HEPATITIS B VACCINATION POLICY - WHICH APPROACH IS THE MOST COST EFFECTIVE?

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Outline

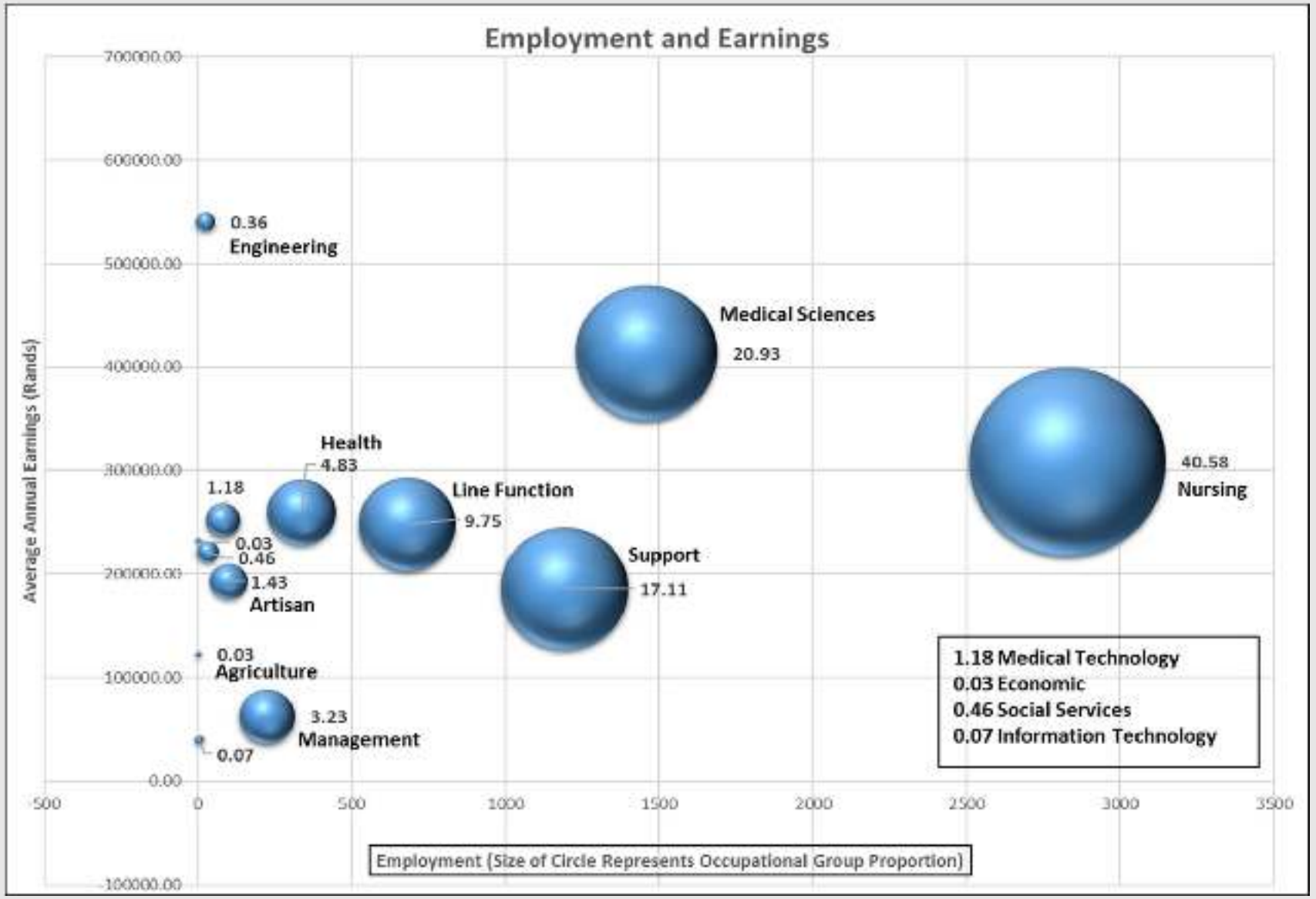
- Introduction and Background
- The Research Project
- Conclusion

Introduction

Study setting

- Academic Hospital
- 1 384-bed hospital
- Approximately 4 300 employees

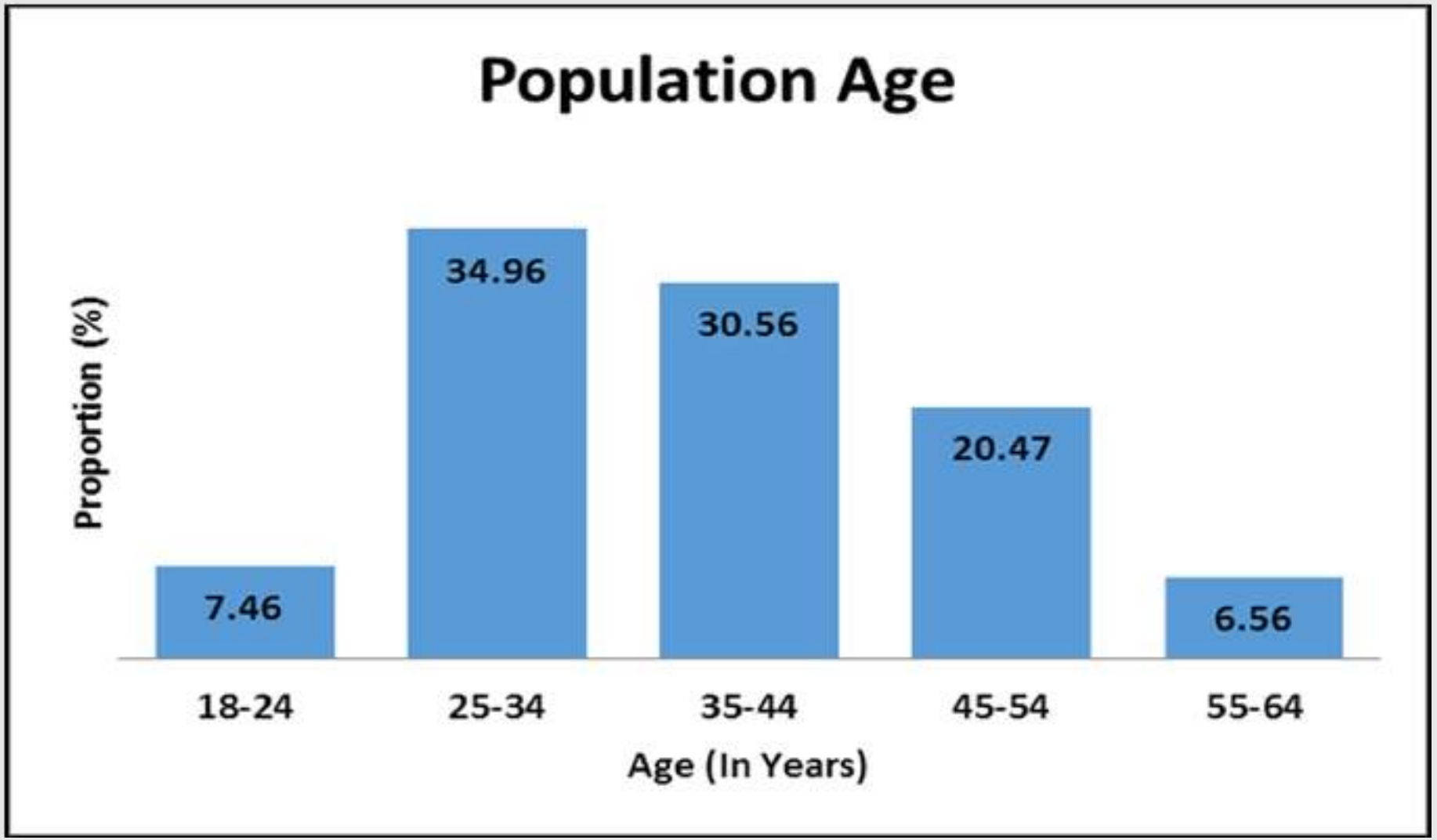
Introduction



Scatter Plot of Occupation Group Proportion and Average Annual Income 2008-2014

Andrews BN. Occupational injuries reported at an Academic Hospital: 2008-2014 (MMed Long Report, Stellenbosch University, 2017).

