCV co-infection\(^{(18)}\). Little is known about the physiological outcomes of re-infection after treatment in comparison to co-infection which suppress and clears less virulent strains. Further work is required to fully understand physiological and biological effects of the disease and its treatment on host immunity.

The psychological effect of re-infection after treatment was evident among participants in this study. Coping skills observed among participants lead to the conclusion that prison based mental health services attached to HCV diagnosis and treatment would be beneficial. It is crucial for prison based HCV services to integrate mental health/support services into their clinical model, although it is acknowledged that resources to do so are limited.

HITS had a lower mean age of incidence (25.7 years) compared to the current study mean age (30 years)\(^{(19)}\), and it was noted in this study that younger inmates were being taught injecting behaviours by older inmates. A number of participants expressed worry about younger inmates and inmates who use drugs but do not inject being initiated into injecting while in prison. Power dynamics within the prison system are potential influences of HCV incidence, though little is known about pressures associated with user dynamics in the prison context.

### 4.18.1 Limitations
This is a small descriptive case series. The constraints of the prison setting would require more time and resources to conduct a case-control or cohort study and may not yield different results, therefore the current study design was chosen taking into consideration the setting and ensuring confidentiality of participants. The strength of the mixed methods approach included providing a unique insight into the lives of participants and their perspective of HCV, which is missing from current literature. Sample size was small; however the mixed methods
approach to in-prison incidence has been conducted for the first time recently with a similar number of inmates in a different jurisdiction (not yet published).

There may have been a level of recall bias. Interviews were conducted in July 2014, where participants were asked to recall behaviours and situations as far back as May 2009. It is also possible illegal behaviour and repercussions of sharing information could have resulted in participants withholding information. Findings from this study are, however, similar to a general community based qualitative study in which prior offenders who had injected while in prison shared their experiences\(^{33}\).

Incident cases were identified due to increased testing as a result of a voluntary HCV treatment program. This may have influenced participants’ levels of knowledge and understanding of HCV, risk factors, treatment and prevention. It also meant the group included in the study was a high risk group. Each participant, however, had an individual story to add a different perspective to in-prison incidence.

No female detainees were included in this study. All female incident cases identified in the original 30 cases where not in prison at the time of interviews. Women tend to have shorter sentences and therefore in-prison incidence is harder to determine\(^{34}\). From 2003 to 2013 incarceration of women in Australia increased by 46.6\(^{\%}\)\(^{34}\), yet information on incidence and risk factors in the context of female prison facilities is limited and findings from this study may not be generalisable to female inmate incidence.

### 4.19 Conclusion
This study provides evidence of in prison HCV incidence, highlighting the extent to which a group of high risk prisoners are exposed to blood while residing in prison. Limitations of the current national HCV case definition create a barrier to reporting HCV in-prison incidence. This study identifies new acquisition of HCV among a group of high risk inmates that is not notifiable under the current case definition. True in-prison incidence may be under-reported.

This prison facility is providing a number of harm minimisation and reduction strategies to decrease HCV infection. However, there is evidence of in-prison HCV incidence despite availability of these strategies. This finding would imply current harm minimisation and reduction strategies are not adequately meeting the needs of a subsection of high risk prisoners. The findings of this investigation add to a body of evidence pointing to the need to implement NSPs in Australian prisons to complement current strategies.
4.20 Recommended control measures

1. Harm minimisation and reduction activities currently available should be continued and continually improved.

2. Sharing of injecting equipment in prison among inmates is a major factor in HCV incidence. Introduction of a NSP could reduce sharing of injecting equipment among inmates.

3. HCV information should be targeted at the right education level and take into consideration other activities in which inmates come into contact with another inmate’s blood. Educational tools should include information about how to sterilise equipment (injecting, hair clippers, tattoo equipment or anything coming into contact with blood) in a way that is considerate of the illegal activity.

4. Targeted education for young non-injecting drug users entering the prison system and fast track opiate treatment for individuals withdrawing on entry or risk of withdrawal could assist in decreasing isolated instances of sharing injecting equipment without cleaning.

5. Taught and learnt behaviour should be taken advantage of through prison peer education programs.

6. Inmates should be given the opportunity to do treatment while incarcerated, as reducing the circulating HCV prevalence could decrease incidence. However, the criteria for treatment should take into consideration inmate concerns around time of sentence to undertake treatment, inmate’s perceived mental state and/or coping skills.

7. HCV treatment as prevention in an environment that does not offer safe and clean injecting alternatives should only be looked at as a combination prevention strategy. Treatment as prevention may be appropriate in the general community context, where access and the choice to use clean injecting equipment are available. Until prisons introduce strategies to decrease sharing of injecting equipment, inmates who continue to inject in prison will continue to become reinfected during or after treatment. However, those that choose to abstain and
those that do not inject should be looked at as optimal candidates for treatment programs while in prison.

8. The HCV newly acquired case definition should to be revisited to capture true incidence rates in Australia. This is a public health issue not only for prisons, but the general Australian population.

**4.21 References**


Appendix 1: Participant Information Sheet

Incident Hepatitis C cases detected through a custodial HCV treatment program study

**Investigators:** [Redacted], A/Prof Stuart Kinner, Ms Rachel Sacks-Davis, Professor Margaret Hellard, Dr Joseph Doyle, Professor Tony Butler and Ms Dina Saulo.

**About the study**

Hepatitis C Virus (Hep C) is a virus that lives in the blood. It is transmitted when there is blood to blood contact with a person that is infected with the virus. This can happen through injecting drug use, sharing needles and injecting equipment, tattooing, sharing razors and toothbrushes.

This study aims to identify and describe potential risk factors for Hep C transmission while in custody at [Redacted] and to explore if the viruses are linked genetically. The study’s results will be used to inform policies that may protect people in custody from becoming infected with hepatitis C virus in future.

**Why were you selected?**

You have been invited to be involved in this study due to taking part in testing that was a part of the [Redacted] Hep C treatment program.

**What will happen if you consent to be a part of the study?**

There are three parts to the study:

1. **Medical record review**

[Redacted] records will be reviewed by a research team member for history of Hep C testing, the results of any tests, blood samples and other clinical information such as receipt of opiate replacement therapy, HCV treatment, HIV testing and treatment. No identifying information will be collected.

2. **Survey and Interview**

An interviewer will ask you some details about yourself, Hep C, and health behaviours and past experiences. We expect the interview on average to take around 60 minutes depending on your responses. Interviews will be recorded for the purpose of the interviewer to write up later; recordings will be destroyed once answers have been typed up. No one else will hear the recording but the interviewer.

3. **Viral sequencing of stored blood samples**

All hep C viruses are made up of genetic material. The research team want to sequence the genetic material of the virus. There are two purposes of this: 1) if you were treated for hepatitis C or spontaneously cleared an infection, you might have become reinfected with a new hepatitis C virus. It’s also possible that your original virus was not 100% eradicated and you had a relapse during or after treatment. Viral sequencing can distinguish between re-infection and viral relapse. The reason that the researchers are interested in this is that they want to understand whether you might have become infected with a new hepatitis C virus while you were at [Redacted]. 2) The researchers are interested in whether hepatitis C viruses in one individual have a link to another at the [Redacted]. This is in order to see whether there is evidence of transmission of hepatitis C at the [Redacted]. If you give permission, this will be tested by examining stored blood samples. Note, that this does not involve testing of your genes. The genetic material of the virus is different to your genes, and it is only the genetic material of the virus that the researchers are interested in.
CHAPTER 4 | OUTBREAK

Do I have to participate?
No, it’s your choice whether or not to participate. If you choose to participate but would like to pull out at any stage or skip questions, you do not need to explain why you don’t want to continue and this will not disadvantage you or the care that you receive in the future in any way.

Will anyone else see my information or know my results?
All your answers and results are confidential and at no point will we reveal any of your answers to Corrective Services in ACT or to any other persons outside of this research project. No one’s names will be mentioned in any reports or papers that we might publish from this study after the survey. It will be anonymous.

Will there be a benefit for me?
There will be no direct benefit to you from your participation in the study although it may have an indirect benefit. The study will help us to develop potential harm reduction measures at AMC.

What are the potential risks of doing the survey?
All answers are confidential but if you feel distressed at any time you can stop the interview or skip a question. Simply let the interviewer know and they will move on to the next question or stop the interview. This will not affect your relationship or the health care and support you receive from AMC. Another risk is that if you disclose illegal activities you have been involved in the past for which you have not been tried or convicted, we are required to report this information by law.

How do I get more information about this study?
If you would like to know more about the study or if you have any additional questions later, Professor Michael Levy will be happy to answer them.

Name

Phone

Email

What if I have a complaint about the research?
Should you have any problems or queries about the way in which the study was conducted, and you do not feel comfortable contacting the study staff, you can contact the ACT Health ethics secretariat. Any complaint you make will be treated in confidence and investigated, and you will be informed of the outcome.

What to do now?
The next step is for you to decide what you would like to do. You can ask any questions about the study or you can talk to one of the researchers. You can then sign the consent form if you wish to participate.
4.21.2 Appendix 2: Survey and Interview Tool

Incident Hepatitis C cases detected through a custodial HCV treatment program study

Thanks for agreeing to participating in this survey and interview process. The following survey is being conducted to collect information about risk behaviours and exposure to Hepatitis C infection in prison. We would like to better understand the risk factors associated with transmission of this viral infection. Questions about your background information; date of birth, country of birth, followed by possible exposures, questions about tattooing, body piercing, drug use and sexual practices. All questions will only be in relation to your current period of incarceration. In particular the time period between last negative Hepatitis C test and first positive test for the particular time period stated for each interviewee. This will be followed by unstructured interview, the whole process may take up to that 1½ hours.

This survey is anonymous and your responses are confidential. Your honest response to questions is important. You have the ability to refuse answering any question and to cease the interview at any stage.

Interviewer: Please ensure the following have been completed before interview

☐ Explained the study or given participant the opportunity to read the information sheet.

☐ Participant knows identity and personal details will remain completely confidential and anonymous at all times.

☐ Have you obtained a signed consent form participant? If so please attach to survey.
CHAPTER 4 | OUTBREAK

Background Information

<table>
<thead>
<tr>
<th>Study ID Number</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Birth</td>
<td>D</td>
</tr>
<tr>
<td>Current Age (in years)</td>
<td></td>
</tr>
</tbody>
</table>

1. How many times has the detainee been in a juvenile detention centre? __________
   Don’t Know 9

2. How many times has the detainee been in a Adult detention centre? __________
   Don’t Know 9

3. Are you Aboriginal or Torres Strait Islander? Yes 1
   No 2
   both 3
   Neither 4
   Don’t Know 9

4. What country were you born in? ______________________

5. Would you describe yourself as: Straight 1
   Gay/Lesbian 2
   Bisexual 3
6. How many years of schooling have you completed? [Interviewer: for answers like “intermediate school”, or “junior high”, ask the number of the years and tick the appropriate box]

- No formal education
- 0 years
- 1-6 years at school
- 1
- 7-10 years at school
- 2
- 11-12 years at school
- 3
- Tertiary Education
- 4

7. Have you ever suffered from any mental health problem such as depression, anxiety, bipolar disorder, psychosis or schizophrenia?

- Yes
- 1
- No
- 2
- Don’t know
- 9

8. In which area(s) of this prison have you been housed during your current stay? (please name all and period of time spent in each specifying month and year and number of people housed in your cell)

<table>
<thead>
<tr>
<th>Name of housing block</th>
<th>Block Capacity</th>
<th>Time period</th>
<th>Number of cell mates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
In the next section I will be asking questions about possible exposures or risk behaviours such as Piercing, tattooing, drugs, Injecting drug use, sexual practices or other activities that could have caused blood to blood contact during your current time in prison. You can decline to answer questions at anytime or cease the interview. We ask that you not disclose information that might incriminate you.

**Time frame**

Please only give answers in relation to your current stay in prison between the time frame of last negative HCV test _____________  to first positive HCV test _____________
Piercing

9. Have you ever had any part of your body pierced during your current stay in prison?  
   Yes (Go to 23)  
   No (Go to 25)  
   Don’t Recall (Go to 25)  

[Interviewer: must mention that piercing includes ear piercing as well]

10. How many times have you had your body pierced? ______________

[Interviewer: include piercings that do not currently have a ring in them]  
[Interviewer: if only ears are pierced, write the total number of the piercing in both ears, i.e. 1 piercing each ear = 2 in total]

11. The following questions are to find out more detail about 1) date of piercing 2) description of the equipment used 3) if the equipment was used by others.

<table>
<thead>
<tr>
<th>Piercing No.</th>
<th>Date of piercing</th>
<th>Type of piercing (where on your body) and Description of equipment used</th>
<th>Was the equipment used by other inmates prior to you?</th>
<th>Pierced by</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>
12. Have you had a tattoo since you last negative HCV test?  
Yes (Go to Q4)  
No (Go to Q7)  
Don’t Recall (Go to Q7)

13. How many different times have you been tattooed since your last negative HCV result?

__________________  

[Interviewer: Consider each session of tattooing as a separate tattoo]  
[Interviewer: Include tattoos that have been removed]

14. The following questions are to find out more detail about 1) date of the tattoo 2) description of the equipment used 3) if the equipment was used by others.

<table>
<thead>
<tr>
<th>Tattoo No.</th>
<th>Date of tattoo</th>
<th>Description of equipment used (including ink)</th>
<th>How many were tattooed with the same device or ink?</th>
<th>Tattooed by</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td>1 2 3-5 6-10 11-20 more than 20 don’t know</td>
<td>Self cell mate other Inmate</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td>1 2 3-5 6-10 11-20 more than 20 don’t know</td>
<td>Self cell mate other Inmate</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td></td>
<td>1 2 3-5 6-10 11-20 more than 20 don’t know</td>
<td>Self cell mate other Inmate</td>
</tr>
<tr>
<td>4</td>
<td></td>
<td></td>
<td>1 2 3-5 6-10 11-20 more than 20 don’t know</td>
<td>Self cell mate other Inmate</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td>1 2 3-5 6-10 11-20 more than 20 don’t know</td>
<td>Self cell mate other Inmate</td>
</tr>
</tbody>
</table>
Infectious Diseases among Marginalised Populations

Injecting drug use and drugs

This next section is to record the general pattern of IDU since the last HCV negative and first positive

### Question 15
Between your last negative and your first positive HCV result have you injected drugs?
- Yes (go to Q23) [1]
- No (go to Q42) [2]
- Don’t recall (go to Q42) [9]

**Interviewer:** this includes injecting either self or someone else

### Question 16
If yes, how often have you injected?
- Less than monthly [1]
- Monthly or more often [2]
- Weekly or more often [3]
- Daily [4]
- More than once a day [5]
- Don’t recall [9]

**Interviewer:** check that “daily” and “more than once a day” are distinguished

### Question 17
During current imprisonment this time compared to the rest of your life, has your injecting frequency been...
- Stable [1]
- Increasing [2]
- Decreasing [3]
- Don’t recall [9]

**Interviewer:** assess the lifetime pattern of injecting and code yes if frequency, sharing behaviour or drug of choice have changed
18. Which drug/s did you injected during your last negative and first positive HCV result? 

<table>
<thead>
<tr>
<th>Option</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heroin</td>
<td>1</td>
</tr>
<tr>
<td>Buprenorphine (Subutex)</td>
<td>2</td>
</tr>
<tr>
<td>Ice (crystal meth/amphetamine)</td>
<td>3</td>
</tr>
<tr>
<td>GHB/GBH/ liquid e/fantasy</td>
<td>4</td>
</tr>
<tr>
<td>Cocaine/ Coke</td>
<td>5</td>
</tr>
<tr>
<td>Benzodiazepines/Benzos</td>
<td>6</td>
</tr>
<tr>
<td>Anabolic/Steroids</td>
<td>7</td>
</tr>
<tr>
<td>Other opiates/codeine/pethidine/opium/omnopon</td>
<td>8</td>
</tr>
<tr>
<td>Hallucinogens/LSD/ Acid/Magic/Mushies/Daitura</td>
<td>9</td>
</tr>
<tr>
<td>Ecstasy/ E/MDA/MDMA</td>
<td>10</td>
</tr>
<tr>
<td>Ketamine/Special K</td>
<td>11</td>
</tr>
<tr>
<td>Oxycodone (e.g. Oxycontin, Endone)</td>
<td>12</td>
</tr>
<tr>
<td>Methadone</td>
<td>13</td>
</tr>
<tr>
<td>Morphine (e.g. MS Contin)</td>
<td>14</td>
</tr>
<tr>
<td>Speed/base (or other methamphetamine)</td>
<td>15</td>
</tr>
<tr>
<td>Other (please specify)</td>
<td>16</td>
</tr>
</tbody>
</table>
19. Which one of these was your injecting drug of choice between last negative and first positive HCV result? [Interviewer: the most commonly injected drug]

20. During this time has someone else ever injected you with drugs? (Given you a hit?)
   - Yes
   - No
   - Don’t recall

21. Between last negative and first positive HCV test result did you use injecting equipment that was not new and sterile?
   - Yes
   - No
   - Don’t recall

22. Between last negative and first positive HCV test result have you ever shared any part of the injecting equipment or used any injecting equipment after someone else had used it? That includes the needle, syringe, spoon, swabs, filters, mix or tourniquet.
   - Yes (Go to Q30)
   - No (Go to Q37)
   - Don’t recall (Go to Q37)

23. Between last negative and first positive HCV test result how often did you share any part of the injecting equipment, or use equipment after someone else?
   - Less than monthly
   - Monthly or more often
   - Weekly or more often
   - Daily
24. Between last negative and first positive HCV test result which equipment did you share?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
<th>Don’t know</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Needle and syringe</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>b. Spoon</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>c. Mix</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>d. Mix in the spoon</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>e. Mix in the syringe</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>f. Mix in other receptacle</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>g. Filter</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>h. Swab</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>i. Tourniquet</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>j. Rinse water</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

25. Between last negative and first positive HCV test result how many times have you used the same needle and syringe after someone else used it.

| None | 1 | 1 |
| 1 time | 2 | 2 |
| 2 times | 3 | 3 |
| 3 to 5 times | 4 | 4 |
| 6 to 10 times | 5 | 5 |
| 11 to 20 times | 6 | 6 |
| More than 20 times | 7 | 7 |
| Don’t know | 99 | 99 |
26. Between last negative and first positive HCV test result how many people did you share injecting equipment with, both before and after injecting?

