

# Laboratory surveillance of invasive pneumococcal disease in Australia in 2001 to 2002—implications for vaccine serotype coverage

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## Abstract

**This paper reports the results of comprehensive laboratory surveillance of invasive pneumococcal disease (IPD) in Australia during 2001 and 2002. The 7-valent conjugate pneumococcal vaccine was introduced for high risk paediatric groups, including Indigenous children, in late 2001. Of 1,355 isolates from non-Indigenous children, 86 per cent belonged to serotypes and 93 per cent to serogroups represented in the 7-valent pneumococcal conjugate vaccine. Thirteen per cent and 24 per cent of isolates had reduced susceptibility to penicillin and erythromycin, respectively and of these, more than 99 per cent belonged to serogroups represented in the 7-valent vaccine. Of the 1,504 isolates from non-Indigenous adults, 96 per cent belonged to serotypes included in the 23-valent polysaccharide vaccine; 14 per cent and 15 per cent had reduced susceptibility to penicillin and erythromycin, respectively and more than 95 per cent of these belonged to serotypes included in the 7-valent conjugate vaccine. In Western Australia and the Northern Territory (the only states for which Indigenous status was consistently available), there were 29 cases of IPD in Indigenous children, of which 21 were due to 7-valent vaccine serotypes in 2001, compared with 24 cases, including 10 due to vaccine serotypes, in 2002. This represents a statistically significant increase in the proportion of total isolates due to non-vaccine serotypes ( $\chi^2 = 3.93$ ,  $p = 0.048$ ) following the introduction of the 7-valent conjugate vaccine, principally due to serotypes 7F and 12F. The number of episodes due to penicillin resistant isolates decreased from nine in 2001 to two in 2002. Ninety per cent of isolates from Indigenous adults were included in the 23-valent polysaccharide vaccine and six per cent and five per cent had reduced susceptibility to penicillin and erythromycin, respectively. Conjugate pneumococcal vaccines can be expected to reduce the incidence of IPD due to vaccine serotypes in vaccinated children and potentially, their adult contacts. It may also impact favourably on the incidence of IPD due to penicillin and erythromycin resistant strains. Continued surveillance of both serotype distribution and antibiotic susceptibility are required to identify serotype replacement by non-vaccine serotypes and to monitor the overall impact of current and future vaccine programs on invasive pneumococcal disease in Australia. *Commun Dis Intell* 2003;27:478–487.**

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## Introduction

*Streptococcus pneumoniae* is a major cause of morbidity and mortality worldwide.<sup>1-4</sup> Knowledge of the serotypes responsible for invasive pneumococcal disease (IPD) is essential for planning and monitoring the introduction of vaccines against pneumococcus.<sup>5,6</sup> Although laboratory surveillance of IPD was already taking place independently in Australian states and territories,<sup>7-10</sup> the commencement of funding of laboratory surveillance by the Commonwealth Government in January 2002 has facilitated a national approach to laboratory surveillance of IPD. Data on serotypes responsible for IPD is now comprehensive, although data on antimicrobial resistance remains incomplete.

In late 2001, a 7-valent conjugate pneumococcal vaccine program was introduced for high risk paediatric groups including Indigenous children. We report on the early impact this program has had on IPD in Indigenous children in Western Australia and the Northern Territory and the potential impact in the wider community.

Antimicrobial resistance in invasive pneumococci is an emerging problem in Australia.<sup>11</sup> Laboratory data on resistance to penicillin and erythromycin is presented although these data are not available for Victoria and are largely generated from the routine clinical laboratories in other states such as New South Wales. Analysis has necessarily been limited to categorisation into fully susceptible or resistant (intermediate and high level resistance) to penicillin and erythromycin. The serotype coverage for the future 11-valent conjugate pneumococcal vaccine and the existing 23-valent polysaccharide vaccine have been examined.