Introduction



Tygerberg Hospital Population Age 2008-2014

Andrews BN. Occupational injuries reported at an Academic Hospital: 2008-2014 (MMed Long Report, Stellenbosch University, 2017).

Introduction

Hepatitis B virus

- Well recognized risk within healthcare environment
- Contributes the **highest risk** of blood-borne infections in health care personnel (HCP) world-wide.
- may be **transmitted** to employees in the healthcare setting through **contact** with **infected blood and body fluids.**

Introduction

Hepatitis B virus

- Contact
  - *Direct: needlestick injuries or splashes contaminating mucous membranes or open wounds. [**NSI events**]*
  - *Indirect: may occur when surfaces contaminated with blood products comes into contact with mucous membranes or open wounds.*

    (HBV can survive on surfaces for up to seven days without losing the ability to cause infection)

Introduction

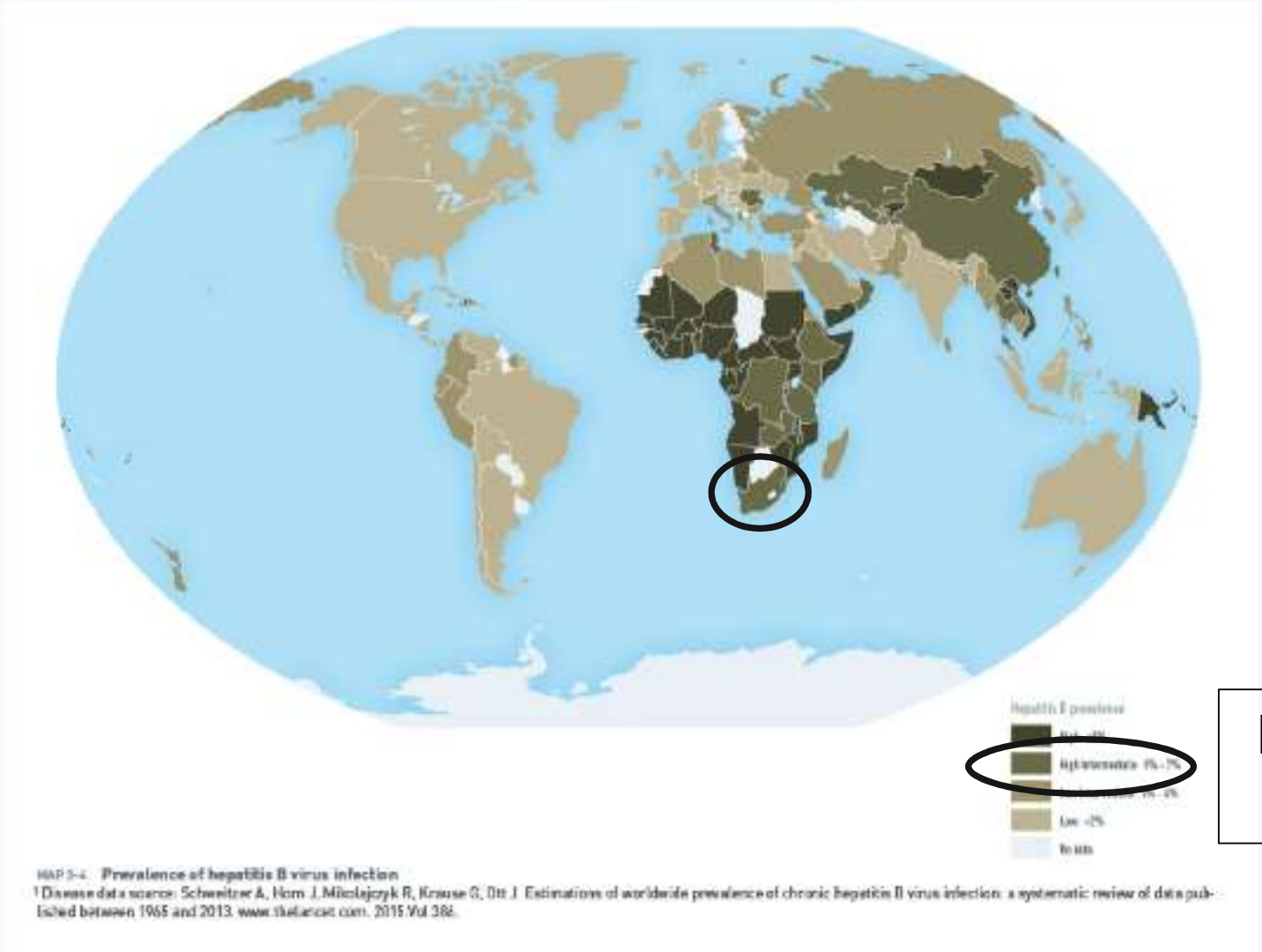
Healthcare Personnel (HCP)

Defined by US Centers for Disease Control and Prevention (CDC) as

- paid and unpaid persons working in healthcare setting who are at risk of exposure to infectious agents
  - *Medical Doctors/Dentists*
  - *Nurses*
  - *Physiotherapists/Occupational therapists/Human nutritionists*
  - *Laboratory staff*
- Includes persons not directly involved in patient care but with potential exposure to infectious agents
  - *Ward clerks, household assistants/cleaners, porters, laundry and maintenance employees*

Both the prevalence of HBV, as well as the presence or absence of vaccine-induced protection influences the risk of hepatitis B to healthcare personnel (HCP)

Hepatitis B Prevalence



MAP 3-4 **Prevalence of hepatitis B virus infection**
† Disease data source: Schweitzer A, Horn J, Mikolajczyk R, Krause G, Ott J. Estimations of worldwide prevalence of chronic hepatitis B virus infection: a systematic review of data published between 1965 and 2013. www.thelancet.com. 2015 Vol 386.

High intermediate – 6.7%

Hepatitis B Vaccination

Vaccine Preventable Condition

- Employees who have been immunised and developed adequate immunity to the virus have little risk for infection.

