

NSW HBV AND LIVER CANCER PILOT PROGRAM: AN UPDATE ON THE 'B POSITIVE' PROJECT

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Abstract

The 'B Positive' Project, sponsored by Cancer Council NSW, aims to facilitate the earlier detection and optimised management of chronic hepatitis B and hepatocellular cancer. The pilot project in Sydney's south-west is based on evidence indicating the clustering of hepatocellular cancer cases in NSW, along geographical and ethnic lines. This provides opportunities for devising targeted public health interventions that can bring about significant reductions in the future burden of liver cancer. The project will test the feasibility, acceptability, and cost-effectiveness of hepatitis B screening and surveillance in individuals with chronic hepatitis B infection and aims to determine what role targeted screening and surveillance may have in preventing the development of liver cancer. This paper outlines the key features of this project, highlighting the development and implementation of the 'B Positive' Project in Sydney's south-west since mid-2007 to early 2009.

In New South Wales (NSW), liver cancer accounts for over 400 new cancer cases and nearly 300 deaths per year and its incidence is rising faster than any other internal cancer in NSW.¹

The 'B Positive' Project has been developed based upon the following premises:

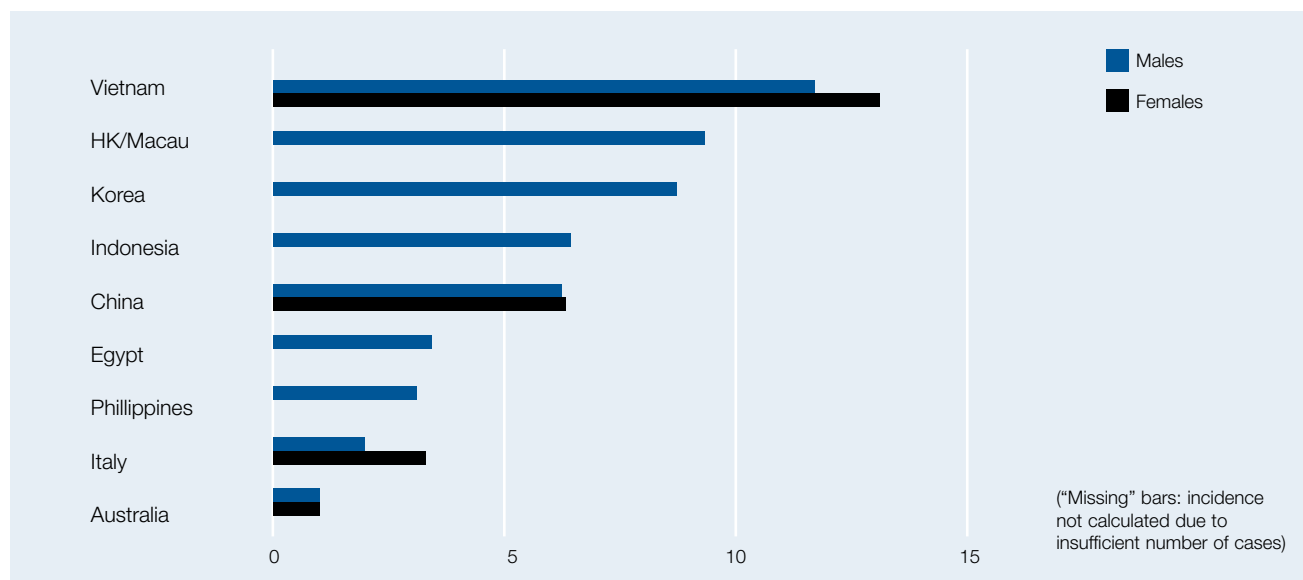
- In NSW, hepatocellular cancer (HCC) incidence and mortality have increased ~5-fold since 1972 and, at the current rate, may double again by 2020.¹
- In NSW, people born in countries of high prevalence of chronic hepatitis B infection (CHB) are 6-12 times more likely to be diagnosed with HCC than Australian-born individuals (figure 1).²

- As migrant populations are concentrated in particular urban areas, the clustering of CHB and HCC cases along ethnic and geographical lines (figure 2) provides opportunities for devising targeted public health interventions aimed at reducing the future cancer burden.

