Treatment of Hepatitis within the Prison System – a New Model of Care for Victoria

Prof. Alex Thompson, MBBS PhD FRACP
St. Vincent's Hospital &
The University of Melbourne

CREIDU Colloqium, October 12, 2015

State Government Victoria
Department of Justice & Regulation

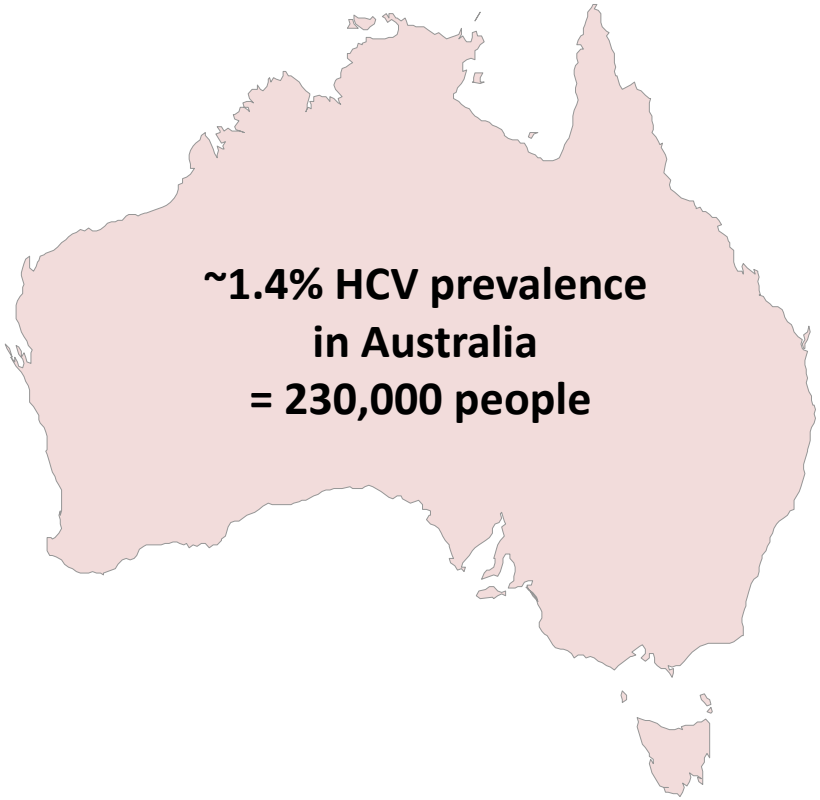
ST VINCENT'S HEALTH AUSTRALIA
UNDER THE STEWARDSHIP OF MARY AIKENHEAD MINISTRIES

Acknowledgement to Country

- We recognise the traditional custodians of the land and sea on which we live and work

HEPATITIS C: THE AUSTRALIAN EPIDEMIC

Hepatitis C burden in Australia

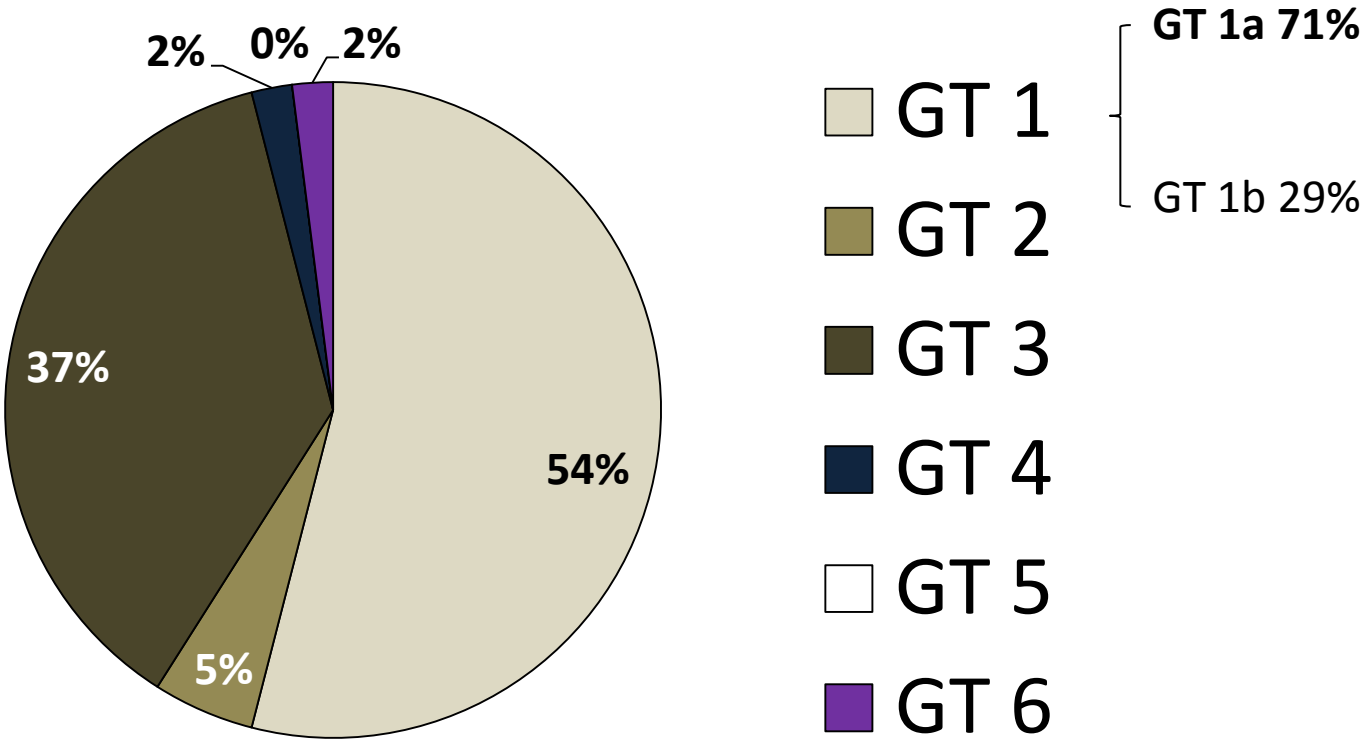


ST VINCENT'S HEALTH AUSTRALIA
UNDER THE STEWARDSHIP OF MARY AIKENHEAD MINISTRIES

Sievert, J Gastro Hep, 2014;
HIV, viral hepatitis and sexually transmissible infections in Australia. Annual surveillance report, Kirby Institute, 2013
MacLachlan, J.H., et al; 2011. Aust N Z J Public Health 2013.

HCV Genotypes among Aus patients

Data from >10,000 patients at VIDRL in Melbourne



VIDRL, data on file

Who has viral hepatitis?

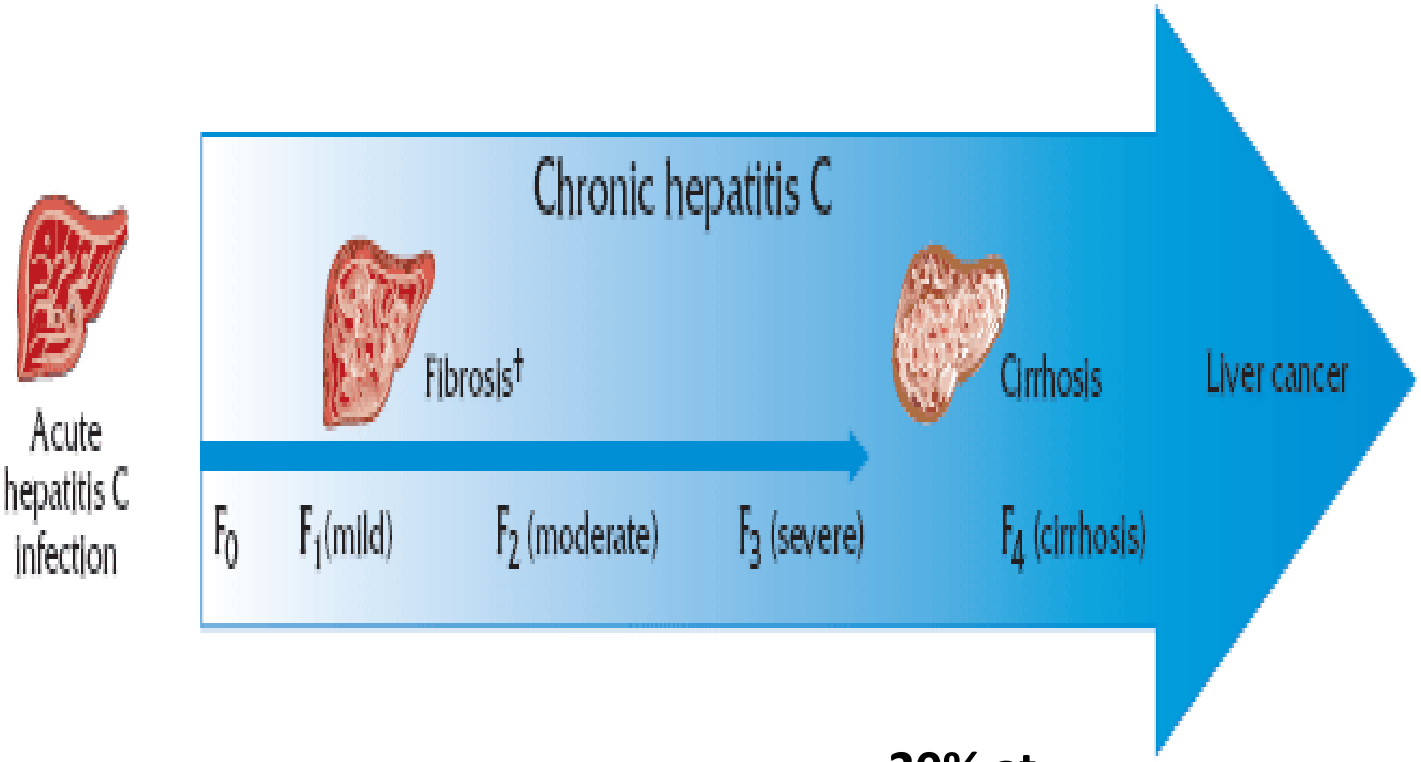
Risk factors for viral hepatitis
People who inject drugs or who have ever injected drugs
People in custodial settings
People who received a blood transfusion / organ transplant prior to 1990
Sex workers
Tattooing or body piercing
Children born to infected mothers
Sexual partners of infected persons
People infected with human immunodeficiency virus or hepatitis B virus
People with evidence of liver disease (persistently elevated ALT level)
People who have had a needle-stick injury
Migrants from high prevalence regions (Egypt, Pakistan, Mediterranean and Eastern Europe, Africa and Southern Asia)

- **HCV – there is NO HCV vaccine**
- **HBV – HBV IS vaccine preventable**

Thompson and Holmes, Australian Prescriber, 2015

Why is HCV a problem?

