THE USEFULNESS OF A REGISTRY IN ASSESSING IMMUNIZATION RATES AND TIMELINESS IN PRESCHOOL-AGE CHILDREN

by

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ABSTRACT

Immunization of preschool-age children is one of public health's top priorities, yet significant barriers exist in achieving the goal of over 90% "adequate immunization" by the Year 2000. One of the barriers is parents' lack of awareness that additional immunizations are needed for their children. In 1994, Benton County implemented an immunization registry to track children, and to remind and recall them for needed shots. A study was conducted to assess the usefulness of the Registry in assessing immunization rates and timeliness in preschool-age children. In this study, immunization rates were examined by three month intervals after the age of 12 months for the Benton County birth cohorts of 1992 and 1995, and for a sample of Oregon children born between October 1993 and March 1995 (Benton County excluded) surveyed by the Oregon Health Division. For the children in the Benton County cohorts with immunization data in the Registry, the rates of "adequate immunization" (4 DTP, 3 OPV, and 1 MMR) by age 2 increased significantly in 1995, after Registry implementation, compared to 1992 and to the sample of Oregon children. There was also a "shift

to the left" in immunization rates in 1995 relative to the comparison groups as children served by the Registry were immunized at younger ages than the other groups. Notably, however, Registry data was incomplete for these shots in 23-29% of the birth cohorts. Because the Registry is dynamic, inherently reflecting population flux, it is not useful for measuring immunization rates in populations, but by tracking infants and children, and sending recall and reminder notices to their parents, the Registry does significantly increase the timeliness of "adequate immunization" in young children.

INTRODUCTION

Background

Prevention of the common diseases of childhood has become one of the top items on the public health agenda. These diseases caused significant morbidity and mortality in the first decades of this century, but the global elimination of smallpox and the eradication of polio from the Americas together with the decrease in the number of cases of diphtheria, pertussis, tetanus, polio, measles, rubella and mumps to less than 10% of the incidence in peak years led to the belief that the vaccine-preventable diseases of childhood would soon become history (Hinman, 1990; Cutts et al, 1992). In 1989-1991, however, a measles epidemic occurred. Fifty-five thousand cases and more than 130 deaths were reported, over half of them involving preschool-age children. It became apparent that despite near universal immunization of school-age children, younger children, the ones most susceptible to these preventable diseases, were not being immunized in a timely manner (Orenstein and Bernier, 1994).

Immunization represents one of the most cost-effective and

measurable preventive health strategies (Orenstein and Bernier, 1994). Nationally, more than 95% of school-aged children are completely immunized (Cutts et al, 1992). At school entry, for example, 97% of Oregon's children are considered to be "adequately immunized", having received 4 doses of Diphtheria-Tetanus-Pertussis (DTP), 3 doses of Oral Polio Vaccine (OPV), and one dose of Measles-Mumps-Rubella (MMR) (Oregon Health Division (OHD), 1995). These vaccines are all scheduled to be given in the first 12-15 months of life, since infants and young children are at highest risk for these diseases and their sequelae. Yet surveys nationally and in Oregon indicate that only two-thirds of preschoolers have received the recommended regimen (Centers for Disease Control (CDC), 1995). The recognition of this serious gap has led to nation-wide and state-wide efforts to raise immunization levels in the preschool-age population with a goal of 90% coverage for most childhood vaccines (Bernier, 1994).

Several impediments to immunization are recognized, such as financial and geographical barriers and parental religious or philosophical beliefs. Since most parents have never witnessed epidemics of these "usual diseases of childhood", they may view

them as less of a threat to the health of their children than the rare adverse effects of immunization.

A daunting number (over 20) of immunizations may be recommended before age 2. New vaccines are continually being developed and they either replace existing ones or must be integrated into the schedule. In the past, consensus guidelines varied among provider groups and have changed several times over the last few years. These guidelines are quite complex. Parents and providers both have a hard time keeping track of which immunizations are needed (Cetta, 1993; Huston, 1993). One way to get more children adequately immunized is to have a system to remind ALL parents when immunizations are due. Experts have advocated for universal and nation-wide immunization registries to track all newborn children, to remind their parents when shots are due or overdue, and to provide information regarding immunization status to health care providers in order to avoid missing any opportunity to immunize children. It is beyond the scope of this paper to address all of the barriers to preschool immunization. Rather, the focus will be on one: keeping track of children's immunizations so that parents are made aware of their child's

immunization needs. Immunization registries have been implemented throughout the United States in an effort to do this, and thereby improve immunization rates, despite little critical evaluation of their effectiveness.

In a review of the literature examining the effectiveness of immunization registries in improving immunization rates, no reports that immunization registries *per se* change immunization rates in populations could be found. Therefore, direct and indirect evidence were integrated to construct an evidence model examining the question "Do immunization registries improve immunization rates?"(Figure 1). This question was then directly addressed by evaluating the effect of Benton County's Immunization Registry on diphtheria-tetanus-pertussis (DTP), polio (OPV), and measles-mumps-rubella (MMR) immunization rates in Benton County children by age two.