<table>
<thead>
<tr>
<th>Number of People</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>1</td>
</tr>
<tr>
<td>One</td>
<td>2</td>
</tr>
<tr>
<td>Two</td>
<td>3</td>
</tr>
<tr>
<td>3-5</td>
<td>4</td>
</tr>
<tr>
<td>6-10</td>
<td>5</td>
</tr>
<tr>
<td>11-20</td>
<td>6</td>
</tr>
<tr>
<td>More than 20</td>
<td>7</td>
</tr>
<tr>
<td>Don’t recall</td>
<td>9</td>
</tr>
</tbody>
</table>

27. Between last negative and first positive HCV test result did you share injecting equipment with someone known to have hepatitis C?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
</tr>
<tr>
<td>Don’t recall</td>
<td>9</td>
</tr>
</tbody>
</table>

28. Between last negative and first positive HCV test result did you attempt to bleach or Fincol the shared equipment in any way?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, always (Go to Q35)</td>
<td>1</td>
</tr>
<tr>
<td>Yes, sometimes (Go to Q35)</td>
<td>2</td>
</tr>
<tr>
<td>Never (Go to Q36)</td>
<td>3</td>
</tr>
<tr>
<td>Don’t recall (Go to Q36)</td>
<td>9</td>
</tr>
</tbody>
</table>

29. Did you bleach or Fincol the shared equipment properly?

[Interviewer Explain that ‘properly’ means 2 flushes of water, 2 flushes of bleach or Fincol, and a 30 second soak of the equipment in bleach or Fincol, and then 2 flushes of water]

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, always</td>
<td>1</td>
</tr>
<tr>
<td>Yes, sometimes</td>
<td>2</td>
</tr>
<tr>
<td>Never</td>
<td>3</td>
</tr>
<tr>
<td>Don’t recall</td>
<td>9</td>
</tr>
</tbody>
</table>
### 30. Between last negative and first positive HCV test result did someone else help you inject?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, always</td>
<td>1</td>
</tr>
<tr>
<td>Yes, sometimes</td>
<td>2</td>
</tr>
<tr>
<td>Never</td>
<td>3</td>
</tr>
<tr>
<td>Don’t recall</td>
<td>9</td>
</tr>
</tbody>
</table>

*Interviewer: do not include medical injections*

### 31. Between last negative and first positive HCV test result did you help someone else to inject drugs?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
</tr>
<tr>
<td>Don’t recall</td>
<td>9</td>
</tr>
</tbody>
</table>

*Interviewer: do not include medical injections*

### 32. If you were using on the outside before this current stay in prison did you collect clean fits to use from a needle and syringe exchange?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Never</td>
<td>0</td>
</tr>
<tr>
<td>Some times</td>
<td>1</td>
</tr>
<tr>
<td>Most times I needed</td>
<td>2</td>
</tr>
<tr>
<td>Every time I needed</td>
<td>3</td>
</tr>
</tbody>
</table>

Other exposures

In relation to Last negative and first positive HCV result during current prison stay

### 33. Have you had sexual contact with another inmate during last negative and first positive HCV result?

<table>
<thead>
<tr>
<th>Response</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes (go to 55)</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
</tr>
<tr>
<td>Don’t recall</td>
<td>9</td>
</tr>
</tbody>
</table>

*Interviewer: if had anal sex, not including oral sex*
34. Did you use a condom?  

- Never 1  
- Sometimes 2  
- Always 9  
- Don’t recall 9

35. Have you inserted a penile implant between last negative and first positive HCV result?  

- Yes 1  
- No 2  
- Don’t recall 9

36. Between last negative and first positive HCV result were you in a fight where blood from another person may have come in contact with your mouth, eyes or an open wound?  

- Yes 1  
- No 2  
- Don’t Recall 9

37. Between last negative and first positive HCV result were you ever stabbed?  

- Yes 1  
- No 2  
- Don’t recall 9

38. Between last negative and first positive HCV result did you have a haircut where your skin or scalp was cut?  

- Yes 1  
- No 2  
- Don’t recall 9
### Chapter 4: Outbreak

#### 39. Between last negative and first positive HCV result did you ever share the same razor as someone else?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
</tr>
<tr>
<td>Don’t recall</td>
<td>9</td>
</tr>
</tbody>
</table>

#### 40. Between last negative and first positive HCV result have you had someone else’s blood on you during sport? *(e.g. during a football game)*

<table>
<thead>
<tr>
<th>Answer</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
</tr>
<tr>
<td>Don’t recall</td>
<td>9</td>
</tr>
</tbody>
</table>

#### 41. Between last negative and first positive HCV result have you been accidentally pricked by a needle? *(e.g. needle stick injury)*

<table>
<thead>
<tr>
<th>Answer</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
</tr>
<tr>
<td>Don’t recall</td>
<td>9</td>
</tr>
</tbody>
</table>

*Interviewer: do not include IDU*

#### 42. Between last negative and first positive HCV result have you ever shared the same toothbrush as someone else?

<table>
<thead>
<tr>
<th>Answer</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>2</td>
</tr>
<tr>
<td>Don’t recall</td>
<td>9</td>
</tr>
</tbody>
</table>

The end

We have come to the end of the survey, your input into this study has been important. Thank you for your participation!
5 Epidemiological Project

Impact of Australia's HPV vaccination program on the prevalence of HPV genotypes among Aboriginal and Torres Strait Islander women
### 5.1 Abbreviation list

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCHS</td>
<td>Aboriginal Community Controlled Health Service</td>
</tr>
<tr>
<td>ARIA</td>
<td>Area Remoteness Index of Australia</td>
</tr>
<tr>
<td>CEO</td>
<td>Chief executive officer</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence intervals</td>
</tr>
<tr>
<td>CIN</td>
<td>Cervical intraepithelial neoplasia</td>
</tr>
<tr>
<td>CIN1</td>
<td>Cervical intraepithelial neoplasia grade one</td>
</tr>
<tr>
<td>CIN2</td>
<td>Cervical intraepithelial neoplasia grade two</td>
</tr>
<tr>
<td>CIN3</td>
<td>Cervical intraepithelial neoplasia grade three</td>
</tr>
<tr>
<td>DNA</td>
<td>Deoxyribonucleic acid</td>
</tr>
<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>HPV</td>
<td>Human papillomavirus</td>
</tr>
<tr>
<td>LBC</td>
<td>Liquid based cytology</td>
</tr>
<tr>
<td>MSM</td>
<td>Men who have sex with men</td>
</tr>
<tr>
<td>NHMD</td>
<td>National Hospital Morbidity Database</td>
</tr>
<tr>
<td>NHVPR</td>
<td>National human papillomavirus vaccine program register</td>
</tr>
<tr>
<td>Pap test</td>
<td>Papanicolaou smear or cervical screening</td>
</tr>
<tr>
<td>PCR</td>
<td>Polymerase chain reaction</td>
</tr>
<tr>
<td>VE</td>
<td>Vaccine effectiveness</td>
</tr>
<tr>
<td>VIP</td>
<td>Vaccine impact in the population (post-vaccine genotype prevalence study)</td>
</tr>
<tr>
<td>VIP-I</td>
<td>Vaccine impact in the Indigenous population</td>
</tr>
<tr>
<td>WHINURS</td>
<td>Women’s Human papillomavirus Indigenous Non-indigenous Urban Rural Study (pre-vaccine genotype prevalence study)</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
</tbody>
</table>
5.2 Prologue

5.2.1 My role
On commencement at the Kirby Institute I had a number of discussions with my field supervisors about potential projects to meet the requirements of the MAE epidemiological project. There were a few possible epidemiological studies mentioned. I steered towards a national human papillomavirus (HPV) research project to evaluate the effectiveness of the HPV vaccine on circulating genotypes among Indigenous women aged 18 – 26 years in Australia, namely the ‘Vaccine impact in the Indigenous population’ (VIP-I) study.

This project was attractive to me for a number of reasons: the focus on Indigenous women in Australia and particularly the post vaccine cohort of 18 – 26 year olds; the ability to engage Aboriginal Community Controlled Health Service (ACCHS) and the opportunity to work with and learn from experienced investigators who have been instrumental in sexual and reproductive medicine and research in Australia.

VIP-I Investigators include; John Kaldor (Chief investigator, The Kirby Institute, UNSW), Skye McGregor (The Kirby Institute, UNSW), Bette Liu (The Kirby Institute & School of Public Health, UNSW), Sepehr Tabrizi (Royal Hospital Women, Melbourne), Suzanne Garland (Royal Hospital Women, Melbourne), Julia Brotherton (Royal Hospital Women, Melbourne and Victorian Cytology Service, Melbourne), Rachel Skinner (University of Sydney) and Mary Stewart (Family Planning Australia)

When I was brought onto this project as an investigator a funding application had been submitted. Funding was approved by the Commonwealth Department of Health and Aging (now known as the Department of Health) in May 2013 through to December 2014. The timeline, although tight, was a good fit for the MAE duration. However, sample collection is still currently (November 2014) underway and only preliminary findings are provided in this chapter.

My role as field coordinator was predominantly to engage services, identify a site coordinator, sign services onto the study and ensure services understood and followed study procedures. I negotiated with VIP-I site coordinators to develop sample procedures to fit each service’s internal process and became the main point of contact for most sites. From the beginning of my involvement on the project I was tasked with coordinating meetings with investigators and sites, and ensuring investigators were up to date. Additionally, I worked closely with Ms Skye McGregor (Program manager, Public Health Interventions Research Group, The Kirby Institute) in developing study documents for ethics applications including the protocol, questionnaire (appendix 1), patient information and consent forms (appendix 2). Skye prepared and
submitted six out of seven ethics applications and I applied for approval through the ANU Human Research Ethics Committee. I worked with Dr Julia Brotherton (Medical Director, National HPV Vaccination Program Register Victorian Cytology Service) to understand the data extraction approval process for the HPV vaccine registry. I filled out and circulated the National HPV vaccine program register (NHVPR) data request form to other investigators for feedback. I then submitted the request to gain access to VIP-I study participant vaccination status and dose coverage.

We adapted the questionnaire for the ‘Vaccine impact in the population’ study (VIP) to be culturally sensitive, an improved design based on feedback from use in the VIP study. I did this in consultation with other investigators, Dr Bette Lui (Head of Research Assets, The Sax Institute), Dr Julia Brotherton, Associate Professor Rachael Skinner (Paediatrics & Child Health, Sydney University and Children's Hospital, Westmead) and feedback from service providers.

Once sites had signed service agreements I organised to conduct training for clinical staff at sites, including VIP-I procedures. I developed a VIP-I training manual (appendix 3) along with a PowerPoint presentation. The training was to ensure sites were aware of all procedures and we had discussions with coordinators and staff about sample storage and transport processes. Training sessions included a HPV update covering HPV infection and disease, epidemiology of HPV, particularly within the Indigenous population, as well as the vaccine and the vaccination program. I provided the HPV update when senior investigators were not available. I provided training at three out of five sites (I did not conduct training at other sites due to MAE commitments these were undertaken by Skye McGregor).

I met with Sepehr Tabrizi (Senior Research Scientist and Associate Professor) and Samuel Phillips (Laboratory assistant) at the Molecular Microbiology Laboratory, The Department of Microbiology and Infectious Diseases at the Royal Women’s Hospital in Melbourne. This Laboratory is a part of the HPV WHO reference laboratory network. I was taken through the laboratory procedures for the VIP-I study and the aliquot procedure. Aliquots were required if a site was using liquid based cytology (LBC) rather than conventional methods for Papanicolaou smear testing (Pap test). Some sites had indicated they were using liquid based cytology. I was taught the aliquot procedure to then train sites to collect samples from the LBC solution without having to collect an extra Pap sample from patients. Spending just a day in the laboratory trying to understand the VIP-I study processes so I could talk to services about them gave me a new appreciation for the time that just one sample takes to process.
In 2014 I had the opportunity to attend the International HPV conference. I presented the VIP-I project methodology and Australia’s present and future approach to evaluating the impact of the HPV vaccine among the Indigenous population. I presented during a morning satellite session organised by the International Indigenous HPV alliance (appendix 4. HPV conference powerpoint presentation). I have also been asked to present at Preventing Cervical Cancer 2015: Integrating screening and vaccination conference in February 2015 and I have participated in a cancer institute Indigenous specific health promotion campaign in which I was interviewed about the importance of screening after vaccination. This is also a print campaign which will be sent to all Aboriginal Community Controlled Health Organisations in NSW.

Although this project is not complete at time of thesis submission, the comprehensive nature of this study has allowed me to meet MAE competencies of designing and conducting an epidemiological study.

5.2.2 Lessons Learnt
This was the first ethics application process I was involved in and I was fortunate that Skye McGregor was leading the ethics process. Seeing the process of submitting an ethics application by someone experienced at the beginning of the MAE led to a quicker, less arduous process when time came to submit ethics applications for other MAE projects. After VIP-I I had a greater understanding of confidentiality of participants and study sites; understanding of ethics implications of collecting biological samples; consent required from participants and collection of samples; and laboratory methods. I was also exposed to the importance of algorithms of care and follow up required for studies including testing of biological samples, or more so disease outcomes, as a result of testing that required clinical action.

Prior to this study I had not engaged with laboratories. During VIP-I I had the opportunity to observe laboratory processes, methods required to store and test samples to ensure their integrity at the WHO HPV reference laboratory in Melbourne. This experience has allowed me to appreciate the important role laboratories play in epidemiological investigations.

I had planned to apply vaccine effectiveness calculations, and although for this preliminary analysis I was unable to apply this knowledge, it was a good lesson and brought more clarity to exercises undertaken in classes.

5.2.3 Outcomes and potential public health impact
VIP-I will demonstrate the effectiveness of the vaccine at a population level among Indigenous women who have a higher incidence and mortality rate of cervical cancer compared to non-Indigenous women\(^{(1)}\). The vaccine has the ability to protect against the two most common high risk genotypes known to lead to cervical cell abnormalities and in some cases progress to
cervical cancer\textsuperscript{12, 31}. Understanding the impact of the vaccine targeted HPV types within the Indigenous and non-Indigenous population is an important indicator of; 1) effectiveness of the vaccine program within the population; 2) vaccine coverage and 3) disease outcomes. Accurate estimates provide a better understanding of what is actually happening within the population and lead to more precise modelling projections for Indigenous and non-Indigenous populations evidencing future resource allocation, program focus and gaps.

This study will provide the first Indigenous specific genotype prevalence comparisons between pre and post-vaccine populations. Additionally, comparisons between post-vaccine vaccinated and unvaccinated women will provide vaccine effectiveness among the Indigenous population. This will allow for comparison to recent calculated vaccine effectiveness among non-Indigenous women\textsuperscript{41}. Nationally findings will contribute towards future HPV vaccine program planning and evaluation, policy and program development, ongoing surveillance initiatives and could provide some insight for the national cervical screening program.

5.2.4 Acknowledgments
It was fantastic to have an introduction to working in a large research team through the VIP-I project and investigators, I have gained many skills from observing and working with such experienced investigators. I would like to acknowledge all VIP-I investigators who have provided me with support throughout the process, in particular thank you to John Kaldor, Skye McGregor, Julia Brotherton, Sepehr Tabrizi, Suzanne Garland, Bette Liu and Sam Phillips. Additionally, thank you to all participating study sites and coordinators.
5.3 Abstract

5.3.1 Background
The National Human Papilloma Virus (HPV) vaccine program was implemented in 2007 using the quadrivalent vaccine which provides coverage for HPV genotypes 6, 11, 16 and 18. As a result of the vaccine implementation through school and catch-up programs there have been documented reductions in genotype prevalence and disease outcome associated with HPV. However no studies have had a sufficient sample to determine if reductions in genotype prevalence are equivalent within the Indigenous population. The ‘Vaccine impact in the Indigenous population’ (VIP-I) study aims to evaluate the effectiveness of the vaccine program on circulating HPV genotypes among Indigenous women.

5.3.2 Method
VIP-I is a repeat cross sectional genotype prevalence survey targeted at recruiting Indigenous women aged 18-26 years attending participating sites. Samples were collected during a routine Pap screen and tested for HPV DNA and genotype. A short demographic and behavioural survey was administered and additional consent obtained to access participant information from the National HPV vaccination program registry (NHVPR). Using Indigenous specific data from a previous pre-vaccine study, genotype prevalence was compared between pre-vaccine (2005-2007) and post-vaccine (2013-2014) (VIP-I) cohorts.

5.3.3 Results
In this preliminary analysis data from 31 participants from one VIP-I study site were included. The prevalence of HPV DNA among Indigenous women aged 18 – 26 years significantly decreased from 57.7% among pre-vaccine to 29.3% (p=0.006) post-vaccine. There was also a significant decrease in vaccine targeted HPV types 6, 11, 16 and 18 from 25% pre-vaccine compared to 2.4% post-vaccine era (p<0.003). Of post-vaccine women, 92.7% had either full or partial self reported vaccination.

5.3.4 Conclusion
A decrease in HPV vaccine targeted genotypes 16 and 18 in this preliminary analysis indicates promising results for the wider VIP-I study on conclusion.
5.4 Introduction

5.4.1 Epidemiology of HPV
HPV is a sexually transmissible infection. Transmission occurs through skin to skin contact or mucosa to mucosa contact with an infected person. Most people will be infected with one or more HPV genotypes within 12 months of first sexual intercourse and throughout their sexual lifetime\(^5\).