## Methods and materials

### Case definition

A case of IPD was defined as isolation of *Streptococcus pneumoniae* from a normally sterile body site (e.g. blood culture, cerebrospinal fluid, joint fluid, etc). A new episode was deemed to occur if the isolate occurred more than 14 days from the previous positive culture.

### Data sources and collection

A network of pneumococcal laboratories in Australia (see list of participating laboratories) obtained pneumococcal isolates referred from all major private and public microbiology laboratories in Australia. Isolates were referred for storage and later serotyping at one of the three designated pneumococcal typing laboratories. Indigenous status data was obtained from enhanced surveillance data and was able to

be efficiently linked to laboratory data for Western Australia and the Northern Territory. IPD data for Indigenous patients from Western Australia and the Northern Territory were combined for the purpose of data analysis. In other states, the Indigenous status data was either incomplete or could not be linked efficiently with laboratory data. Where Indigenous status was unknown, patients were deemed to be non-Indigenous for the purposes of data analysis. This may have resulted in some Indigenous patient data from New South Wales, South Australia, Victoria and Queensland being included in the non-Indigenous Australian paediatric and adult data that has been presented. Data from the Australian Capital Territory and Tasmania were only available for 2002 and so were not included in the analysis.

### Serotyping

Pneumococcal serotyping was performed at the Pneumococcal Reference Laboratory of Queensland Health Scientific Services (Western Australia, the Northern Territory, Queensland), the Children's Hospital at Westmead's New South Wales Pneumococcal Reference Laboratory (New South Wales) and the Microbiological Diagnostic Unit (Victoria, South Australia). Serotyping was performed by the Quellung reaction using antisera from the Statens Seruminstitut, Copenhagen, Denmark.

### Susceptibility testing

Susceptibility testing was performed by a range of different methods. In New South Wales and South Australia the available results were from routine diagnostic laboratories. These laboratories used NCCLS disc diffusion, CDS disc diffusion or agar dilution susceptibility testing methods. Most laboratories also confirmed penicillin resistance using the E test method. Results from Queensland and Western Australia were performed using NCCLS disc diffusion and E test methods in a reference laboratory.

Isolates were categorised as fully sensitive to penicillin or resistant (includes intermediate and high level resistance using NCCLS breakpoints). Isolates to erythromycin were categorised as either sensitive or resistant (those with intermediate resistance were categorised as resistant).

### Statistical analysis

Yates corrected Chi square test was used for univariate analysis using Epi Info statistical software V6.02 (Centers for Disease Control and Prevention, USA). Patients were classified as children if their age was under 15 years and adults if they were 15 years of age or over.

## Results

### Serotypes responsible for invasive pneumococcal disease and antimicrobial resistance in non-Indigenous Australian children

Data from Queensland, Victoria, New South Wales, South Australia, Western Australia and the Northern Territory for children were initially analysed separately but then combined, as the serotype distributions were comparable. Of the 1,383 episodes recorded by the laboratory surveillance system, isolates from 1,355 (98%) were serotyped. The serotype distribution and vaccine serotype coverage for children for the 7-valent and future 11-valent conjugate pneumococcal vaccines is illustrated in Figure 1. Those serotypes not covered

in the conjugate vaccines are illustrated in Table 1. Eighty-six per cent of isolates were a serotype match for the 7-valent vaccine and 93 per cent of isolates were a serogroup match. The future 11-valent vaccine (addition of serotype 1, 7F, 5 and 3) provided an additional three per cent serotype coverage. The serotype distribution for neonates (<28 days of age) was found to be different when compared to older children (Table 2).

Of the 1,383 isolates from children, 1,140 were serotyped and had susceptibility results recorded for penicillin. One hundred and forty-six (12.8%) had reduced susceptibility to penicillin. Over 99 per cent of the penicillin resistant isolates belonged to serogroups in the 7-valent conjugate vaccine (Table 3).