The Effectiveness of Registries: Direct Evidence

Many states and communities throughout the United States are currently developing immunization registries (Faherty et al, 1996). Is there evidence showing their effectiveness? To answer this

question directly, one would ideally randomly assign a population to a registry or no registry and compare outcomes. No such study exists. The success of the public sector's Infant Tracking and Recall System (ITARS), however, suggests that elements of a registry do improve immunization rates. Traditionally, public health has relied on cost subsidies, parent education, and tracking and recall to remind parents when immunizations are due. These strategies appear to help. The latest Oregon survey indicated that children served in public immunization clinics (about one-third of the population), which use ITARS, had as good a record of being "adequately immunized" as children served in the private sector, despite representing a less advantaged population (OHD, 1995). The survey also indicated that most parents of incompletely immunized children did not realize that their children needed more shots.

Immunization registries have been successfully implemented in other countries, where a single payer system simplifies data collection, but they are a new concept in the U.S. (Loeser et al, 1983; Verbrugge, 1990; Paunio et al, 1991; Roberts et al, 1994). In the United States, tracking has usually been site-specific, I.e. limited to a single clinic (Klachko et al, 1989; Szilgayi et al, 1992) or Health

Maintenance Organization (HMO) (Lieu et al, 1994; Davis, 1997) and therefore has not followed enrollees if they change providers or move out of the jurisdiction. The topic is, however, well represented in the medical literature. The major problem is that while many articles advocate or discuss developing registries, a very small number actually evaluate them, and none include all the characteristics which are considered essential for effectiveness (Gostin and Lazzarini, 1995). Articles by Loeser and Roberts in Canada, and by Verbrugge in the Netherlands and Paunio in Finland measured immunization levels using data from registries, but did not measure the impact of the registries themselves. The HMO-based registry in Lieu's paper was described, but its effectiveness was not evaluated. Klachko and Szilgayi examined the effectiveness of tracking and reminder/recall systems in clinics rather than in registries.

The Effectiveness of Registries: Indirect Evidence

Since little direct evidence is available, one can search for indirect evidence linking the intervention (an immunization registry) with outcome (immunization rates) (Mulrow et al, 1997). An

effective immunization registry has several components (Gostin and Lazzarini, 1995). It must include a core data set (unique personal identifier, vaccine dose, lot number, and type, vaccination date, vaccine provider) for all children, who should be enrolled at birth or when entering care as a new resident. There must be interactive communication between the registry and healthcare providers to permit computer forecasting of future doses and provider and parent notification (reminder and recall function). Aggregate data should be used to identify pockets of need and evaluate the effectiveness of outreach. Finally, to ensure that enrollees and their families do not suffer adverse effects, confidentiality of these records must be maintained. An evidence model using a series of questions to evaluate the components of an immunization registry for effectiveness was developed (Figure 1). The direct question (Arrow #1), " Do children entered and tracked in an immunization registry have better immunization rates than other children?", can be broken down into several smaller ones for which there might be some answers. The following were selected: How does one ensure complete "capture" of the entire population so that all children are identified and tracked (Arrow # 2)? If immunizations are missing

or delayed, are there interventions that help (Arrow # 3)? Are there adverse effects associated with being in a registry (Arrow # 4)?

An essential component of an effective registry is to include the entire population so that all children are tracked. How does one identify and register all children? The most successful in terms of producing high coverage levels are population-based registries linked with immunization records, such as those of Finland, the Netherlands, and Manitoba, Canada (Verbrugge, 1990; Paunio, 1991; Roberts, 1994). The Finnish system, while described only in the context of an MMR campaign, seems particularly effective, since it achieved an overall immunization rate of 96.4%. In the Netherlands, the National Immunization Program achieved rates of 90 to 95% for 4 DPT/OPV and one measles-containing vaccine in every birth cohort since 1977. The article, while acknowledging that these shots are given to infants, does not, however, actually specify if these rates were achieved by age 2. In Manitoba, the registry system described after its first year of operation, was not yet universal, since it did not include Indian children, whose care is financed by the federal rather than the provincial government. Yet it achieved immunization rates in 1-year-olds of 79% overall, and of 91% if Indian children or

the small number who had recently migrated were excluded. A centralized immunization registry developed in Montreal was not universal, since only 93% of eligible providers agreed to participate, yet it led to significant improvement in immunization in the population served (Loeser,1983).

Once children are entered in the registry, their adherence to the recommended schedule must be tracked so that interventions can be applied if necessary. Computer forecasting was used in the systems described by Loeser, Klachko, Paunio, Roberts, Verbrugge, and Lieu, although it is only implied in the last study. The first four provided notification to the physician. Generally, this was in the form of a list of children who were overdue. Not all studies measured the effect of this intervention, but in the clinic setting described by Klachko, a summary of the immunization history attached to the front of the chart, with a note if immunizations were due, led to a significant increase in immunization rates in the clinic population. In Montreal, provider notification resulted in a significant reduction (33-60% depending on practice type) in the number of children who were overdue.

Some studies have evaluated the effect of parental reminders (a

shot is due) and recall (a shot is overdue). The Oregon Health Division ITARS study cited above, as well as the systems described by Verbrugge, Paunio, and Roberts sent parents notification that immunizations were overdue. The frequency of reminder notices varied from only once, at 5 years of age (in Manitoba), to every time a shot was missed (in the Netherlands). In the Szilgayi article, a pediatric clinic (not an immunization registry) sent a parental advisory out in October recommending a flu shot for certain children. This was the only study that was found evaluating a reminder rather than a recall, and immunization was significantly higher in the reminder group than in the control (no reminder) group. None of the other papers assessed the effectiveness of reminder/recall versus no reminder/recall notices.