- A vaccinated employee with inadequate antibody response or
- An unvaccinated employee

6-30% risk

Hepatitis B Vaccination

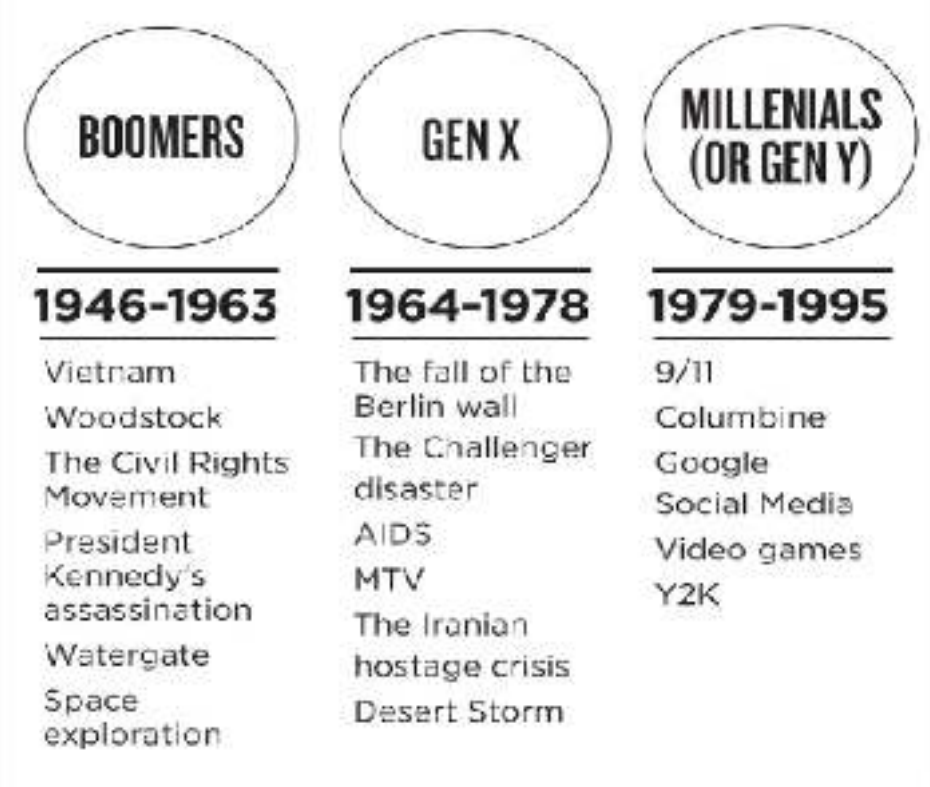
- The hepatitis B vaccine was introduced into South Africa's Expanded Programme of Immunisation (EPI) in April 1995

Graph: WHO indicating % coverage of the third dose of hepatitis B vaccine among 1-year olds in South Africa.

Healthcare Workforce

1

Established Health Workforce- require adult vaccination



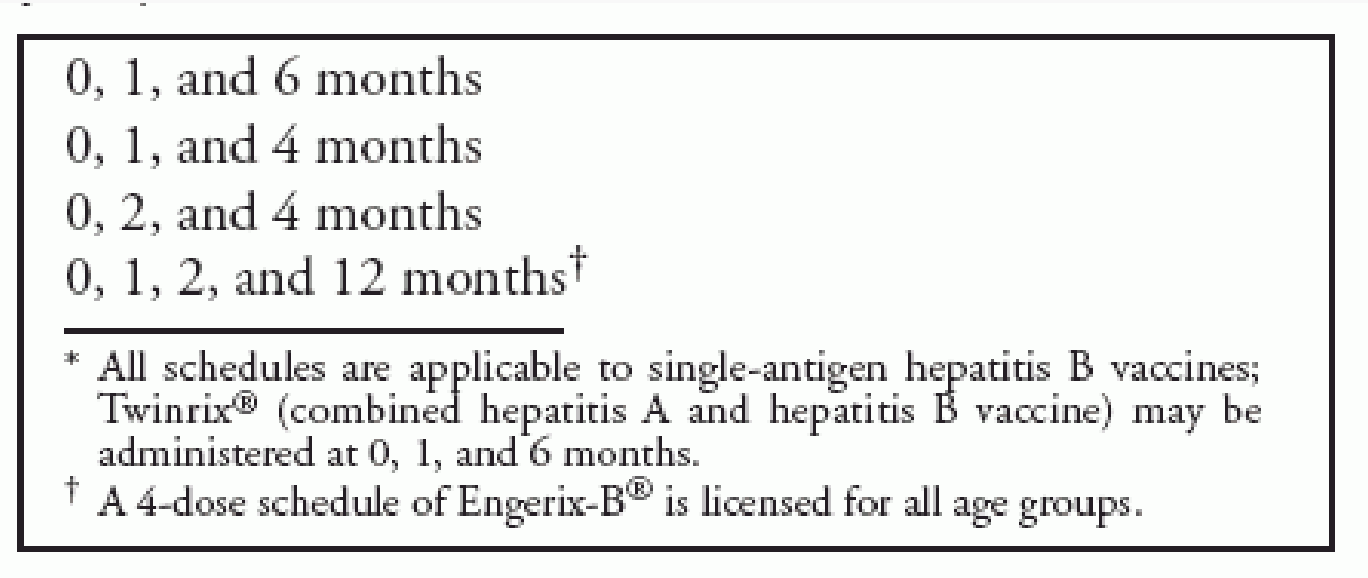
2

Trainees/New employees- vaccination in distant past (EPI)

Unvaccinated proportion approximates 30%

Hepatitis B Vaccination

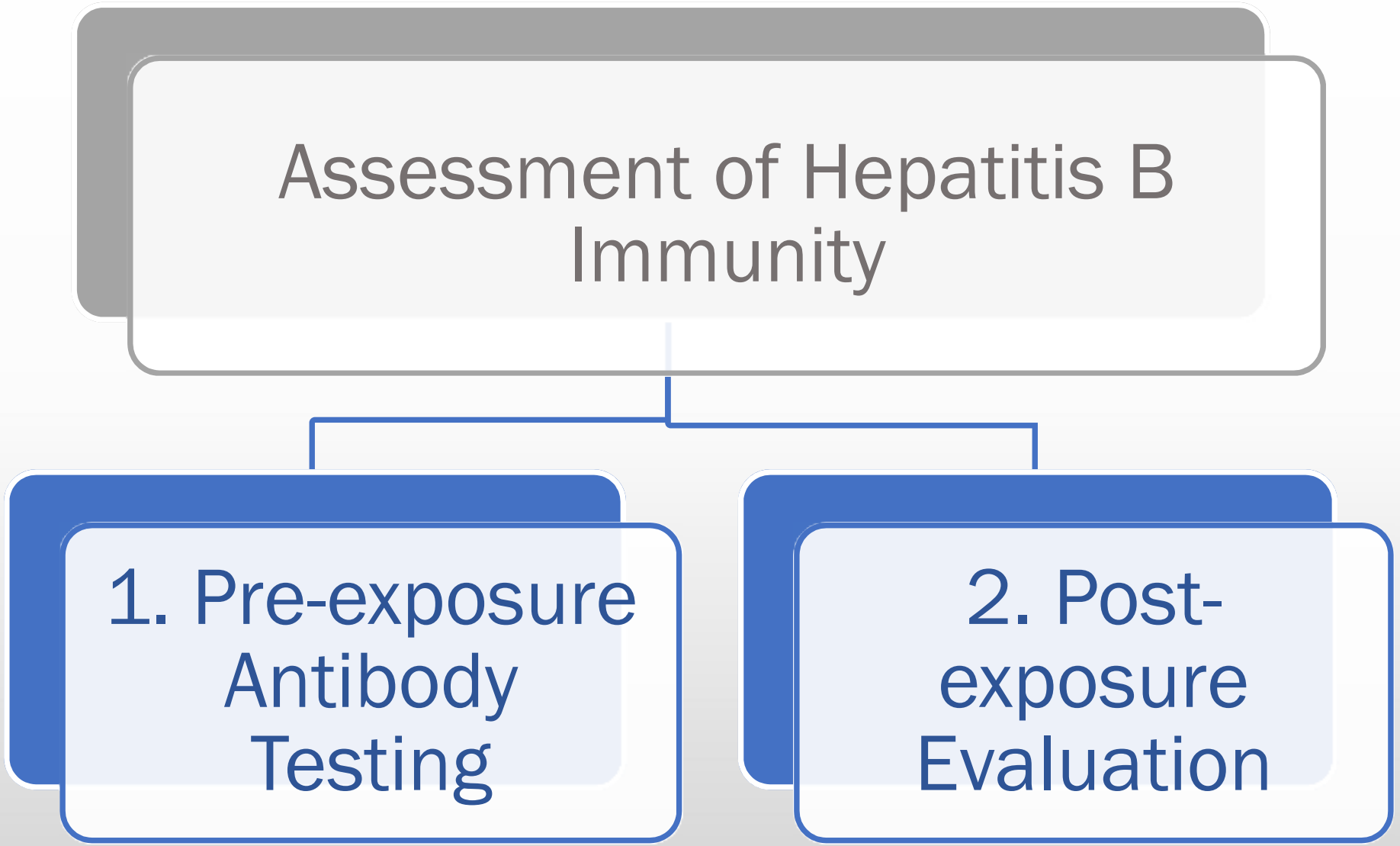
- Among adults (age > 20 years), the hepatitis B vaccine is administered in a three or four-dose schedule