**Table 1. Non-conjugate vaccine serotypes from non-Indigenous children less than 15 years, Australia, 2001 to 2002**

Serotype	23-valent polysaccharide vaccine serotype								23-valent polysaccharide vaccine serogroup		Non-vaccine serotypes					
	15B	8	22F	17F	11A	33F	12F	10A	15C	22A	35F	13	35B	38	16F	NT
Number of isolates	8	1	5	1	3	3	3	2	6	1	2	1	2	7	4	3
Cumulative (%)	15.4	17.3	26.9	28.8	34.6	40.4	46.2	50.0	61.5	63.5	67.3	69.2	73.1	86.5	94.2	100.0

NT Non-typable

**Table 2. Non-Indigenous neonatal (<28 days) serotypes, Australia, 2001 to 2002**

Serotype	7-valent conjugate vaccine serotype							7-valent conjugate vaccine serogroup		11-valent conjugate vaccine serotype		23-valent polysaccharide vaccine serotype		Non-vaccine serotype	
	14	6B	19F	18C	4	23F	9V	19A	6A	1	7F	22F	10A	16F	38
Total number	1	2	3	1	1	0	1	0	1	0	1	1	1	1	1
Cumulative %	6.7	20.0	40.0	46.7	53.3	53.3	60.0	60.0	66.7	66.7	73.3	80.0	86.7	93.3	100.0

**Table 3. Penicillin resistant serotypes in non-Indigenous Australian children less than 15 years, 2001 to 2002**

Serotype	7-valent conjugate vaccine serotype					7-valent conjugate vaccine serogroup		23-valent polysaccharide vaccine serotype
	19F	9V	6B	14	23F	19A	6A	15C
Number of isolates	40	33	30	22	9	9	2	1
Cumulative (%)	27.4	50.0	70.5	85.6	91.8	97.9	99.3	100.0

The percentage of each serotype that was resistant to penicillin varied by state. The percentage resistance also varied for each serotype with a very high proportion of serotype 9V isolates being resistant to penicillin whilst others such as serotype 14 had low percentage resistance (Figure 2).

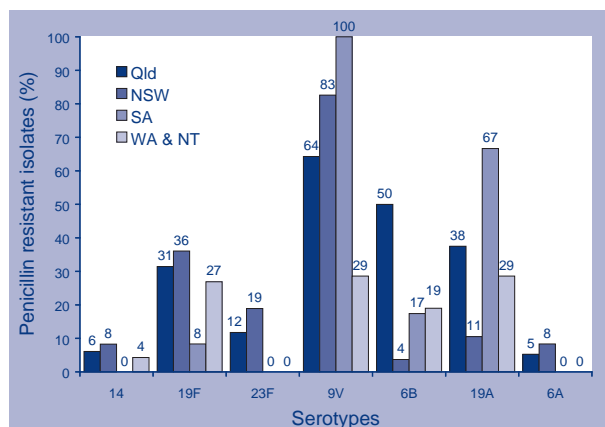
Serotyping results and erythromycin susceptibility was available for 1,092 of 1,383 isolates from children. Two hundred and sixty (23.8%) of these were resistant to erythromycin. The predominant serotype responsible for erythromycin resistance was serotype 14 (Table 4). All erythromycin resistant strains belong to serogroups contained in the 7-valent conjugate vaccine.

**Serotypes responsible for invasive pneumococcal disease and antimicrobial resistance in non-Indigenous Australian adults**

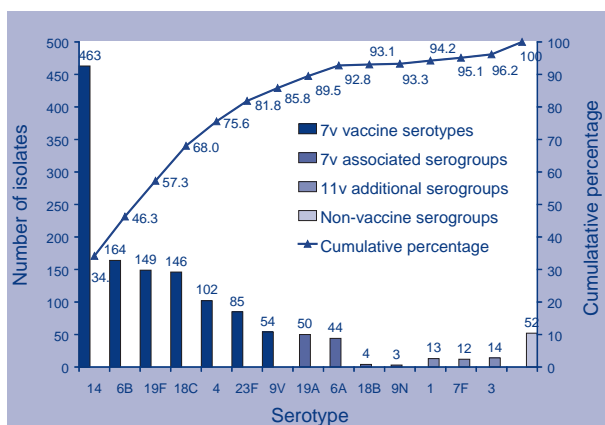
Serotype data from Queensland, Victoria, New South Wales, South Australia, Western Australia and Northern Territory adults were combined. The serotype distribution and serotype coverage for adults for the 7-and 11-valent conjugate pneumococcal