- Antiviral treatment is likely to significantly reduce CHB progression to cirrhosis and HCC.³

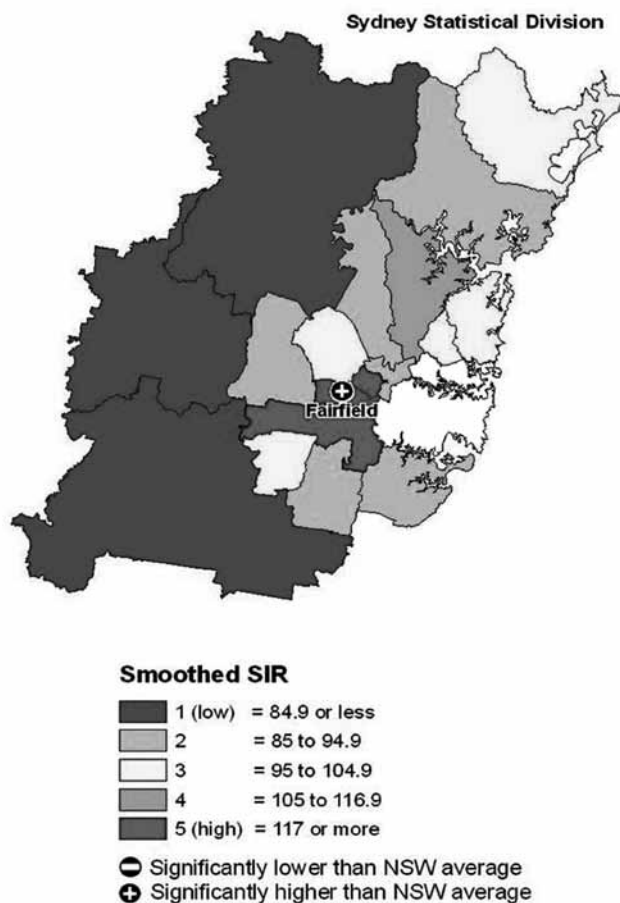
The project will address the significant challenge of reducing the disease burden for a cancer with poor prognosis and limited options for curative treatment, which affects some of the least well-served populations in NSW.

Figure 1. SIRs for HCC diagnosed in NSW (1991-2001) by place of birth: ¹ (SIR % compared to the Australian-born population)



An overarching project evaluation process has been planned with collection of relevant key indicator measures and outcomes. Currently the project is in implementation phase and too immature for formal project evaluation; this paper provides the descriptive findings and statistical results to date.

Figure 2. Standardised Incidence Ratio of primary liver cancer per 100,000 NSW population (Figure for male only shown, data 1998-2002)²



Methodology for project development

An analysis of data from the NSW cancer registry, national census and reviews of relevant literature about hepatitis B infection and liver cancer provided the evidence-base underpinning the planning, development of resources and implementation of the project.

Cancer Council NSW has responsibility for the overall governance of the project and key responsibilities for developing communication strategies with primary care practitioners and at-risk communities.

Project activities are supported by culturally appropriate community advertising, education and media liaison. Community and patient engagement is mediated by local GPs and community-based organisations serving the needs of specific migrant groups. The collaboration of high-profile professionals, clinicians and community organisational representatives with links to the relevant target populations is a key component of the development and implementation of the project.

The project has five main focus areas, detailed below:

1. Development of a hepatitis B screening and HCC surveillance protocol using input from experts on the project steering committee, including a comprehensive review of world literature, clinical decision support algorithm and recruitment process. These components had development feedback from peer GPs.
2. Development of a register of people with chronic hepatitis B infection (CHB) – data collection forms and participant information and consent forms were developed in English, Vietnamese and Chinese, with community input. Engagement with pathology service providers, supported by project and clinical experts was initiated early in 2008 to develop the pathology test data capture and database download processes. The patient enrolment and follow-up data collection process was designed by Cancer Council NSW project staff in collaboration with an academic with clinical and information systems knowledge. A contracted database developer was engaged to build the register and with Cancer Council NSW the data custodian.
3. Development of an economic model, to estimate the cost-effectiveness of different screening and surveillance strategies, was managed through a working party process. This working party included Cancer Council NSW project staff and clinical investigators from the project steering committee, and received expert input from consultants. Critical review of the model was undertaken by health economist academics from the University of Sydney and a modelling expert from the National Centre for HIV Epidemiology and Clinical Research. This component of the pilot project included modelling the cost effectiveness for a targeted program of hepatitis B and liver cancer detection through screening on a geographical basis. Four scenarios were investigated, based in the pilot project area (Fairfield-Liverpool), a Greater Sydney, NSW-wide and national scenario, each targeting populations with high hepatitis B seroprevalence.
4. Development of educational resources for primary care providers in collaboration with the local GP Division, the Royal Australian College of General practitioners (RACGP), the Australian Society for HIV Medicine and other interest groups. A range of resources were developed, including a hepatitis B monograph, a 'B Positive' Project GP Kit of decision support and related patient information resources. The knowledge and skill needs of GPs in the target geographical region were assessed in 2008. An RACGP accredited educational program was developed encompassing the prevention, diagnosis and management of hepatitis B infection and liver cancer.
5. Development and implementation of effective communication strategies about hepatitis B infection and HCC management for at-risk community populations. In collaboration with local medical practitioners and prominent community leaders,