Natural history

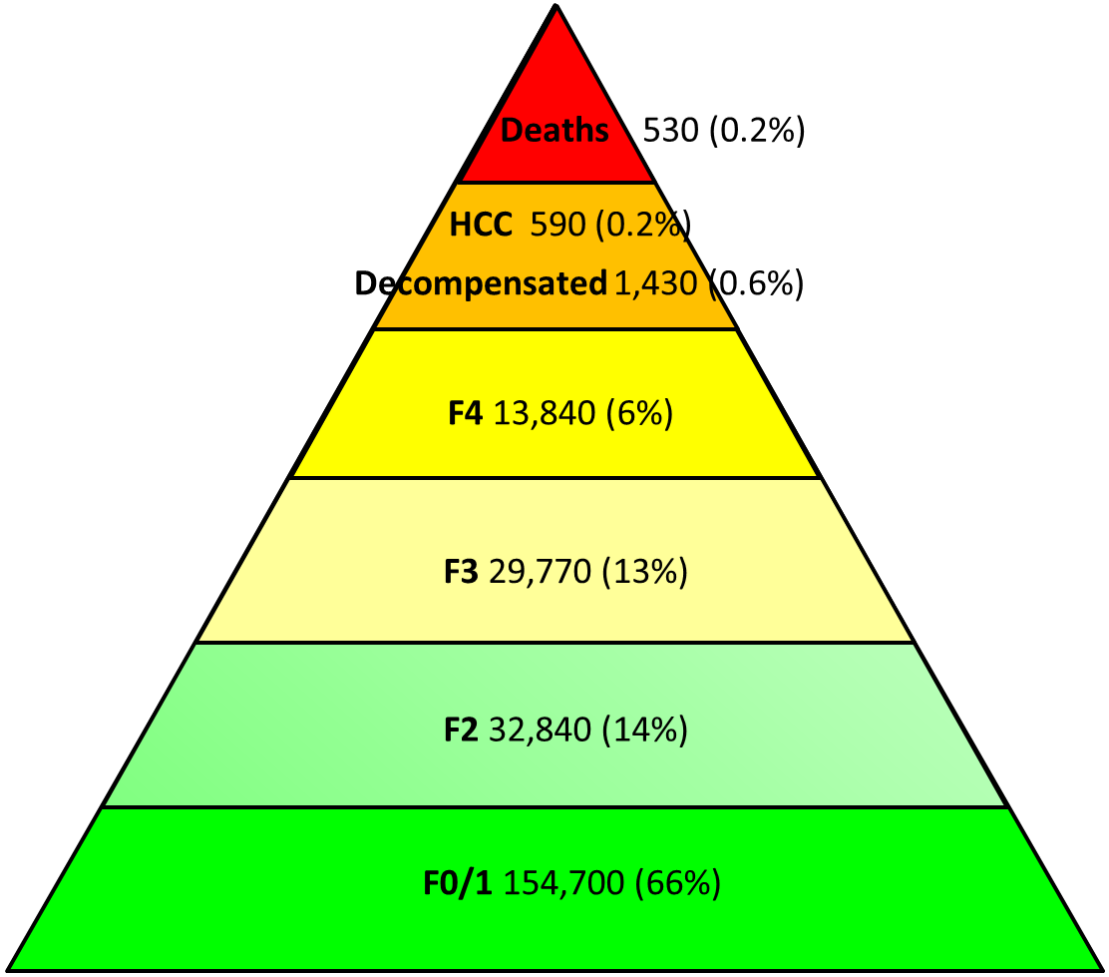


20% at 20 years

Bisceglie AM. Natural History of Hepatitis C: Its Impact on Clinical Management. Hepatology 2000; 31(4): 1014-018.

Why is HCV a problem?

HCV burden in Australia, 2013



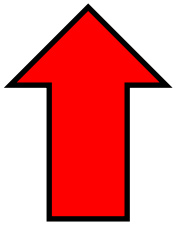
ST VINCENT'S HEALTH AUSTRALIA
UNDER THE STEWARDSHIP OF MARY AIKENHEAD MINISTRIES

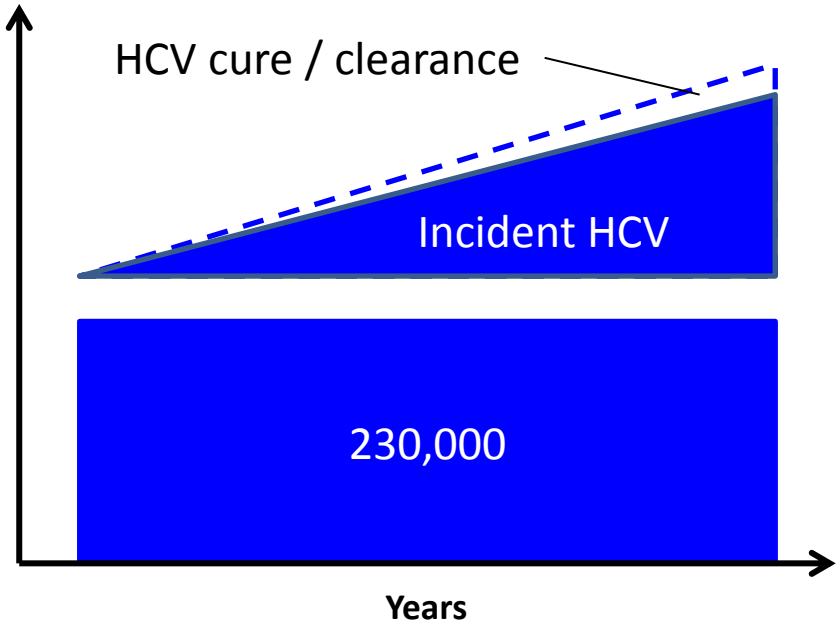
Sievert, J Gastro Hep, 2014;
ALA report, The economic cost and health burden of liver diseases in Australia, 2013