vaccines is illustrated in Figure 3. The serogroup coverage for the future 11-valent conjugate vaccine is 85.5 per cent. The 23-valent polysaccharide vaccine provides 96 per cent serotype coverage (Figure 4). Serotype 16F is the predominant serotype not covered by the 23-valent vaccine (Table 5).

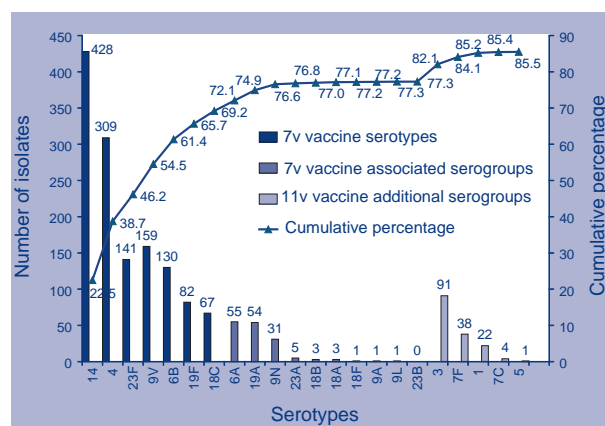
**Figure 2. Percentage of penicillin resistant isolates of each serotype in non-Indigenous children less than 15 years, Australia, 2001-2002, by state**



**Figure 1. Serotype distribution of Streptococcus pneumoniae from non-Indigenous Australian children less than 15 years, 2001 to 2002**



**Figure 3. Conjugate vaccine related serogroups of Streptococcus pneumoniae responsible for invasive pneumococcal disease in non-Indigenous Australian adults, 2001-2002**

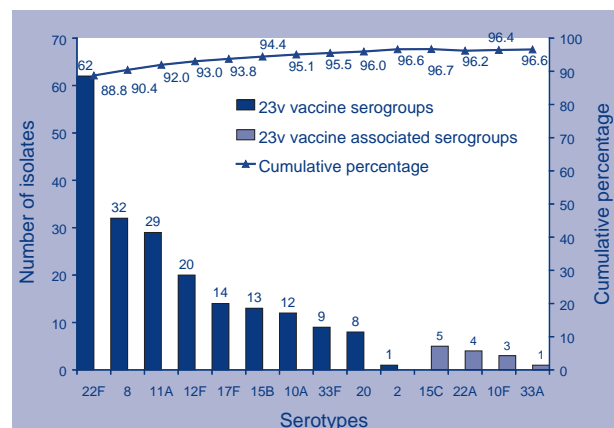


**Table 4. Erythromycin resistant serotypes in non-Indigenous Australian children less than 15 years, Australia, 2001 to 2002**

Serotype	7-valent conjugate vaccine serotype							7-valent conjugate vaccine serogroup	
	14	19F	6B	23F	9V	18C	4	19A	6A
Number of isolates	170	38	30	11	1	1	0	6	3
Cumulative (%)	65.4	80.0	91.6	95.8	96.2	96.6	96.6	98.9	100.0

Of the 1,948 isolates from adults, 1,504 were serotyped and had susceptibility results recorded for penicillin. Two hundred and four (13.6%) had reduced susceptibility to penicillin. Over 95 per cent of the penicillin resistant isolates belonged to serogroups in the 7-valent conjugate vaccine (Table 6). Serotyping results and erythromycin susceptibility was available for 1,439 of 1,948 isolates in adults. Two hundred and fourteen (14.9%) of these were resistant to erythromycin. The predominant serotype responsible for erythromycin resistance was serotype 14 (Table 7). Over 95 per cent of erythromycin resistant strains belong to serogroups contained in the 7-valent conjugate vaccine and 99 per cent of the 23-valent polysaccharide vaccine.