There are around 150 HPV types of which 40 are mucosal/genital HPV genotypes categorised as high risk or low risk\(^6\). High risk genotypes like 16 and 18 can cause low grade cervical abnormalities, cancer precursors and anogenital cancers. Low risk genotypes such as 6 and 11 cause low grade cervical abnormalities, genital warts and laryngeal papillomas\(^7\). Mediated immune cellular response will clear most high risk genotypes within 9.8 months and low risk genotypes in 4.3 months of acquisition\(^8\). Additionally, cellular abnormalities as a result of HPV can regress after clearance of infection\(^1\). The persistence of high risk genotypes may explain the consistently higher prevalence of the most common genotypes 16 and 18 in epidemiological studies internationally.

The cause-effect relationship between HPV and cervical cancer is strong. HPV DNA is present in 99.7% of cervical cancers worldwide\(^2\)\(^3\). HPV16 and HPV18 are present in 70% of cervical cancers and 50% of cervical intraepithelial neoplasia grade 3 (CIN3)\(^4\). HPV6 and HPV11 account for >90% of genital warts\(^7\), leading to the assumption that a vaccine for HPV6 and HPV11 could almost eliminate new cases of genital warts.

5.4.2 The national cervical screening program
Cervical screening programs can detect cervical abnormalities early, monitor changes in cytology and lead to appropriate and timely treatment. Cervical screening uses a Papanicolaou smear, known as the “Pap test”. A Pap test involves the scraping of cells from the transformation zone. The transformation zone is the area where squamous cells from the cervix and the glandular cells from the uterus meet. The cells collected by a brush during a Pap test are transferred onto a slide. A film is then fixed to the slide and the slide is sent to a pathology laboratory for assessment of cells under a microscope for abnormalities\(^1\).

In Australia, cervical screening from the 1960s onwards was ad hoc until 1991, when Australia established an organised approach to screening 18 – 69 year old women. This systematic approach included standardisation of: the conventional Pap smear process, interpretation of cytology, reporting terminology and laboratory accreditation. Pap smears were, and still are,
recommended for women every two years from 18 (or 1 - 2 years after first sexual intercourse) to 69 years of age. Cervical screening (Pap test) registers were legislated in each state and territory to monitor and evaluate the program. Benefits of this approach are evident from 1991 onwards with declines in incidence and mortality rates as a result of the cervical screening program among Australian women\(^{(1)}\).

### 5.4.3 HPV Vaccine

In Australia, since mid-2006 two HPV vaccines have been commercially available. A bivalent vaccine (Cervarix\textsuperscript{®} GlaxoSmithKline Inc.), which is a three dose schedule administered at 0, 1 and 6 months. Cervarix provides coverage against HPV genotypes 16 and 18, the most common high risk genotypes found in 70% of cervical cancers worldwide and in Australia\(^{(9)}\). Currently used (and subsidised) in the national HPV vaccine program is the quadrivalent vaccine (Gardasil\textsuperscript{®} CSL Biotherapies), also a three dose schedule administered at 0, 2 and 6 months. Gardasil provides protection against the above mentioned high risk HPV genotypes 16 and 18, it also provides protection against low risk HPV genotypes 6 and 11 which cause 90% of genital warts\(^{(7)}\).

### 5.4.4 The National HPV Vaccine Program

The Australian government implemented a national HPV vaccine program in 2007; the first government to fully fund an HPV vaccine program worldwide\(^{(10)}\). The program included an ongoing school based program targeting 12 - 13 year old girls (girls in first year of high school) and from 2007-2009 a catch up program including 14 - 17 year old girls in school. A community based program for 12-26 year old girls and women attending primary health clinics and general practitioners (GPs) also ran from 2007-2009\(^{(10)}\). In 2013 this program was extended to include boys 12 - 15 years old in the school based program with an ongoing program of 12 - 13 year old boys from 2014 onwards. All eligible people receiving the vaccine as a part of the national program receive the vaccine free of charge. People not eligible or those who miss the school based program doses will need to attend GP or primary health clinics and pay the price of $450\(^{(11)}\) plus the cost of attending the clinic to receive the vaccine.
Figure 1. Australian national HPV vaccination program rollout timeline

5.4.5 National HPV vaccine program registry
In 2007 the federal parliament amended the National Health Act to establish a National HPV vaccine program registry (NHVPR) to support the national vaccine program. The registry needs doctors (namely GPs) or vaccine administrators to submit dose information to the registry. It is compulsory for school-based programs to provide vaccine details to the registry in every state and territory of Australia but not compulsory for GPs. During the community-based catch-up program from 2007-2009 a small monetary incentive was available to GPs to encourage completion of records in the registry, however this is no longer available\(^{(12)}\).

In order to understand the current environment post vaccine program implementation in Australia, and to meet MAE requirements of producing a literature review, a focused literature review was conducted for this project as follows.
5.5 Focused literature review

Question

What impact has the government funded HPV vaccination program had in the Australian population since implementation in 2007?

Method

A literature search was carried out in Pub Med, Medline and Web of Science

Search terms

In all searches

- HPV or Human papillomavirus
- Impact or evaluation or decline or decrease

Search terms used for different outcomes:

- Genital warts
- Cervical abnormalities
- Cervical cancer
- Prevalence

Limits used for some disease outcomes:

- Australia
- 2007-current

Papers published in 2014 which are included in the review were received from investigators circulating new publications via email to VIP-I investigators.

5.5.1 Findings of literature review

In Australia, since the implementation of the vaccine program, 11 population based studies have been undertaken to evaluate the effect of the HPV vaccine program on genital warts, cervical abnormalities, and HPV genotype prevalence. These eleven studies have been reviewed here by different disease outcome.
5.5.2 Genital warts

Genital warts have an incubation period of 3 weeks to 8 months with an average incubation period of 2-8 months\(^2\). Due to short disease progression, evaluating the effect of the quadrivalent vaccine on the outcome of genital warts commenced early after program implementation. Six population based studies on this outcome were identified for review\(^{11, 13-17}\); these publications include retrospective clinical data from a number of different sources to compare trends over time and binary comparisons of pre and post vaccine populations. All study samples have included both females and males, even before the inclusion of boys in the school based program.

One year into the vaccine program, the first impact study documented a rapid decline (25%) in genital wart diagnosis among vaccine eligible women (women under 28 years of age) attending a large metropolitan sexual health clinic in Melbourne\(^16\). This study also demonstrated early signs of herd immunity among heterosexual men less than 28 years of age. This modest decline was not seen among men who have sex with men (MSM)\(^16\). A subsequent follow up study at the same clinic compared pre vaccine (2004-2007) and post vaccine (2007-2011) cohorts using identical methodology\(^13\). On implementation of the vaccine program, genital wart diagnosis among women less than 21 years of age declined from 18.6% to 1.9% in 2010-2011, a reduction of nearly 90%\(^11\). Declines were also seen in heterosexual men less than 21 years of age and 21 – 29 year old women and men but not in women or men over 30 years\(^11\).

These studies report different age ranges, Fairly et al 2009\(^16\) reporting age groups as women under 28 years, women 28 years and over, with no age breakdown of heterosexual men or MSM, though this was an early study\(^16\). Read et al 2011 reported age ranges of <21, 21-29 and ≥30 years for both women and men who have sex with women\(^11\). This age range allowed analysis based on vaccine program eligibility. Those aged <21 years of age would have been eligible for the school based vaccination program, those aged 21 – 29 years would have been eligible for the community based program, while those over 30 years of age would not have been eligible for the free vaccine program in 2007. To compare to a non-vaccinated group, MSM and female non-residents were reported, but not by age group. Melbourne sexual health clinic provides services for the community at large with a focus on those from at risk populations such as MSM and lower socioeconomic backgrounds. This study is an indication of a well serviced metropolitan community in Victoria. This may not be comparable to rural and remote areas of the Australian population outside of metropolitan Victoria, in addition, higher vaccine coverage has been reported in Victoria compared to other states and territories\(^23\).
The following paragraph deals with a number of studies that report on data from a sentinel surveillance program. In 2004, a sentinel surveillance system was established to automatically report genital wart diagnosis, demographic and behavioural data from patient information systems of eight sexual health clinics across Australia\(^\text{15}\). From 2004 - 2009 at surveillance clinics, 9% (9867/112083) of all patients had a first diagnosis of genital warts. Genital wart diagnoses were stable from 2004 - 2007 in both men and women, but post-vaccine there were significant declines among Australian resident women and heterosexual men aged under 26 years. No significant changes were seen among those without access to the free vaccine program; namely non-resident women, women over 26 years, heterosexual men over 26 years or MSM. This study compared Australian women residents less than 26 years old (a vaccine eligible group) to a vaccine naive group, Australian non-residents. In the absence of vaccination status, comparing vaccine eligible and non-eligible groups would appear to allow meaningful comparisons leading to the assumption of vaccine program effectiveness. Ali et al 2013 published a trend analysis of genital warts surveillance network data adding an extra two post-vaccine years\(^\text{13}\). From 2004 – 2011 there was a 9% prevalence among new patients attending the clinics. This study observed dramatic declines in genital warts prevalence in both women (92.6%, p<0.001) and heterosexual men (81.8%, p<0.001) under 21 years of age from 2007 to 2011.

To rule out potential influence of decreased risk behaviour during the HPV post vaccine period this study reported chlamydia (also a sexually transmissible infection) diagnosis at study sites\(^\text{13}\). Over the same time period of HPV decline, there were increases in chlamydia diagnosis among women, heterosexual men and MSM under 21 years of age. This change indicates that HPV decline post-vaccine was not due to a decrease in risk behaviour among this age group. Genital warts are not a notifiable disease in Australia therefore sentinel surveillance sites from around Australia provide a good source of ongoing impact data.

Other data sources used to monitor vaccine program impact on clinical burden of genital warts included large private and public hospital databases. Ali et al 2013\(^{14}\) assessed vaccine program effectiveness through trends in hospital treatment of warts. This study used the publicly available Medicare scheme database, where data were extracted if in-patients were itemised as undergoing anaesthetic for genital or anal wart removal. Analysis included procedures conducted at all private hospitals in Australia. In-patient treatment of vulval or vaginal warts among women aged 15 -24 years declined by 85.3% during the vaccine period from 2007 to 2011. Between 2000 to 2007 in-patient treatments numbers for penile warts increased by 200% (17 - 51 treatments) among 15 - 24 year old men. After the vaccine implementation targeting women in 2007, in-patient penile wart treatment decreased by 70.6% among men.
Likewise, treatment for anal warts among men aged 15 - 24 years was increasing during the pre-vaccine period, but decreased by 49.1% in the post-vaccine period suggesting herd immunity among young men.

The most recent study\(^{[17]}\) included all private and public hospital admissions with genital warts diagnosis (primary or contributing diagnosis) from the National Hospital Morbidity Database (NHMD). The NHMD is a comprehensive national database that represents most private and public hospital admissions and diagnosis. This study had a large sample size of 39 350 men and women and assessed rate of admissions. As found in above mentioned studies, declines in genital warts diagnosis were seen at admission; of note this study provided the first indication of impact within the Indigenous population. Comparing 2006-2007 to 2010-2011, declines in genital warts diagnosis at admission were similar between non-Indigenous (76.1%, CI 71.6%-79.9%) and Indigenous (86.7%, CI 76.0%-92.7%) women. Indigenous men were not included in the analysis due to small sample size. Additionally, two jurisdictions were excluded from the subset analysis due to low completion rate of Indigenous status field on medical records.

No studies evaluating vaccine impact on anogenital warts have linked data with the NHVPR to confirm vaccine status of participants. Two studies\(^{[11, 15]}\) obtained self-reported vaccine status at sexual health clinics, however these were conducted in large metropolitan clinics and vaccine coverage may differ by area of remoteness. Most investigators have removed the need for vaccine confirmation by comparing vaccine eligible and non-eligible populations, collecting self-reported vaccination, referring to vaccine coverage publications, calculating coverage by vaccine distribution or correspondence with vaccine registry. These studies would be further validated through NHVPR confirmation, but the significant decrease in the clinical burden of genital warts is in line with vaccine efficacy against genital warts in clinical trials\(^{[2]}\). Researchers have provided age breakdowns to determine vaccine eligible age groups and downward trends among a vaccine eligible population. However, more consistency of age range analysis among published data would allow for improved comparison of results over time. Strengths of genital warts impact studies include large sample sizes and the ability to assess whole of population data through large ongoing databases.

**5.5.3 Cervical abnormalities**
Cervical abnormalities can occur around 12 months after high risk HPV infection. Disease progression to cervical cancer and the true impact of the vaccine on morbidity and mortality will not be seen for decades. In 2011 Brotherton et al\(^{[18]}\) reported an early decrease in high grade abnormalities (HGA) (CIN2 and greater) among young women aged 12 – 17 years using Victorian Cervical Cytology Registry (VCCR) population data. In the year before vaccination
(2006) HGA among young women aged 12-17 were 0.86% and declined to 0.22% in 2009, 2 years into the vaccination program\(^\text{[18]}\). This significant decline (0.83%, CI 0.61-0.16, p=0.003) was only seen in young women under the age of 18 years\(^\text{[18]}\). Low grade abnormalities were declining but considered a part of a long term downward trend and therefore not significant.

In a retrospective cohort study Gertig et al 2013\(^\text{[20]}\) linked Victorian Cervical Cytology Registry (VCCR) data and NHVPR data to determine the effectiveness of the vaccine program on outcomes of high-grade or low-grade cervical abnormalities. In this cohort study, vaccinated women were compared to those who were unvaccinated (women aged 12-17 years at commencement of the vaccine program) and hazard ratios determined in the outcome of high-grade or low-grade cervical and cytological abnormalities. Outcomes of cervical intraepithelial lesions (CIN) low grade 1 (CIN1), high-grade 2 (CIN2) and 3 (CIN3) and adenocarcinoma in situ (AIS) were calculated. Rate of histological abnormality was lower among women receiving any vaccine dose compared to unvaccinated women. Unvaccinated women compared to vaccinated woman were less likely to develop a high grade abnormality (hazard ratio 0.53, CI 0.36-0.77). Woman with 1-2 vaccine doses compared to unvaccinated women were less likely to develop a low grade abnormality (hazard ratio 0.72, CI 0.58 to 0.91). The linkage of a screened vaccine eligible population demonstrated the reduced risk of cervical abnormalities among vaccinated women who had completed a full vaccine schedule.

An advantage of registry data is they represent the whole of the screened population; however health services access is required for inclusion in these observational studies. Only looking at a screened population could bias disease outcome data regardless of vaccination status. One group that could be affected by this bias are Indigenous women, who have an 18% lower participation rate in the national cervical screening program\(^\text{[24]}\) yet a higher cervical cancer incidence and mortality rate than non-Indigenous women\(^\text{[25]}\). Additionally, extracting Indigenous specific data from Pap registries is problematic as Indigenous status is not collected on pathology forms and therefore the validity of this variable is unreliable; this variable is currently being reviewed for quality improvement. Targeted Indigenous specific studies could gain consent from participants to retrieve Pap registry data on an ongoing basis for longitudinal cohort data. Linking these data with genoprevalence over time would strengthen data on the biological effect of the vaccine on cervical abnormalities and cancer outcomes.

5.5.4 Genotype prevalence
Genotype data do not exist in large registry or health related databases like the above reported genital warts, cervical abnormalities and cancer outcomes because HPV genotype is not routinely collected. Samples stored at the Pap registry cannot be used to obtain HPV DNA results as the procedure required to assess the cells requires destruction of the Pap registry
sample. Therefore, each study using HPV genotype testing requires in-population collection of samples. Two HPV genotype prevalence studies have been conducted in Australia; a pre-vaccine study ‘Women, Human papillomavirus prevalence, Indigenous, Non-indigenous, Urban, Rural Study’ (WHINURS)\(^{(26)}\) and a follow up post-vaccine study ‘Vaccine impact in the population’ (VIP-I)\(^{(4, 21)}\). WHINURS aimed to determine the prevalence of circulating HPV genotypes among Indigenous and non-Indigenous women in Australia, establishing an important pre-vaccine baseline for future genotype prevalence monitoring. From July 2005 to February 2008 this study recruited 2156 woman from 43 sites around Australia. Targeted recruitment at remote and Indigenous specific clinics contributed to a large Indigenous sample size of 655 women. WHINURS found no significant difference in HPV vaccine types 6, 11, 16 and 18 between Indigenous and non-Indigenous women (table 1), although factors associated with HPV detection were higher among Indigenous women including smoking (OR=1.4 p =0.010) and abnormal Pap test result. Of women in WHINURS who had a current Pap test resulting in a high grade abnormality, 97.8% had detectable HPV. Compared to detection of HPV in women with normal results, women with high grade abnormality were more likely to have detectable HPV (OR=76, p<0.001) and women with low grade abnormality results were also more likely to have detectable HPV (OR=10, p<0.001)\(^{(26)}\).