No article could be found evaluating outreach efforts in the context of an immunization registry. There is some evidence, however, that intensive case management of a population known to have low immunization rates can significantly increase immunization levels compared to a control group (immunization completion rate at 1 year: 63.8% versus 50.6%; p=.01) (Wood et al, 1998). The authors suggest that better methods of tracking and

targeting, such as immunization registries, need to be developed.

Concerns regarding adverse effects of immunization registries have generally revolved around violation of confidentiality (Gostin and Lazzarini, 1995). I was unable to find any documentation of the occurrence of such events.

Evaluation of a Registry

There are scant data assessing the effectiveness of registries in improving immunization rates. The evidence found, while supportive, was from countries in which health care authority is centralized, and responsibility for children being immunized on time is clearly assigned. That has not been the case in this country. Developing an immunization information system in the United States requires a great deal of collaboration among health departments, private providers, local volunteer and professional organizations, and many others. Unlike most other industrial countries, the United States has chosen to develop such systems at the state and local level, rather than nationally.

In 1992, Benton County began planning an immunization registry for all children age 5 and under living in or seeking medical care in

the County. Benton County began prospectively entering all new births into the Registry in January, 1994. The first reminder and recall notices went out in July, 1994. Benton County is the only county in Oregon with a functioning immunization registry. A State Registry is being developed, and Benton County will eventually be able to upload its Registry data into this system when it becomes operational.

If registries are truly effective, one would expect communities with registries, such as Benton County, to see an overall improvement in their immunization rates and timeliness. Similarly, one would expect areas with registries to achieve higher immunization rates and in a more timely manner than areas without registries. This paper will evaluate these expectations and should provide direct evidence to answer the question (arrow # 1) "Do children entered and tracked in an immunization registry have better immunization rates than other children?"

Objectives

The objectives of the study are:

1) To assess the usefulness of an immunization registry in determining immunization status, defined as "adequate immunization" (4 DTP, 3 OPV and1 MMR), of Benton County two-year-olds.

2) To determine if the timeliness of "adequate immunization" of Benton County two-year-olds differs in those born before and after implementation of the Benton County Registry and if the timeliness of "adequate immunization" differs in those born after implementation of the County Registry compared to children born in the rest of Oregon, which does not yet have a registry.

METHODS

A description of the Benton County Immunization Registry is in Appendix 1. This information was obtained from Judy Blackburn, who has operated the Registry since 1996. A description of the methods used to collect data from a state-wide sample of children in the Two-Year-Old Immunization Survey was provided by Stacey Schubert, Oregon Health Division. It is in Appendix 2.

Study Groups

The study groups in this cross-sectional observational study consist of a birth cohort of two-year-old Benton County residents born in 1995 and two comparison groups: a) a birth cohort of two-year-old Benton County residents born in 1992 and b) a random sample of Oregon two-year-olds, with Benton County residents excluded, surveyed by the Oregon Health Division in its Two-Year-Old Immunization Survey.

Subject Selection

Registry data and birth certificate names and dates of birth for

the 1992 and 1995 birth cohorts were obtained.

A Registry enrollee was defined as a Benton County resident if the birth certificate indicated that the mother resided in Benton County at time of birth. Two criteria were necessary for Benton County subject selection. The child had to be a) born in 1992 or in 1995 to a Benton County resident mother, identified through birth certificate data (Oregon Center for Health Statistics, 1992 and 1995) and b) entered in the Benton County Immunization Registry. The 1995 Benton County residents were enrolled prospectively in an operational registry either at time of birth or at the time of a visit to a provider for an immunization (see Appendix 1), whereas the 1992 Benton County residents, one of the two comparison groups, were entered retrospectively into the Registry system beginning in 1994, the year they turned 2.

The other comparison group, a random sample of two-year-olds from Oregon born between November 1, 1993 and March 30, 1995 was sampled as described in Appendix 2 for the Oregon Health Division's Two-Year-Old Immunization Survey. From this sample, Benton County resident births were excluded.

Variables

The predictor variable is prospective enrollment in the Benton County Registry. The outcome variable is the proportion of children who received 4 DTP, 3 OPV and 1 MMR by age two.

Data Analysis

The names of children born to Benton County resident mothers in 1992 and 1995 respectively were sorted alphabetically and were manually matched by last and first names to an alphabetical list of names of children in the Registry master list who were born in those years, resulting in comparison and study groups respectively. The Oregon birth certificate dataset also included a birth date, which was used as an additional point of comparison in the few instances where there were discrepancies in the names between the birth certificate data and Registry data.

The Registry data was entered into a Microsoft Access database. Then, for each child in the comparison and study groups, Benton County resident children, as defined by birth certificate, born in 1992 and 1995 who were in the master table, were linked with immunization tables for DTP, OPV and MMR, using each child's unique

client number. All identifiers except for the client number were then removed. Thus the 1992 and 1995 datasets contained the following fields: client number, date of birth (DOB), activity code (see Appendix 1), and date that the following immunizations were received: DTP 1, 2, 3, and 4; OPV 1, 2, and 3; MMR 1. *Haemophilus influenzae* b and hepatitis B data were not included in the analysis because universal use of these vaccines in the 1992 birth cohort would have been fairly recent, and likely not comparable with level of use in 1995, when familiarity with these vaccines was much greater.