**Figure 4. Additional 23-valent vaccine-related serotypes responsible for IPD in non-Indigenous Australian adults, 2001-2002**



**Table 5. Non-vaccine serotypes from non-Indigenous adults less than 15 years, Australia, 2001 to 2002**

Serotypes	13	34	16F	38	25	35*	35B	35F	48	NT
Number of Isolates	3	3	26	6	1	5	3	6	1	9
Cumulative (%)	96.8	97.0	98.4	98.7	98.7	99.0	99.2	99.5	99.5	100.0

NT Non-typable.

\* Serogrouping only, performed.

**Table 6. Penicillin resistant serotypes in non-Indigenous Australian adults greater than 15 years, 2001 to 2002**

Serotype	7-valent conjugate vaccine serotype					7-valent conjugate vaccine serogroup		11-valent conjugate vaccine serotype	23-valent polysaccharide vaccine serotype			23-valent polysaccharide vaccine serogroup
	9V	14	6B	19F	23F	19A	6A	3	12F	15B	22F	15C
Number of isolates	88	39	26	22	15	5	3	2	1	1	1	1
Cumulative %	43.1	62.3	75.0	85.8	93.1	95.6	97.1	98.0	98.5	99.0	99.5	100.0

**Table 7. Erythromycin resistant serotypes in non-Indigenous Australian adults greater than 15 years, 2001 to 2002**

Serotype	7-valent conjugate vaccine serotype						7-valent conjugate vaccine serogroup			11-valent conjugate vaccine serotype	23-valent polysaccharide vaccine serotype		23-valent polysaccharide vaccine serogroup	Non-vaccine serotype
	14	6B	19F	23F	9V	4	19A	6A	9N	3	22F	33F	10F	NT
Number of isolates	129	32	23	14	2	1	2	3	1	2	1	1	1	2
Cumulative %	60.3	75.2	86.0	92.5	93.5	93.9	94.9	96.3	96.7	97.7	98.1	98.6	99.1	100.0

**Serotypes responsible for invasive pneumococcal disease in Indigenous children from Western Australia and the Northern Territory and the potential impact of the 7-valent conjugate vaccine program**

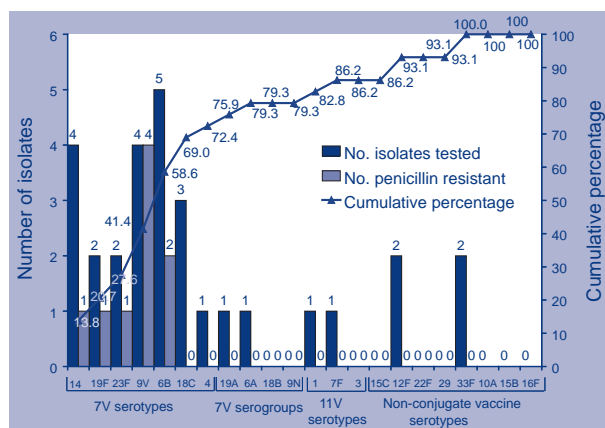
Of the 57 cases of IPD in Indigenous children from 2001 and 2002, 53 isolates were serotyped and sensitivity tested. Of the four cases without these data two cases were from 2001 and two cases were from 2002. In 2001, 29 cases of IPD occurred of which 21 were serotypes in the 7-valent vaccine. In 2002 there were 24 cases of IPD, 10 of which were serotypes in the 7-valent vaccine. The rate of disease for 7-valent vaccine and non-vaccine serotypes was not statistically significantly different between 2001 and 2002. The proportion of 7-valent vaccine serotypes was, however, significantly lower in 2002 compared to 2001 ( $\chi^2 = 3.93, p = 0.048$ ). The serotype and penicillin resistance data for 2001 and 2002 are represented in Figures 5 and 6. There were nine penicillin resistant isolates in 2001 and only two in 2002. This difference was not statistically significant. No difference was seen in erythromycin resistance with two cases occurring in each year.