Cancer Council NSW engaged with community associations/societies in the pilot project area in south western Sydney. Two part-time Community Liaison Officers (Chinese & Vietnamese) with advanced language skills were appointed, and targeted activities in two phases – a community education campaign aimed at awareness raising in 2008, followed by a patient recruitment phase, which commenced in the first half of 2009.

The distribution of consumer resources was supported by a media strategy, using ethnic and local media (newspapers, radio, community magazines). A detailed marketing plan was implemented with various information posters and pamphlets. All were pilot tested with community group feedback.

The communications plan included briefings of Members of Parliament and local government representatives (Fairfield and Liverpool city councils elected officials and staff) throughout the project.

Results

Screening and surveillance protocol

A protocol to support individualised treatment planning has been developed, with treatment decisions based on liver function and viral load. This included a key 'B Positive' Project decision-support resource (algorithm schematic figure 3), with a matching GP process flowchart for patient enrolment and follow-up produced as a laminated two-sided sheet. The GP kit includes both GP resources and patient information packs in relevant languages for use in

recruitment and follow-up consultations. The protocol and related materials have been approved by both the RACGP National Research and Evaluation Ethics Committee and National Ethics Application Form processes.

Prototype register

The register of patients enrolling in the 'B Positive' Project is currently in final-phase testing by Cancer Council NSW, in collaboration with clinicians at Liverpool and Westmead Hospitals. Since the initiation of the patient-recruitment phase in February 2009, recruitment has been incremental, however the number of GPs participating in education (see below) and visited to date by project staff, indicates the target of 250 enrolments by June 2009 and 1000 by December 2009 is achievable.

Successful collaborations were developed among staff and researchers from three NSW tertiary hospitals (Westmead, Liverpool and Royal Prince Alfred) with Cancer Council NSW project staff in the pilot project.

