The urgent need for re-branding - simplification of HBV treatment to reach everyone

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discovery for a healthy tomorrow

Some common myths

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	HBeAg positive		HBeAg negative	
	Chronic infection	Chronic hepatitis	Chronic infection	Chronic hepatitis
HBsAg	High	High/intermediate	Low	Intermediate
HBeAg	Positive	Positive	Negative	Negative
HBV DNA	$>10^7$ IU/ml	10^4-10^7 IU/ml	<2,000 IU/ml**	>2,000 IU/ml
ALT	Normal	Elevated	Normal	Elevated*
Liver disease	None/minimal	Moderate/severe	None	Moderate/severe
Old terminology	Immune tolerant	Immune reactive HBeAg positive	Inactive carrier	HBeAg negative chronic hepatitis

Fig. 1. Natural history and assessment of patients with chronic HBV infection based upon HBV and liver disease markers. *Persistently or intermittently. **HBV DNA levels can be between 2,000 and 20,000 IU/ml in some patients without sings of chronic hepatitis.

- All patients with HBeAg-positive or -negative chronic hepatitis B, defined by HBV DNA >2,000 IU/ml, ALT >ULN and/or at least moderate liver necroinflammation or fibrosis, should be treated (Evidence level I, grade of recommendation 1).
- Patients with compensated or decompensated cirrhosis need treatment, with any detectable HBV DNA level and regardless of ALT levels (Evidence level I, grade of recommendation 1).
- Patients with HBV DNA >20,000 IU/ml and ALT >2xULN should start treatment regardless of the degree of fibrosis (Evidence level II-2, grade of recommendation 1).
- Patients with HBeAg-positive chronic HBV infection, defined by persistently normal ALT and high HBV DNA levels, may be treated if they are older than 30 years regardless of the severity of liver histological lesions (Evidence level III, grade of recommendation 2).
- Patients with HBeAg-positive or HBeAg-negative chronic HBV infection and family history of HCC or cirrhosis and extrahepatic manifestations can be treated even if typical treatment indications are not fulfilled (Evidence level III, grade of recommendation 2).

EASL 2017 guidelines

Who should we NOT treat?

Some requirements

What we have…….

- ✓ Access to a vaccine
- ✓ Access to testing
- ✓ Access to effective treatments
- ✓ Access to up to date guidelines
- ✓ A national Strategy with targets to aim for
- ✓ Access to education for S100 prescribers

What we need…….

- ➢ A cure
- ➢ To continue to fill knowledge gaps around the importance of genotypes
- ➢ Point of care diagnostics
- ➢ Equitable access to what we have for everyone
- ➢ BUT we can also make optimise the impact of what we have……

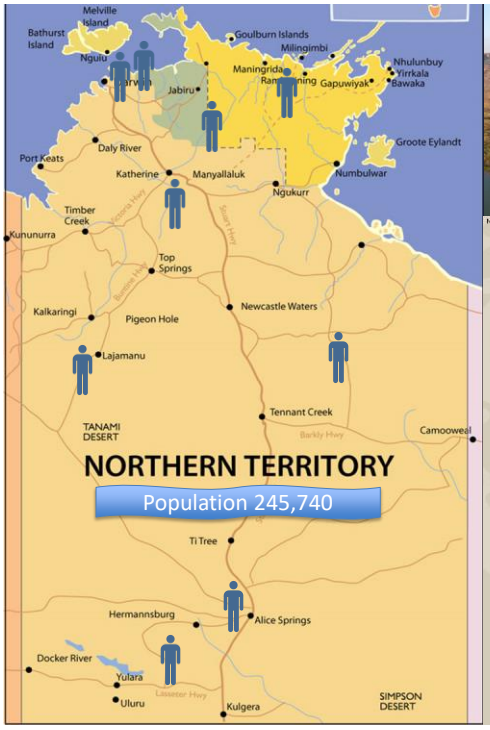
Some numbers

Figure 1: Heat map of CHB prevalence, diagnosis, treatment, and care uptake by Primary Health Network, 2016 (green = lowest; red = highest)

	PREVALENCE	DIAGNOSIS	TREATMENT	CARE
	Proportion of the population living with CHB	CHB notification rate per 100,000	Proportion of people with CHB who received treatment	Proportion of people receiving CHB treatment or monitoring
Northern Territory	1.71%	45.8	4.9%	19.0%

2007-2011 inclusive	Overall N=35,633	Indigenous n=14,025 (39%)	Non-Indigenous n=21,608 (61%)
Median age in years at sample date (IQR)	32.4 (24.5-43.7)	30.8 (21.5-43.3)	33.2 (26.3-44.0)
Sex Female % (95% CI)	57.8 (57.3-58.3)	53.7 (52.8-54.5)	60.5 (59.9-61.2)
HBsAg positive % (95% CI)	3.40 (3.19-3.61)	6.08 (5.65-6.53)	1.56 (1.38-1.76)

MacLachlan J Cowie B. Hepatitis B Mapping Project: Australian Society for HIV, Viral Hepatitis and Sexual Health Medicine (ASHM); 2016.
Davies J et al.