HCV prevalence is increasing

New infections > HCV cure / clearance

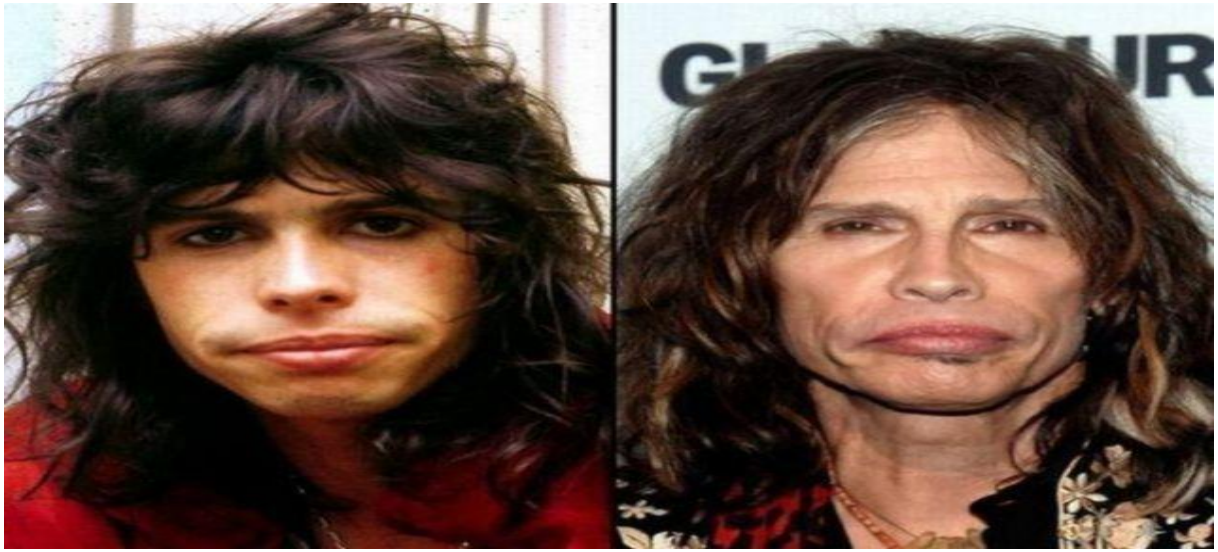
9000 – 10,000
new infections / year

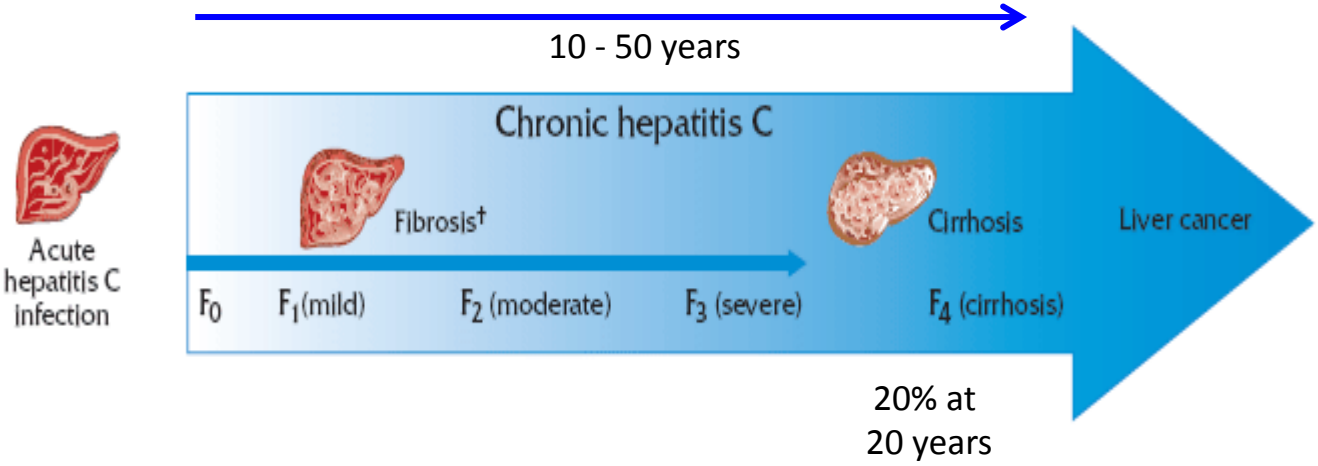




2000 - 3000
treatments / year

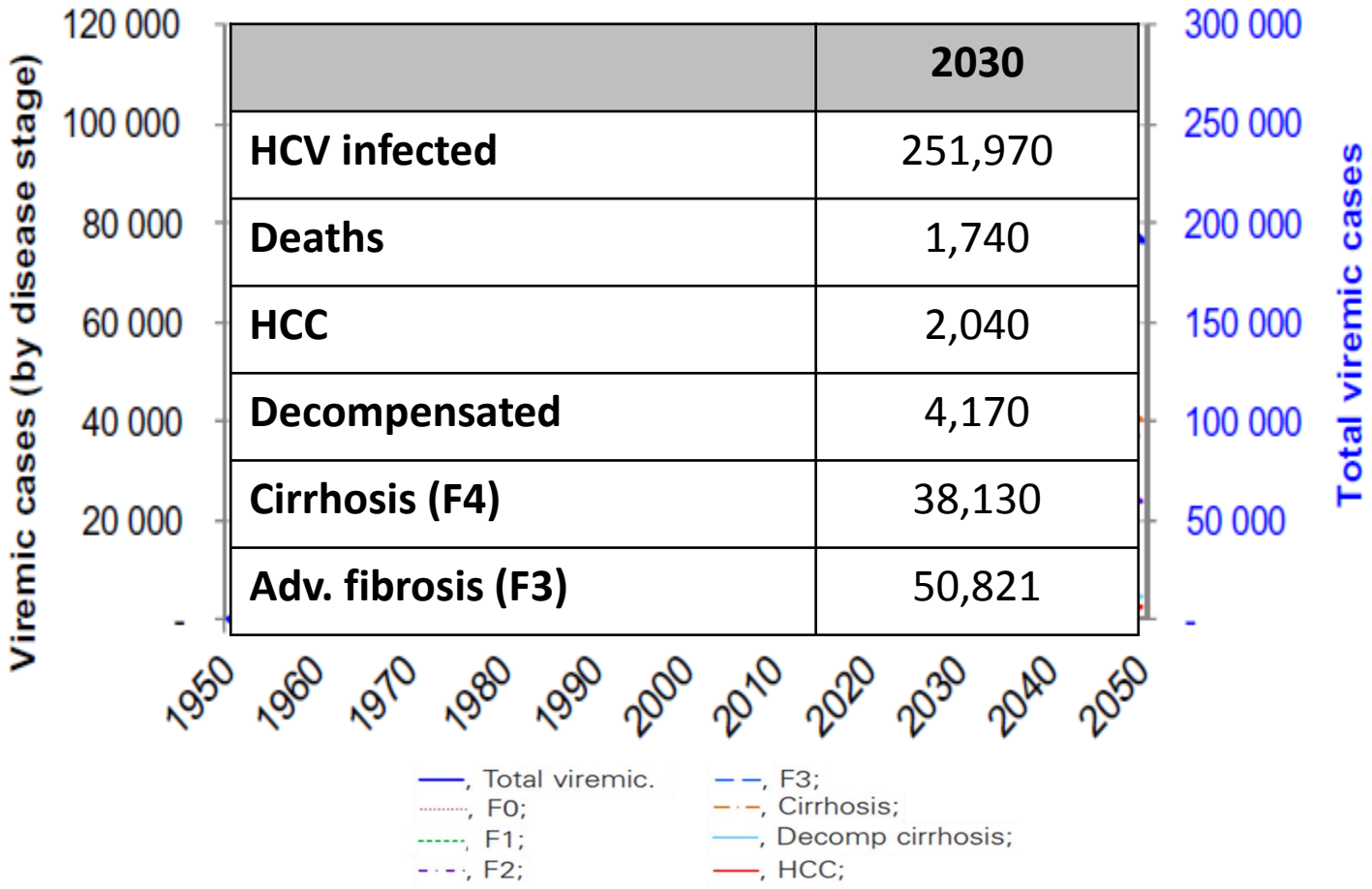
And…the HCV population is aging





The burden of HCV in increasing

HCV burden in Australia, 2013 – 2030



	2030
HCV infected	251,970
Deaths	1,740
HCC	2,040
Decompensated	4,170
Cirrhosis (F4)	38,130
Adv. fibrosis (F3)	50,821

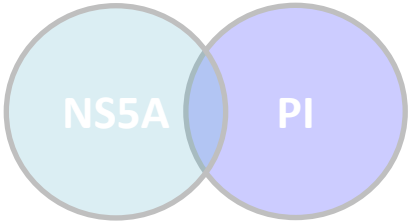
ST VINCENT'S HEALTH AUSTRALIA

Sievert, J Gastro Hep, 2014;
ALA report, The economic cost and health burden of liver diseases in Australia, 2013

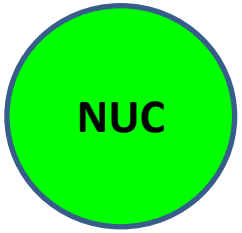
DAAs approved* in Australia in 2015

IN COMBINATION WITH PEG-IFN + RBV

TVR, BOC [GT 1]
SMV [Gt 1, 4]

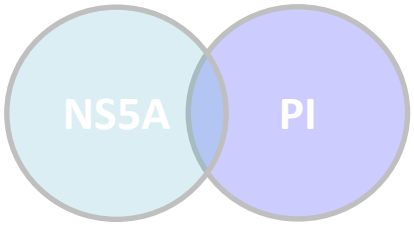


DCV + ASV
[Gt 1, 4]

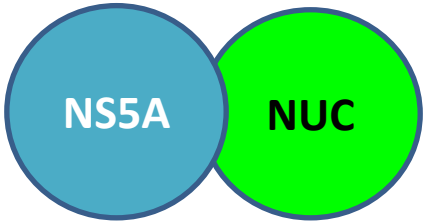


SOF
[Gt 1, 4, 5, 6]
[Gt 3*]

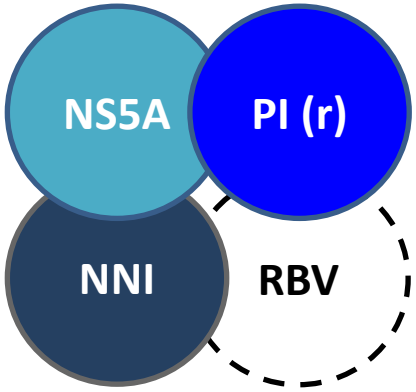
IFN-FREE THERAPY



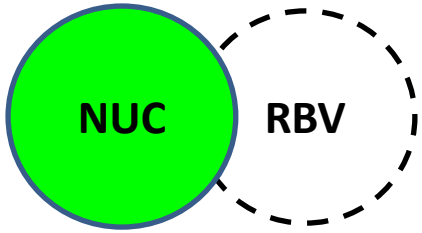
DCV / ASV
[Gt 1b]



LDV / SOF [Gt 1]
DCV / SOF [Gt 1, 3]



OMV/PTV(r)/DSV
± RBV [Gt 1]



SOF / RBV
[Gt 2, 3]

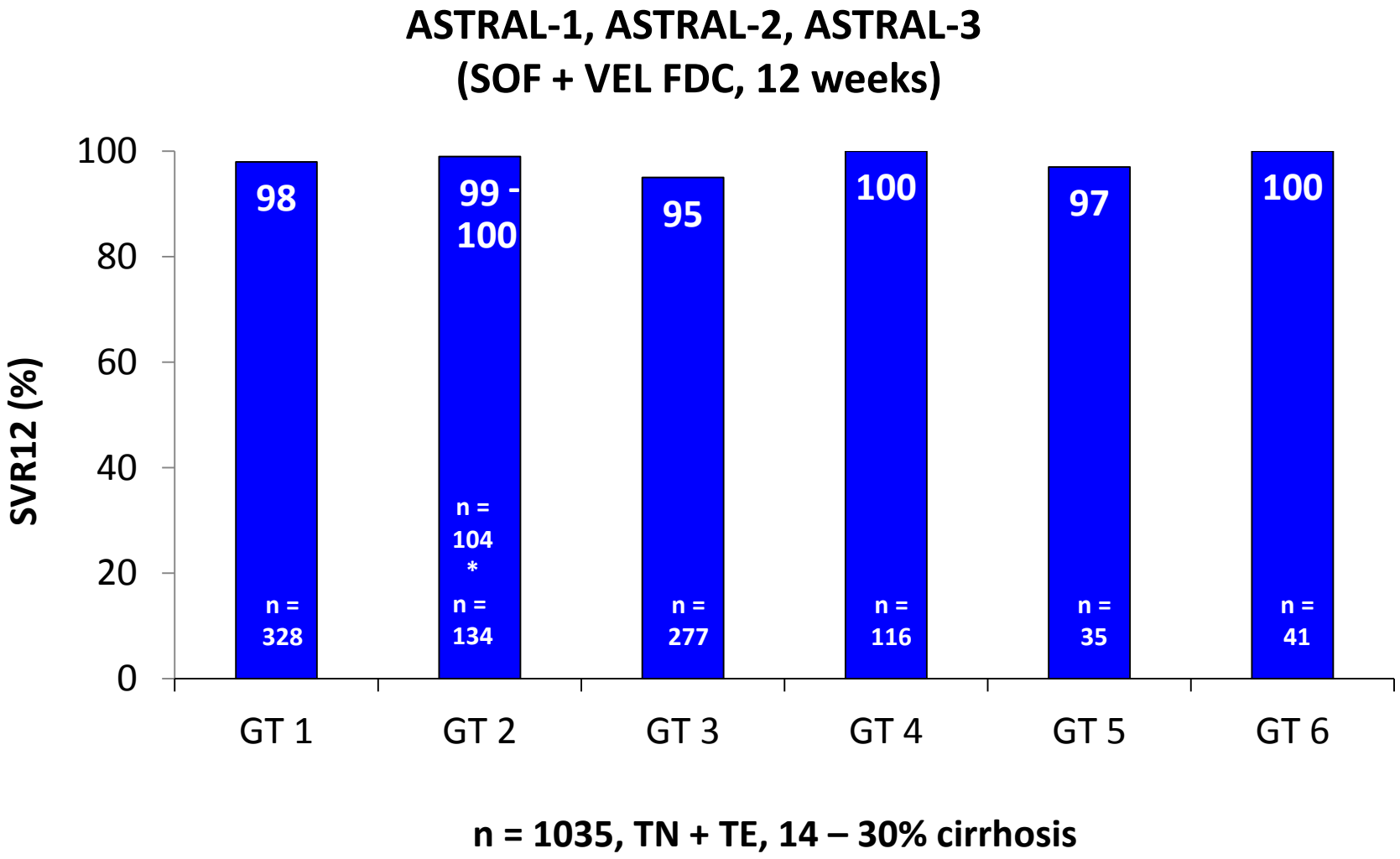
DAAs approved* in Australia in 2015

Regimen	HCV Gt	No cirrhosis	Cirrhosis [a]	Cirrhosis + treatment-experienced*	SVR
Sofosbuvir + ledipasvir	**Gt 1a/b**	8-12 weeks **	12 weeks	24 weeks	≥ 95%
Paritaprevir/r + ombitasvir + dasabuvir ± ribavirin	**Gt 1a**	12 weeks + RBV	12 weeks + RBV	12 weeks + RBV†	≥ 95%
	Gt 1b	12 weeks	12 weeks ‡	12 weeks ‡	
Sofosbuvir + ribavirin	**Gt 2**	12 weeks	12 weeks [i]	12 weeks [i]	> 90% [i]
Sofosbuvir + ribavirin	**Gt 3**	24 weeks	24 weeks	24 weeks @	> 85% @
Sofosbuvir + daclatasvir ± ribavirin	**Gt 1, 3**	12 weeks	12 weeks + RBV OR 24 weeks [j]	12 weeks + RBV OR 24 weeks [j]	> 90% [j]
Sofosbuvir + peginterferon + ribavirin	**Gt 4, 5, 6**	12 weeks	12 weeks	12 weeks	> 85%

DAAs approved* in Australia in 2015

Regimen	HCV Gt	No cirrhosis	Cirrhosis [a]	Cirrhosis + treatment-experienced*	SVR
Sofosbuvir + ledipasvir	**Gt 1a/b**	8-12 weeks **	12 weeks	24 weeks	**≥ 95%**
Paritaprevir/r + ombitasvir + dasabuvir ± ribavirin	**Gt 1a**	12 weeks + RBV	12 weeks + RBV	12 weeks + RBV†	**≥ 95%**
	Gt 1b	12 weeks	12 weeks ‡	12 weeks ‡	
Sofosbuvir + ribavirin	**Gt 2**	12 weeks	12 weeks [i]	12 weeks [i]	**> 90% [i]**
Sofosbuvir + ribavirin	**Gt 3**	24 weeks	24 weeks	24 weeks @	**> 85% @**
Sofosbuvir + daclatasvir ± ribavirin	**Gt 1, 3**	12 weeks	12 weeks + RBV OR 24 weeks [j]	12 weeks + RBV OR 24 weeks [j]	**> 90% [j]**
Sofosbuvir + peginterferon + ribavirin	**Gt 4, 5, 6**	12 weeks	12 weeks	12 weeks	**> 85%**

One size fits all?