**Table 1. HPV types in vaccine naive women ≤ 40 by Indigenous status, WHINURS study**

<table>
<thead>
<tr>
<th>HPV types</th>
<th>Non-Indigenous women (n=1494)</th>
<th>Indigenous women (n=655)</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>47 (3.1%)</td>
<td>13 (2.0%)</td>
</tr>
<tr>
<td>11</td>
<td>9 (0.6%)</td>
<td>6 (0.9%)</td>
</tr>
<tr>
<td>16</td>
<td>141 (9.4%)</td>
<td>69 (10.5%)</td>
</tr>
<tr>
<td>18</td>
<td>62 (4.1%)</td>
<td>25 (3.8%)</td>
</tr>
</tbody>
</table>

Source: Garland et al 2011 pg.7\(^{(26)}\)

There was a significantly higher prevalence of 11 high risk HPV types, other than HPV 16 and 18, among Indigenous women aged 31-35 and 36-40 years, but younger age groups had no significant difference. The disproportionate representation of Indigenous women over the age of 30 years with high risk non-vaccine preventable strains is of high importance for future monitoring to ensure Indigenous women do not continue to have higher cervical cancer rates than non-Indigenous women. WHINURS is the first national prevalence study to assess HPV prevalence among Indigenous and non-Indigenous women. Recruitment, sampling and laboratory techniques were developed to be repeatable for ongoing monitoring and evaluation purposes. To recruit a comparable Indigenous sample again the targeted approach will be necessary to ensure ongoing data of a comparable sample. A limitation of this study was the
targeted recruitment, where the higher remote recruitment may not be representative of the general population as the majority of Indigenous people live in metropolitan areas\(^{[27]}\).

The VIP-I study, repeated the WHINURS cross sectional prevalence methodology. Between 2010 to 2012, 1058 women aged 18-24 years were recruited from 6 family planning clinics in the major metropolitan cities of Melbourne, Sydney and Perth\(^{[4, 21]}\). Three clinics from each location participated in the WHINURS study and one additional clinic located in each city, made a comparable post-vaccine cohort. Two papers from this study have been published. The first publication presented preliminary findings of vaccine impact on genotype prevalence comparing pre and post-vaccine implementation cohorts\(^{[21]}\). This paper reported findings from data collected from 2010 to 2011 (404 women, the comparable pre-vaccine implementation sample was 202 [2005 -2007]). Marked reductions in any HPV genotype, high risk genotypes and vaccine preventable types 6, 11, 16 and 18 were seen in post-vaccine women compared to pre-vaccine women. Reduction in vaccine preventable HPV types among post-vaccine vaccinated women was larger than reductions seen in non-vaccinated women in the same period. Vaccine effectiveness (VE) was calculated using VE=1-RR where rate ratio (RR) = adjusted rate ratio between post-vaccine unvaccinated and vaccinated women. VE on HPV vaccine types 6, 11, 16 and 18 was 73% (CI 48%-86%, p<0.001). This preliminary report was the first genoprevalence study outside of clinical trials.

The second publication\(^{[4]}\) provided genotype prevalence, direct impact, herd immunity, cross protection effects of the vaccine program using concluded study data (1058 women). VE against 6, 11, 16 and 18 was 86% (CI 71-93, p<0.0001) and VE against genetically related types 31, 33 and 45 was 58% (CI 26-76, p=0.003) demonstrating significant cross protection on closely related HPV types. Herd immunity was demonstrated by the significant decrease of vaccine type HPV among unvaccinated women. No genoprevalence studies have linked data with the cervical screening registries yet. Linkage of HPV genotype, cervical cytology and vaccination status will provide direct biological impact of the vaccine on cervical cancer in the future. WHINURS discussed the difficulties in linking genotype and HPV DNA to cervical cytology due to sampling processes, however planning and overcoming this barrier may lead to more comprehensive understanding of vaccine impact on cervical cancer among Australian women in the future. The strength of genoprevalence studies is the ability to further demonstrate impact of the HPV vaccine in the population and monitor effects of the vaccine on non-vaccine HPV genotypes.
5.5.5 Challenges and future work
Other HPV disease outcomes not included in this analysis and areas of future work could include oropharyngeal cancer. One pre-vaccine study\textsuperscript{[28]} could be used as a baseline to compare effectiveness of HPV vaccine related types on oropharyngeal cancer outcomes among young women and men.

Australia has established itself as a progressive world leader in HPV vaccine implementation and is placed in a good position to adapt to the rapidly changing HPV environment. This leadership has vision and is forward planning for foreseeable changes. Targeted populations for future focus in surveillance are Indigenous women and men, MSM and people from culturally and linguistically diverse backgrounds\textsuperscript{[10, 29]}. Considerations for future studies and analysis include determining vaccine coverage, dose and vaccine type, dose completion and disease outcomes based on dose completion, conformity of age range analysis, disease outcomes as a result of vaccination or herd immunity, the demographics of unvaccinated populations, monitoring change of circulating HPV genotypes, the prospect of a nonavalent vaccine (nine HPV type targeted vaccine) and what complexities its introduction will bring to monitoring and reporting.

5.5.6 Conclusion
The Australian HPV vaccination program has been evaluated based on common HPV outcomes of genital warts, cervical abnormalities and targeted genoprevalence studies. Reproducible methodologies and large health databases have been utilised where possible to assess impact. Vaccine effectiveness on HPV vaccine genotypes is high at 87\% of those women vaccinated\textsuperscript{[4]}. Both genotype prevalence and genital wart studies have reported herd immunity among unvaccinated populations. Decreases in cervical abnormalities and cancer outcomes have shown early decline\textsuperscript{[18-20]} although longitudinal studies into the future will demonstrate true impact on cervical cancer. Ongoing surveillance is needed to understand the long term effect of the vaccine in the population and type replacement or evolution of the virus as a result of vaccination. Genotype prevalence surveillance is essential to the future monitoring of the HPV vaccination program impact on the Australian population.

5.6 VIP-I Study background
Indigenous women in Australia have higher cervical cancer incidence and mortality rates than non-Indigenous women, there is a need to provide evidence of the impact of the HPV vaccine program on genotypes among Indigenous women\textsuperscript{[1]}. Monitoring is required to ensure any changes to vaccine preventable genotypes as a result of the vaccination program benefit both Indigenous and non-Indigenous women. If there are inconsistencies in vaccine effectiveness on genotypes or vaccine coverage between both groups, steps can be taken to ensure...
improved delivery of the vaccine program. There has been one study showing comparable
decreases in genital warts diagnosis at hospital admission among Indigenous and non-
Indigenous women\(^{(17)}\). There has also been a documented decrease in HPV vaccine genotypes
in other studies\(^{(4)}\), there has not been a sufficient Indigenous sample size to determine
whether there has been a comparable decrease in genotype prevalence among the Indigenous
population\(^{(4,21)}\). Data from the current study (VIP-I) and a pre vaccination genotype prevalence
study (WHINURS\(^{(26)}\)) will be utilised in the attempt to answer the following questions:

1. Does the pre and post-vaccine data show evidence of a decrease in the prevalence of
   vaccine targeted HPV types (16, 18, 6 and 11) circulating in the Indigenous population?

2. Is a decrease observed in strains not targeted by the vaccine but known to be
   phylogenetically related to the vaccine types (e.g. types 31 and 45), suggesting vaccine
cross protection?

3. Is there a significant increase in the prevalence of any non-targeted HPV types which
   may point to potential type replacement?

5.7 Aims and objectives
To evaluate the effectiveness of the national HPV vaccination program among Indigenous
women VIP-I aims to:

- Estimate the proportion of Indigenous women vaccinated among those aged 18-26
  years attending for Pap testing.

- Estimate the prevalence of HPV types (including vaccine-specific types 6, 11, 16 and 18
  and other high risk HPV types) among Indigenous women in the post-vaccine era and
  compare to pre-vaccine era.

5.8 Methods
The current ‘Vaccine Impact in the Indigenous Population’ (VIP-I) study is a repeat cross-
sectional genoprevalence study with similar methodology to the pre-vaccine WHINURS
study\(^{(26)}\) and post-vaccine VIP study\(^{(4,21)}\). The VIP-I study data collection consisted of three main
components; 1) A demographic and behavioural questionnaire, 2) HPV sample collection for
genotyping and 3) HPV registry data linkage, all discussed in more detail below.
5.8.1 VIP-I Study population
The VIP-I study was focused on recruiting Indigenous women to ensure collection of a sample of Indigenous women comparable to a subset of Indigenous women from the pre-vaccine WHINURS study. This was achieved through the following methodology.

5.8.2 Sample size
Sample size calculations were based on the estimated HPV prevalence among Indigenous women in the prior vaccine impact study ‘WHINURS’. Suspected reduction in prevalence was based on the 75% decrease in vaccine targeted HPV genotypes from the post-vaccine study ‘VIP’ from 28% - 6%. Sample size calculations for the VIP-I study were made using baseline (pre-vaccine) vaccine targeted HPV prevalence and using the post vaccine reduction to 6%. Using this HPV prevalence and the reduction of HPV vaccine genotypes observed in the VIP study, we estimated that 205 women would need to be recruited from the four to six sites to give sufficient statistical power (>0.9, alpha=0.05) to detect a difference in HPV prevalence between post-vaccine era and pre-vaccine era populations.

5.8.3 Site recruitment
Six study sites which had previously recruited larger numbers of Indigenous women during the pre-vaccine WHINURS study were approached to take part in the VIP-I study. Initial contact was made with site chief executive officer (CEO) and key contacts. Teleconferences were held with services regarding the VIP-I project, service capacity (workforce, ability to take on research, numbers of 18 – 26 year olds Indigenous women attending service and number of Pap smears conducted per month). Once sites expressed interest to participate in the study, site agreements were established and signed by the CEO or board chair.

5.8.4 Site training
Site visits were conducted at each participating service (following signed site agreements). Site visits included VIP-I study training and HPV update for clinical staff, health workers and interested workers from local health organisations. Training materials included: VIP-I procedures manual (appendix 2), VIP-I presentation (appendix 3) and an adapted HPV update presentation. Where possible, a HPV expert provided the HPV update.

5.8.5 Participants
Study sites recruited Indigenous women aged 18-26 years presenting or overdue for cervical screening. These were women aged between 11 and 20 years in 2007 when the vaccine program started. Age limits were determined according to participant’s eligibility for the vaccination program in 2007. Those eligible for vaccine in 2007 were either 11 – 13 years in the school based program, or 18-26 years in the community based catch-up program.
5.8.6 Inclusion criteria
- Indigenous women aged 18-26 years at the time of sample collection
- Presenting at a participating ACCHS collaborating health service
- Treatment at clinic to include Pap screening
- Adequate English and comprehension skills to give informed consent

5.8.7 Exclusion criteria
- Males
- Children and/or young people (i.e. <18 years)
- Women aged 27 years and over at the time of sample collection
- People highly dependent on medical care
- People with a cognitive impairment, an intellectual disability or a mental illness
- People with insufficient English to allow clear communication of study details

5.9 VIP-I Study data sources

5.9.1 Consent
Identified clinical staff at study sites gained informed consent from participants. A patient information and consent form (appendix 2) was provided to participants. Clinical staff also verbally conveyed study information to ensure participants could give their informed consent to the study. If patients agreed to participate, two consent forms were signed.

1) VIP-I study consent included:
   a) Questionnaire collection
   b) Use of biological samples from routine Pap smear for HPV DNA and genotype testing
   c) Review of medical records for last Pap test date and result plus current Pap result

2) NHVPR data retrieval consent

5.9.2 Questionnaire
The VIP-I Questionnaire (appendix 1) was adapted from the post vaccine VIP study. The adaption process included the removal and rewording of some questions to be culturally appropriate and also took on board feedback from VIP-I study site staff and health professionals involved in the VIP study. After the consent process, the VIP-I questionnaire was completed by each participant or completed with the assistance of a health professional. Variables included: demographics, self-reported vaccination year, vaccine dose, last Pap result, age at first sexual intercourse, contraception use and smoking habits. VIP-I has seen the introduction of a survey to gather demographic and behaviour data to be used in subsequent
surveillance, but not all variables will have a corresponding variable from the pre-vaccine study for the purpose of this analysis.

5.9.3 HPV sample collection, storage, transport and laboratory genotyping methods
When a routine Pap smear was conducted on each participant, a conventional Pap slide was prepared to be sent to local laboratories as per general clinic procedure at each site. After the preparation of a conventional Pap slide an extra step was added for the VIP-I study sample. The brush used to collect the conventional Pap was placed into a Thin Prep Preservcyt® jar (provided by the study) and rinsed vigorously to allow cervix cells to dislodge from the brush and suspend in the Thin Prep Preservcyt®. Jars were labelled with appropriate study labels, placed in a zip lock bag and stored in a provided esky. Completed samples in Thin Prep jars could be stored at room temperature (any temperature under 38 degrees Celsius). Samples could be stored at sites for up to a month before courier transport to the HPV WHO reference laboratory at the Department for Microbiology and Infectious Diseases, The Royal Women’s Hospital, Melbourne. All sites received VIP-I training along with study procedures for sample collection, labelling, storage and transport to ensure quality samples for laboratory testing. (See Appendix 3 ‘VIP-I procedures manual’ for detailed descriptions of sample collection, labelling and transport procedures). Samples were couriered from study sites each month.

The methods for HPV genotype detection were the same as those used in the pre-vaccine WHINURS study and post-vaccine VIP study\(^{(4, 21)}\). In short, 1 ml of cervical cells in Thin Prep Preservcyt® was prepared for DNA extraction. All samples were assessed for the presence of HPV DNA and genotype including any of the 13 mucosal HPV types considered “high risk”\(^{(16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)}\). HPV genotyping profiles were manually interpreted and verified using the HPV reference guide provided with each test kit. Results were returned to services for usual results procedures and follow up. A clinical algorithm of care for appropriate follow up as per study protocol was provided to services.

5.9.4 National HPV Vaccine Program Registry data
Participant consent was obtained to confirm vaccination status by retrieving data from the NHVPR. The following variables were collected; participant presence on the registry, current vaccination status, vaccination dose date, where dose was received, provider details, Indigenous status and required follow-up.

5.9.5 Pre-vaccine data source
The pre-vaccine implementation sample included Indigenous women aged 18-26 years attending WHINURS sites for routine Pap smears from 2005 to 2007. This cohort of Indigenous women was established prior to the implementation of the vaccine program and represents a
vaccine naive group. A subset of Indigenous women who attended WHINURS sites are now enrolled in the follow up VIP-I study, therefore making a comparable pre-vaccine cohort. A questionnaire was not administered during the pre-vaccine study however, general demographic information, Pap result, smoking history, contraceptive use and postcode were obtained from general medical records with the consent of participants.

5.10 Data analysis methods
Preliminary findings are provided here. Due to submission date requirements of the MAE this analysis was conducted on data and samples from one VIP-I service available on the 17th October 2014. Interpretation of these preliminary data should be done with caution. Full analysis of will take place mid next year (2015) on completion of recruitment. Due to the power of the preliminary analysis provided here, vaccine effectiveness cannot be calculated. Only descriptive analysis and HPV prevalence have been calculated.

5.10.1 Preliminary analysis
Using preliminary data, a descriptive analysis of demographic and behavioural characteristics of both pre (WHINURS) and post (VIP-I) vaccine cohorts such as age, area remoteness, last Pap test, result of last Pap test and cigarette smoking have been conducted. Chi-squared tests have been performed to detect any demographic and behavioural variance between the pre and post vaccine groups, where numbers were below 5 in any cell Fisher’s exact test was used. The Accessibility/Remoteness Index of Australia (ARIA) was used to categorises participants into very remote, remote, rural and metropolitan regions based on provided postcode of residence\(^{(30)}\). Pre and post vaccine era HPV prevalence by genotype were calculated. HPV genotype prevalence comparisons were made between; 1) pre and post-vaccine cohorts and; 2) vaccinated and unvaccinated women among the post-vaccine cohort. Where appropriate, \(\chi^2\) test or Fisher’s exact test were used to compare groups.

Variables of interest included:

1. Any HPV genotype
2. HPV vaccine types 6, 11, 16, and 18
3. Any high risk HPV genotype\((16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, \text{or} 68)\)
4. Any high risk HPV genotype excluding 16 and 18 \((31, 33, 35, 39, 45, 51, 52, 56, 58, 59, \text{or} 68)\)

Additional groupings of HPV types were analysed; HPV types 31, 33, and 45 grouped due to their genetic linkage to vaccine targeted HPV types; and HPV 11 and 16 were grouped because of their disease outcome of genital warts.
Vaccine effectiveness (VE) would have been determined using $VE = 1 - PR$ where $PR =$ ratio of prevalence between post vaccine vaccinated and unvaccinated women, but this preliminary analysis was not powered to find significance. The required sample size for this calculation was 57 participants in each group based on reductions in vaccine targeted HPV seen in a previous study\(^{(4)}\).

5.10.2 Ethics
Ethics approval was obtained from 6 relevant Human Research Ethics Committees in all study jurisdictions and the Australian National University Human Research Ethics Committee.

5.11 VIP-I Study update
On date of reporting these results the VIP-I study had recruited five study sites and around 80 samples had been collected at 3 of those sites. There were a number of issues in lead time for site recruitment and participant recruitment. These included; ethics delays; turnover of staff at services (even though services had participated in the previous study staff members who coordinated the study were no longer present); new engagement with services; difficulties engaging Indigenous women aged 18-26 and Indigenous women’s lower participation in Pap screening. All of these factors have resulted in delay and funding agreements have been extended to meet the challenges of the project.

5.12 Results
Preliminary results reported here represent VIP-I data collected up until 17\(^{th}\) October, 2014. A total of 57 out of the target 200 Indigenous women aged 18-26 were available for this analysis. Results reported are from one VIP-I study site, an ACCHS in the Northern Territory (41 Indigenous women).

Fifty-two vaccine naive Indigenous women aged 18-26 years were recruited from the identical participating Northern Territory ACCHS during the WHINURS pre-vaccine phase. This cohort made up the baseline comparison group for assessing changes in genotype prevalence within the post-vaccine VIP-I study population.