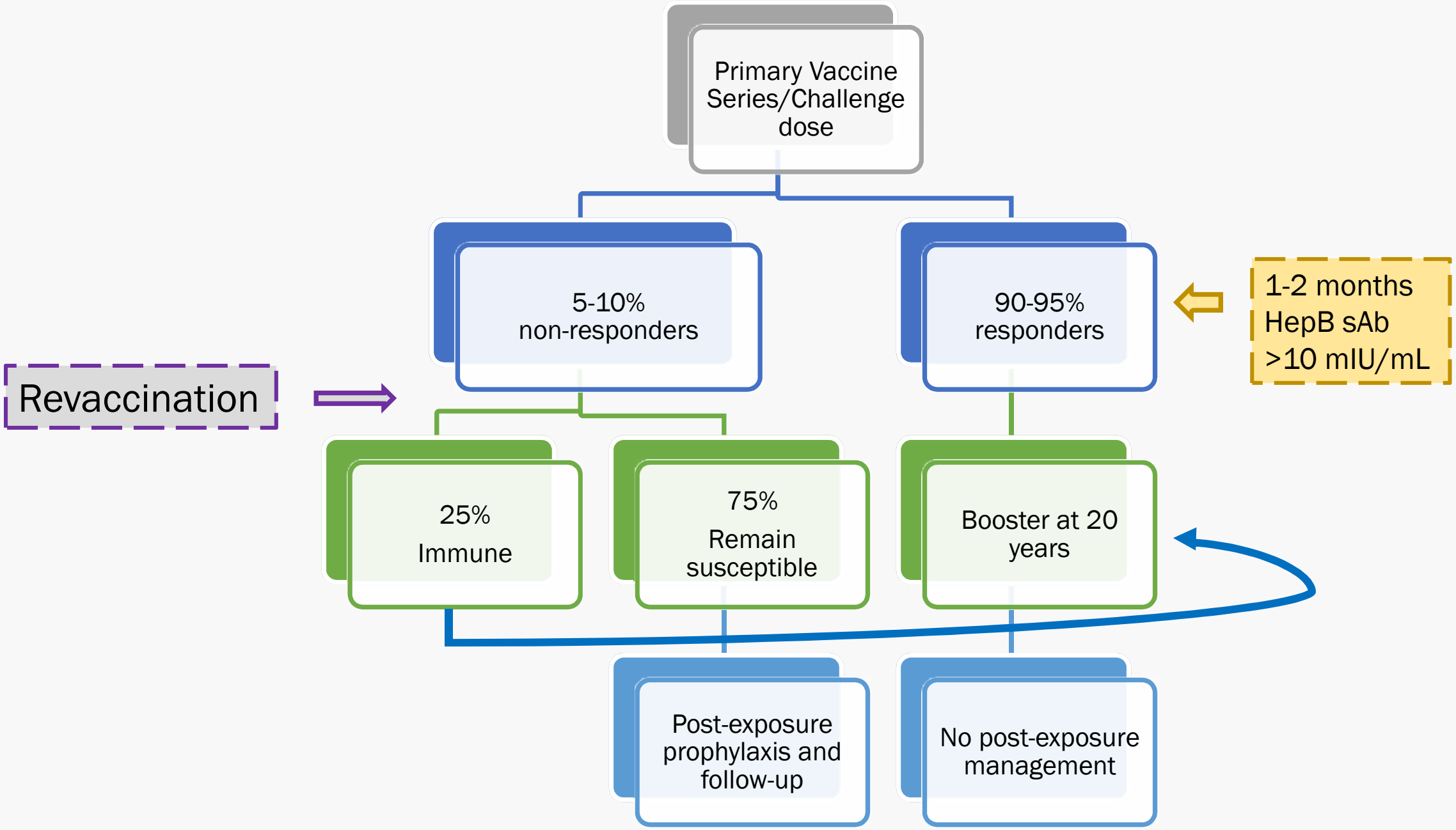
0, 1, and 6 months
0, 1, and 4 months
0, 2, and 4 months
0, 1, 2, and 12 months†

* All schedules are applicable to single-antigen hepatitis B vaccines; Twinrix® (combined hepatitis A and hepatitis B vaccine) may be administered at 0, 1, and 6 months.
† A 4-dose schedule of Engerix-B® is licensed for all age groups.

- CDC guidelines recommend that a challenge dose should be administered to employees vaccinated during childhood


Assessment of Hepatitis B Immunity
1. Pre-exposure Antibody Testing
2. Post-exposure Evaluation