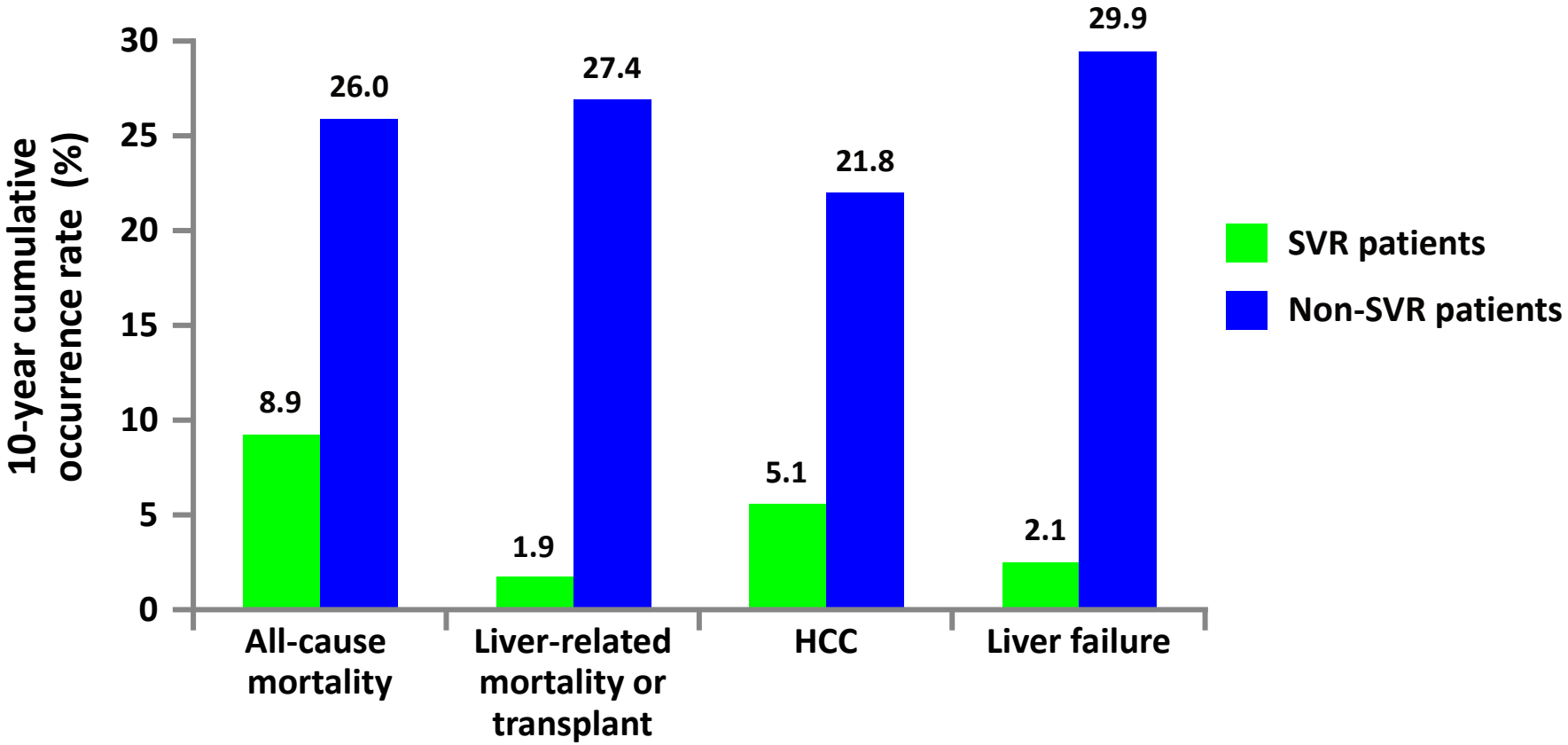


Gilead press release, Sep 21, 2015

For Individuals:

Eliminating HCV prevents death, liver cancer

530 patients with advanced fibrosis or cirrhosis were followed for a median of 8.4 years



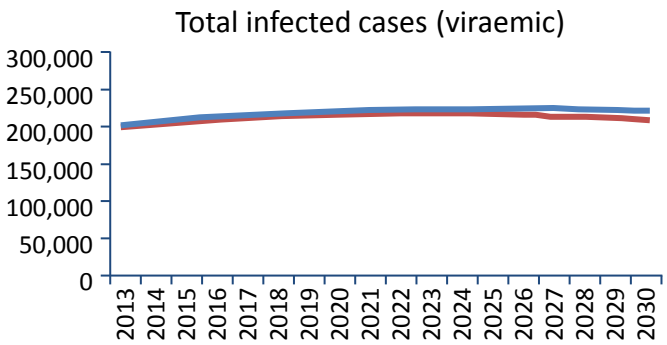
Van der Meer et al. JAMA. 2012;308(24):2584-2593

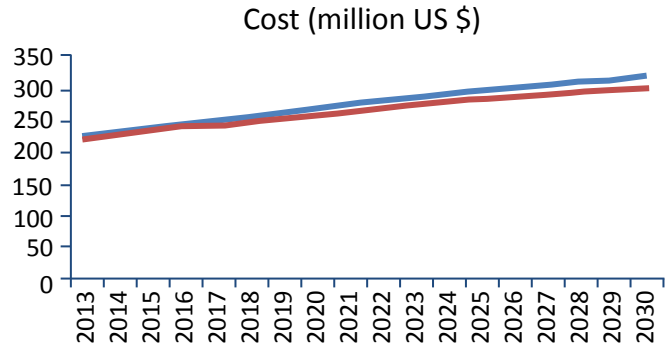
For Society:

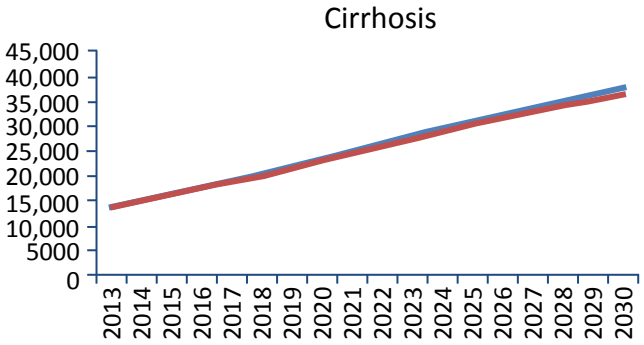
High SVR AND TREATMENT UPTAKE will reduce the burden of disease

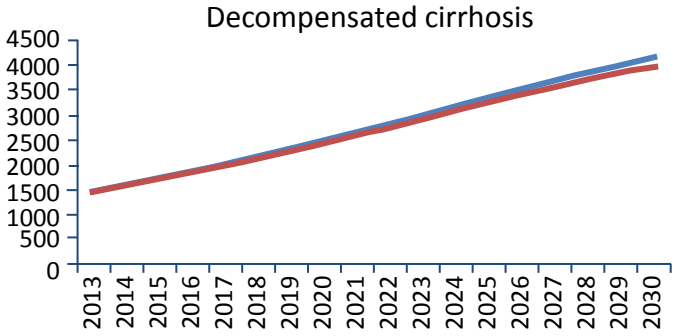
Base case: No change

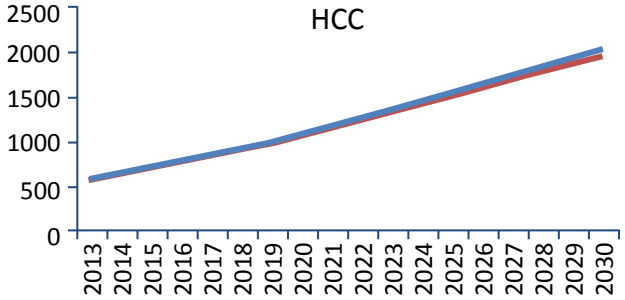
↑ SVR

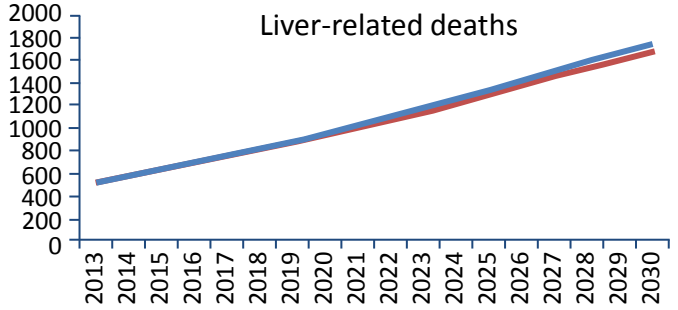












Sievert W, et al. J Gastro Hep 2014;29 (Suppl 1):1–9.