The records were then sorted by activity codes used in the Registry (Appendix 1). In general, immunization data are more complete for children with A (active) or O (out of County) or CS (Children's Services Division) codes than they are for children with codes signifying inactivity (I or IA or IP) or history needed (PH or R) codes. Thus, all children or selected categories of children could be examined by activity code.

For each birth cohort year, a series of queries were constructed to measure the number of children who were "adequately immunized" (DTP 4, OPV 3, and MMR 1) by 15 months, the 3 month

interval after age 12 months at which they could first reasonably be expected to be "adequately immunized", and at succeeding 3 month intervals till 36 months for the 1995 birth cohort and annually until 72 months for the 1992 birth cohort. Whether DTP 3, OPV 3, and MMR 1 had been received by age 2 was also queried.

The same criteria were applied to the sample collected for the Oregon Two-Year-Old Immunization Survey, from which Benton County residents were removed. Number of children "adequately immunized" each 3 month interval from 15 through 36 months, then annually until 48 months of age, were counted, as were the number who had received DTP 3, OPV 3, and MMR 1 by age 2.

Immunization rates were calculated for the 1995 group and for both comparison groups using 95% confidence intervals. Since there are usually 600-700 births annually in Benton County, it was expected that with a birth cohort size of 600, an 8% increase in immunization rate could be detected. Relative risk and confidence intervals were calculated using Epi Info statistical software.

RESULTS

In 1992, there were 775 births to Benton County mothers; the number for 1995 was 800 (Oregon Vital Statistics Report, 1992; 1995). In 1992 and 1995, 5 and 3 names respectively had been deleted. The remaining 770 and 797 names of children born to Benton County mothers in 1992 and 1995 respectively were manually matched to names of children in the Registry who were born in those years. In 1992, there were 2098 children entered in the Registry. The number of children entered in 1995 was 1524. Matches were found for 673 (87.4%) children born in 1992 (the comparison group) and for 763 (95.7%) children born in 1995 (the study group) (RR=1.10; CI: 1.06<RR<1.13; p=<0.0001). Of this number, data on DTP 4, OPV 3, and MMR 1 was available for 77% (517) and 71% (542) of them, respectively (RR=0.92; CI: 0.87<RR<0.98; p=0.01). Immunization data were therefore not available in the Registry for 23% of the 1992 cohort and 29% of the 1995 cohort, generally in children with the I or IA activity codes. A flow sheet illustrates the method used in defining the population of interest (Figure 2).

Thus, there were 517 and 542 of the 1992 and 1995 Benton

County resident birth children who had received the 4:3:1 series according to the Registry, but in order to have comparable cohorts, the number of children in each cohort immunized by age 36 months was used as denominator (474 and 538), since the 1995 cohort will only be turning 4 this year (Figure 2). The 4:3:1 immunization rate for the 1992 cohort at 24 months was 419/474 or 88%, and for the 1995 cohort it was 520/538 or 97% (RR=1.09; CI: 1.05<RR<1.13; p=<0.0001) (Figure 2 and Table 1). For the 3:3:1 series, the denominator used was the number of children receiving 3:3:1 by 36 months (508 and 559) (Table 2). Of the 508 children born in 1992 who had received this series by age 36 months, 452 or 89% had had it by age 2. In 1995, of the 559 children who had received the series, 544 or 97% had received it by age 2 (RR=1.09; CI: 1.06<RR<1.13; p=<0.0001).

The number and percentage of children who had received the 4:3:1 series at various ages were then calculated (Table 1) and the rate of 4:3:1 series completion by age in 3 month intervals after the first year of life was graphed (Figure 3). By 24 months of age, 88% of the 1992 birth cohort compared to 97% of the 1995 cohort was "adequately immunized", but the difference was most striking in the

younger age brackets. By 15 months, six times as many of the 1995-born versus 1992-born children (18% versus 3%) had received their 4:3:1 series (RR=5.64; CI: 3.32<RR<9.58; p=<0.0001). At 18 months, 80% of the 1995 cohort group versus 42% of the 1992 cohort group had completed the 4:3:1 series (RR=1.91; CI: 1.91<RR<2.14; p=<0.0001). The curves come together in the older age brackets, as older children born in 1992 get immunized, but the percent of immunized children remains significantly higher in the 1995 than in the 1992 group until 30 months, when the difference becomes non-significant. Comparison was then halted, since the 1995 cohort will only be turning 4 this year. For the 1992 cohort, 100% of the children in the Registry were "adequately immunized" by 72 months. Thus there was a "shift to the left" as immunization occurred in younger age groups in the 1995 cohort compared to the 1992 cohort.

Age at which the individual antigens, DTP 4, OPV 3, and MMR 1 were received was examined, counting the number and percentage of children, of those having received each antigen by age 36 months, who had received it at each 3 month interval. Again, there was a marked "shift to the left" for each antigen in 1995 as compared to 1992, as children were immunized sooner in 1995. This was

particularly noteworthy for DTP 4 and OPV 3 (Figure 4 and 5). Even the MMR 1 appeared to be received sooner in the 1995 than in the 1992 cohort (Figure 6).