1. Pre-exposure Antibody Testing



2. Post-exposure Evaluation

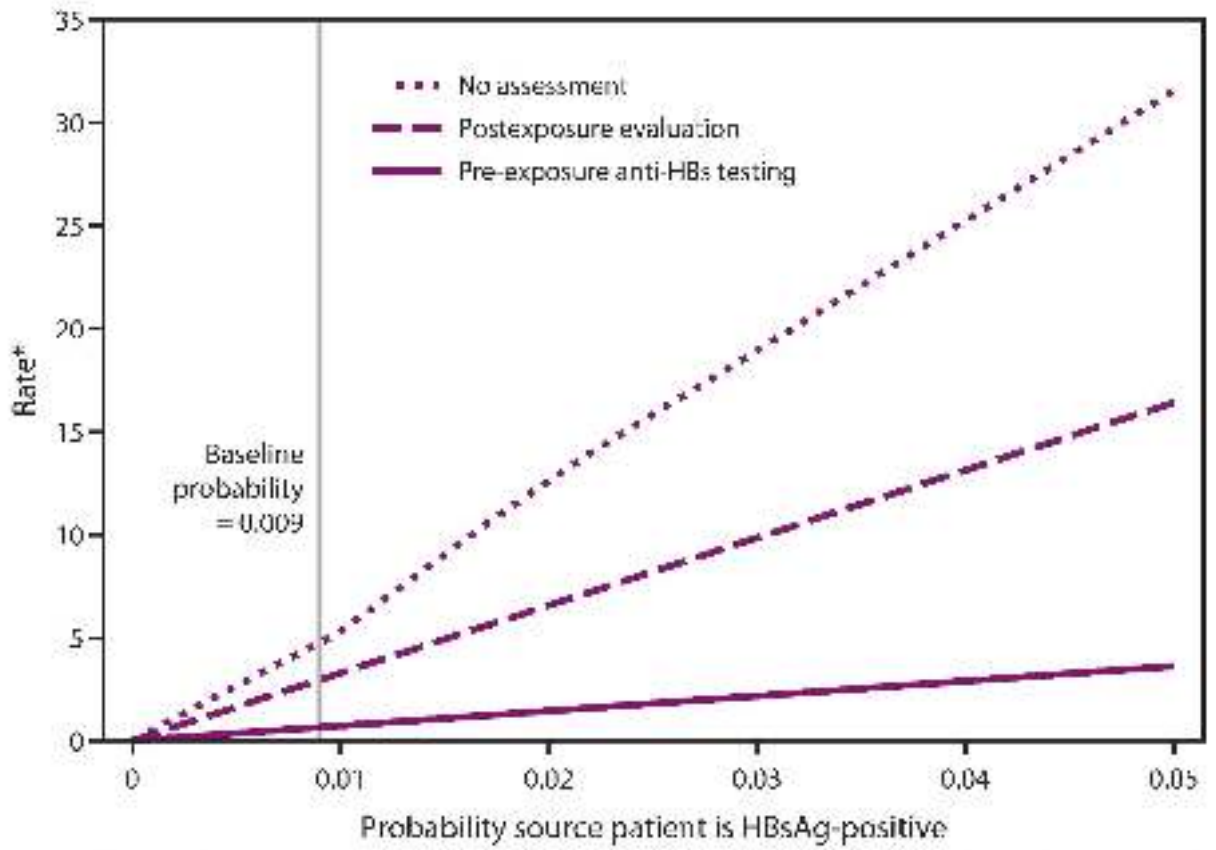
Assessment of HepB sAb status and appropriate follow-up done at the time of exposure to potentially infectious blood or body fluids

- CDC guidelines note that it may be appropriate for
  - *Low risk work*

  (for example counselling as opposed to performing procedures)
  - *Low prevalence settings (decreased risk of exposure)*
- Reliant on HCP recognition and reporting of NSI events
- It may be applied on basis of cost considerations

Pre- versus Post-exposure Evaluation of Hepatitis B Immunity

FIGURE 4. Hepatitis B virus infection rate among health-care personnel trainees, by prevalence of hepatitis B surface antigen positivity of source patients and approach to assessment



Source: Personal communication. Hoerger TJ, Ludlow-Bradley C. Durham, North Carolina: Research Triangle Institute, International; 2012.

* Per 100,000 population of health-care personnel.

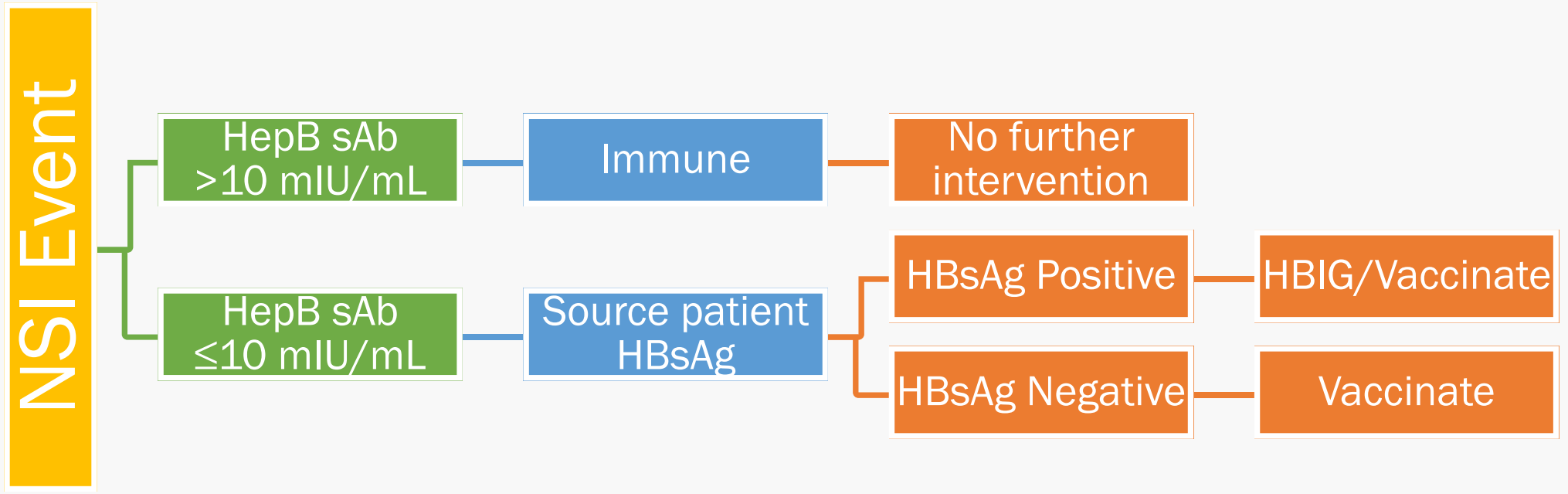
Study Setting Hospital Practice

- Vaccine freely available on request to all employees

(Initial vaccine series and 5 yearly boosters)

- No compulsory vaccination programme
- Proof of vaccination not required at the commencement of employment
- **No post vaccination HepB sAb testing** is performed to confirm immunity.
- HepB sAb testing **only done in the event of a NSI event** and managed accordingly

Study Setting Hospital Practice



Study Setting Hospital Practice

- Based on the post-exposure approach
- Passive in nature
  - *Self reporting of staff members*
  - *No systematic pre-exposure evaluation and management of employees*

Cost implications of moving to structured vaccination programme with pre-exposure antibody testing?

Study Objectives

To determine from 1 January 2009- 31 December 2014:

- the cumulative incidence of reported NSI among healthcare personnel

- the proportion of employees found to have inadequate immunity with post-exposure evaluation.

(Non-immunity defined as anti-HBs ≤ 10mIU/mL)