**Serotypes responsible for invasive pneumococcal disease and antimicrobial resistance in Indigenous adults from Western Australia and the Northern Territory**

Laboratory data from Western Australia and the Northern Territory for Indigenous adults were combined. The serotype distribution and serotype coverage for Indigenous adults for the 7- and the future 11-valent conjugate pneumococcal vaccines is illustrated in Figure 7. The serogroup coverage for the 11-valent conjugate vaccine was 61.3 per cent. The 23-valent polysaccharide vaccine provided 90.1 per cent serogroup coverage (Figure 8). The serotypes not covered by the 23-valent vaccine are shown in Table 8.

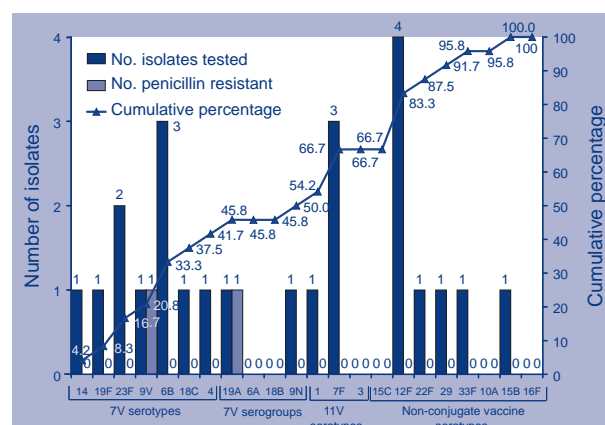
Of the 115 isolates from Indigenous adults in 2001 and 2002, 111 were serotyped and had susceptibility results recorded for penicillin. Seven (6.3%) had reduced susceptibility to penicillin. All the penicillin resistant isolates belonged to serogroups in the 7-valent conjugate vaccine. Serotyping results and erythromycin susceptibility were available for 104 of 115 isolates in adults. Five (4.8%) of these were resistant to erythromycin. Only one of the five erythromycin resistant strains belonged to serotypes contained in the 7-valent conjugate vaccine and two of the five were serotypes in the 23-valent vaccine.

**Figure 5. Serotypes and penicillin resistance in Indigenous children\* less than 15 years, 2001, (pre 7v vaccine introduction)**



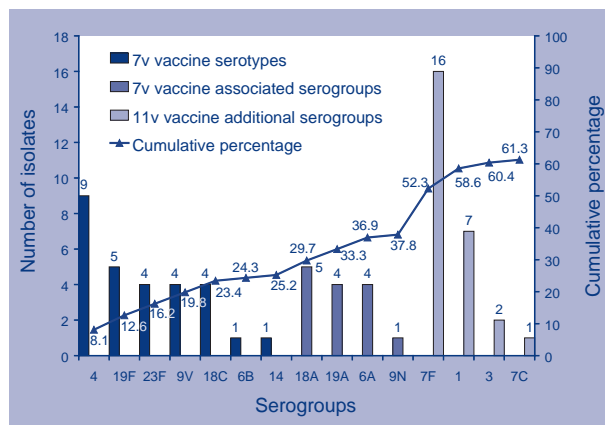
\* Data from Western Australia and the Northern Territory combined.

**Figure 6. Serotypes and penicillin resistance in Indigenous children less than 15 years,\* 2002 (post 7v vaccine introduction)**



\* Data from Western Australia and the Northern Territory combined.