Immunization rates by 3 month interval after 12 months of age were examined for the Oregon survey data as well, using as denominator the sample less the 26 Benton County births (N=2285) (Table 3). For two-year-olds, immunization rates for 4:3:1 and 3:3:1 were 77% and 85% respectively. This was compared with the 1995 Benton County cohort. In this comparison, 4 additional children in the cohort for whom data after age 36 months was available were also included, so that the denominator was 542 rather than 538. Comparing the number of children who had completed the 4:3:1 series at age 2 in the two groups, 97% of the 1995 cohort and 77% of the sample were "adequately immunized" (RR=1.24; CI: 1.21<RR<1.28; p<0.0001). Again the difference was most pronounced in younger age groups. At 15 months, 18% of the Benton County children and 3% of the sample had completed the series (RR= 1.81; CI:1.46<RR<2.26; p<0.0001). At 18 and 21 months, 81% versus 53% (RR=1.50; CI: 1.42<RR<1.59; p<0.0001) and 94% versus 73% (RR=1.28; CI: 1.24<RR<1.32; p<0.0001) were "adequately immunized". The

difference remained significant, though smaller, up to and including 36 months (RR=1.15; CI: 1.13>RR<1.17; p<0.0001). Figure 7 illustrates immunization rates for the Oregon sample by 3 month interval after age 12 months for the 4:3:1 series as well as for the individual antigens, DTP 4, OPV 3, and MMR 1. It will be noted that for the 4:3:1 series, the sample curve resembles the curve for the 1992 cohort seen on Figure 3, since the "shift to the left", the steep rise in early series completion, seen in the 1995 cohort graph, is absent. In comparing rates for the 3:3:1 series, 97% of the 1995 cohort versus 85% of the sample had completed this series by age 24 months (RR=1.14; CI: 1.12<RR<1.17; p<0.0001).

The 1992 cohort was then compared with the Oregon sample. First, total number of documented immunizations for the cohort were used as denominator, that is 517. At age 2, 88% of the 1992 Benton County cohort was "adequately immunized" and 77% of the Oregon sample was "adequately immunized" (RR=1.17; CI: 1.13<RR<1.22; p=<0.0001). The comparison was repeated using documented immunizations by 36 months (474) as denominator for the cohort. The relative risk was slightly smaller, but still significant. When the comparison was made at age 15 months,

however, the 1992 Benton County cohort had only 3% "adequately immunized". The Oregon sample had 10% "adequately immunized" (RR=3.36; CI: 2.01<RR<5.62; p=<0.0001), and again, whether the denominator included only those children immunized by age 3 or all the children immunized in the 1992 cohort made little difference. The sample also showed slightly more children immunized at 18 months than in the 1992 cohort. After 18 months, percent immunized is higher in the Benton County cohort than in the sample.

DISCUSSION

Several barriers to immunizing preschool-age children have been identified. One of the barriers is that parents simply are not aware that their children need more shots. With the recent addition of rotavirus vaccine, the 1999 Recommended Childhood Immunization Schedule now lists 19 immunizations to be given to children before age 2 (CDC, 1999), and consideration is being given to adding hepatitis A vaccine in Oregon. Thus it is not surprising that parents might not realize that their children are lacking immunizations.

One of the key requirements of a registry is to capture the entire population, including all new resident births. County of residence was not one of the data fields when the Benton County Immunization Registry was developed. A code has since been added but is often left blank, and a surprising number of mothers do not know which county they resided in when their child was born. Matching the birth certificate names to the names of children in the Registry, however, provides a measure of how completely the Registry captures newborn Benton County residents. The 1992 birth cohort was not enrolled at time of birth, but 673 (87.4%) of the 770 children born

that year could be identified in the Registry list. The capture of the 1995 birth cohort by the Registry was significantly better, almost 96% (763 of the 797 births). While matched in the same way, the higher number of birth certificate names in the Registry in 1995 compared to 1992 could be due to incomplete retrospective capture of 1992-born children. Nonetheless, even in 1995, a small discrepancy exists between the birth certificate names and the Registry, which may well be explained by children moving away or receiving a new surname. It is also possible that a few are missed. The primary function of the birth certificate is as legal documentation of place of birth. Therefore, Benton County Vital Statistics has birth certificates only for children born within Benton County; out-of-County births are reported to Registry personnel by the State Vital Statistics office. If a report is delayed, the child may escape enrollment at birth and come to the attention of the Registry only when he or she subsequently receives an immunization and that event is reported to the Registry by a provider. It is difficult to estimate how often this scenario occurs, since It is not possible to determine when a child was enrolled in the Registry.

The effectiveness of an immunization registry in immunizing ALL children, particularly preschool-age children, on time, has not been previously evaluated. This study cannot do this either, since Registry data may be incomplete in nearly 30% of the birth cohort, depending on which individual shot or shot series is examined. Thus, while initial enrollment in the Registry at birth appears to be very good (almost 96% in 1995), the capture of shot data seems much less complete (only 29% of the 1995 cohort had 4:3:1 data in the Registry). Underreporting is an unlikely culprit (though "double entry" by providers is a problem (Appendix 1)), since only 31 children had audit (PH or R) codes. We live in a highly mobile society, however, and even if families do not move, their insurance may change, dictating a change in physicians, so that even health care providers may not be a resource in keeping track of needed immunizations. A registry system was conceived to mitigate this problem. The Benton County system is County-based, so that if children move, they can still be tracked, as long as they stay within County jurisdiction or continue to see a provider in Benton County or affiliated with a Benton County health care system. If they leave the County, however, no further data will be available. Most of the

children with missing data had I or IA codes, suggesting that this is what had occurred. Benton County has a population bulge among adults of childbearing age. This may explain missing data for many children, since a large proportion of these young adults are students who leave the area after graduation. Poorly educated transient populations are less likely to be responsible for missing data due to Benton County's relatively high cost of living and lack of unskilled job opportunities. Further study of the population lost to follow up would be of interest to assess how representative it is of children in the County. Oregon Immunization Alert, the statewide registry under development to which the Benton County Registry will eventually upload its data, would permit continued tracking of the children if their families remained in Oregon. Then immunization rates for the entire population cohort could be calculated.