Study Objectives

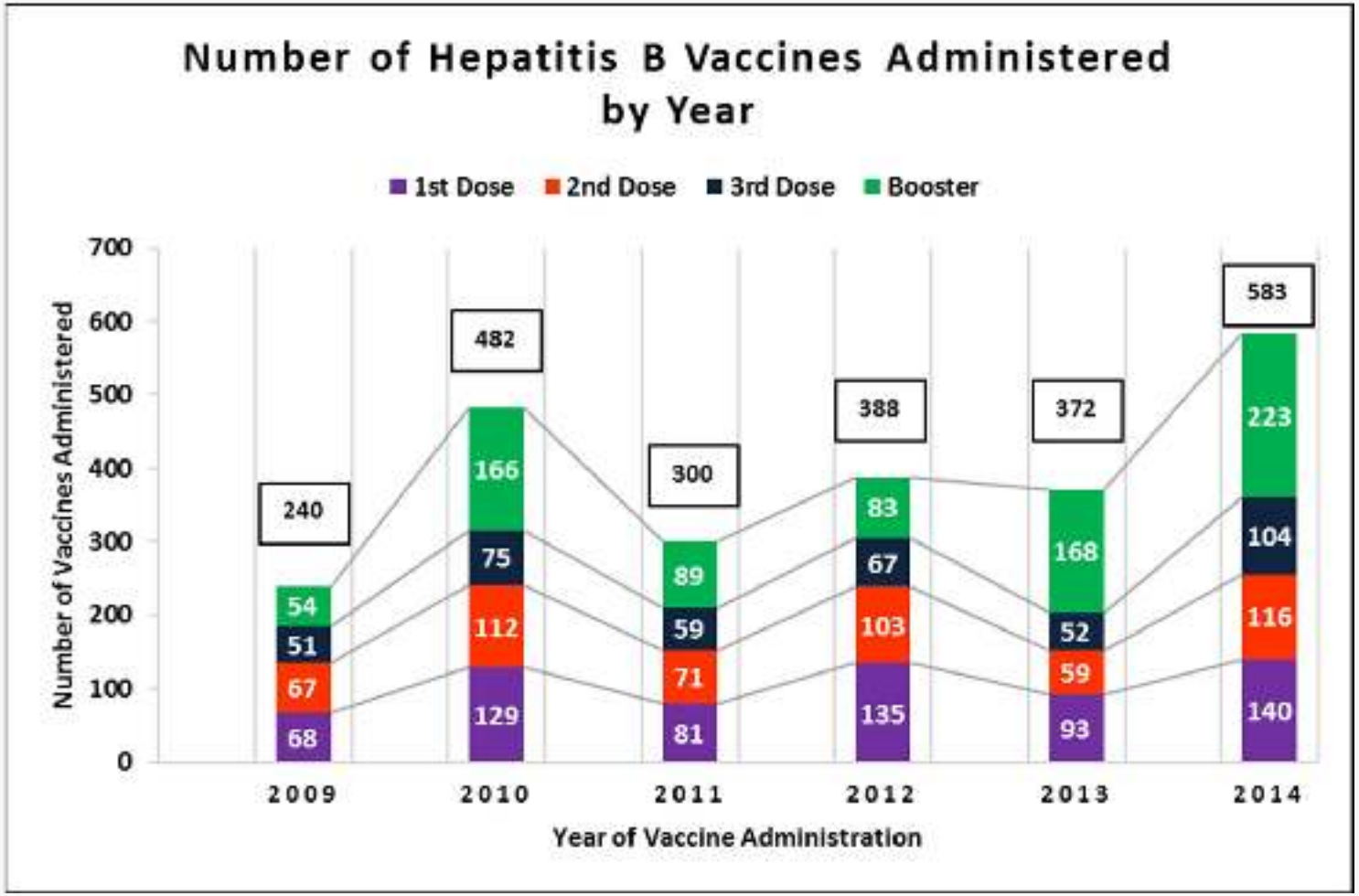
- The proportion of employees requiring immunoglobulin coverage following an exposure incident
- The proportion of all staff members presenting for hepatitis B vaccinations
- Exploratory analysis of the direct costs associated with the pre- and post-exposure approach within TBH setting

(Resources and time not available for full economic evaluation)

Methods

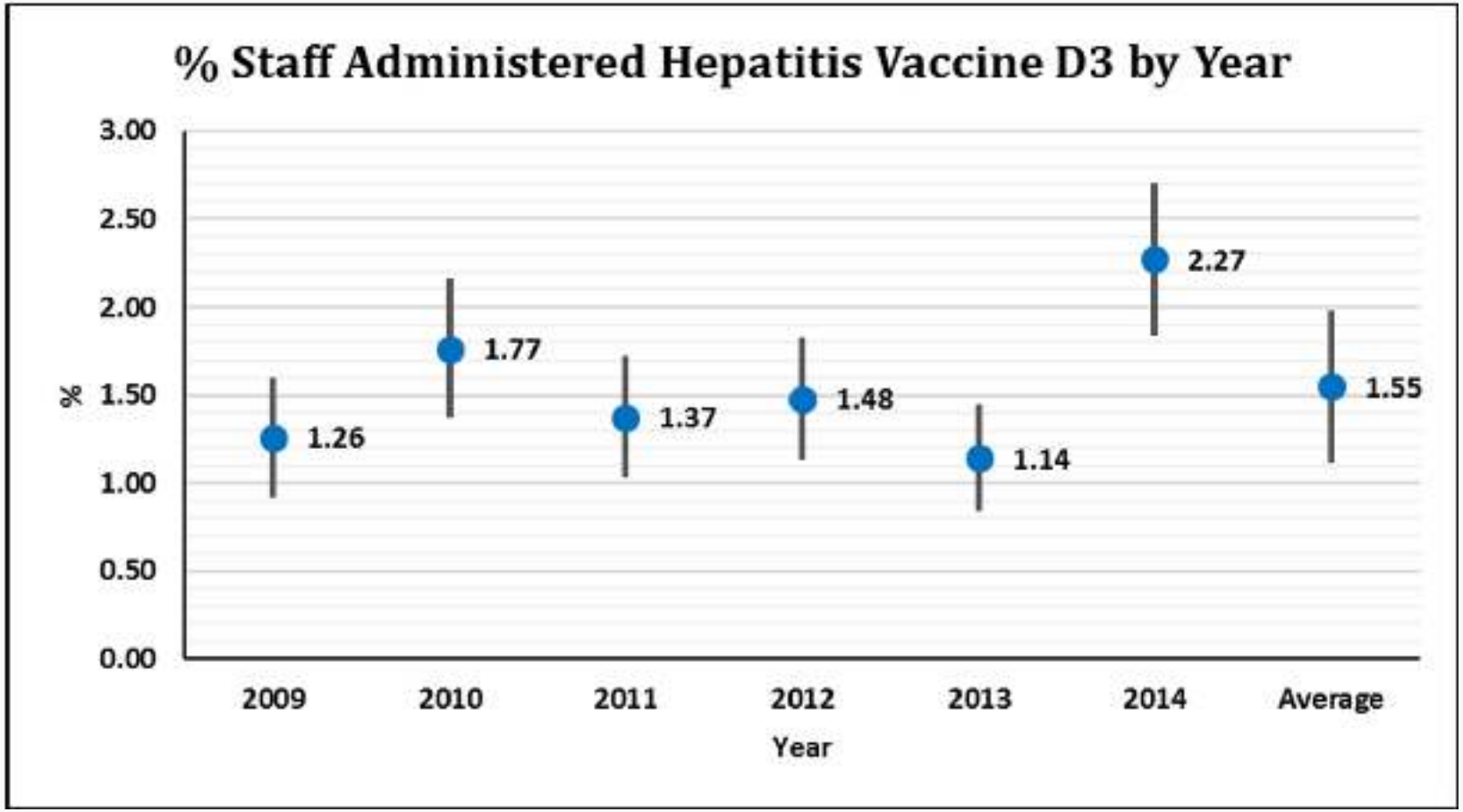
- Retrospective analysis TBH OH Clinic NSI data performed
- Time period: 1 January 2009- 31 December 2014
- Staff demographic data obtained from HR department
- Cost data obtained from
  - *TBH Pharmacy database*
  - *National Health Laboratory Service (NHLS)*
  - *TBH Stores department*