For Society:

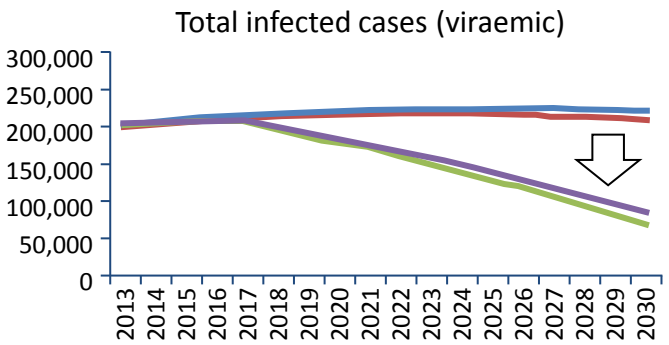
High SVR AND TREATMENT UPTAKE will reduce the burden of disease

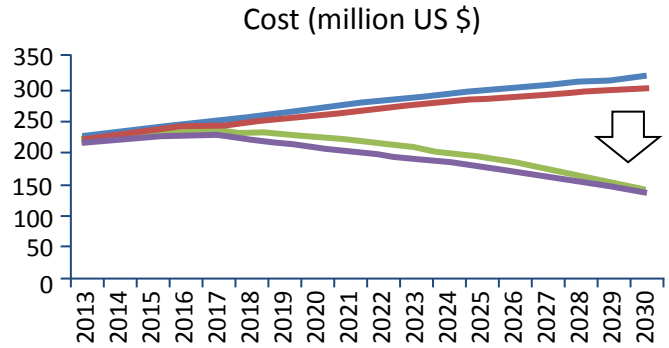
Base case: No change

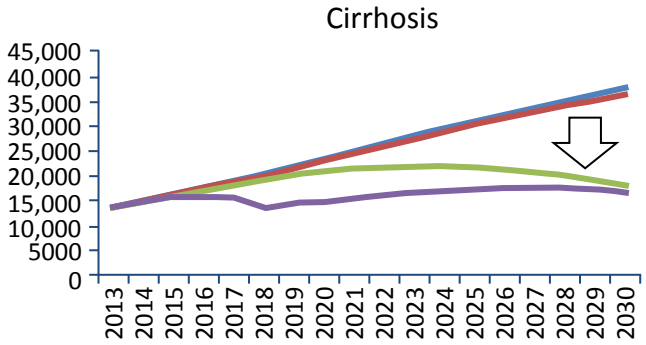
↑ SVR

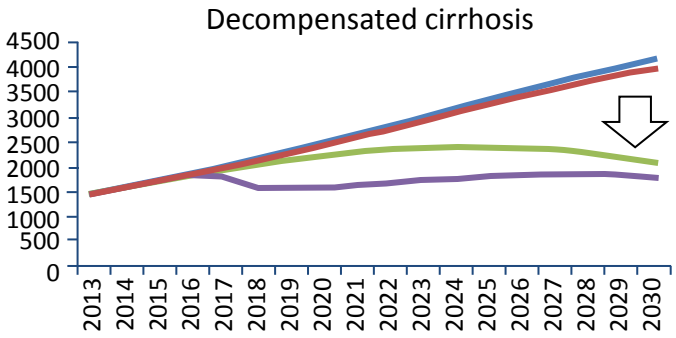
↑ SVR + ↑ treatment numbers

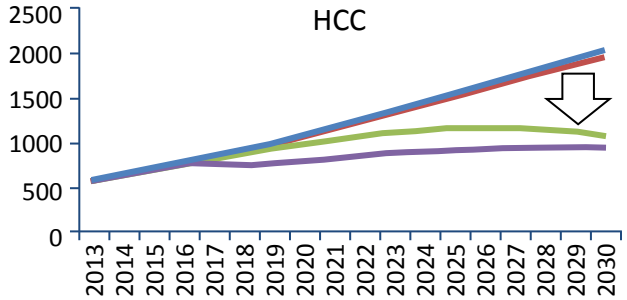
↑ SVR + ↑ treatment numbers + prioritise F3–F4 for first 2 years

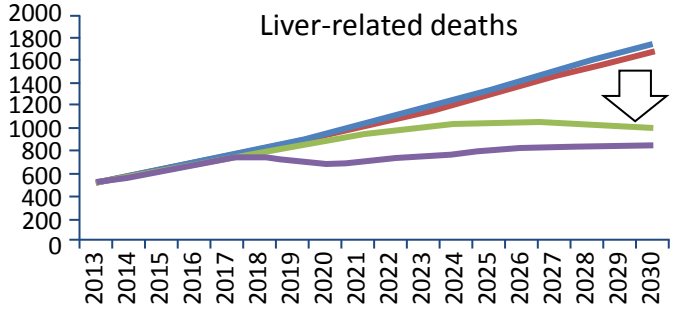








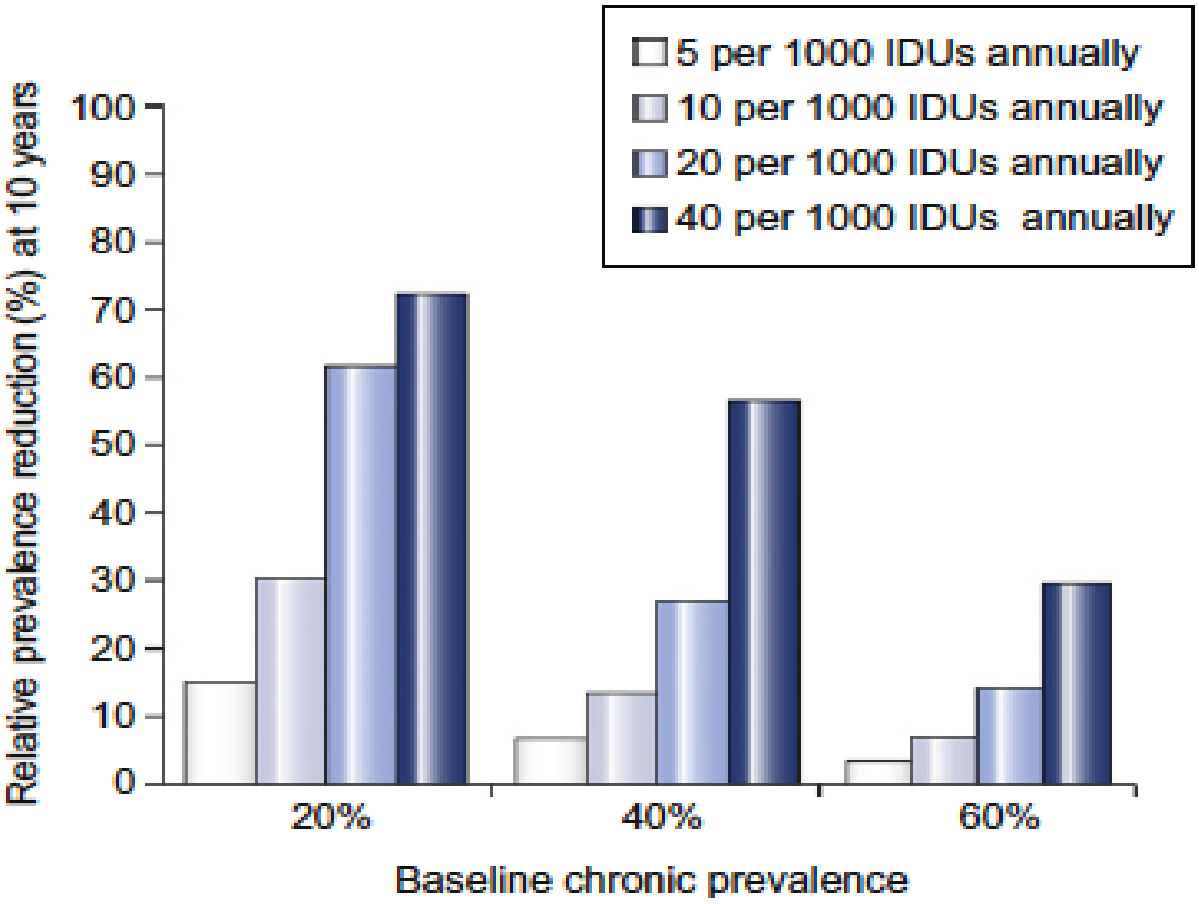




Sievert W, et al. J Gastro Hep 2014;29 (Suppl 1):1–9.

For Society:

Eliminating transmission will reduce the prevalence of HCV



Martin et al. J Hep 2011

Summary

- There are defined risk factors for HCV
- HCV is epidemic in Australia
- HCV causes liver failure and liver cancer
- Safe, simple, effective treatment cures HCV
- HCV has traditionally been considered a health issue for individuals
- HCV must now also be considered a
  PUBLIC HEALTH issue

HEPATITIS C AND THE PRISON SYSTEM

Prison population and HCV

- Prison population[1]
  - Global: **10 million**

- Imprisonment is an independent risk factor for HCV among PWID
- Prevalence in prisons[2]
  - Overall: **26%**
  - Among PWID: **64%**

1. Walmsley, R. World Prison Population List, 9th Edition. Available at: www.idcr.org.uk/wp-content/uploads/2010/09/WPPL-9-22.pdf (accessed September 2015); 3. Larney S, et al. Hepatology 2013; 58:1215–24.

Hepatitis in the Prison System

- Australian prison population: 35,9492

- Inmates of Australian prisons are among the most at risk population for HCV
  - Prevalence of HCV is 40x higher than in the general population
  - 35-50% of the total full-time prison population is infected
  - one in three male inmates have HCV infection
  - two thirds of all female inmates are anti-HCV positive

- Each year between 5,000 and 10,000 inmates are released from prison into the community

ABS report, 2015;
3rd National Hepatitis C Strategy, 2010 – 2013
2007 National Prison Entrants' Bloodborne Virus and Risk Behaviour Survey

Hepatitis in the Victorian Prison System

Factor	No. of prisoners	…based on
Number of Victorian prisoners	**5340**	Australian Bureau of Statistics, at 30 June 2013
Evidence of hepatitis B or C infection	**2402**	**41% with hepatitis C antibodies** **3-4% with hepatitis B infection**
With chronic hepatitis B or C infection, requiring some form of specialist assessment followed by monitoring or management by primary health providers	**1801**	75% with hepatitis C antibodies have chronic hepatitis C infection 3-4% with hepatitis B infection
Sentence longer than 12 months, allowing treatment	**900**	Departmental data
With chronic hepatitis B or C infection, requiring treatment in the short term	**180**	Natural history

Butler T, Lim D and Callander D (2011) National Prison Entrants' Bloodborne Virus and Risk Behaviour Survey 2004, 2007 and 2010. The Kirby Institute and National Drug Research Institute; Hellard M, Crofts N and Hocking J (2002) Hepatitis C among inmates in Victorian correctional facilities. The Burnet Institute

Prisons: Current prevention strategies

Limited access to harm reduction

No needle and syringe programs

Hepatitis C Incidence and Transmission in Prisons (HITS-p, NSW)

- 49% reported injecting drug use in follow-up
- 31% reported sharing apparatus
- HCV incidence of 9.4% per year