By the time children go to school, the overwhelming majority of them have received their shots, and this was true for the 1992 Benton County birth cohort as well, all of whom turned 6 in 1998, and would have required these immunizations for school entry. Using Registry data, however, we can only say that 77% (517/673) of the 1992 population was "adequately immunized". Since the 1995

cohort is only turning 4 this year, we cannot assess its immunization rate at school age, but at this point in time, its "adequate immunization" rate is only 71% (542/763), virtually identical to the "adequate immunization" rate for the 1992 cohort at age 36 months (70% or 465/673). Thus, although one can compare rates in the 1992 and 1995 cohort groups since they were selected and analyzed in the same manner, it does not appear feasible to assess population immunization rates using Registry data. Again, as discussed above, a statewide registry with its wider catchement area, might increase feasibility, but many people move in and out of state as well. Local or even state immunization registries were not designed with the goal of measuring population rates in mind. A registry, like the population it serves, is dynamic. People move in and out of the area, new information is received from multiple sources, omissions and errors in information received and/or entered occurs, and histories constantly need updating as information is audited. Although the original concept of this study had been to establish population rates for "adequate immunization", this was not feasible due to missing data. Data could be missing because providers' offices do not enter it, but if this were so, there

would be a preponderance of R or PH rather than I or IA activity codes among children with missing data. There is a continuum of data content, with A, O and CS codes being most complete, and I, IA, IP, and D codes having the least complete data. Most categories of code, however, contain some children who have had the three shots of interest, and none contained only children with all the data of interest. Even using only A codes, which represent Benton County children known to be receiving and responding to postcards, is not useful due to the changing nature of the codes, which reflect changes in the children's status. For example, not all A codes were born Benton County residents. They may have moved here some time after birth, be receiving immunization services currently, and after an audit for past immunization history (PH or R code), have provided records of past immunizations, so that they are now A codes. That is why there were only 506 A code children in the 1995 cohort of Benton County resident-born children, while the Registry's A code children number 732. Similarly, I code children may have left the area after any number of immunizations; their records contain information only for doses received until their departure. Since data are not deleted, the number of children enrolled in the Registry for

1995 (1524) is much larger than the number of Benton County resident births (800) that year.

If shot dates are missing, one cannot know how timely they were or even if shots were received or not. It is possible that the children for whom there are no data are less likely to be immunized on time, and conversely, that those for whom there are data do get immunized on time, which would represent confounding, since being in the Registry would be related both to exposure and outcome. In this study, outcomes could only be measured in children with data, so rates of immunization by age group were examined only in those children. To assess overall immunization levels in Benton County children, one would need to select a sample, as was done for the Oregon survey in progress. Unfortunately, only 26 Benton County children were randomly selected in that sample, which is too few to provide meaningful information. Perhaps a future survey could oversample Benton County births, permitting comparison of immunization rates in Benton County children and children from the rest of the state.

Registries were designed to track children and generate reminder and recall notices to advise regarding immunization needs. If this

system is effective, one would expect more timely immunization of younger children, and this was observed. It is possible for a child to be adequately immunized after he turns 12 months old. In the 1995 cohort compared to the 1992 cohort, a "shift to the left" of "adequate immunization" was seen as early as 15 months, the first 3 month interval after 12 months when the 4:3:1 series could be complete. The increase in "adequate immunization" (4:3:1) rates for 15- and 18-month-old children was highly significant for the 1995 cohort compared to the 1992 cohort and the Oregon sample. The effect was particularly striking for the DTP 4 and OPV 3 antigens, although even MMR 1 was affected. This is noteworthy because although the Benton County Registry does send out reminder cards at 11 months of age for the MMR to be given at 12 months, recall notices do not go out until the 19th month. This supports the assertion that parents generally want their children to be immunized, but are simply unaware of the need.

A higher percentage of 15- and 18-month-olds had received their 4:3:1 series in the State Survey sample than in the 1992 Benton County cohort, but it was well below the percentage immunized in the 1995 Benton County cohort. The increase among sampled

children may represent the secular improvement in immunization rates which has occurred as public health has put more emphasis on preschool immunization. It is unlikely that the very significant "shift to the left" in the 1995 cohort is attributable solely to this trend. It would be interesting to compare 4:3:1 immunization rates by 3 month interval after 12 months of age in the current and in the previous 2-year-old Oregon sample. If a "shift to the left" of the current sample compared to the earlier sample is absent or minimal, this would support the assertion that registries have an additional positive effect on timeliness beyond secular improvement.