Age among pre and post -vaccine cohorts was similar with a median of 22 years for both groups.
Table 2. Demographic characteristics of pre and post-vaccine Indigenous women age 18 -26

<table>
<thead>
<tr>
<th></th>
<th>Pre-vaccine (2005-2007) n=52</th>
<th>Post-vaccine (2013-2014) n=41</th>
<th>Chi² p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remoteness</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very remote</td>
<td>12 (23%)</td>
<td>1 (2%)</td>
<td>0.005*</td>
</tr>
<tr>
<td>Remote</td>
<td>40 (77%)</td>
<td>39 (95%)</td>
<td></td>
</tr>
<tr>
<td>Metropolitan</td>
<td>0 (0%)</td>
<td>1 (2%)</td>
<td></td>
</tr>
<tr>
<td>Smoker</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>35 (67%)</td>
<td>21 (59%)</td>
<td>0.191</td>
</tr>
<tr>
<td>No</td>
<td>17 (33%)</td>
<td>17 (46%)</td>
<td></td>
</tr>
<tr>
<td>Pap test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First Pap</td>
<td>10 (23%)</td>
<td>10 (26%)</td>
<td>0.757</td>
</tr>
<tr>
<td>Had previous Pap</td>
<td>34 (77%)</td>
<td>29 (74%)</td>
<td></td>
</tr>
<tr>
<td>Most recent Pap test</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>47 (90%)</td>
<td>26 (87%)</td>
<td>0.604</td>
</tr>
<tr>
<td>Abnormal</td>
<td>5 (10%)</td>
<td>4 (13%)</td>
<td></td>
</tr>
</tbody>
</table>

*Fisher’s exact used

There was no significant difference in HPV predictors such as tobacco smoking and a recent abnormal pap test between the pre and post vaccine cohorts (table 2). Thirty-five (67%) pre-vaccine participants had ever smoked compared to 21 (59%) participants among the post-vaccine cohort. Likewise, a similar proportion of abnormal Pap results were present in both pre-vaccine (n=5, 10%) and post-vaccine (n=4, 13%) cohorts. Area of remoteness was significantly different (p=0.005) as the post-vaccine sample included mostly participants that resided in remote areas (95%) and one participant each from a metropolitan and very remote area. The pre-vaccine cohort was from remote (77%) and very remote areas (23%) (Table 2).

The majority of women in both cohorts were returning for a subsequent Pap test. Only 10 (23%) participants in the pre-vaccine and 10 (26%) in the post-vaccine cohorts were attending for their first Pap smear (Table 2). In the post vaccine group, 12 (32%) women had their last Pap smear two to three years and three to four years ago; which is greater than the recommended two yearly screens.
Table 3. HPV genotype prevalence among pre and post-vaccine Indigenous women aged 18 - 26 years

<table>
<thead>
<tr>
<th>HPV genotype</th>
<th>Overall prevalence</th>
<th>Fisher’s exact p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-vaccine n=52 (%)</td>
<td>Post-vaccine n=41 (%)</td>
</tr>
<tr>
<td>Any HPV type</td>
<td>30 (58)</td>
<td>12 (29)</td>
</tr>
<tr>
<td>Vaccine targeted HPV types 6, 11, 16 &amp; 18</td>
<td>13 (25)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>High-risk HPV types*</td>
<td>24 (46)</td>
<td>7 (17)</td>
</tr>
<tr>
<td>High-risk HPV types excluding 16 &amp; 18</td>
<td>13 (25)</td>
<td>6 (15)</td>
</tr>
<tr>
<td>HPV 16</td>
<td>8 (15)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>HPV 18</td>
<td>4 (8)</td>
<td>0</td>
</tr>
<tr>
<td>HPV 6</td>
<td>1 (2)</td>
<td>0</td>
</tr>
<tr>
<td>HPV 11</td>
<td>1 (12)</td>
<td>0</td>
</tr>
<tr>
<td>HPV 6 or 11</td>
<td>2 (4)</td>
<td>0</td>
</tr>
<tr>
<td>HPV 31, 33, or 45</td>
<td>5 (10)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>HPV 31</td>
<td>2 (4)</td>
<td>0</td>
</tr>
<tr>
<td>HPV 33</td>
<td>2 (4)</td>
<td>1 (2)</td>
</tr>
<tr>
<td>HPV 45</td>
<td>1 (2)</td>
<td>0</td>
</tr>
<tr>
<td>HPV 52</td>
<td>3 (6)</td>
<td>3 (7)</td>
</tr>
<tr>
<td>HPV 58</td>
<td>5 (10)</td>
<td>1 (2)</td>
</tr>
</tbody>
</table>

* High risk types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, or 68
**statistical comparisons could not be reliably made in these groups
*** Chi2 used instead of Fisher’s exact

### 5.12.1 HPV genotype prevalence

Overall, the prevalence of HPV DNA among Indigenous women aged 18 – 26 years significantly decreased from 58% among pre-vaccine to 29% (p=0.006) post-vaccine (Table 3). These preliminary findings demonstrates a significant decrease in vaccine targeted HPV types 6, 11, 16 and 18 from 25% pre-vaccine (2005-2007) compared to 2% in the post-vaccine era (2013-2014) (p0.003). A significant reduction in 13 high risk HPV genotypes (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, or 68) (46% down to 17%, p=0.003). However, when HPV genotypes 16 and 18 were excluded from this analysis the decrease was no longer significant (25% compared to 15%, p=0.218). Individually, no HPV genotypes significantly decreased between pre-vaccine to post-vaccine era. HPV types 6 and 11 were of low prevalence among Indigenous women in the pre-vaccine cohort with only one case of each.
5.12.2 Self-reported vaccination status
Self-reported vaccination status from the VIP-I survey has been used for this preliminary analysis as registry data was unable to be obtained (only requested) in time for this analysis.

Of the VIP-I sample (post vaccine era), 27 (66%) self-reported full vaccination, 11 (27%) reported only partial vaccination and three (7%) reported no vaccination (Table 4).

<table>
<thead>
<tr>
<th>Table 4. Frequency of vaccination among VIP-I women, and by remoteness</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
<tr>
<td>Self-reported vaccination</td>
</tr>
<tr>
<td>Very remote</td>
</tr>
<tr>
<td>Remote</td>
</tr>
<tr>
<td>Rural</td>
</tr>
<tr>
<td>Metropolitan</td>
</tr>
</tbody>
</table>

Table five presents VIP-I prevalence of HPV genotypes by self-reported vaccination status. The full vaccination group included individuals self-reporting full vaccination, and the unvaccinated group included those self-reporting no or partial vaccination. Full vaccination was reported by 66% of participants (27/31). The participant with a positive HPV 16 result in the VIP-I study self-reported no vaccination and resided in a very remote location.
Table 5. HPV genotype prevalence among Indigenous women from the VIP-I study by vaccination status

<table>
<thead>
<tr>
<th>HPV genotype</th>
<th>Post-vaccine prevalence (self-reported vaccination)</th>
<th>No or partial vaccination n=25 (%)</th>
<th>Full vaccination n=31 (%)</th>
<th>Fisher’s exact p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any HPV type</td>
<td></td>
<td>4(27)</td>
<td>8(30)</td>
<td>0.944 ***</td>
</tr>
<tr>
<td>Vaccine HPV types 16, 18, 6, 11</td>
<td></td>
<td>1(7)</td>
<td>0</td>
<td>0.341 **</td>
</tr>
<tr>
<td>High-risk HPV types*</td>
<td></td>
<td>3(21)</td>
<td>4(15)</td>
<td>0.673</td>
</tr>
<tr>
<td>High-risk HPV types excluding 16 &amp; 18</td>
<td></td>
<td>2(14)</td>
<td>4(15)</td>
<td>1</td>
</tr>
<tr>
<td>HPV 16</td>
<td></td>
<td>1(7)</td>
<td>0</td>
<td>**</td>
</tr>
<tr>
<td>HPV 18</td>
<td></td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>HPV 6</td>
<td></td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>HPV 11</td>
<td></td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>HPV 6 or 11</td>
<td></td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>HPV 31, 33, or 45</td>
<td></td>
<td>1(7)</td>
<td>0</td>
<td>**</td>
</tr>
<tr>
<td>HPV 31</td>
<td></td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>HPV 33</td>
<td></td>
<td>1(7)</td>
<td>0</td>
<td>**</td>
</tr>
<tr>
<td>HPV 45</td>
<td></td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>HPV 52</td>
<td></td>
<td>2(14)</td>
<td>1(4)</td>
<td>0.265</td>
</tr>
<tr>
<td>HPV 58</td>
<td></td>
<td>1(7)</td>
<td>0</td>
<td>**</td>
</tr>
</tbody>
</table>

* HR types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, or 68

** chi² test used

5.13 Discussion
By returning to services involved in the WHUNIRS pre-vaccine study to run a repeat cross sectional prevalence survey, we were able to provide preliminary evidence to demonstrate the effectiveness of the HPV vaccine program among Indigenous women. Data used for this analysis are from the first site to complete data collection. Significant decreases were seen in HPV genotypes covered by the vaccine (6, 11, 16, and 18) among post-vaccine 18-26 year old Indigenous women, with only one of 31 study participants reporting any of these genotypes in the current VIP-I study. The largest prevalence reductions were seen in HPV 16 and 18, but low prevalence of HPV6 and HPV11 were reported among the pre-vaccine era Indigenous women so reductions in this type were unlikely to be significant. No women in the VIP-I post-vaccine cohort tested positive for HPV 6, 11, 18 and only one participant returned a positive HPV 16 result. Sample size in this preliminary analysis was too small to compare to the dramatic
vaccine targeted HPV reduction seen among predominantly non-Indigenous women in the VIP study which recorded 86% VE against vaccine targeted HPV types\(^4\). Statistical comparisons of individual HPV types with small prevalence and sample size within this preliminary analysis are not reliably made and need to be interpreted with caution.

VIP-I participants self-reported full vaccination at 66%, similar to self-reported three dose coverage in a previous study which identified lower vaccine coverage and dose completion among Indigenous women, 63% self-reported three dose coverage compared to 83% among non-Indigenous responders\(^3\). However, the Northern Territory where women in this preliminary analysis reside, has recorded higher coverage rates than other states and territories in Australia\(^2\). The VIP-I study (on completion) will validate self-reported vaccination against NHPVR vaccine dose confirmation, currently it is too early to draw conclusions from these data alone. VIP-I will be the largest sample of Indigenous women allowing meaningful analysis of registry notification data against vaccination rates within the population, as well as providing an indication of Indigenous status completion on NHPVR forms. Obtaining vaccine confirmation through the NHVPR will provide a stronger biological link to impact of the vaccine in the Indigenous population.

Half of VIP-I participants reported cigarette smoking (59%), a predictor for detection of HPV DNA. Smoking prevalence was similar to that of the pre-vaccine WHINURS cohort (67\%),\(^2\) but higher than national prevalence (45\%), potentially due to smoking rates increasing with remoteness\(^3\). Other HPV DNA predictors identified in WHINURS included younger age (less than 21 years of age) and an abnormal Pap result\(^2\). The Indigenous population is younger than the non-indigenous population; in 2011 the median age of the Indigenous population was 21 years compared to 37 years of the non-Indigenous population\(^3\). The Indigenous population peaks at the age of highest HPV incidence and the potential burden of disease is, therefore, elevated. On completion, the VIP-I study will provide an indication of potential disease burden decreases through genotype identification within the population, however ongoing genotype surveillance is required to truly understand the impact of the vaccine with in all age groups.

Factors such as low participation in cervical screening\(^2\) and disproportionately high HPV predictors\(^2\) among Indigenous women could be the defining difference between disease progression and outcomes among Indigenous and non-Indigenous women in the vaccine era. Therefore close attention to vaccine coverage, monitoring of HPV genotypes and continued campaigns for cervical screens are necessary into the future for Indigenous women. This requires a targeted approach as we have seen from post-vaccine studies, sufficient Indigenous sample size is not obtainable solely through mainstream health services and medical databases.
It will be imperative to ensure targeted messaging to Indigenous women of the importance of continued cervical screening as per national guidelines after vaccination. There is evidence to indicate vaccinated women are being screened at a lower rate compared to unvaccinated women\textsuperscript{(34)}. To ensure maximum impact of the national HPV vaccination program Indigenous specific screening program messages should be delivered in a culturally sensitive and locally tailored manor.

5.13.1 Limitations
As mentioned throughout, sample size was a limitation in this preliminary analysis. Results have demonstrated the decrease in all HPV genotypes, high risk genotypes and vaccine targeted types when comparing per and post-vaccine cohorts. Analysis beyond this point was not possible. This analysis is an indication that VIP-I study objectives will be met on completion of recruitment. There are such small numbers in this preliminary analysis that any more cases of vaccine targeted HPV could change the results and therefore no definitive conclusions should be made until further data is available.

Preliminary data analysis here consists of participants residing in remote areas of Australia. It is acknowledged the Indigenous population is geographically, culturally and linguistically diverse. There are also varying levels of access to health services. A finding from WHINURS is that Indigenous and non-Indigenous women residing in remote areas were at lower risk for HPV 16 and 18\textsuperscript{(26)}. This sample from the NT is not representative of the wider Indigenous population. Caution should be taken in using these data to describe vaccine program effectiveness until completion of the full VIP-I sample target is met. In its current state findings should not be generalised to the wider Indigenous population. VIP-I service sites have been selected to ensure a comparative sample by completion of the study as sites will reflect recruitment from a variety of location in a number of jurisdictions.

5.13.2 Methodological recommendations
Due to ongoing surveillance of HPV in the population, continued targeted recruitment of Indigenous women and the inclusion of men (due to inclusion of boys in the vaccination program and monitoring of herd immunity) is required. Below are some methodological considerations for future work.

- Due to lower uptake of cervical screening by Indigenous women compared to non-Indigenous women and the imminent cervical screening guidelines change to genotype testing and screening based on risk\textsuperscript{(35)}, collecting samples only during routine cervical screening may result in long recruitment times. Using self-collected samples in
addition to clinician collected samples could reduce recruitment times and research burden on services. This method has been successful in other settings\textsuperscript{[36]}.  

- The dedication of a full-time/part-time coordinator and the establishment of an Indigenous surveillance advisory committee could result in more meaningful engagement and longevity of partnerships with services.

### 5.14 Conclusion

This preliminary analysis of the VIP-I study provides some evidence of reductions in circulating HPV DNA and vaccine targeted genotypes among Indigenous women of vaccine eligible age. This finding implies effectiveness of the national vaccine program among Indigenous women. While results here demonstrate promise for the larger VIP-I study objectives, conclusions should not be drawn purely from this analysis. Compared to pre-vaccine, predictors for presence of HPV DNA did not change among Indigenous women post-vaccine. The known burden of HPV related disease outcomes among the Indigenous populations warrant ongoing and targeted surveillance initiatives to monitor effect of the HPV vaccine program.

### 5.15 References


Appendix 1. VIP-I questionnaire

1. Date of Birth
   DDMYY

2. Home postcode

3. Do you identify as Aboriginal and/or Torres Strait Islander?
   □ Aboriginal □ Torres Strait Islander
   □ Both □ Neither

4. What is the highest level of education you have completed?
   □ Primary school □ University degree
   □ High school □ Higher degree
   □ TAFE or trade

5. Have you had the HPV Vaccine? (Also known as cervical cancer vaccine, Gardasil, or Cervarix)
   □ Yes, 1 dose (go to Q6)
   □ Yes, 2 doses (go to Q6)
   □ Yes, 3 or more doses (go to Q6)

6. Have you had a Pap test before? If yes, when?
   □ No, I haven’t had a Pap test □ Not sure
   → If no or not sure, continue to Q7
   □ Yes, in the past 12 months □ Yes, 3-4yrs ago
   □ Yes, 1-2yrs ago □ Yes, 4-5yrs ago
   □ Yes, 2-3yrs ago □ Yes, 5+yrs
   → If yes, please answer Q 6a) before continuing

6a) If yes, what was the result of your last test?
   (Circle one)
   Normal Abnormal Unsure

7. Do you smoke?
   □ No □ Yes

8. What age were you when you first had sex?

9. What contraception do you currently use?
   (Please tick all that apply)
   □ I do not have a male partner
   □ Condoms □ Oral contraceptives (Pill)
   □ Depo Provera (Injection) □ Vaginal ring
   □ IUD (hormone) □ Implanon (Implant/Rod)
   □ IDU (copper) □ Emergency Contraception (past 6mths)
   □ Diaphragm or cap □ Withdrawal (pulling out)
   □ Do not use any □ Other

Please turn over page
Appendix 2: VIP-I participant information and consent form

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM

Has the cervical cancer vaccine made a difference to types of HPV in Indigenous women? (HPV stands for ‘human papillomavirus’, sometimes known as the ‘wart virus’, or the virus that can cause cervical cancer)

Principal Investigator

John Kaldor on behalf of the research team (Suzanne Garland, Sepehr Tabrizi, Bette Liu, Julia Brotherton, Dina Saulo, Rachel Skinner, Mary Stewart, Liz Sullivan, Skye McGregor).

About the study

HPV (human papillomavirus) is the main cause of cervical cancer worldwide. The vaccine to protect against cervical cancer was introduced in Australia in 2007. We are undertaking a research study to understand the impact of the vaccine in Indigenous women.

You are being asked to take part in a study to test for the presence of HPV and type of HPV among Aboriginal and Torres Strait Islander woman age 18-26. Information from this study will be used to determine if the types of HPV virus in the Aboriginal and Torres Strait Islander population have changed since the cervical cancer vaccine was introduced. The study will also evaluate if HPV has decreased at the same level among Indigenous woman compared to non Indigenous women.

Do I have to participate?

No, it is your choice whether or not to participate. If you choose to participate but would like to pull out at any stage you can. You do not need to explain why you don’t want to do the study and this will not disadvantage you in any way.

What will happen if I participate?

If you choose to participate, there are three steps

1) A health professional will talk to you about the study and you will be asked to sign two consent forms. One to consent to the study and a second optional one allowing the study group access to your details on the HPV register. This gives information about the number of doses of HPV vaccine you have had. The personal information you give us will only be used to link you to the register, not for any other purposes. Any information you provide is confidential.

2) The health professional will ask you questions about health behaviour and past experiences from a short confidential survey. Alternatively you can fill out the survey yourself. The survey asks some personal questions but please note this is a confidential survey: in the survey we will not collect any of your personal contact details such as your name, phone number or address.