Results



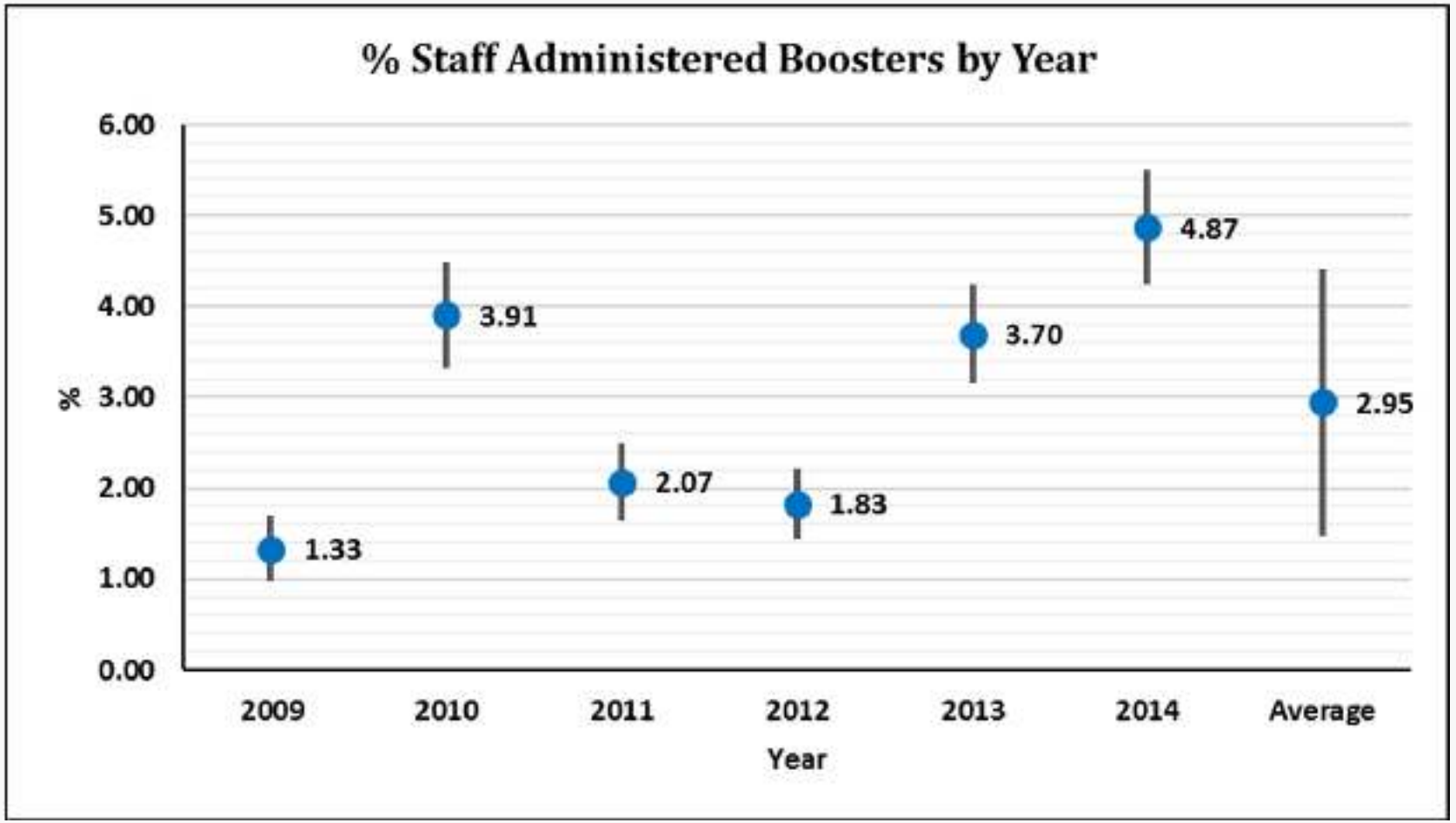
Number of Hepatitis B Vaccinations among Staff

Results



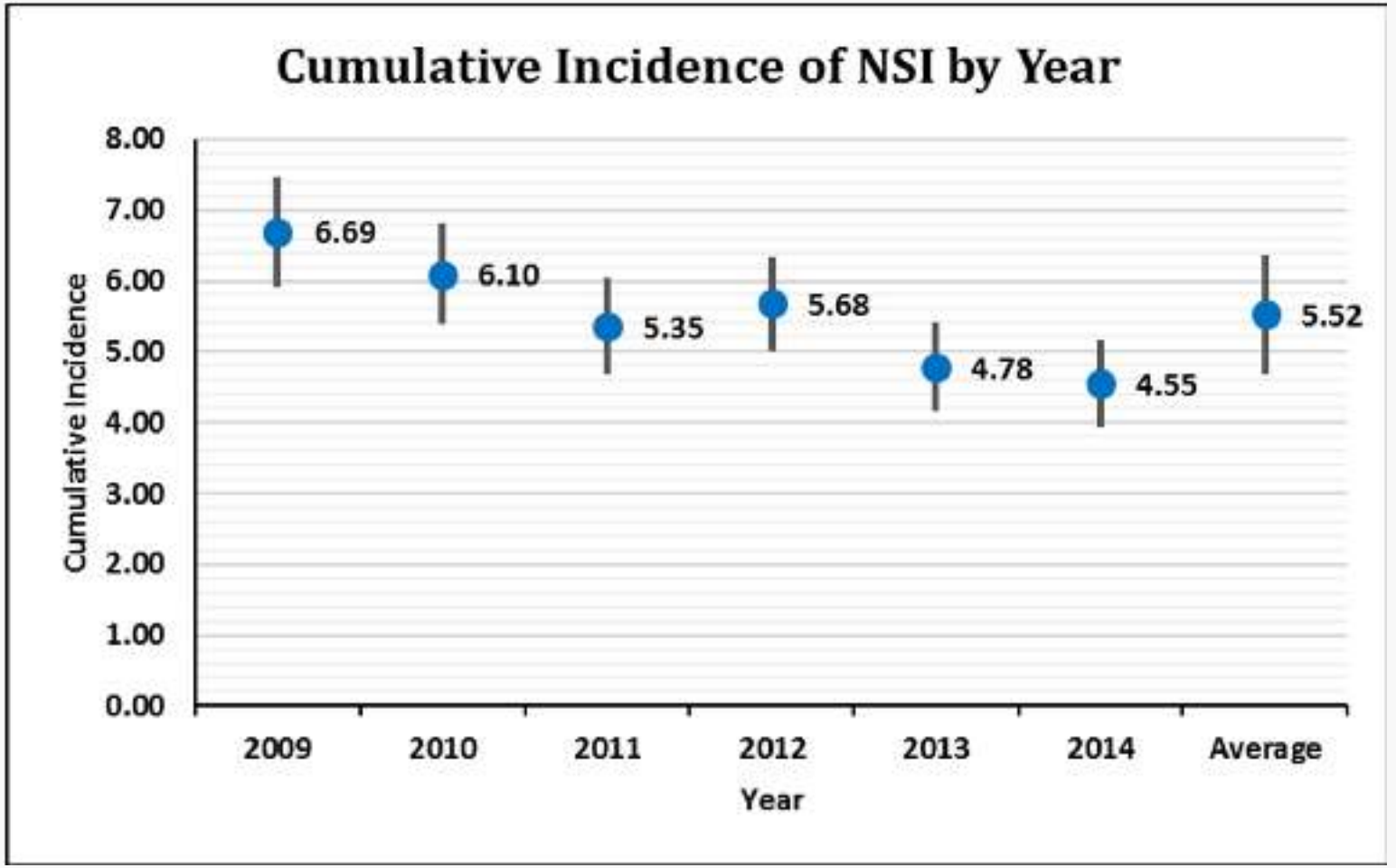
Percentage of Staff Administered D3 of Vaccine