The Oregon Two-Year-Old Survey showed improvement over the results seen in the previous survey (OHD, 1995). In the current sample, 77% received their 4:3:1 series by age 2, up 10% from the previous sample, though short of the Year 2000 goal; almost 85% had received 3:3:1. The "shift to the left" seen in the 1995 Benton County cohort is not apparent in the current sample, however, supporting the conclusion that a registry doesn't ensure that children get their shots so much as facilitate their receipt in a more timely manner.

Assumptions

I made several assumptions in analyzing the data. I assumed that underreporting of data would be the same in 1992 and 1995. One of my concerns was that I would not have complete capture of the 1992 population, despite the efforts in 1994 and 1997 to obtain information about these children (Appendix 1). This was mitigated by two factors, however. Firstly, that the 1992 cohort turned 6 in 1998, and had to get immunized for school, which provided an opportunity to complete and update records, and secondly, that children still in the community after six years represent a more stable population than the one lost to follow up. These children would therefore be expected to get immunized, and get immunized in a more timely manner than a more mobile population, thus tending to bias my results toward the null of not finding a difference between the 1992 and 1995 cohort.

Another assumption I made was that if children got a fourth DTP or a third OPV, they had received the other antigens in the series. There were rare "blanks" in those fields, and even requesting the information from the provider or parent will not always assure that documentation is received. I assumed that if a provider called these

shots DPT 4 or OPV 3, this was in fact the sequence number.

I also assumed that the information I received on residence at time of birth and date of birth on the birth certificate was correct, and that shot dates were correctly entered. Although error may have been introduced at any one of a number of data entry or recording opportunities, there is no reason to assume this would differ in a systematic way for the study or comparison groups.

Limitations

There are several problems inherent in the design of this study. For example, the study population, the control or comparison population, and the survey control group were selected differently and at different times. Migration of 1995-born Benton County children to the rest of the State could possibly make the immunization rates for the rest of the State look better, while migration of children born in 1995 from the rest of the State, without a registry, into Benton County might make immunization rates in Benton County look worse. In either case, a mingling of groups would bias the results to the null.

The capture of the two cohorts, 1992 and 1995, differed, but we

have no reason to believe that children who are lost to follow up have better immunization rates than those who aren't, in fact, the contrary is more likely, and again would bias results toward the null. Unfortunately, in public health, limitations of time and money often preclude doing the "gold standard", a randomized control trial, to answer questions about the effectiveness of interventions.

It may be that removing financial barriers or increasing awareness about the importance of immunization among physicians and parents are the crucial components to successfully immunize preschoolers. In fact, the difference in immunization rates observed between the 1992 Benton County cohort and the Oregon sample, or between the previous (OHD, 1995) and current Oregon surveys may reflect a lowering of these barriers. Usually, many other immunization-promoting activities occur in conjunction with setting up a registry, which may confound the apparent improvement seen in immunization rates. It is unlikely, however, that the marked improvement in timeliness seen in the 1995 Benton County cohort served by the Registry is due to these other interventions alone.

SUMMARY AND CONCLUSION

It is generally accepted that immunization registries are necessary to improve immunization rates in young children. They have been used in other countries with excellent immunization levels. Computerized registries have more accurate data than parental vaccination cards (Ortega et al, 1997), and reminder systems such as postcards and computerized telephone calls increase coverage (Litt and Lake, 1993; Linkens et al, 1994), yet it is difficult to assess the direct effect of registries on immunization levels of populations.

In this observational study, the usefulness of an immunization registry in assessing immunization rates and timeliness in preschool-age children was explored. As discussed above, the Registry could not be used to assess immunization levels in ALL Benton County children before and after its implementation or compared to children in the rest of the state. Examination of Registry information did show, however, that immunizations are now received in a much more timely way in Benton County. This improvement should increase, as reminder and recall notices now go

out on a monthly basis, as compared to the 5 mailings in 1995. In terms of raising overall immunization rates in preschool age children to the goal of over 90% by Year 2000, a registry is likely to be quite helpful, since it has been shown that most inadequately immunized children are missing one to three shots, usually because parents are unaware of the need for more (OHD, 1995). Anecdotal comments from parents and providers also indicate that the Registry is valued by its users.

Although not demonstrated in this study, a registry can also be quite useful in identifying geographic pockets of underserved individuals for outreach, since address information is included in the data fields. A registry is unlikely, however, to improve immunization levels in cases where medical contraindications to vaccination are present, or in families where religious or philosophical beliefs preclude immunization, or in families where parents think that the risk of immunization outweighs the benefit of preventing diseases they don't view as a threat. It will require other strategies, such as the development of safer vaccines or education, to overcome these barriers, and it may not be possible to completely eliminate them, leaving a small population at risk of

acquiring and spreading these infections to other vulnerable individuals. In those who can have or want adequate protection, however, registries can improve the timely and effective immunization of young children.

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Table 1. Number and percent of Benton County children born in 1992 and 1995 and entered into the Benton County Immunization Registry who had received "adequate immunization" (4:3:1) after age 12 months. (Shown by quarter until 36 months, then for the 1992 cohort only, at 72 months).

Age (Months)	1992 Number N=517	%	1995 Number N=542	%
15	15	3%	96	18%
18	200	42%	433	80%
21	371	78%	506	94%
24	419	88%	520	97%
27	448	95%	527	98%
30	465	98%	532	99%
33	468	99%	535	99%
36	474	100%	538	100%
48	494			
60	507			
72	517	100%		

Table 2. Number and percent of Benton County children born in 1992 and 1995 entered into the Benton County Immunization Registry and of children recently surveyed by OHD who had received DTP 3, OPV 3, and MMR 1 (3:3:1) by age 2. (For Benton County cohort, N=the children immunized by age 3).