HEP B PAST – NT NHMRC Partnership grant

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NORTHERN TERRITORY GOVERNMENT

DEPARTMENT OF HEALTH

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TEHS primary health care
CAHS primary health care

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Katherine West Health Board

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Goal - Elimination of Chronic Hepatitis B from Indigenous Australians in the Northern Territory*

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- Systematic approach
- Sustainable approach - partnerships
- Simplified approach*
  - "shared understandings"
- * not dumbed down provides the full story BUT not confusing

Partnership **A**pproach to **S**ustainably eliminating Chronic Hepatitis B in the Northern **T**erritory

Hep B PAST

BACKGROUND

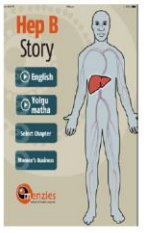
Chronic hepatitis B virus infection (CHB) is endemic in the Indigenous Communities of the Northern Territory (NT) with a prevalence of 3-12%, meaning the NT has the highest CHB prevalence in Australia at 1.77% (including non-indigenous people). Of those living with CHB 25% will die from decompensated cirrhosis or hepatocellular carcinoma (HCC). Liver disease is the third most important contributor to the gap in life expectancy between Indigenous and non-Indigenous Australians.

GOAL – Elimination of CHB from Indigenous Australians in the NT

We have the necessary tools in place to achieve elimination of CHB: an effective vaccine, effective antivirals, and long-term relationships between project partners and Indigenous communities. Our aim is that with significant investment over the next 5 years we can substantially improve community health literacy, determine sero-status of >80% of Indigenous individuals, and by shifting CHB to a chronic disease care model have >80% of individuals with CHB engaged in guideline based management with 15% receiving and remaining on treatment.

AIM 1 - To improve health literacy about HBV amongst indigenous communities, people living with HBV and primary healthcare providers.

We will enable people living with CHB and their communities to have access to culturally appropriate effective education tools in their first language. We will evaluate and translate the existing "Hep B Story" educational app into a further 10 languages which will cover >70% of the NT Indigenous population.



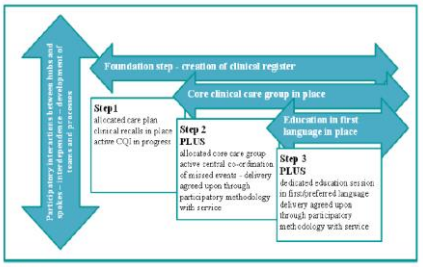
Language	No. of Speakers	Region
Kriol	20,000	Katherine
Yolnu Matha	6806	East Arnhem
Arrernte	5475	Alice Springs
Murrinh-Patha	3100	Wadeye
Pitjantjatjara	3000	Western Desert
Warlpiri	2509	Central
Tiwi	2102	Tiwi Islands
Kunwinjku	2000	West Arnhem
Anindilyakwa	1600	Groote Eylandt
Burarra	1000	Maningrida
Gurindji	900	Katherine West

Hep B PAST

AIM 2 – Improve the cascade of care for individuals living with CHB in the NT

CHB care will be transitioned into the primary care setting in the remote NT context using the chronic disease model. Central coordination through an NT HBV clinical register and an allocated core clinical care team will improve the cascade of care for CHB.

- **Clinical register – Individuals will be allocated a hepatitis B sero-status .**
- **S100 prescriber course – We will enable and maintain a competent cohort of primary healthcare professionals to proved gold standard CHB care and prescribe HBV antivirals.**
- **Implement and evaluate the transition of gold standard care for CHB into primary care using a hub and spoke model.**



PARTNERS

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Education

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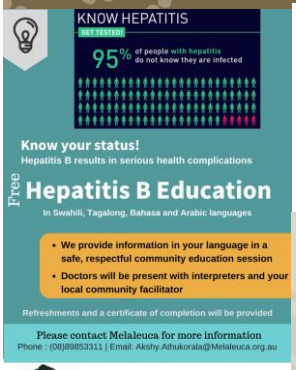
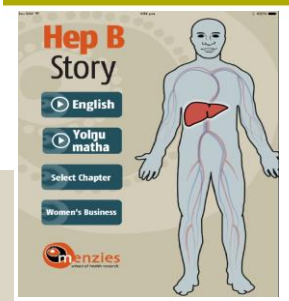