3) A health professional will collect a Pap test sample during your routine Pap test. This is the same type of sample as they would take if you were not in the study. Your sample
will be tested for in the normal way to check for changes, as well as an extra test for the types of HPV that can cause cervical cancer.

4) The health professional will retrieve from you medical record; information about your last Pap test and the result.

5) Once the tests have been done on your Pap sample and when the study is finished, all samples will be destroyed.

What about my results?

The results of your Pap test will be given to you by your doctor or nurse just as if you were not in the study. If it is abnormal they will explain to you what this means and what you need to do. If the extra test we do for the types of HPV genotypes that can cause cervical cancer is positive you will be invited to have a follow-up test a year later. There will be no cost to you for this test.

Will anyone else see my information or know about my results?

The result of your Pap test will be given to you in the usual way your health service would deliver results normally. No one will see your answers to the survey except the researchers, and even then there will be no identifying information available. All information about individuals that is collected in this study is confidential. You will not be identified in any report or publication that results from this survey. We plan to publish the results of the survey in reports and in academic papers.

What if I have a complaint or concern about the research?

Complaints may be directed to the relevant Ethics Secretariat, details of which are provided below. Any complaint you make will be investigated promptly and you will be informed of the outcome.

University of New South Wales HREC
02 9385 7251 or ethics.gmo@unsw.edu.au
Application ID: TBA

Central Australian HREC
08 8951 4700 or cahrec@flinders.edu.au
Application ID: TBA

Western Australian Aboriginal Health Ethics Committee
08 9227 1631 or ethics@ahcwa.org
Application ID: TBA

Aboriginal Health and Medical Research Council Ethics Committee
02 9212 4777 or ethics@ahmrc.org.au
Application ID: TBA

Townsville Hospital and Health Service Human Research Ethics Committee
07 4433 1140 or TSV-Ethics-Committee@health.qld.gov.au
Application ID: TBA

Family Planning NSW Ethics Committee
How do I get more information about this study?

If you would like to know more about the study or if you have any additional questions later, Ms Dina Saulo will be happy to answer them. Dina can be contacted on the free call number 1800 066 141 or by email dsaulo@kirby.unsw.edu.au

You are making a decision whether or not to participate. Your signature on the consent form indicates that you have read the information provided above or a health professional has gone through the information with you and you have decided to participate.

You will be given a copy of this form to keep.

Thank you!
You are making a decision whether or not to participate. Your signature indicates that, having read the information provided above, you have decided to participate.

I, ____________________________, voluntarily consent to taking part in this study, which has been explained to my by ____________________________

I have been asked if I would like to have a family member or friend with me while the project was explained. I understand that if I do not wish to participate, or if I withdraw from the study at any time without explanation, this will not affect my relationship with the health service I attend, the researchers involved in or anyone affiliated with the study.

I understand that I will receive a copy of this consent form.

_________________________  ____________________________
Signature of Research Participant  Signature of Witness

_________________________
(Please PRINT name)

_________________________
Date  Nature of Witness
I hereby wish to WITHDRAW my consent to participate in the research proposal described above and understand that such withdrawal WILL NOT jeopardise your relationship with the health service nor with any of the organisations affiliated with this research project.

Signature

Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to:

Ms Dina Saulo
The Kirby Institute
University of New South Wales
CFI Building
Corner West and Boundary Streets
Darlinghurst NSW 2010
Email: dsaulo@kirby.unsw.edu.au
Authorisation for collection of HPV vaccine data from the HPV Register

The researchers of this study would like to verify your HPV vaccination status by sending your details (your name, date of birth and address of residence when vaccinations were received) to the National Human Papillomavirus Vaccination Program Register (NHVPR). This is an Australian register which records HPV vaccine doses administered to individuals and is owned by the Australian Department of Health. **We would like to determine whether your vaccine history is in the register, the number of doses of the vaccine which you have received and the dates of each of the doses.** Because some people are not always certain of what vaccines they have received and when, we would like to request this data even if you think you may not have received the HPV vaccine. It is important to note that if you received the HPV vaccination with your General Practitioner it may not be registered with the HPV Vaccination Register yet. In this event, with your consent, we would like to verify your vaccination status with your General Practitioner. We are more than happy to relay the information that we obtain from the register to you for your personal records if you would like us to do so.

First name: .................................
Surname: ................................. Previous name *(if applicable)*: .................................
Date of Birth (DD/MM/YY): __ / __ / ___
Current address: ................................. Previous address *(if applicable)*:
Street ........................................ Street ........................................
Suburb ........................................ Suburb ........................................
Postcode /State.. ................................. Postcode /State.. .................................
Place where vaccinations were received *(if applicable)*:
☐ School ☐ General Practitioner ☐ AMS ☐ remote clinic nurse ☐ Other
Name of school / General Practitioner: ..............................................................
Location of school / General Practitioner: ..............................................................
Other: ..............................................................................................................
*If vaccine doses were received at multiple locations, please provide details of each location
Medicare number: ..............................................................
*(this will help the Register find your record and will not be used for any other purpose)*
I would like to receive confirmation of my HPV vaccination status:
☐ Yes ☐ No ☐ Not applicable
Consent: I have read, or have had this document read to me in a language that I understand, and I consent to having my details sent to the National Human Papillomavirus Vaccination Program Register for verification of my HPV vaccination status and the dates when I received my vaccination doses. I consent to the Register providing my vaccination status and dates of doses back to the researchers. I consent to this information being confidentially stored and used for the purposes of this research project.

Signature: .............................................................. Date: __ / __ / ___
VIP-I Training Manual

HPV Vaccine Impact in the Australian Indigenous Population
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Funded by:
Office of Health Protection, Australian Government Department of Health, Canberra

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M: 014 0231 8891
Fax: +61 (0)2 9385 0891
Email: smcgregor@kirby.unsw.edu.au

Service Coordinator
A service coordinator will be the main point of contact during the study, responsible for ensuring samples and study documents are stored correctly and transported, send through requests for extra materials and encourage staff to achieve targets.

Name:
E:
Ph:
Fax:
About VIP-I

Background

During 2005-2008 the Women’s HPV Indigenous Non-Indigenous Urban Rural Study (WHINURS) (1) recruited Indigenous and non Indigenous woman throughout Australia undergoing cervical cytology screening, in order to estimate the prevalence of human papillomavirus (HPV) genotypes in this population. Participants in WHINURS were recruited via ACCHS, General practitioner clinics and family planning clinics. As a majority of woman were recruited prior to the implementation of Australia’s HPV vaccination program, the WHINURS study established an important baseline for post-vaccine program surveillance of HPV types in this population.

A second study called VIP compared a post-vaccine sample, recruited through family planning clinics, to the pre-vaccine WHINURS sample and found a significant decrease in vaccine preventable HPV genotypes (2). The reduction was consistent with what would have been expected based on clinical trials that demonstrated vaccine efficacy.

Rationale

There is a need to evaluate the impact of the HPV vaccine program on the prevalence of infection among Indigenous women in Australia. Although there has been a documented decrease in HPV vaccine genotypes by other studies they have not had a sufficiently large Indigenous sample size to determine whether there has been a corresponding decrease in the prevalence of infection among Aboriginal and Torres Strait Islander women.

Design

Six ACCHS which recruited substantial numbers to the WHINURS studies will be approached to participate in the VIP-I study to ensure a comparable sample. VIP-I is targeting recruitment of 220 Indigenous women aged 18 - 26 who attend ACCHS (or other service providers with a high proportion of Indigenous clients) for routine cytology screening over the study period.

Aims of VIP-I

- To estimate the proportion of Indigenous women who have been vaccinated among 18-26 years old women attending for cervical cytology screening

- To estimate and compare the prevalence of HPV types (including vaccine-specific types 6/11/16/18 and other high risk HPV types) among Indigenous women in the post-vaccine era compared to pre-vaccine era
CHAPTER 5 EPIDEMILOGICAL PROJECT

Time frame
VIP-I study is funded from May 2013 – December 2014

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2013</td>
<td>Study design and development</td>
</tr>
<tr>
<td>June 2014</td>
<td>Ethics committees approval through Townsville HREC</td>
</tr>
<tr>
<td>June 2013 4</td>
<td>TAIHS - Site agreement approved</td>
</tr>
<tr>
<td>October 2014</td>
<td>Site training</td>
</tr>
<tr>
<td>October 2014 – March 2015 (or until reaching recruitment target )</td>
<td>Participant recruitment at TAIHS</td>
</tr>
<tr>
<td>March 2015</td>
<td>Site report provided to TAIHS</td>
</tr>
<tr>
<td>June 2015</td>
<td>Outputs from research provided to services</td>
</tr>
</tbody>
</table>
Study Steps

1. Provide **participant Information Sheet** and **explain study** to potential study participants.

2. Use **participation log** to document declines or consents to study.

3. Gain consent for study & information and signature for **Pap Registry Consent form**.

4. Administer **Questionnaire**.

5. **Collect Sample**.

6. **Label** samples and documentation.

7. **Store** sample and Study documents.

8. **Transport of samples** to RWH, melbourne. via courier once a month or when provided esky is full.

9. **Fax documentation weekly** to investigators - participation log, completed questionnaires and consent forms.
1. Recruitment

During the study period any Aboriginal and/or Torres Strait Islander women between the ages of 18 – 26 attending the clinic can be asked to participate in the study. The following criteria apply to participation in the study.

Who can participate?

- Aboriginal and Torres Strait Islander women aged 18-26 years at the time of sample collection
- Adequate English and comprehension skills to give informed consent
- Presenting at a participating Aboriginal Community Controlled Health Service or collaborating health service and are presenting for a Pap or are overdue for a Pap and therefore offered the service.

Who cannot participate?

- Males
- People less than 18 years of age
- People aged 27 and over at the time of sample collection
- People highly dependent on medical care
- People with a cognitive impairment, an intellectual disability or a mental illness
- People with insufficient English to allow clear communication of study details, which would prevent informed consent

Participant Information

Every potential participant must be provided with a participant information sheet and/or the participant information sheet verbally communicated to potential participant.

It’s essential to ensure a clear understanding of the study to allow potential participants ability to provide informed consent.
2. Participation Log
Logging refusals and participation in the VIP-I participation log will allow understanding of the following:

- Number of 18-26 year old Aboriginal and Torres Strait Islander women attending the service
- Number being offered participation in VIP-I
- Uptake of the study among attending 18-26 year old women

Regardless of reason for attending clinic log 18-26 year old Aboriginal and Torres Strait Islander patients in the participation log documenting the following:

1. Current Date
2. Date of birth
3. If the patient has been approached to participate
4. If the patient declines or participates

Logging participation will allow investigators to gauge the representativeness of the samples provided by your service. Additionally if numbers are low it will allow for understanding of how to engage participants in the study, for example, whether a community based drive to increase numbers of women in the age range to attend the clinic would assist or if Pap providers need particular prompts in clinic rooms to remember to ask patients during consultations.

- All Pap providers should have a participation log
- Fax participation log each month to Dina on 02 9385 0891
3. **Consent Process**

- All participants must receive a Participant Information Sheet (PIS).
- All participants must sign consent forms before participating in the study.
- There are 2 consent forms, both are a part of the Participant information and consent form.

### 3.1 Study Consent form

Consenting to participate in the study which includes access to information in patient records such as vaccine dose dates, participation in the questionnaire and sample collection.

#### 3.2 Pap register consent form

This consent form gives investigators permission to access the participants HPV vaccine information on the national HPV vaccine registry, this information will only be provided to the research group.

- *Please ensure patients although there is identifying information being collected on the Pap register consent form only the research group will have access to it and once researchers receive information from the registry all information will de-identify. No identifying information will be published in study outputs.*

### 3.1 Consent process flow chart

<table>
<thead>
<tr>
<th>1. Participant Information Sheet (PIS) provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>Run through the Participant information sheet with patients to ensure they have a full understanding of the study</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. Study consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>If participants understand the study and would like to participate gain written consent. This requires a signature from the participant, once signed provide the participant with the PIS to take home</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. Pap registry consent</th>
</tr>
</thead>
<tbody>
<tr>
<td>We would like to gain access to participants Pap registry information such as dose and where dose was administered. This requires an extra consent form with extra information</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. Label consent forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attach an allocated piggy-back label so the consent forms correlate with sample and questionnaire</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. File consent forms in central VIP-I Study folder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consent forms should be couriered along with other study documents and samples to Melbourne*</td>
</tr>
</tbody>
</table>

*see section 9 for transport and courier information*
4. Questionnaire

Questionnaires can be self administered or administered by health staff. This is up to the services and the participant.

After Consent forms are completed administer the questionnaire or allow the patient to complete the questionnaire.

While we would like the questionnaire to be complete as possible we understand that some participants may not be comfortable in answering certain questions. It is optimal that the participant if comfortable

1. Administer Questionnaire
   Administered by health staff or allow the participant to complete the questionnaire

2. Label Questionnaire
   Attach correlating VIP-I piggy-back label to front of Questionnaire

3. File Questionnaire in central VIP-I Study folder
   Questionnaire should be couriered along with other study documents and samples to Melbourne*

*see section 9 for transport and courier information
5. Sample collection
Participating services will be provided ThinPrep sample jars by study coordinators. Sample jars will be sent in 2 batches 25.

Sample target: 50

PAP PRACTITIONER COLLECTION DOCUMENT
- Obtaining the Thin Prep sample - Labelling the VIP-I request slip

Obtain and adequate sample from the cervix

1. To obtain an adequate sample from the cervix;
   ➢ Insert central bristles of the BRUSH into the endocervical canal
   ➢ Apply enough pressure to bend lateral bristles against the ectocervix and,
   ➢ ROTATE BRUSH 5 TIMES

Prepare the conventional smear

2. Prepare the conventional smear by;
   ➢ ‘SMEARING’ first one side of the brush on the glass slide, and then the other

Prepare Thin Prep jar

3. ➢ RINSE the brush in the Thin Prep jar by pushing it into the bottom of the vial 10 times, forcing the bristles apart
   ➢ SWIRL the BRUSH vigorously to release more material
   ➢ Discard all collection devices. DO NOT leave them in the solution
   ➢ Re-cap the vial and tighten so that the small black mark passes the corresponding line on the vial
Label study documents and sample

- **RECORD** clients name as per usual clinic procedure
- **Place** a ‘VIP-I’ pink label on Preservecyt lid
- **ADD** a ‘VIP-I’ piggy back label to the vial, filling in D.O.B, and initials (first name initial and surname)
- **Place** Preservecyt labelled bottled into the Biohazard Bag and place in the shipping box for couriering to the RWH Laboratory.
- **Place** a ‘VIP-I’ piggy back label on your patient records, as well as on consents and questionnaire.

For women with previous history of cone biopsy/cervical ablation use the endocervical canal brush (with the spatula) and the cervix brush as in these patients the broom may not be able to reach the transformation zone, which in these patients may recede up the endocervical canal.
# Chapter 5: Epidemiological Project

## Labelling

Labelling of samples and study documents will ensure all study components correlate.

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td><strong>Clearly write participants details on 4 piggy back Labels</strong></td>
</tr>
<tr>
<td></td>
<td>patient initials, patient DOB and date of sample collection on four sample labels</td>
</tr>
<tr>
<td>2.</td>
<td><strong>Place 2 piggy back labels on ThinPrep sample jar</strong></td>
</tr>
<tr>
<td></td>
<td>place piggy back labels around the thinPrep jar</td>
</tr>
<tr>
<td>3.</td>
<td><strong>Place 2 pink VIP-I study sticker on Thin Prep sample jar</strong></td>
</tr>
<tr>
<td></td>
<td>Place the 1 Pink VIP-I stickers on the lid and 1 on the side of the sample jar</td>
</tr>
<tr>
<td>4.</td>
<td><strong>Label Questionnaire with 1 piggy back label</strong></td>
</tr>
<tr>
<td></td>
<td>place label on front page of questionnaire</td>
</tr>
<tr>
<td>5.</td>
<td><strong>Label information and consent form with 1 piggy back label</strong></td>
</tr>
<tr>
<td></td>
<td>Place label on first page</td>
</tr>
</tbody>
</table>
Labelling for VIP-I HPV Study Samples

1. Clearly write sample details – patient initials, patient DOB and date of sample collection on four sample labels (generally an additional two spare labels have been provided for each participant ID – total of 6 labels).

2. If the ThinPrep sample jars do not already have pink VIP study identification stickers, please label as shown (left).

3. Place one pair of patient ID stickers – still on their double backing – onto the appropriate sample jar as shown.

4. The second pair of stickers is separated – one for the patient’s questionnaire and one for the consent form. This ensures full traceability between the patient’s sample, documentation and receipt logs when the sample reaches the lab.
6. Storing samples and study documents
Samples can be stored in less than 30°C, in most cases storing at room temperature is acceptable. Services will be provided with an esky for storing and transporting samples. Additionally service will be provided a study folder including all study documents.

For efficiency allocate a location for the esky and folder so health service staff have one central place to store study samples and completed documents. Samples and completed document should be stored after each collection.

The sample esky is located........................................................................................................

The study folder is located........................................................................................................

7. Sending samples by Courier
Samples can be transported when esky is full or every 4 weeks depending which is more frequent.

The preferred courier for sample transport to the Royal Women’s Hospital laboratory in Melbourne is PDP Couriers (http://www.pdpcouriers.com).

Contact Dina or Skye when samples are ready, they will organise pickup of esky and send through a consignment note to be attached to esky box.