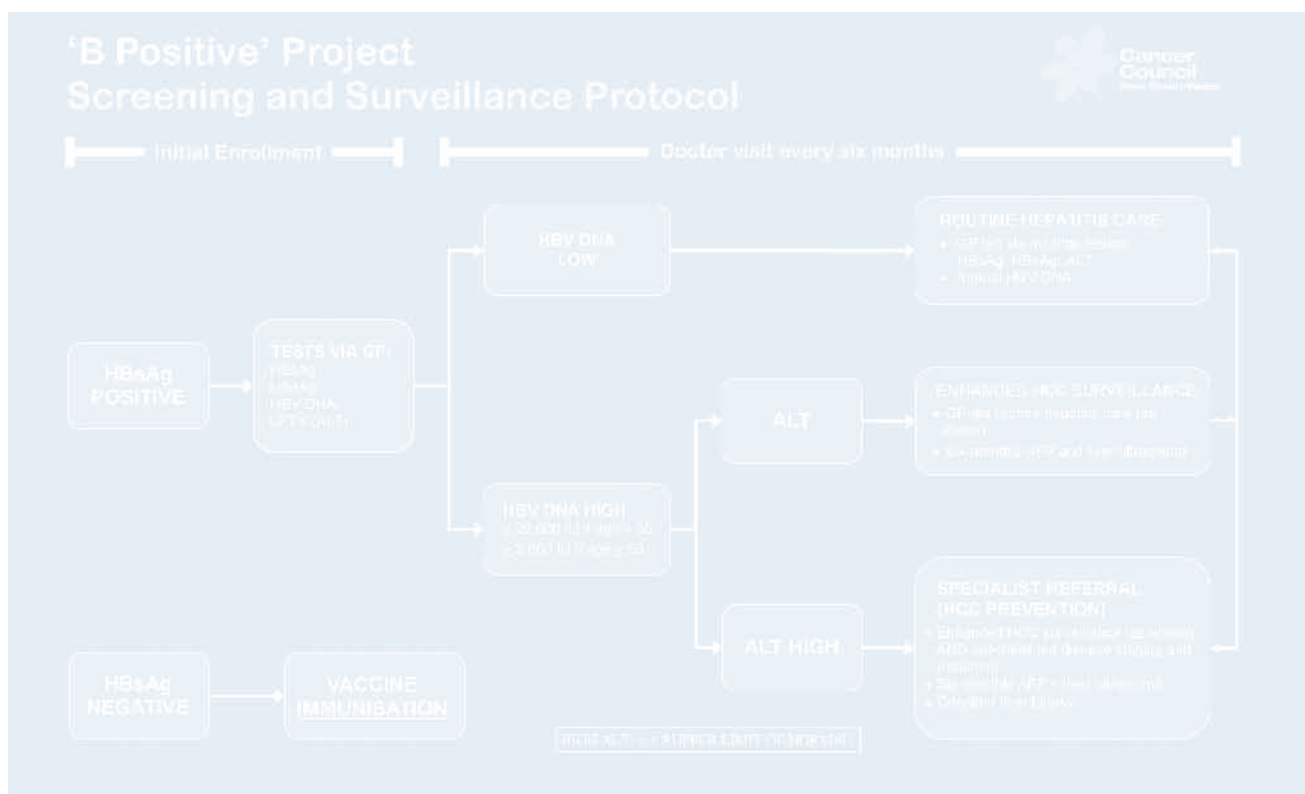
Economic model

The outputs of the model can be summarised as:

A program of CHB screening, follow-up and treatment could significantly reduce the proportion of people progressing to cirrhosis (by 52%), HCC (by 47%) and HBV-related deaths (by 56%).

The current management practice of limited hepatocellular carcinoma screening and treatment would cost about AU\$26 million over 50 years. In comparison a CHB screening, follow-up and treatment program would cost

Figure 3: Hepatitis B screening and liver cancer surveillance protocol



about AU\$146 million, for an additional 9279 Quality Adjusted Life Years (QALYs) gained. The incremental cost effectiveness (discounted) was calculated to be AU\$12,913 per QALY gained.⁴

For the four scenarios investigated, the model found that a comprehensive screening and treatment program of high-risk populations across NSW was both feasible and cost-effective, compared to current clinical practice. The cost, based on liver function tests and viral load, is comparable to that of existing population-based cancer screening programs in Australia (breast, cervical and colorectal cancer). The results have recently been reported in a peer-reviewed international journal article with an accompanying editorial.^{5,6} Cancer Council's economic model estimated the costs incurred by different participants and funding bodies in this program. By far the largest expenses were associated with disease staging (hepatitis B viral load testing) and drug treatment (entecavir and interferon), borne by the Federal Government through the Pharmaceutical Benefits Scheme. According to the model, the Federal Government would bear at least 70% of the program cost in the first year, rising to 90% by the fifth year.⁷

Educational resources

A Hepatitis B monograph, *B Positive - all you wanted to know about hepatitis B*, was developed specifically for GPs by the Australasian Society for HIV Medicine, in collaboration with clinicians and Cancer Council NSW. The publication was distributed nationally, with state/territory government funding, and formally launched in October 2008 at the 6th Australasian Viral Hepatitis Conference.⁸

Cancer Council NSW has developed and delivered a series of educational workshops (November 2007 - November 2008) in the Fairfield - Liverpool area for GPs participating in the 'B Positive' Project. All 329 GPs in the local divisions were invited to participate, with 57 in 2008 attending at least one evening seminar. Early results were presented at the World Organisation of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians and RACGP combined conference in November 2008.⁹

The first GP education seminar in March 2009 attracted 30 new GPs into the accredited education program, supported by the monograph and a comprehensive GP resource kit. This included language-specific patient information packs about the project and other Cancer Council NSW information for patients and carers. The GP Kit resources have recently been made accessible on-line from a new Cancer Council NSW micro-site at www.cancercouncil.com.au/bpositive

Cancer Council NSW has become an RACGP Accredited Provider Organisation, with management-level staff completing accredited training. This enables the design, delivery and administrative support needed for the GP education component of the 'B Positive' Project consistent with implementation of the broader Cancer Council NSW GP Engagement Strategy.