Language	Number of speakers	Region	Consultation
Kriol	20,000	Katherine region	commenced
Yolŋu matha	6806	East Arnhem	complete
Arrarnte	5475	Alice Springs	commenced
Murrinh-Patha	3100	Wadeye	commenced
Pitjantjatjara	3000	Western desert	planned
Warlpiri	2509	Central	planned
Tiwi	2102	Tiwi Islands	planned
Kunwinjku	2000	West Arnhem	commenced
Anindilyakwa	1600	Groote Island	planned
Burarra	1000	Maningrida	planned



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Systematic

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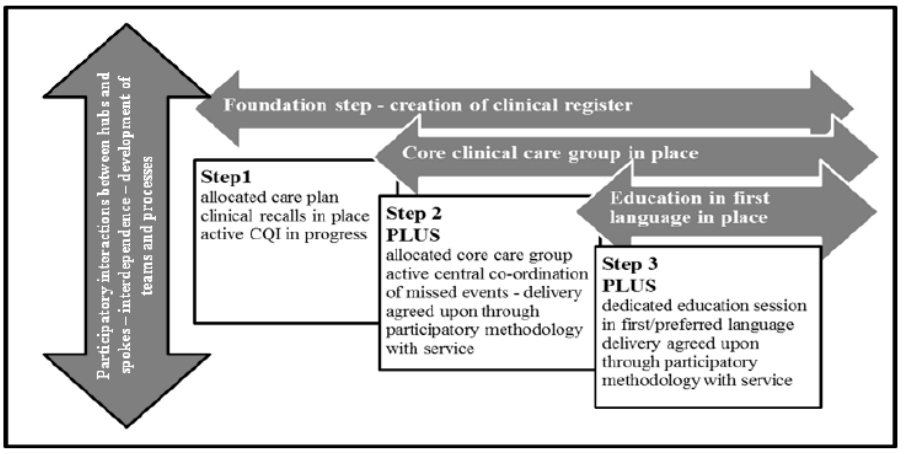
	WAM	TEC	TEW	KR	TOTAL	%
ATSI population (06/04/2018)	5337	2403	3769	1303	**12812**	
Hep B: Fully Vaccinated	3744 (70%)	1506 (63%)	2409 (64%)	685 (53%)	**8344**	**65%**
Hep B: Immune by Exposure	923 (17%)	436 (18%)	620 (16%)	156 (12%)	**2135**	**17%**
Hep B Infected ON Treatment	19 (0.4%)	6 (0.2%)	12 (0.3%)	1 (0.1%)	**38**	**0.3%**
Hep B Infected NOT on Treatment	105 (2%)	26 (1%)	85 (2.3%)	33 (2.5%)	**249**	**2%**
Hep B; Non-immune	219 (4%)	116 (5%)	140 (4%)	109 (8%)	**584**	**6%**
No data	327 (6.1%)	313 (13%)	503 (13%)	319 (24%)	**1462**	**11%**
TOTAL (with serocode):	5010 (94%)	2090 (87%)	3266 (87%)	984 (76%)	**11350**	**89%**
TOTAL population who require follow up	546 (10%)	429 (18%)	643 (17%)	428 (33%)	**2046**	**17%**

Sustainable



Simplify

No need for treatment	Needs to see a specialist	Definitely treat
Patients with: • Persistently normal ALT • No evidence of accumulated liver damage (e.g. fibrosis, or moderate to severe inflammation) • No evidence of cirrhosis Either • eAb positive and HBV DNA < 2000IU/ml or • eAg positive with any level of HBV DNA *These patients are likely to be in the immune tolerance or immune control phase and require yearly monitoring only as per CARPA p384*	Patients: • with cirrhosis or evidence of advanced liver damage (e.g. fibrosis, or moderate to severe inflammation) • concern about another cause for liver disease • with ALT 1-2 ULN (but less than 2 x) • who are pregnant • with possible HCC found on surveillance • with HIV or HCV co-infection • undergoing immune suppression • You want to get an opinion	Patients with: • High ALT (2 x ULN for more than six months without an alternative cause) Plus • If e Antigen (eAg) positive and HBV DNA > 20,000 IU/mL Or • If e Antigen (eAg) negative and HBV DNA > 2,000 IU/mL

ALT ULN Men >30 IU/L and Women >19 IU/L for females

Individual perspective

"a virus that affects the liver"
OR
"a liver disease that happens to be caused by a virus"

What is the viral load?
What is the ALT?
Does this person have cirrhosis?
Does this person need liver cancer screening?
Should I offer this person antiviral treatment?
OR
Is there a reason NOT to offer this person antiviral treatment?
How often do I need to review them?

The three S's

- Systematic approach – know the status of your population
- Sustainable approach – partnerships, appropriate education
- Simplified approach
  - "shared understandings"
  - Know what the virus is doing and what the liver is doing
  - Treat, don't treat or phone a friend

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