Dina Saulo
The Kirby Institute
University of New South Wales
Wallace Wurth Building, Sydney NSW 2052
NSW 2052
Email: dsaulo@kirby.unsw.edu.au
Ph: 02 9385 9002
Fax: +612 9385 0891

Skye McGregor
The Kirby Institute
University of New South Wales
Wallace Wurth Building, Sydney
Email: smcgregor@kirby.unsw.edu.au
Ph: 02 9385 0958
M: 014 0231 8891
Fax: +61 (0)2 9385 0891

Testing Laboratory Address
Molecular Microbiology Laboratory
Royal Women’s Hospital – Department of Microbiology and Infectious Diseases
Delivery Entrance C, Business Incubator Building (Bldg 404)
Rear of Bio21 Institute, 30 Flemington Road
Parkville, 3052

➢ Contact Dina or Skye if you require more information
8. Results and follow up

- Reports will be sent to clinics in the form of a letter addressed to Pap providers. The letter will contain a HPV positive or negative result.

- A further report will be sent to clinics on completion of sample collection after all information has been processed.

- Clinics should continue their conventional pap smear, abnormal and normal results should be fed back to clients as per usual. Along with usual follow up and recall procedures.

- A recommended algorithm of care for HPV testing has been provided by the research team.

- If a Colposcopy is required as per recommended algorithm, costs for Colposcopy testing will be covered by the research institutes.

9. Study outputs
The following research outputs will be produced:

- Patient results sent to Pap providers to feed back to participants
- Clinic report
- Paper for publication
- Conference presentations

No mention of service names or participants identified in outputs.

All outputs will be sent to services for approval in sufficient time before publication, or presentation.

Due to the type of research, there may be media interest in findings. No services will be mentioned in any media communication.
**Recommended algorithm of care for HPV testing**

- **Pap**
  - Normal
    - High risk HPV DNA detected?
      - No → No follow-up. Recommend routine Pap in 2 years
      - Yes → Invite for repeat Pap and HPV test in 12 months
  - Abnormal → Treat as per standard algorithm for abnormal Pap

- **Abnormal**
  - Pap
    - Normal → No follow-up. Recommend routine Pap in 2 years
    - High risk HPV DNA detected?
      - No → No follow-up. Recommend routine Pap in 2 years
      - Yes → Refer genotype report from laboratory

  - Infection with different high-risk genotypes at each test point
    - No follow-up. Recommend routine Pap in 2 years
  - Persistent (i.e. same genotype detected at both test points) infection with high-risk type(s) other than 16 or 18
    - Repeat Pap and HPV in 12 months
  - Persistent infection with HPV 16 or 18
    - Recommend colposcopy

  - If Pap at 24 months is normal but same high-risk HPV type infection persists, recommend colposcopy
Study pack
At the commencement of the study services will be provided with the following items. If services require more please contact the VIP-I coordinator.

- 1 folder containing study documents
- 50 Precervcyt ThinPrep sample jars – sent in two batches of 25
- 50 snap lock bags
- 300 piggy back VIP-I study labels
- 150 round pink VIP-I study stickers
- 60 questionnaires
- 60 participant information and consent forms
- 1 Sample storage and transport Esky, more to be provided as needed
Evaluating the effectiveness of the HPV vaccine among Indigenous women in Australia

Dina Saulo1, Skye McGregor1, John Kaldor1, Bette Liu1, Siapehr Tabrizi2, Suzanne Garland3, Julia Brotherton4, Bette Liu1,2, Sepehr Tabrizi3, Suzanne Garland3, Julia Brotherton4, Rachel Skinner5 & Mary Stewart6


Approaches to evaluating HPV vaccine program in Australia

The importance of evaluating vaccination program impact on HPV genotypes among Indigenous women

Greater burden of cervical cancer in Indigenous vs non-Indigenous women

Cervical cancer incidence and mortality is disproportionately higher (AIHW 2010)

Cervical cancer screening participation estimated to be ~18% lower (Binns 2006)

HPV vaccine coverage

Overall 3 dose 70% coverage in women

Limited estimates of vaccine coverage in Indigenous girls and women

Appendix 4: VIP-I international HPV conference presentation
INFECTIOUS DISEASES AMONG MARGINALISED POPULATIONS

Vaccine Impact in Indigenous Population (VIP-I)

Objective
Evaluation of the impact of the Australian Vaccination Program on the prevalence of circulating HPV genotypes among Aboriginal and Torres Strait Islander women.

Aim
• To estimate the proportion of Aboriginal and Torres Strait Islander women who have been vaccinated
• To estimate and compare the prevalence of HPV types among demographically similar post-vaccine era and pre-vaccine era (WHINURS participants) cohorts.

Target
• Aboriginal & Torres Strait Islander woman aged 18 – 26 years
• Attending study sites for Pap testing

Methods
1. Demographic and behavioural questionnaire
2. Laboratory confirmation of HPV DNA and genotype
3. Linking participant dose coverage data from the National HPV vaccination program register (NHVPR)

VIP-I study sites
Sample size = 200

Methods
• Service led
  – Site coordinator
  – Collaborative team – Aboriginal health workers, doctors, nursing and midwifery/ mothers & babies staff and health promotion workers
• Capacity building
  – HPV update
  – VIP-I training
  – Pap provider training available for health staff
Conclusion

- There is potential the HPV vaccine program could reduce cervical cancer rates in the Indigenous population if:
  - Indigenous and non-Indigenous women have similar HPV prevalence profiles, as was found in the baseline survey
  - Vaccine coverage does not differ by Indigenous status

Future work

- Indigenous HPV Surveillance network
- Inclusion of Indigenous boys and men
- Possibility of self-collected samples
- Novel methodologies such as utilising social media networks to recruit and using new technologies

Acknowledgement

- Participating women
- Participating Services
- Site coordinators
- WHINURS and VIP investigators

Funding: Commonwealth Department of Health
6 Teaching Experience
## Contents

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6.1 Lessons from the field

Lessons from the field (LFF) are a teaching exercise created by each MAE student focusing on an issue, learning or strength from their field placement. Each student develops guided learning exercises for fellow students to complete. Students are required to attend a teleconference to discuss and reflect on the LFF responses. I developed a LFF on project management with a focus on principles, qualities and transfer of knowledge in research.

Although I had project managed in the past, I had not explored project management theory. The principles of project management I developed over time evolved through previous work and personal experiences. I believe strong project management skills are needed in the field of epidemiology. I began by gathering project management resources, I then collected publications and resources focused on areas I thought would benefit other MAE students.

Students completed the exercises (Appendix 1) and I held a teleconference to discuss responses on 22nd May 2014.

6.2 MAE teaching experience

A half day teaching session ran by the entire 2013 MAE cohort was conducted in March 2014. This year, our cohort taught first year MAE students over a half day. We divided into small groups, running four different lessons, each team created lesson plans, teaching resources and presentations.

I formed a group with colleagues Pip Chidzgey and Jason Agostino. Our MAE data analysis projects shared two similarities, a focus on the Indigenous population and analysis of trends over time. We came together on teleconferences to discuss our own data sets and develop a lesson plan with set learning objectives, the lesson plan evolved as we narrowed our focus (Appendix 2). As a team and in consultation with our academic supervisors we develop a session entitled “interpreting rate change in time series data”. We went about creating a systematic framework for assessing change using each team member’s data analysis as a case study.

To create a framework we documented our own process for interpreting rate change in time series data. As a team we brought our own processes together to develop a streamlined framework (Appendix 3). We identified common steps and discussed order and we soon realised steps set out in our framework could be used interchangeably.
We structured a lesson flow using our case studies to demonstrate steps of the framework (see lesson PowerPoint Appendix 4). We worked well together contributing to all aspects of the exercise.

Students evaluated the lesson very highly with one student commenting “Excellent session – well presented and interesting case studies”.

The LFF was an individual effort so working in a team for the teaching exercise was fantastic. We worked well together to produce a well thought out simplistic approach to teaching on what could have been a complex topic. Frameworks when teaching provide a lasting structure for students to use in the future.

6.3 Lessons learnt
While the LFF is a learning experience for fellow MAE students, I also learnt more about project management and the work invested into producing teaching resources. This LFF has given me the opportunity to validate some of the processes I use but mostly it has equipped me with new tools, language and understanding of project management fundamentals and opened my eyes to an entirely new application of these skills.

I explored the process of learning through reading literature and discussed with others Blooms taxonomy domains and Robert Gagné’s Nine Steps of Instruction to improve the objectives, structure and delivery\(^3\,^4\).
6.3.1  Appendix 1: Lessons from the field 4: Project management

Lessons from the field 4: Project Management

Please save your answers in this word document

Send answers back by: Thursday 15\textsuperscript{th} May 2014

Teleconference: Wednesday 21\textsuperscript{st} May, 2014

Learning Objectives

- Understand what project management, a project and activities are
- Understand the advantages of a trans-disciplinary team and the qualities needed to successful project manager a trans-disciplinary team
- Apply project management principles and qualities to case study and own practice
- Understand the vital role of knowledge transfer in research
- Understand the fluidity and interactions of project activities and how they impact planning
Background

During 2005-2008 the Women’s HPV Indigenous Non-Indigenous Urban Rural Study (WHINURS)\(^1\) recruited Indigenous and non-Indigenous women throughout Australia undergoing cervical cytology screening in order to estimate the prevalence of human papillomavirus (HPV) genotypes in this population. Participants in WHINURS were recruited via Aboriginal Community Controlled Health Services (ACCHS), General Practitioner clinics and family planning clinics. As a majority of woman were recruited prior to the implementation of Australia’s HPV vaccination program, the WHINURS study established an important baseline for post-vaccine program surveillance of HPV types in this population.

A second study called Vaccine Impact in the Population (VIP) compared a post-vaccine sample, recruited through family planning clinics, to the pre-vaccine WHINURS sample and found a significant decrease in vaccine preventable HPV genotypes\(^2\). The reduction was consistent with what would have been expected based on clinical trials that demonstrated vaccine efficacy.

There is a need to evaluate the impact of the HPV vaccine program on the prevalence of infection among Indigenous women in Australia. Although there has been a documented decrease in HPV vaccine genotypes by other studies they have not had a sufficiently large Indigenous sample size to determine whether there has been a corresponding decrease in the prevalence of infection among Aboriginal and Torres Strait Islander women.

The HPV Vaccine Impact in the Australian Indigenous Population (VIP-I) project will evaluate HPV vaccine program effectiveness in Indigenous women by comparing HPV genotype prevalence in cervical samples collected at Pap testing in post-vaccine populations to that in a comparable population tested in the WHINURS study (pre-vaccine).

Aims of VIP-I

- To estimate the proportion of Indigenous women who have been vaccinated among 18-26 years old women attending for cervical cytology screening
- To estimate and compare the prevalence of HPV types (including vaccine-specific types 6/11/16/18 and other high risk HPV types) among Indigenous women in the post-vaccine era compared to pre-vaccine era
Design

VIP-I is a cross sectional prevalence survey. Six ACCHS which recruited substantial numbers to the WHINURS study will be approached to participate in the VIP-I study to ensure a comparable sample. VIP-I is targeting recruitment of 220 Indigenous women aged 18 - 26 who attend ACCHS (or other service providers with a high proportion of Indigenous clients) for routine cytology screening over the study period.

Methods

1. Demographic and behavioural questionnaire
   After gaining consent participating studies will collect the following questionnaire information; age, postcode of residence, education, number of past partners, age of first intercourse, use of hormonal contraception, smoking, receipt of HPV vaccine and the number of doses and Pap test history

2. Laboratory confirmation of HPV DNA and genotype
   Pap test samples collected by participating sites transported to Royal Woman’s Hospital, Melbourne for laboratory testing

3. Accessing participant HPV vaccination register records
   Consent gained from participants to access vaccination status and dose coverage information from the register
Scenario

When you start the MAE you are asked to be the field coordinator of the VIP-I project. You are essentially a project officer for the project from start to finish.

You will work with a small team at your research centre to complete study activities but also link into utilise the resources, skills and knowledge of other investigators. The team of investigators on the project are from six different organisations. The investigators have established relationships, working together on past research projects and publications. Investigators have different professional backgrounds including; epidemiology microbiology, biostatistics, medical, policy and research.

You have been brought on as a project officer to coordinate study activities, recruit services to the study, developing study procedures and processes and ensuring participating sites are trained in study processes. You work with a smaller core group at you research centre to advance the project.

Your first task is to organise a face to face meeting with investigators. From this meeting a number of activities are established; writing the study protocol, study documents and submitting ethics applications to eight different ethics committees as a starting point and starting to contact potential sites to gauge interest in taking part in the study.

The project will only run over a 24month period. It is vital to ensure project activities are completed on time and there is progression at all stages. This is a team effort and at some stages different investigators take on a projects management role depending on the activities.
Task 1: Project management

There are many different frameworks and tools created for project management. These frameworks and tools have been developed mainly for engineering, construction and business purposes. The concepts are transferable across all fields in which projects are undertaken. Apply the concepts from the following resources to your work as an epidemiologist and answer the following questions about project management:

Resources:

a) PM@UTS PROGRAM: Guide to project management pg 4
b) A Guide To The Project Managment Body of Knowledge pg 4-6

c) Applying project management principles to research projects in a health setting

1. What is a project?

ANNA:

A project is a temporary endeavour to create a unique product or service. Projects can be conducted by one or many people or organisations, and is defined by a specific time frame or lifecycle. Unlike operational activities projects must eventually come to a conclusion.

2. What is project management?

ANNA:

Project management is using knowledge, skills, tools and techniques to complete project activities that meet the projects requirements. In other words project management ensures that the outcome of the project is clearly defined, objectives are aligned to the desired outcomes and there is a means to monitor and control the projects progress and its ability to meet defined deadlines.

TIM:
Project management is a systematic approach to do what it says, manage a project. Ensuring milestones, timelines, deliverables are met to achieve successful completion of the project.

3. What key project management principles/stages are identified in “Applying project management principles to research projects in a health setting”\(^{(5)}\)?

**PIP:**

Plan (initiating and planning), monitoring and control (executing and controlling), implementation (closing)

**ANNA:**

Planning

a. Initiate- establish a research question, provide background, study design, identify study population, define desired outcomes, determine how to report findings and plan analyses. Scope of the project should be defined in this stage and a study proposal provided.

b. Plan – define the number of participants in your study population, develop a sampling framework, recruit participants, identify data systems, plan for how funding should be used, determine how to manage stakeholders and identify the number of staff required for the project.- This stage defines the components required to meet the projects objectives.

Monitoring and control

c. Execute-ethical and regulatory requirements are complete, study participants are approached, data is collected, stakeholder consultations and management of these relationship continue and the education of site staff occurs- This stage activates the project proposal or plan.

d. Control- oversight of deadlines, controls and adjusts for changes in timeframes, manages the risk of the project, conducts on-site monitoring, verifies source data, stakeholder consultations and management of these relationships continue and audits the project. This stage provides quality assurance of project activities.

Implement
Close-analyses of the data, write up the results, close the study sites formally, present results to stakeholders and participants, produce a manuscript, refine the research question and if required start the project life cycle again. This stage provides the impact the project has on the area of study and should outline the lessons learnt along the way.

4. There is limited literature on the application of project management principles/stages in epidemiological research. List other principles or stages you would include for the management of the VIP-I project and why.

Community consultation

COURTNEY:
There is some talk of ‘stakeholder management’, however, I think stakeholder consultation could be another stage for this project since there are many different organisations involved and perhaps also community consultation, which while always important, is particularly needed in this project as the research is focussed around Indigenous health and increasing community engagement might help ensure that the research is relevant and acceptable to the community and help increase participation and enthusiasm for the research amongst both sites and individuals.

TOVE:
Consultation with Aboriginal communities- This would be the very first stage for me to explain the proposed study and how it will benefit the communities to ensure that the study is culturally safe and appropriate. I think consultation at the end is also crucial to ensure that the interpretations of the results are correct.

Evaluation

ANNA:
I would add in an evaluation stage. Whilst that is mentioned in the close, I think it’s really important to have a separate stage for this and in a lot of projects it’s not done at all. In the evaluations stage I would look at how the
...project went, whether it achieved its objectives and what could be done better in the future for similar studies.

**PIP:**

I would include an explicit step on its own, “evaluate”. I know this could be part of “monitoring” but when you read the definition provided by Vachan, it is monitoring of the project, not the actual monitoring of the outcomes of the project. Evaluation would allow us to monitor the effect and success of the project, so lessons could be learnt, and the project could be developed into an ongoing program if it achieves its objectives.

### Task 3: Trans-disciplinary teams

As a project officer of the VIP-I project you have submitted an abstract at a conference to ensure knowledge of the project is being disseminated during the research project. You attend a couple of presentations about the importance of partnerships and collaboration in the development of research. At the conference a number of people talk about translation of research by the inclusion of investigators from across different sectors. The inclusion of investigators from other sectors including policy makers can enhance the application of research outcomes. For example, the inclusion of policy makers as investigators could assist in framing research communication to lead to the development of evidence based policy.

The VIP-I project has a trans-disciplinary team consisting of investigators from six different organisations with backgrounds in; epidemiology microbiology, biostatistics, medicine, policy and research.