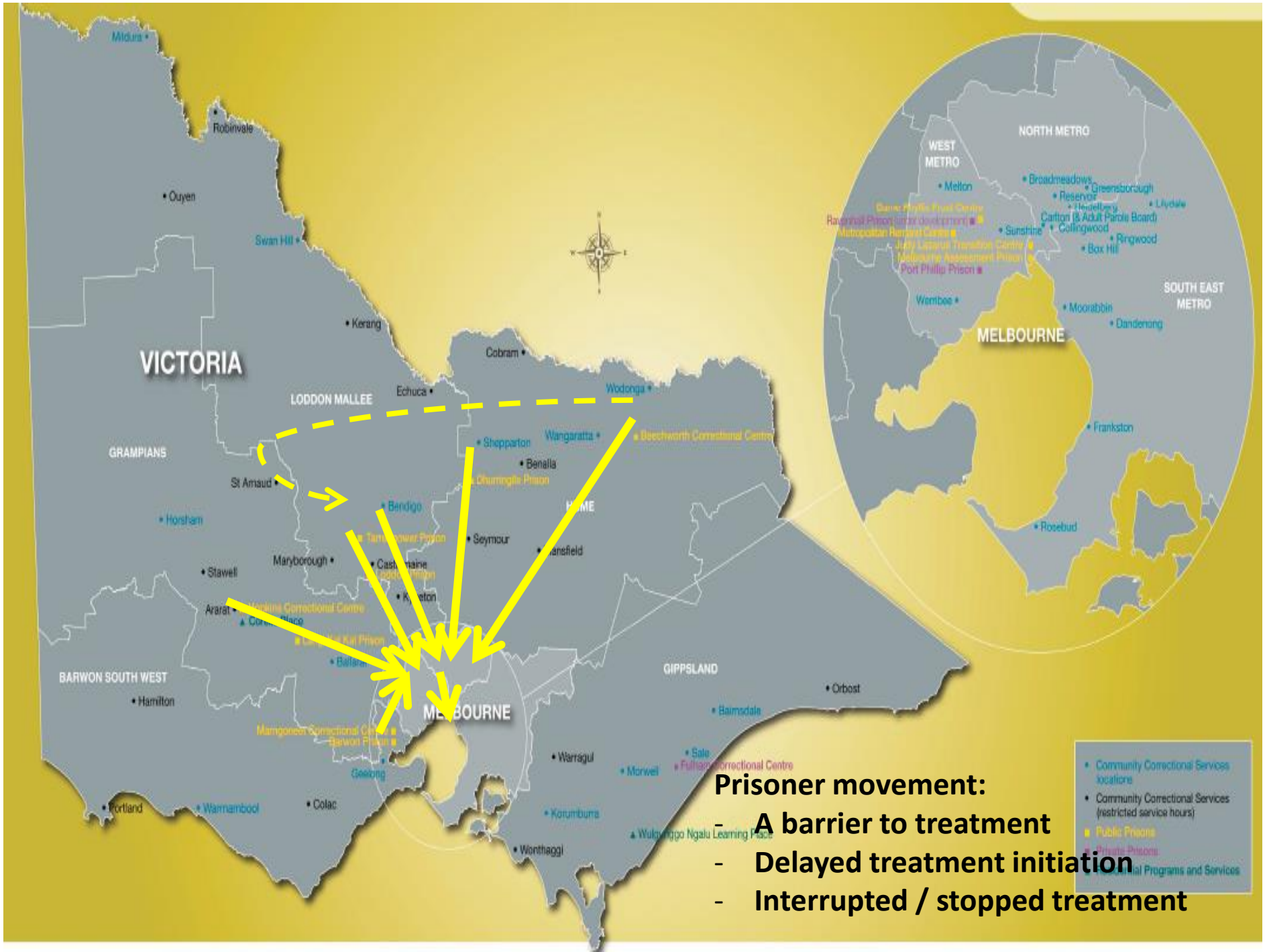
Luciani F, et al. Addiction 2014;109,1695–706

Treatment programs have been limited by:

- **toxicity and duration of IFN-regimens**
- **Short sentences, prison transfer or lost to follow up**

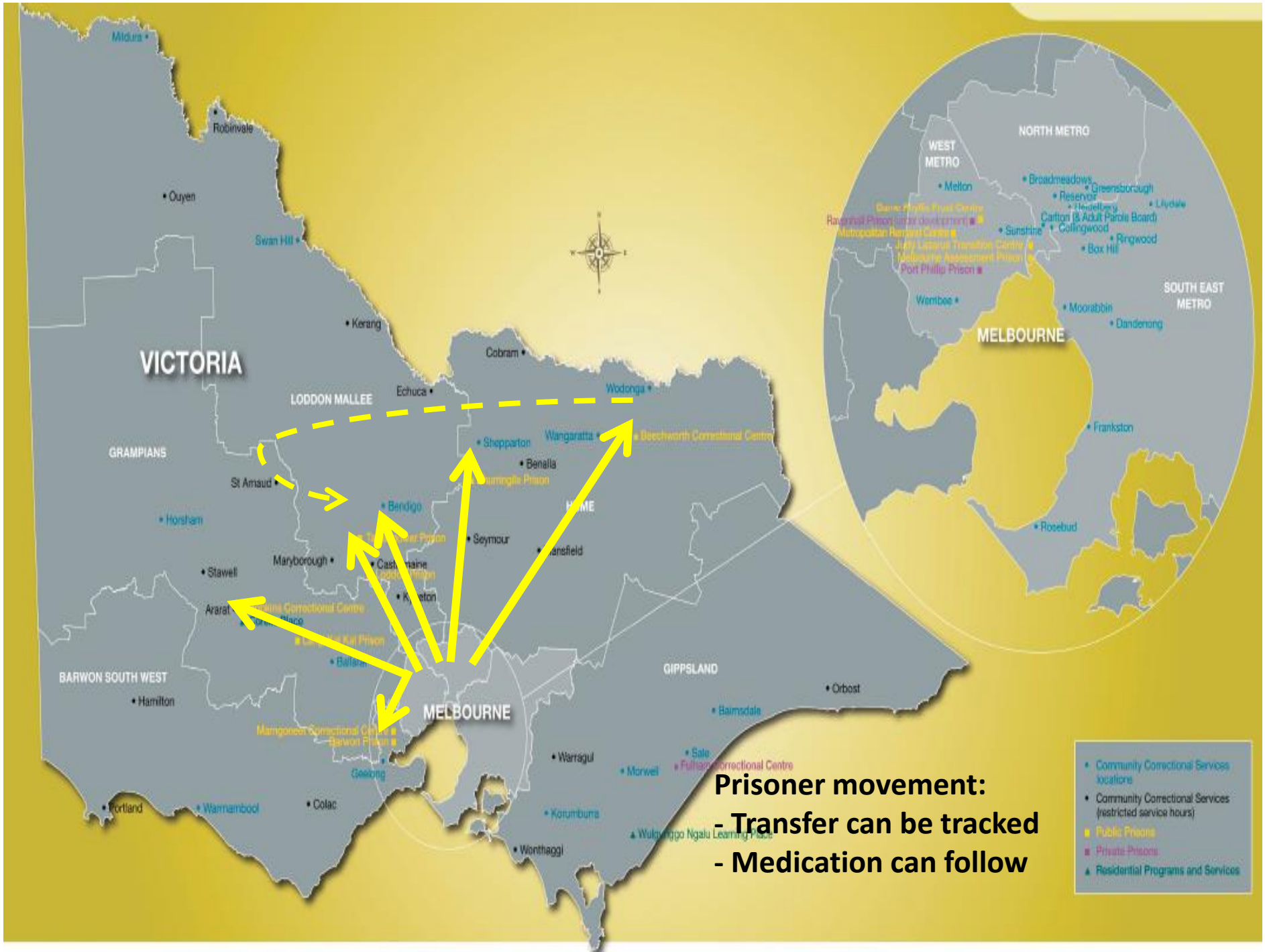
STATEWIDE HEPATITIS PROGRAM IN VICTORIAN PRISONS

July 2015 –



Prisoner movement:

- **A barrier to treatment**
- **Delayed treatment initiation**
- **Interrupted / stopped treatment**



Prisoner movement:

- Transfer can be tracked

- Medication can follow

The St Vincent's Team

- Specialist nurses (full-time)
  - Lucy McDonald
  - Anne Craigie
- Doctors (sessional)
  - Alex Thompson
  - David Iser

The St Vincent's Team

- Technology
  - Fibroscan
  - Tele-health
  - SHP car

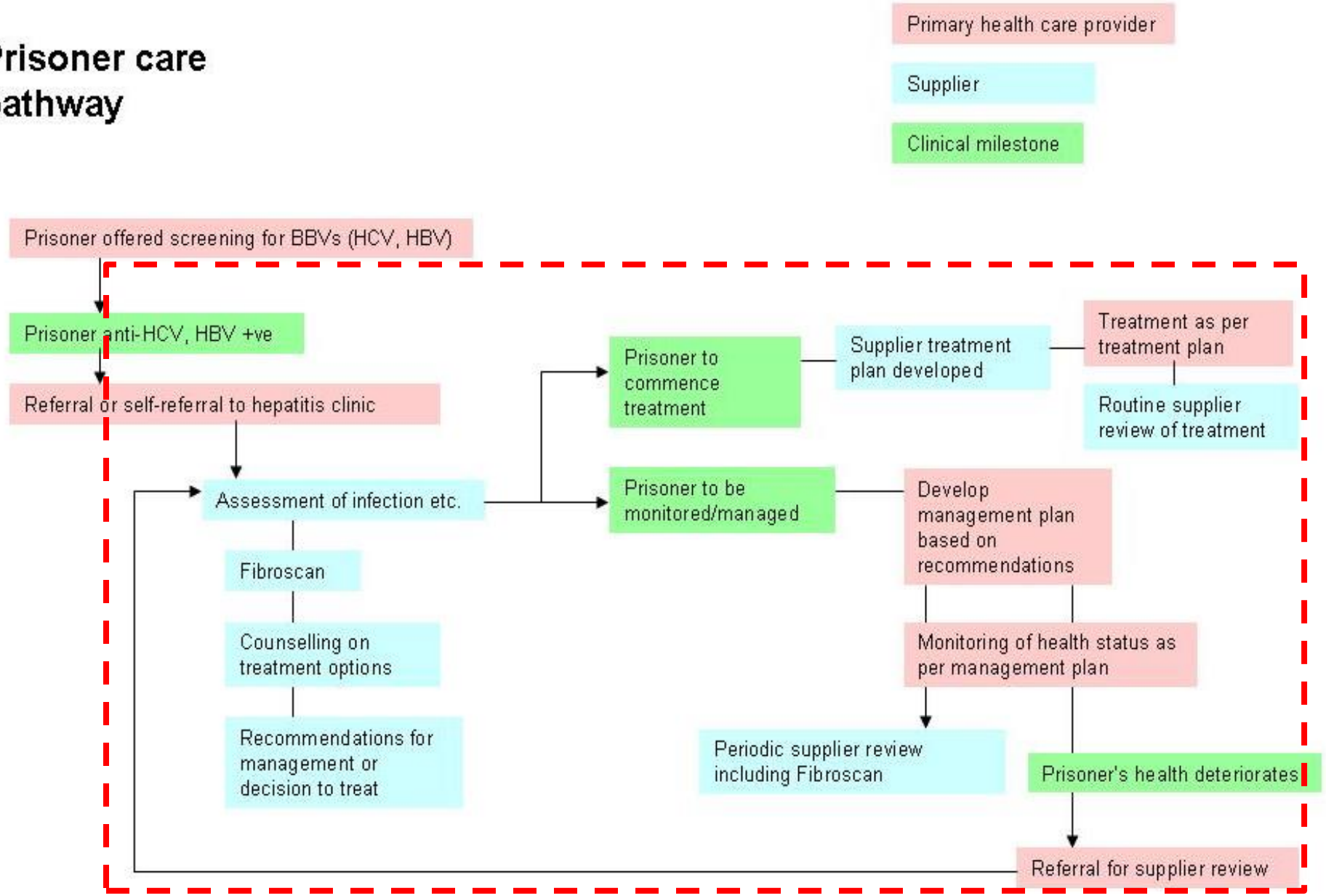
State-wide Hepatitis Program

- Nurse-led
  - protocol-driven assessment & management
- Supervising specialist physicians
  - limited face-to- face involvement
  - most interactions being via telehealth
- The Project places emphasis on a strong and consultative relationship with local prison primary and secondary health care providers
- Delivers treatment locally
  - Minimal prisoner movement