**Figure 7. Conjugate vaccine-related serogroups of Streptococcus pneumoniae in Indigenous adults,\* 2001-2002**

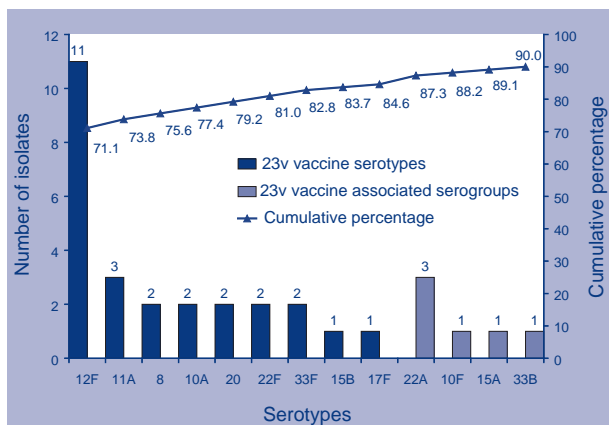


\* Data from Western Australia and the Northern Territory combined.

**Table 8. Non-vaccine serotypes in Indigenous adults in Western Australia and the Northern Territory, 2001 to 2002**

Serotype	13	29	31	34	16F	38	25	35*	35B	35F	48	NT
Number of isolates	0	1	3	0	3	2	0	0	1	0	0	1
Cumulative %	90.1	91.0	93.7	93.7	96.4	98.2	98.2	98.2	99.1	99.1	99.1	100.0

NT Non-typable.

**Figure 8. Additional 23-valent vaccine-related serotypes of *Streptococcus pneumoniae* in Indigenous adults,\* 2001-2002**

\* Data from Western Australia and the Northern Territory combined.

## Discussion

The impact of the 7-valent conjugate pneumococcal vaccine on invasive pneumococcal disease has now been clearly demonstrated in the United States of America (USA).<sup>12</sup> Recently, the National Health and Medical Research Council (NHMRC) has recommended 7-valent pneumococcal conjugate vaccine for all children in Australia as part of their primary immunisation series.<sup>13</sup> It is therefore vital to have baseline data on serotype prevalence in Australian children.

One limitation of the current laboratory surveillance system has been the incompleteness of Indigenous status data and/or the inability to link Indigenous status data with laboratory surveillance data in states other than Western Australia and the Northern Territory. We have made an assumption in combining data from other states that if the Indigenous status was not known, that the patient was not Indigenous. We believe that the overall vaccine serotype coverage results are valid for non-Indigenous children and adults given the relatively small numerical contribution of Indigenous cases to the combined data from these states. Furthermore, we believe that the

accidental inclusion of some Indigenous patients in the serotype analysis is likely to result in our vaccine serotype coverage rates for non-Indigenous adults and children being more conservative (i.e. underestimating serotype coverage).

The data for non-Indigenous Australian children for the years 2001 to 2002 clearly demonstrates a high percentage serotype coverage (86%) and even higher for serogroup coverage (93%). There is now evidence of at least some cross-protection for serogroups contained in the vaccine.<sup>12</sup> It is therefore reasonable to predict that Australia will see a significant decline in IPD in children if vaccine programs based on the new NHMRC guidelines are funded and successfully implemented. There were relatively few cases of IPD in neonates, however it was interesting to note the lower 7-valent vaccine serotype coverage in this age group. This may be a result of the fact that the infection may be acquired from the mother during or soon after birth.

The serotype distribution for penicillin resistant strains in non-Indigenous children is also favourable with over 99 per cent of serotypes covered in the vaccine. There is evidence that a reduction in the rate of IPD due to penicillin resistant strains can be expected with the introduction of the 7-valent conjugate vaccine.<sup>12</sup> It is important to note that the efficacy of the vaccine for the prevention of IPD varies with the serotype. Vaccine efficacy in protecting against disease caused by serotypes 19F and 6B (which are two of the most common strains associated with penicillin resistance in our study) is lower than other serotypes in the 7-valent vaccine, both being around 85 per cent.<sup>14</sup> This could result in a higher proportion of penicillin resistant strains after vaccine implementation, although there would still be a marked reduction in the absolute numbers of cases of these serotypes. The trends in percentage penicillin resistance of each serotype is a very interesting observation. The potential for some penicillin resistant serotypes such as 9V to completely replace penicillin sensitive strains of the same serotype is very concerning. Overall, the percentage of isolates with resistance to penicillin in non-Indigenous children in Australia is 12.8 per cent but erythromycin resistance is almost double this at