Reading: Enhancing Trans-disciplinary Research Through Collaborative Leadership[6]

1. **Using the literature provided and your own experience, discuss the advantages and disadvantages of building and/or working in a trans-disciplinary research team.**

   *Included in the table are responses from Courtney, Kerryn, Anna, Tim and Tove categorised into common themes.*
<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Methodology re-orientation</strong></td>
<td><strong>Ego</strong></td>
</tr>
<tr>
<td>• Creation of new methodologies and science</td>
<td>• Power differences</td>
</tr>
<tr>
<td>• Promotes theoretical, conceptual and methodological re-orientation.</td>
<td>• Need to accommodate egos</td>
</tr>
<tr>
<td>• Emergence of new data and interactions</td>
<td><strong>Conflict</strong></td>
</tr>
<tr>
<td><strong>Integration of knowledge</strong></td>
<td>• Misunderstanding and “groupthink”- disagreements and differences.</td>
</tr>
<tr>
<td>• Improves communication between disciplines</td>
<td>• Personal conflicts between members of the project team can delay or prevent</td>
</tr>
<tr>
<td>• Can ensure a more comprehensive response to a question.</td>
<td>project activities</td>
</tr>
<tr>
<td>• Able to tackle ‘more’ aspects of the problem</td>
<td><strong>Lack of respect or other disciplinary methodologies and concepts</strong></td>
</tr>
<tr>
<td>• Provides a more complete answer to a problem as it provides insight and</td>
<td>• Lack of acceptance of the validity of methodologies of other disciplines</td>
</tr>
<tr>
<td>knowledge from different disciplines</td>
<td>• Differences in reward and therefore aims and priorities</td>
</tr>
<tr>
<td><strong>Comprehensive research and outcomes</strong></td>
<td>• Disagreements between collaborators on the validity of others work and type</td>
</tr>
<tr>
<td>• Improved legitimacy of work</td>
<td>of framework to be used for the project</td>
</tr>
<tr>
<td>• More holistic objectives</td>
<td>• Mismatches between rewards stressing disciplinary competence over innovation</td>
</tr>
<tr>
<td>• Appealing to multiple stakeholders</td>
<td>• Crucial information is not collected due to misunderstanding of its importance or relevance to the overall project</td>
</tr>
<tr>
<td><strong>Creation</strong></td>
<td>• Might be difficult to respond to stakeholders needs.</td>
</tr>
<tr>
<td>• Increased opportunity for creative problem solving and innovation</td>
<td><strong>Communication breakdown</strong></td>
</tr>
<tr>
<td>• Members of a trans-disciplinary team may challenge each other about the</td>
<td>• Lack common problem focus</td>
</tr>
<tr>
<td>research which can encourage researchers to re-think the research</td>
<td>• Multiple agendas/ideas/egos</td>
</tr>
<tr>
<td>and improve on the original plans.</td>
<td>• Greater communication and people management needed</td>
</tr>
<tr>
<td><strong>Multiple Institution interaction</strong></td>
<td><strong>Multiple Institution interaction</strong></td>
</tr>
<tr>
<td>• Institutional disincentives</td>
<td>• Institutional disincentives</td>
</tr>
<tr>
<td>• Multiple bureaucratic clearance processes</td>
<td>• Multiple bureaucratic clearance processes</td>
</tr>
<tr>
<td>• Lack of common goals across sectors</td>
<td>• Lack of common goals across sectors</td>
</tr>
</tbody>
</table>
2. Using your assigned quality required to successfully project manages a research team, answer questions a) and b)

Resources:

- Anita – Influencing, Anna – Problem solving, Pip – Negotiating, Tove - Leading
  Tim – Communicating: Refer to Pg 20, 23 & 24, A Guide To The Project Management Body of Knowledge pg 4-6(4)
- Courtney – Conflict management & Kerryn – Self monitoring: Refer to: How Personality traits and Dimensions of Project Managers Can Conceptually affect Project Success(7)
- Feel free to use other literature including the above Enhancing Trans-disciplinary Research Through Collaborative Leadership(6).

a) Define the quality

b) How can this quality be applied to managing of the VIP-I project?

  Give an example

  **COURTNEY: CONFLICT MANAGEMENT**

  a) Creasy and Anatatmula state that conflict arises when there are incompatible goals, thoughts or emotions between individuals that are the result of differences in opinion, perception or belief. They posit that conflict can be dysfunctional (negative and disruptive), particularly when people-focused, but that task and process orientated conflict can be beneficial and lead to improvements, problem solving and innovation where communication is clear.
  
The text defines three different approaches to conflict management by project managers. The traditional approach is to view conflict as negative and focuses on avoidance of problems. The behavioural view also views conflict as negative but natural and inevitable, this view focuses on managing rather than eliminating conflict. The final, interactionist, view believes that a certain level of conflict should be encouraged to increase performance. The authors propose that behavioural or interactionist approaches to conflict management in project management will have more success than traditional approaches.

  b) As the VIP-I is a trans disciplinary team, conflict about the validity and appropriateness of selected methods may be encountered due to differences in
training and prior beliefs. By taking non-avoidance focused approach to conflict management you can prepare for this conflict by implementing good communication channels. In doing this you may be able to not only ensure everyone is happy with the new arrangements but may be able to innovate and find ways to incorporate multiple methods into the project, strengthening the project output and increasing the application of its findings (due to acceptability across multiple disciplines).

KERRYN: SELF-MONITORING
a) The ability for a person to adapt their behaviour in a situation to achieve the outcomes they want. A high self-monitoring personality is good at this. A low self-monitoring personality is more concerned with maintaining a consistent approach to everything, regardless of the effect on other people, the team or the outcome.

b) This would be an extremely important ability when engaging ACCHS as there is a need to recognise what the ACCHS is trying to achieve, their priorities, resources and training. ACCHS’s operate differently than general GP services and understanding the environment and community that they are operating in and engaging with that would be essential to recruiting ACCHS’s and participants.

ANNA: INFLUENCING
a) Influencing is defined as the ability to get things done. This quality requires an understanding of both the formal and informal structures of all the organisations involved in the project and a comprehensive knowledge of the internal and external politics and positions of power. This includes understanding the organisations itself, its customers, contractors and numerous other people or areas that influence or are affected by the organisations.

b) This quality can be applied the VIP-I study by engaging with local communities in the planning phases of the project to obtain participant and ensure the project does not disadvantage or marginalise the study population. These initial consultations need to include engagement with the health services, elders of the community and potential participants. In addition, a member from each of the communities involved in the study should be appointed as a
member of the research team. This member should be a representative of the community and is someone who is nominated by the community. When managing this project it is essential to ensure all stakeholders are provided with regular information about the project’s progress, the benefits this study will have towards the community and informed about the use of the collected information.

**PIP: NEGOTIATING**

a) Conferring with others in order to come to terms or reach an agreement (Duncan, 1996).

b) I think it would be a good idea at the first team meeting to ask every team member what their goals are for the project and what they would like to get out of the project. I think this would be better than coming in with project objectives and telling everyone it’s your way or the highway. Then, negotiations can take place to come to agreement on team goals and objectives. I think this sort of negotiation would be beneficial, it means everyone will be on the same page and there is a clear focus.

**TIM: COMMUNICATING**

a) Clear and concise exchange of information and ensuring it is understood by all parties.

b) Ensuring all members on the project understand what is going on possibly through regular updates or team meetings. At these meetings each member could feedback as to what they have been doing, any issues they have faced and how they were resolved or ideas from others on how to resolve them.

**TOVE: LEADING**

a) Leading people involves establishing direction for a project, aligning people who work within the project and motivating and inspiring those involved in the project.

b) At the first meeting you could talk about where the project originated from and what is expected out of the study and how this will make a difference in the lives of Indigenous women. You could then talk with the people who are conducting each of the activities and explain how what they are doing individually contributes to the study as a whole and how that fits with the “big picture”.

c)
Task 3: Knowledge brokers

As epidemiologists, we will at some stage lead or be a part of a trans-disciplinary team. Let’s look at our own roles within a trans-disciplinary team as knowledge brokers to ensure knowledge dissemination is optimised within the team, is shared with stakeholders as well as the appropriate dissemination of research outcomes/findings.

Use the provided resources on knowledge brokers and reflect on your role in the VIP-I project team and how a project manager takes on a knowledge broker role.

Readings

“Know–Do” Gap: Knowledge brokering to improve child wellbeing: Chapters 6[

Reflections on Knowledge Brokering Within a Multidisciplinary Research Team[

This cartoon is a great example of how communication can affect a project. Even though this example is in the context of a business solution, the interpretation and communication of concepts between team members and stakeholders in a large research project has a similar impact on outcomes.

Source: http://projectcartoon.com
1. What is a knowledge broker?

COURNTEY:
A knowledge broker is someone who facilitates ongoing communication between team members in an interdisciplinary team and develops and maintains relationships and communication with stakeholders groups and decision makers, with a view to developing an interactive communication process between decision makers and researchers.

ANNA:
A knowledge broker is a person within a research team who understands both the policy and research perspectives of a project and acts as an intermediary between the two worlds. This role requires the person to be a driver change, communicate across professional paradigms, understand different contexts, utilise opportunistic change as it arises and be able to persuade and develop a compromise between disciplines.

2. What does a knowledge broker do to ensure translation of knowledge across a research team and stakeholders? Dot point

Answer reflects combined common themes from responses provided by Courtney, Kerryn, Anna, Tim and Tove.

Communication
- Sustaining team member engagement
- Communicate effectively with people from these different areas to persuade them to put research into policy action or direct research into areas policy needs more evidence
- Developing and maintaining communication skills/strategies
- Medicate conflicts
- Develop communication tools for the project – internal and external

Networking/harnessing relationships
- Seek out and communicate well with all stakeholders
- Build relationships
- Obtain feedback and suggestions from stakeholders
- Facilitating communication (establishing lines of communication if necessary)
- Connecting with all stakeholders
Vision

- Understand both sides of the policy and research worlds
- Understand the broader context and work within this to achieve the best research and policy outcomes.

Facilitate

- Work closely with research team members to develop appropriate research questions and decide upon the most appropriate format for collection and analysis.

Provide the big picture

- Team coordination and building
- Have a clear understanding of all disciplines involved in the project
- Harnessing and sharing team member’s skills and expertise
- Establishing relationships within and between team members and stakeholders
- Sustaining participation and ensuring active involvement by team members
- Harnessing expertise and ensuring it is shared across the project

3. In a couple of sentences, discuss the similarities of a knowledge broker and a project manager.

PIP:

Essentially, a good project manager should be a knowledge broker for their team. Project managers should facilitate communication and meetings and engage with key stakeholders. Knowledge brokers focus on development, which would be a good focus for project managers, as aiding knowledge sharing and education is a good way to build personal skills and team functioning.

TIM:

I’d argue that the roles are almost identical and depending on the size of the project could be done by the same person. For large projects the role may be split, so that the project manager can focus on the project as a whole with someone else ensuring communication happens
CHAPTER 6 TEACHING EXPERIENCE

Task 4: Defining and scheduling activities

Activity sequencing is the identification of interactive dependencies to create a realistic time frame on activities and later developments. The ability to sequence activities in a logical way, understand which activities can be undertaken simultaneously and ability to be flexible with activity timeframes within a larger set project time line are important skills for a project manager.

Readings

- PMBOK resource, pg 62
- Also see PM@UTS PROGRAM: Giude to project management Pg 38

1. The following project activities have been identified; your task is to sequence these activities. Use the PMBOK resource, pg 62 to categorise the below identified project activities into one of the following 3 categories.

   a. Mandatory dependent activities
   b. Externally dependent activities
   c. Discretionary dependent activities – preferred logic

   - Site support for ethics
   - Service Agreement
   - Service training
   - Site recruitment
   - Ethics approvals
   - Apply for data from national HP
   - Reporting back to services
   - Investigator meetings
   - Development of study protocol and study document
   - Adaption of a demographic and behavioural questionnaire
   - Study site training

All responses and teleconference discussion combined below

This exercise was mostly discussed on teleconference. Every response was different for similar reasons. Colleagues identified each activity can be in different categories at different phases of the project. The objective of this exercise was to encourage discussion about planning and the fluidity of activities within a project. There were different ideas of what discretionary dependents meant. Ideas were valid in that they were centred around the unpredicted time impact of activities, based on difference of concept, process understanding of best practise arising among team members and or stakeholders.
2. What scheduling and timeline tools or tasks do you use in your own work?

List two and how you use them.

Collectively the following tools were discussed:

- To-do lists
- Gantt charts
- Calendar lists
- Smart chart

References


**Task Literature**


6.3.2 Appendix 2: Lesson Outline

Description of the Training

A systematic framework for assessing a change in the rate of a health condition using three examples from studies on predominately Aboriginal and Torres Strait Islander populations.

Time: 50 minutes

Learning Objectives: At the end of the lesson, students will be able to:

1. Describe steps for systematically interpreting time series trends
2. Apply the principles of the epidemiological triad in offering alternative explanations of trends in time series data
3. Describe how selection and measurement bias may contribute to artifactual change in time series data
4. Identify issues to consider when interpreting data on vulnerable populations.

Training Techniques: Content on key epidemiological concepts will be delivered alongside three case studies from current MAE scholars.

Content:

Introduction: Introduction to three speakers and MAE placements. Outline of how lesson will run and learning objectives. (<5 mins)

Key concepts (PPT): Introduce framework for interpreting time series data. Describe key concepts such as agent, host, and environment in relation to interpretation of time series trends. Build on earlier teaching principles of selection and measurement bias in determining whether a change is real or artifactual. (15 mins)

Practical activity: Apply framework to case study examples in order to illustrate key concepts and points. (25 minutes) Given the limited timeframe, the group will have key questions to answer in relation to the framework. i.e:

- Is the change real or artifactual?
- What factors relating to the population may have impacted on rates?
- What factors relating to the agent (or disease) may impact on rates?
- What factors relating to the environment may have impacted on rates?
- Could there have been a change in how subjects were included in the study population?
- Could there have been a change in measurement of the outcome?
- What are the ethical and cultural issues to consider in interpreting the results from this study?

**Assessment:** Students will demonstrate achievement of the learning objectives by participating in the group session and by a short pop quiz (5 mins).

**Materials and Equipment**

<table>
<thead>
<tr>
<th>Materials</th>
<th>For the Instructor:</th>
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<tbody>
<tr>
<td></td>
<td>1. PowerPoint file for the presentation</td>
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<tr>
<td></td>
<td>2. Instructor Guide with notes for presentation and course</td>
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<td></td>
<td>3. Handouts (sample questionnaire)</td>
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<tr>
<td>For the Participants:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. Participant guide</td>
</tr>
</tbody>
</table>

| Equipment | |
|-----------| |
|           | 1. Projector |
|           | 2. Whiteboard |

**Prerequisites:** None

**Readings:** None
6.3.3 Appendix 3: Time Series Interpretation Framework

Interpretation of Time series data

1. Context
   Literature review, talk with local experts, know your topic, background, purpose of analysis.

2. Question
   Determine if rate change is real or artefact? This will determine the next step.
   If real continue to steps 3, 4 and 5. If artefact concluded by identifying why it’s false, take learning’s and remember for future application.

3. Epidemiological Triad
   Consider how the time trend may have been impacted by each component of the triad
   - Agent
   - Population
   - Environment

4. Describing your data
   Describe data by person and place: by sex, age, location etc exposure, outcome variables. Cross tabulation to explore risk factors by outcome.
   Stratification to assess confounding and effect modification

5. Validity
   Consider the potential impact of selection or measurement bias on the time series
6.3.4

Time Series Data Interpretation Framework

1. Context

2. Question
   Is rate change real or artefact?

3. Real
   - Population
   - Environment

3. Artefact
   - Identify
   - Learn
   - Remember

5. Validity
6.3.5 Appendix 4: “Interpreting rate change in time series data” Lesson PowerPoint
CHAPTER 6 TEACHING EXPERIENCE

Real or artefact?
Inclusion criteria:
Children who attended a clinic within a study community over at least 12 months of their first two years of life.

Outcome factor:
A diagnosis of underweight based on two weights for age scores two standard deviations below the median

Real or artefact?
Selection bias
Who is excluded?
Could this have affected the results?

Measurement bias
What factors could have could have led to a systematic error in the measurement of underweight?

Epidemiological triad
Three main factors that affect weight
1. Growth potential (born early, born small)
2. Energy in (breast milk, formula, food)
3. Energy out (infections)

Epidemiological triad
- Hazard (agent)
  An exposure that may adversely affect growth
- Population (host)
The children of Cape York communities
- Environment
  The conditions that the children grew up in

Population
- Have their been less children born early or small over the study period?
- Has the population become less susceptible to infection?
Population: Growth Potential

- Early births (premature)
  - Nil change over the study period
- Small births (small for gestational age)
  - Significantly decreased from 2002

Population: Energy Out

- Five childhood vaccines introduced between 1999 and 2008
  - Hepatitis A virus 1999
  - Streptococcus pneumoniae 2001
  - Neisseria meningitidis 2003
  - Varicella-zoster virus 2005
  - Rotavirus 2007

Environment

Energy in:
Food affordability? Disappointingly the same
Money to buy food? Possibly increased with introduction of alcohol management plans

Energy out:
Less overcrowding? Disappointingly the same
Improved access to health care? Large increase in health staff over study period

Hazard (agent)

Energy out:
Clean drinking water: Disappointingly the same

Putting it all together

Proportion of children underweight
Two-year moving average

- Improvement indicated
- Remaining significant
- Health staff increase
Applying framework to Bond

Inclusion: All of Ian Flemming’s books (14)
Exclusions: Books written by other authors (26)
Outcome factor: Assumes drinking pattern on days in books extends to all days.

Case study:
Hepatitis C prevalence among Indigenous and non-Indigenous prison entrants
Context
- 30,000 Australians in prison at one time
- 16% of the prison population are Indigenous
- The median age for Indigenous prisoners is younger than for non-Indigenous prisoners
- The rate of Hepatitis C is lower than in the general population
- The rate of Hepatitis B is higher than in the general population
- The rate of HIV is higher than in the general population

Study design
- Cross-sectional survey
- Purpose of capturing HBV, STI and risk behaviour among prison entrants
- Blood samples collected at prison reception centres before transfer into prison population
- Conducted in NSW, WA, QLD and Tas

Population
- 1752 prison entrants
- 22% Indigenous (N=382)
- 78% Non-Indigenous
- 74% have previously been in prison before

Agent
- Hepatitis C
- Main transmission mode in Australia is injecting
- 55% have ever injected

Validity
- Understand the extent to which bias affects results
- The more bias present in a study the less valid the results
- If you can reduce bias when developing a study you can increase you can increase internal validity

Consider the potential impact of selection bias on the time series

SELECTION BIAS