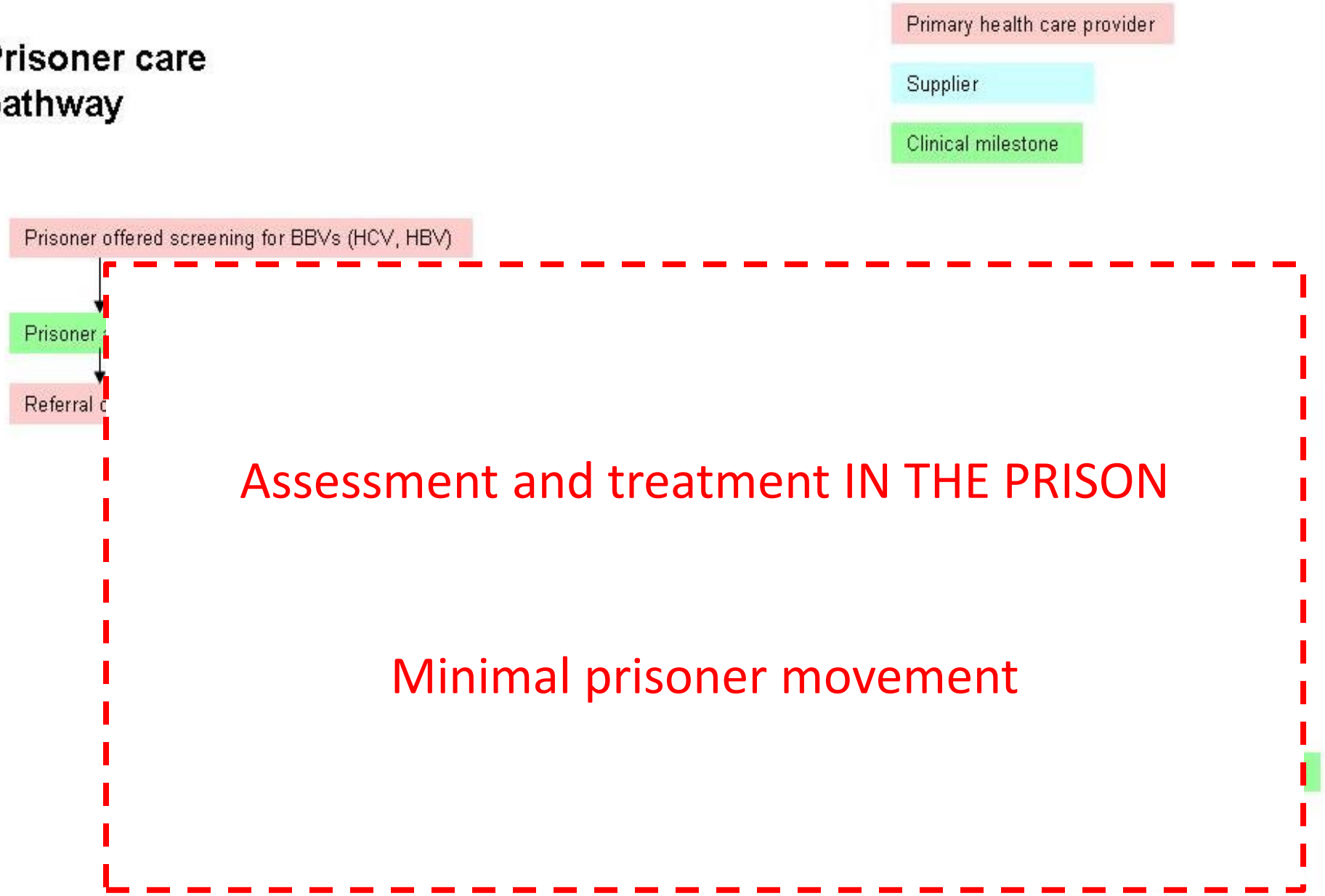
State-wide Hepatitis Program

- **<u>Key goals:</u>**
  - Increase rates of voluntary screening for HCV and HBV infection amongst Victorian prisoners;
  - Provide each prisoner referred to the Program with a liver health assessment and liver health care plan whether undertaking treatment or not
    - In selected cases – antiviral treatment
  - Linkage to care post-release

Prisoner care pathway



Prisoner care pathway



Referral through to Assessment

- The Local Health Service Provider will offer all Victorian prisoners screening for HCV and HBV at the time of incarceration at a Nominated Prison.

- Prisoners may also self-identify and request referral into the program.

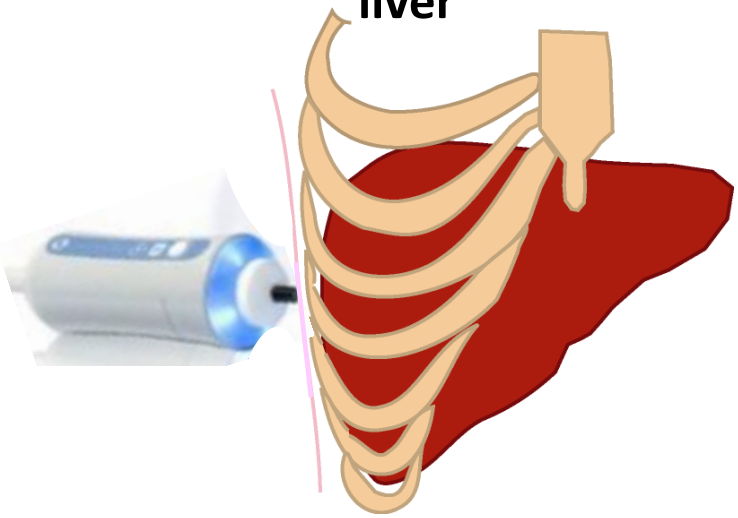
- The Program Team will assess and give instruction to all prisoners who test positive for anti-HCV antibodies, or HBsAg

Pathology

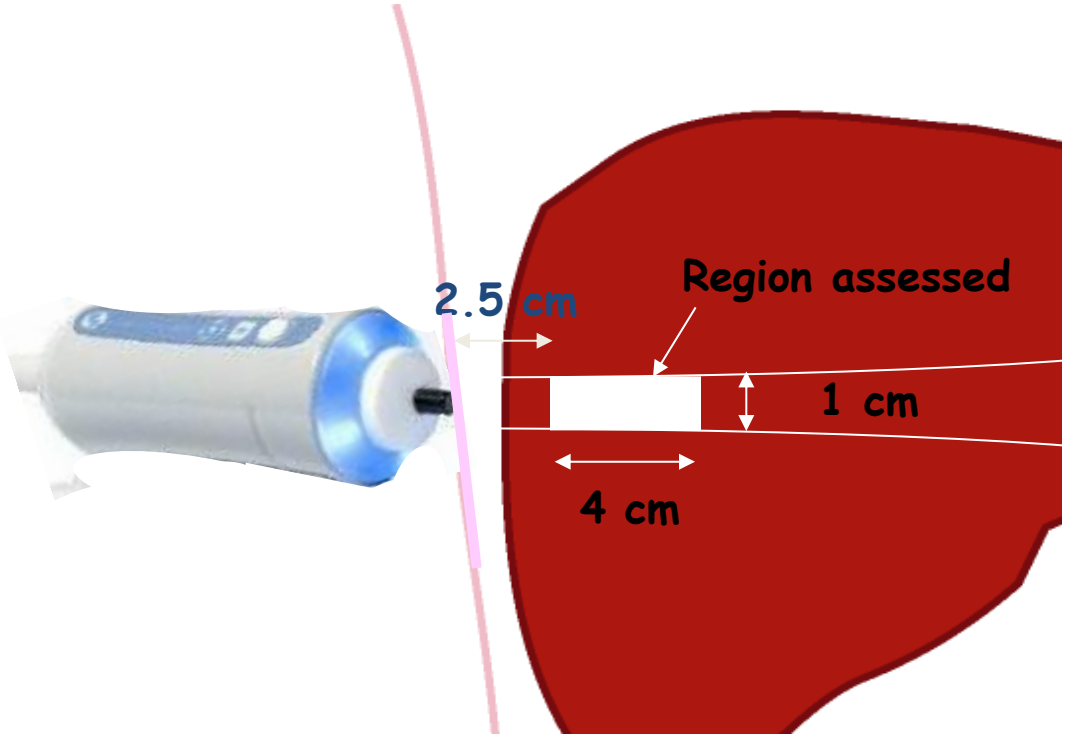
- FBE, U&Es, LFTs, INR, TFTs, glucose, lipids
- HCV genotype
- HCV viral load
- IL28B genotype
- Iron studies, auto-immune screen
- HIV
- Pregnancy test
- Liver US may be required

Transient elastography (FibroScan®)