23.8 per cent. This is due to the fact that in addition to the predominant penicillin resistant strains in children (19F and 6B), which are often also resistant to macrolides, there is a high proportion of serotype 14 isolates that have isolated macrolide resistance. Macrolide resistance is likely to be reduced by the introduction of the 7-valent conjugate vaccine.

Although it is unlikely that the 7-valent conjugate vaccine will be recommended for use in adults, it has now become clear that a reduction in the prevalence of these vaccine serotypes in adults in the community may occur as a result of vaccination of children through the development of herd immunity.<sup>12</sup> Our serotype data suggests that this could have a significant impact in the Australian adult population as almost 70 per cent of cases of adult IPD are due to serotypes within the 7-valent vaccine. This figure is even higher (77%) when serogroups are considered. One problem with the current 23-valent polysaccharide vaccine is the need to give repeat doses. The future 11-valent conjugate vaccine does appear to have acceptable serotype coverage in non-Indigenous adults with the vaccine serogroups covering over 85 per cent of strains. This raises the interesting possibility of the use of an 11-valent conjugate vaccine in non-Indigenous adults if long term immunity can be demonstrated with this vaccine in this target population.

The predominant serotype responsible for penicillin resistance in non-Indigenous adults appears to be different from those in non-Indigenous children. Serotype 9V and 14 are the two most common serotypes associated with penicillin resistance in adults. Both serotypes were shown to have significantly reduced in frequency (in adults over 65 years of age) following introduction of the 7-valent conjugate vaccine in children the USA.<sup>12</sup> This holds the exciting possibility of reducing penicillin resistance in elderly Australians by use of the 7-valent vaccine in children. The percentage of macrolide resistance seen in non-Indigenous adults is almost half that seen in children. This is partly due to the fact that the principal penicillin resistant serotypes in adults (9V and 14) are generally not also resistant to macrolides.

One has to be cautious in attributing the change in numbers of cases of IPD in Indigenous children in Western Australia and the Northern Territory to the impact of the 7-valent conjugate vaccine program. However, it is encouraging that there has been a significant shift in serotypes away from those in the 7-valent vaccine. This however, could result both from a reduction in numbers of 7-valent vaccine serotype isolates, but also an increase in the number of non-7-valent vaccine serotypes. The predominant increase in non-vaccine serotypes was due to serotype 7F and 12F. At this stage it is difficult to determine the relevance of this finding as

natural fluctuations in the numbers of these isolates could occur even in the absence of a 7-valent vaccine program. It does however reinforce the need for careful monitoring to ensure that serotype replacement does not become a significant problem in the future. Another encouraging finding is that the number of cases due to penicillin resistant isolates also fell, although this change did not achieve statistical significance.

The 23-valent polysaccharide vaccine continues to provide good serotype coverage for adults including Indigenous adults in Western Australia and the Northern Territory. Of interest is the relatively low rate of penicillin and erythromycin resistance of pneumococcal isolates from Indigenous adults compared to non-Indigenous adults in Australia.

The continued laboratory surveillance on IPD is a vital component of the pneumococcal vaccine strategy for Australia. The funding of this surveillance has facilitated a national approach to surveillance and reporting of this important reference laboratory work. Our surveillance suggests that implementation of the NHMRC recommendation to introduce 7-valent conjugate vaccine to all children in Australia is likely to lead to major benefits for both children and adults in this country.

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### **List of contributors to pneumococcal laboratory surveillance**

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