Results



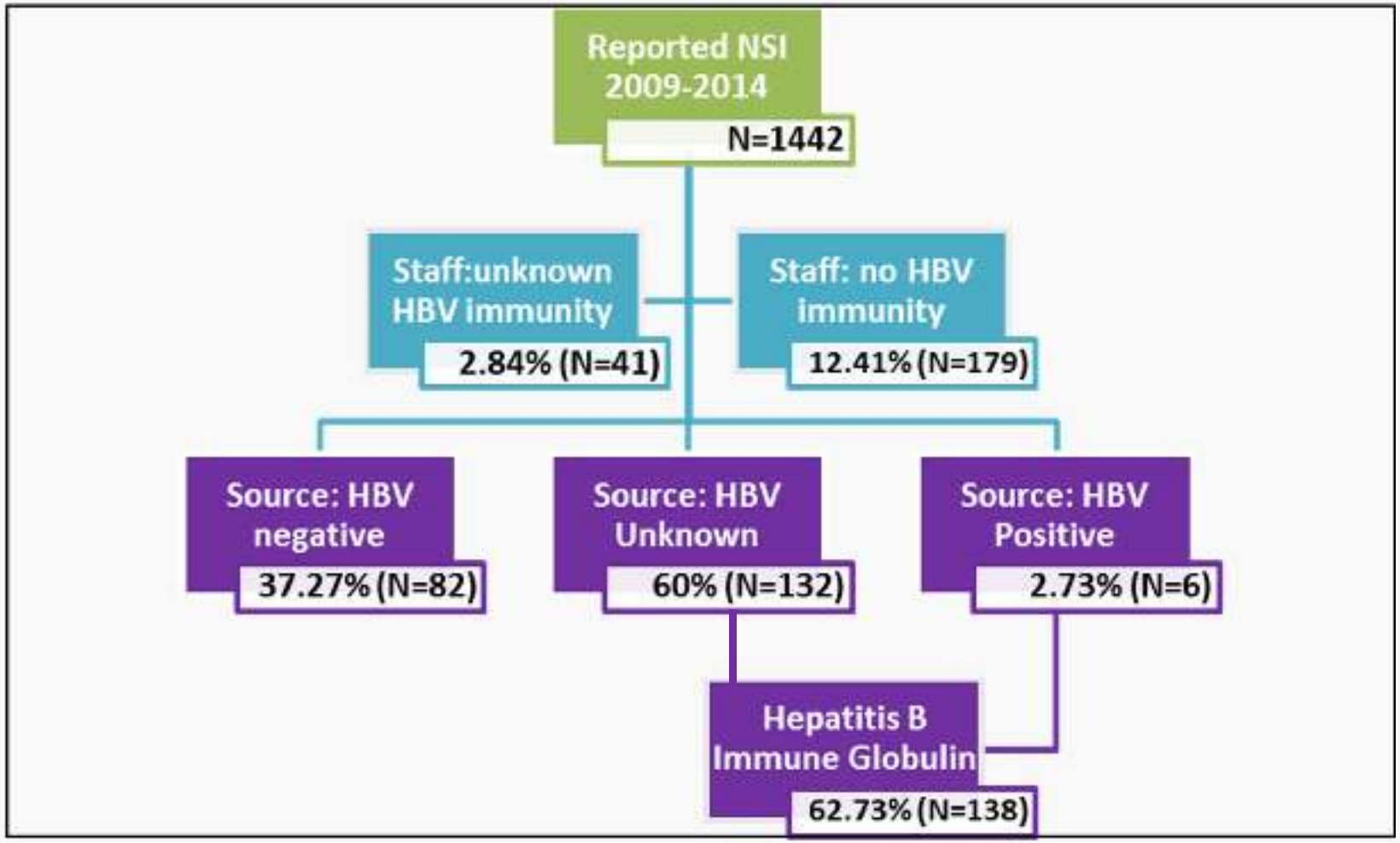
Percentage of Staff Administered a Hepatitis B Booster

Results



Cumulative Incidence of Reported NSI (reported as cases per 100 persons per year)

Results



Staff and Source Patient Hepatitis B Immunity testing for NSI 2009-2014

Direct Costs Post-Exposure Approach 2009-2014

- No initial cost
- R110 691.89 annual average

Influenced by the

1. Number employees requesting vaccination
2. Number of incidents requiring post-exposure management

Costs calculated

- Hepatitis B Vaccines administered
- HBsAb titres requested
- HBsAg tests requested
- Hebagam® administered

Estimated Direct Costs Pre-Exposure Vaccination Programme

- Initial Cost to vaccinate full workforce: R263 429.52
- Annual Costs:
  - *New appointments require vaccination. Average of 1590 new appointments annually. Annual cost to vaccinate new appointments: R95 781.60*
  - *Annual anti-HBs monitoring of at-risk individuals: R60 905.70*
  - *Average annual cost of post-exposure management for vaccine non-responders: R25 723.92*

Total costs: R 263 429.52 initial and R182 411.22 annual (influenced by the number of new employees and number of incidents requiring post-exposure management).

Limitations

1. The analysis was of the full workforce and not stratified by job category.

- Denominator data over-estimated
- Underestimation of proportion of NSI events and employees vaccinated

2. Only specific direct costs were calculated.

- Nursing, administrative, personnel costs and other indirect costs not considered

3. The consumer protection index (CPI) was not considered in cost calculations
4. Crude estimation of costs and-not a complete economic evaluation

Economic Evaluations in Other Settings

- CDC developed 2 economic models
- Calculated the incremental cost per quality-adjusted life-year (QALY) saved and expected no. infections for each approach

	Pre-exposure HB sAb Testing		Post-exposure Management	
	Trainees	Non-trainees	Trainees	Non-trainees
Incremental cost per QALY saved				
Year 1				
Year 10				
Expected no. infections				

Economic Evaluations in Other Settings

- Post exposure approach less costly initially
- Pre-exposure antibody testing with revaccination is more cost-effective over time and smaller number expected infections

	Pre-exposure HB sAb Testing		Post-exposure Management	
	Trainees	Non-trainees	Trainees	Non-trainees
Incremental cost per QALY saved				
Year 1	$4,542,467	$3,149,183	$2,270,801	$1,610,998
Year 10	$893,619	$796,140	$917,859	$1,114,364
Expected no. infections	0.7 per 100,000	0. 4 per 100,000	3 per 100,000	1.7 per 100,000

Economic Evaluations in Other Settings

Sensitivity analysis demonstrated that cost-effectiveness improves in

1. high prevalence settings

2. High risk settings (example- surgeon)

Conclusion

- Further more comprehensive costs analyses required in the study setting
  - *Pre-exposure approach more expensive in this analysis but long-term risk of infection and long-term costs not taken into account*
- Both short and long term costs of any vaccine policy needs to be considered
- Cost analysis of Hepatitis B vaccine programme is workplace specific. Important variables include
  - *Expected population prevalence*
  - *Occupational risk of exposure*
  - *Employee turnover*
  - *OH Budget (cost considerations)*

References

1. Schillie SF, Murphy TV, Sawyer M, Ly K, Hughes E, Jiles R, de Perio MA, Reilly M, Byrd K, Ward JW. CDC guidance for evaluating health-care personnel for hepatitis B virus protection and for administering postexposure management.
2. World Health Organization. Global Health Observatory data repository. 2016; Available at: http://apps.who.int/gho/data/view.main.80300?lang=en. Accessed May 15, 2017.
3. https://wwwnc.cdc.gov/travel/yellowbook/2018/infectious-diseases-related-to-travel/hepatitis-b