The probe induces an elastic wave through the liver



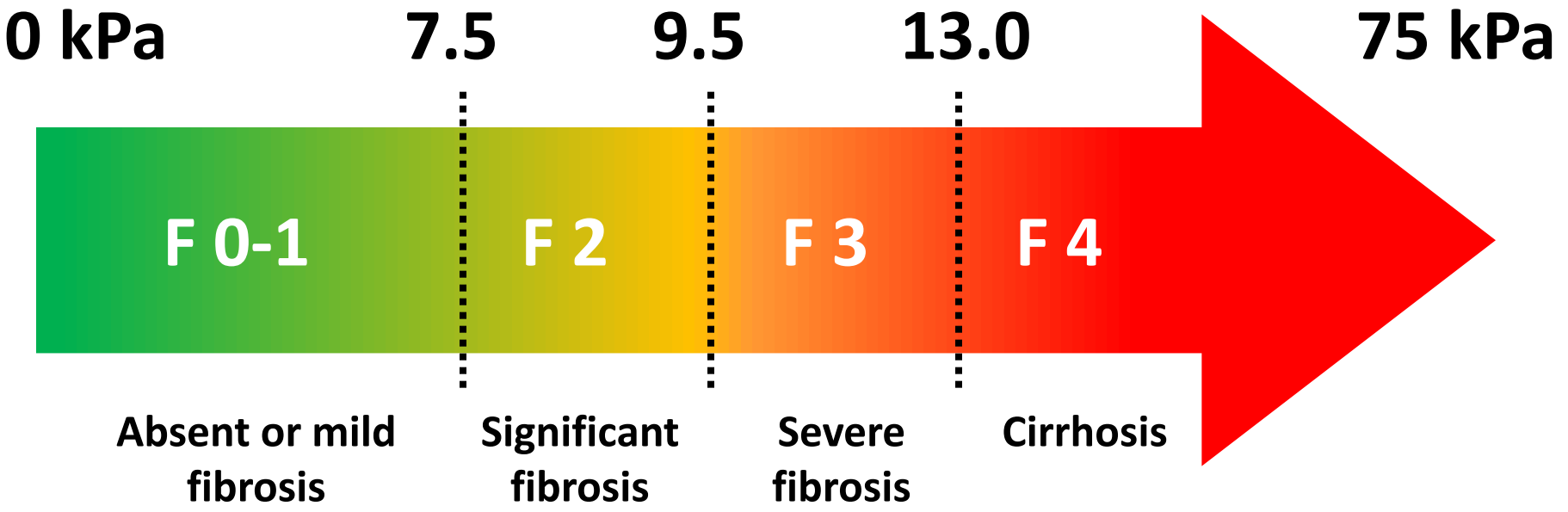
The velocity of the wave is evaluated in a region located from 2.5 to 6.5 cm below the skin surface



The elastic wave travels faster in a stiff (fibrotic) liver

FibroScan® ‘cut-offs’ - HCV

Liver Stiffness Measurement (LSM)



Castera *et al. J Hepatol* 2008
Friedrich-Rust *et al. Gastro* 2008

Mental Health Assessment

- SHP nurse consultant will perform a targeted Mental Health assessment on all patients prior to interferon-based treatment

- Mental health screening by the Local Psychiatric Service will be required for all patients with:
  - pre-existing mental illness and/or
  - past history of suicide or self-harming behaviour and/or
  - indicated in the targeted mental health assessment as an appropriate Patient for a mental health screening assessment.

Drug and alcohol assessment

- SHP nurse consultant must assess all patients for:
  - illicit drug use
  - current/recent prescription medication abuse
  - potential active withdrawal symptoms

- Referral to an Alcohol & Drug treatment provider for ongoing management may be required

- Opiate substitution therapy (OSTP) is not a contra-indication to participation in the Program

After all this, what then?

- ***Patient triage*** :
- ***Category A*** – The Program Nurse consults with Program Specialist (with the Patient) via Tele-health consultation; The Local Health Service nurse or GP may participate.

- ***Category B*** – the more complex Patient is referred for face-to-face consultation with a Program Specialist secondary to hepatic considerations and/or comorbidities.
  - Prisoner will be required to travel to Port Phillip Prison

Category A or B?

Category	Risk of medical or psychiatric complications on treatment	Motivation and psycho-social issues	Considerations	Action
A	Low risk, as there are no apparent medical or psychiatric conditions on history or current evaluation or Low risk, but there are concerns of medical or psychiatric co-morbidity.	Motivated and no significant obstacles to successful completion of treatment and follow-up. or Motivated but may have some issues requiring additional support.	Meets criteria for referral and has no other medical, psychological or social concerns or As above except a history of depression or psychosis, or medical illness, but no longer an active concern.	Provide care plan addressing the individual's specific issues of concern, and arrange telephone consultation with specialist and Patient
B	Significant risk, as there are pre-existing medical and/or psychiatric illness(es) which are likely to impact upon antiviral treatment	Motivated but has psycho-social issues which are likely to impact upon treatment	• Proven or suspected advanced liver disease. • Co-infection with HIV or HBV. • Autoimmune disease. • Any active or unstable psychiatric or medical illness.	Arrange face-to-face consult with Specialist. Work up investigations including consults with ?psychiatrist, ?AOD worker, etc.

Specialist Consultation

- Upon completion of this interaction with a Program Specialist, the following may occur:
- Suitable for AVT
  - Program Specialist completes a prescription and organises the commencement of treatment.
- Not yet suitable for AVT / declines AVT
  - further investigations or referrals may be required, these will be arranged by the Program Nurse. When the Patient is ready for treatment, the Program Nurse will then arrange a follow-up Telehealth consultation with a Program Specialist
  - a liver health care plan is developed and monitoring occurs

Prison	Security	Assessment service/specialist consultation	Commence prisoners on HCV treatment	Maintain prisoners on HCV treatment
Barwon Prison	Maximum	✓	✓	✓
Beechworth	Minimum	✓	Case by case	✓
Dame Phyllis Frost Centre	Maximum	✓	✓	✓
Dhurringile Prison	Minimum	✓	Case by case	✓
Fulham Correctional Centre	Medium	✓	Case by case	✓
Hopkins	Medium	✓	Case by case	✓
Langi Kal Kal	Minimum	✓	Case by case	✓
Loddon Prison	Medium	✓	Case by case	✓
Marngoneet Correctional Centre	Medium	✓	✓	✓
Melbourne Assessment Prison	Maximum	✓	✗	Case by case
Metropolitan Remand Centre	Maximum	✓	Case by case	✓
Port Phillip Prison	Maximum	✓	✓	✓
Tarrengower	Minimum	✓	Case by case	✓

Targets 2015-2017*

- Up to 65% (n = 955) of total HCV & HBV infections requiring specialist assessment will be assessed

Summary Table HCV and HBV Assessments	
Period	**Total Number Assessments**
Y1 (1 month – non clinical) June 2015	4
Y2 (3 months non clinical) July 2015 – June 2016	347
Y3 (12 months clinical) July 2016 – June 2017	500
Y4 (2.3 months clinical) July – Sept 2017	104
Total Assessments deliverable	955

- Up to 297 treatments will be available *

Summary Table HCV Treatment	
Period	**Total Number Treatments**
Y1 (1 month – non clinical) June 2015	1
Y2 (3 months non clinical) July 2015 – June 2016	83
Y3 (12 months clinical) July 2016 – June 2017	150
Y4 (2.3 months clinical) July – Sept 2017	31
Total HCV Treatments deliverable	265

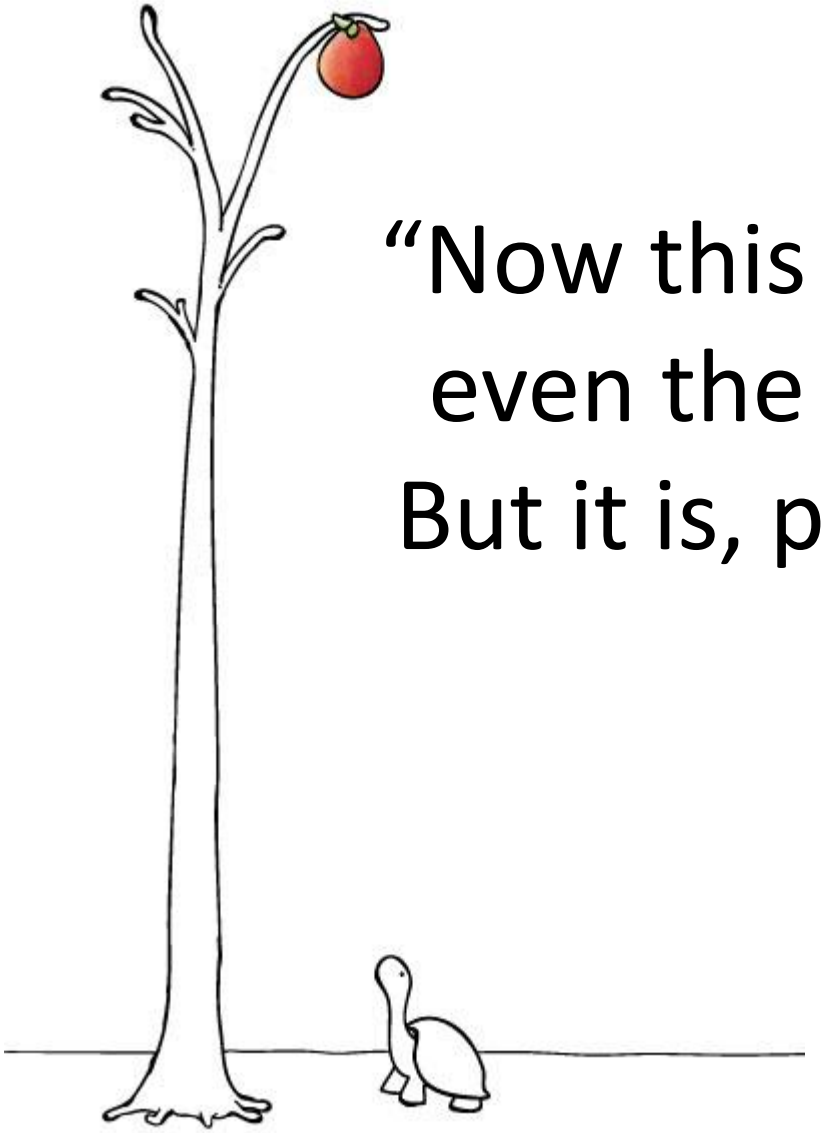
Summary Table HBV Treatment	
Period	**Total Number Treatments**
Y1 (1 month – non clinical) June 2015	0
Y2 (3 months non clinical) July 2015 – June 2016	13
Y3 (12 months clinical) July 2016 – June 2017	15
Y4 (2.3 months clinical) July – Sept 2017	4
Total HBV Treatments deliverable	32

Data collection

- J-Care = centralized clinical management software in the prison
- SHP database
- Reporting metrics
  - Justice Health
  - Academic

Conclusion

- Prisoners have a high prevalence of HCV
- Prisoners have a high incidence of HCV
- Simple, short, highly effective treatment has now been developed
  - Awaiting PBS-listing*
- In Victoria, the SHP will aim to cure prisoners of HCV using 8-12 week IFN-free regimens
  - Reducing the burden of HCV liver disease
  - Reducing prevalence of HCV (treatment as prevention)



“Now this is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning”

Winston Churchill, 1942

Acknowledgements

Lucy McDonald, RN

Anne Craigie, RN

David Iser, MBBS, PhD

St. Vincent's Correctional Health Service

- Kris Mihaly
- Kirsten Rodgers
- Charles Roth

Prof. Margaret Hellard

Prof. Andrew Lloyd

Department of Justice & Regulation

- Larissa Strong
- Rebecca Redpath
- Rebecca Lee
- Joshua Meggitt
- Adam King
- Ujjal Mojumder
- Amanda Ginger
- Paul Desmond