Effective communication strategies

To November 2008, 23 presentations to raise community awareness and ensure program support have been made to over 1000 people from the targeted communities. The 'B Positive' Project was officially launched on 31 October 2008, with approximately 500 participants, mainly from the target Vietnamese and Chinese communities. A parallel activity stream in the pilot project area has provided information about the project and access to its written resources through many migrant resource centres, libraries and similar facilities.

Consumer information about hepatitis B infection (creation of a new pamphlet, slides in relevant languages) and information provided to the target populations at community presentations are accessible on-line, from www.cancercouncil.com.au/bpositive.

To the end of March 2009, more than 60 reports on the 'B Positive' Project have appeared in local newspapers, on ethnic radio or TV and in community publications (society newsletters etc).

Conclusions

Chronic hepatitis B is an important cause of liver cancer, particularly in some overseas-born Australians, so devising cost-effective programs to reduce the burden of disease is a key component of disease management planning.

The disease control challenge in migrant populations is fundamentally different from the vaccine-driven strategies targeted at the Australian born non-Indigenous population. The 'B Positive' Project contributes important field research in accordance with the National Cancer Control Initiative, focused on the educational needs of GPs and patients in responding to the needs of local communities.

Further roll-out from the south western Sydney pilot project to other metropolitan NSW communities has been proposed to the NSW Government.⁷ The development of a 'National Hepatitis B Strategy' would be a significant next step in hepatitis B prevention and control. By systematically engaging affected communities, improving disease detection and opportunities for treatment, enhancing collaborations among clinical and advocacy groups, and prioritising research and surveillance activities, we aim to address the needs of all at-risk communities on a national basis.¹⁰

References

1. Tracey E, Baker D, Chen W, Stavrou E, Bishop J. Cancer in New South Wales: Incidence, Mortality and Prevalence, 2005. Sydney: Cancer Institute NSW, December 2007.
2. Supramaniam R, O'Connell DL, Tracey E, Sitas F. Cancer incidence in New South Wales migrants 1991 to 2001. Sydney: The Cancer Council NSW, 2006.
3. Liaw YF, Sung JJ, Chow WC, Farrell G, Lee CZ, Yuen H, et al. Lamivudine for patients with chronic hepatitis B and advanced liver disease. *N Engl J Med.* 2004;351(15):1521-31.
4. Robotin M, et al Screening And Treatment For Chronic Hepatitis B Infection To Prevent Hepatocellular Cancer In At Risk Australian Populations: A Cost-Effectiveness Analysis. EASL Monothematic Conference on Liver Cancer: June 12-14, 2008, Prague, Czech Republic.

5. Robotin MC, Kansil M, Howard K, George J, Tipper S, Dore GJ, et al. Antiviral therapy for hepatitis B-related liver cancer prevention is more cost-effective than cancer screening. *J Hepatol*. 2009. doi:10.1016/j.jhep.2008.12.022. In press 2009.
6. Sherman M, editor. Prevention of hepatocellular carcinoma: The holy grail of hepatitis B treatment. *J Hepatol*. doi:10.1016/j.jhep.2009.02.005. In press 2009.
7. Cancer Council NSW. Improving outcomes, sparing pain – A new economy for cancer control in NSW. Budget Initiatives for Cancer Control – NSW State Budget 2009/2010. 2008 Nov [cited 2009 Mar 23]. Available from: <http://www.nswcc.org.au/editorial.asp?pageid=2384>.
8. Matthews G, Robotin M, editors. B Positive - all you wanted to know about hepatitis B: a guide for primary care providers. Australasian Society for HIV Medicine, 2008 [cited 2009 Mar 23]. Available from: <http://www.ashm.org.au/B-positive/>.
9. Tipper S, Robotin M, George J, Zwar N. The GP as an innovative cancer control professional: the 'B Positive' Project. World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians WONCA 2008 Asia Pacific Regional Conference. Melbourne: 2008.
10. National Cancer Control Initiative. Report to the Department of Health and Ageing on Phases I and II of the Primary Care Perspective on Cancer Project. Melbourne: NCCI, 2004.