		Number	%
1992 Benton County	N=508	452	89%
1995 Benton County	N=559	544	97%
10/93-3/95 State Survey	N=2285	1933	85%

Table 3. Number and percentage of children surveyed by the Oregon Health Division (Benton County resident-births excluded) who had received 4:3:1, DTP 4, OPV 3, and MMR 1 after age 12 months by three month quarter until 36 months, and at 48 months of age (N=2285)

Age (Months)	4:3:1 Number	4:3:1 %	DPT 4 Number	DPT4 %	OPV 3 Number	OPV3 %	MMR 1 Number	MMR1 %
15	223	10%	261	11%	1282	56%	592	26%
18	1215	53%	1280	56%	1788	78%	1757	77%
21	1669	73%	1729	76%	2009	88%	1956	86%
24	1765	77%	1821	80%	2057	90%	2021	88%
27	1862	81%	1909	84%	2096	92%	2074	91%
30	1903	83%	1947	85%	2115	93%	2096	92%
33	1930	84%	1973	86%	2126	93%	2108	92%
36	1947	85%	1988	87%	2133	93%	2118	93%
48	1975	86%	2013	88%	2147	94%	2139	94%

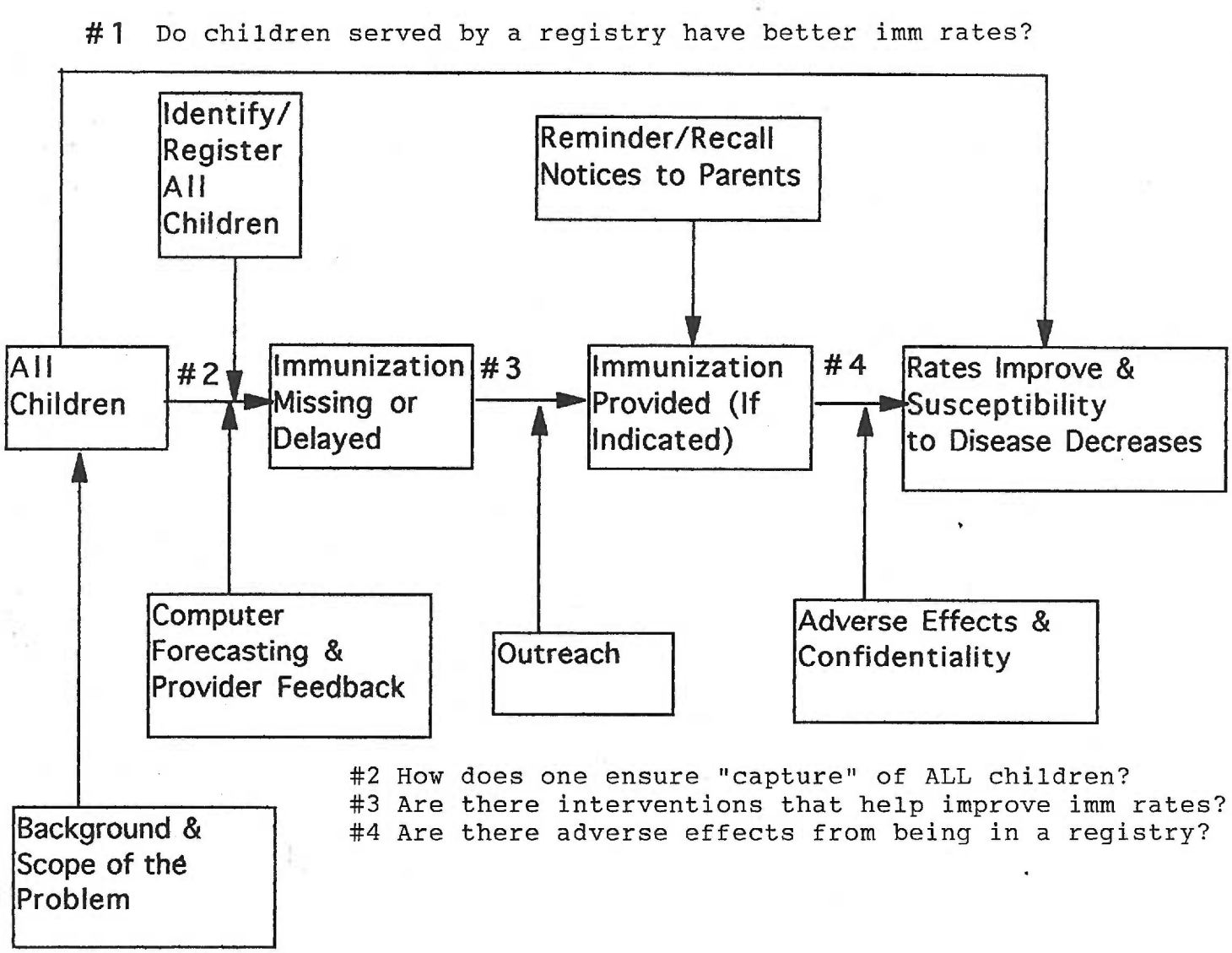

Figure 1

Immunization Registry Evidence Model

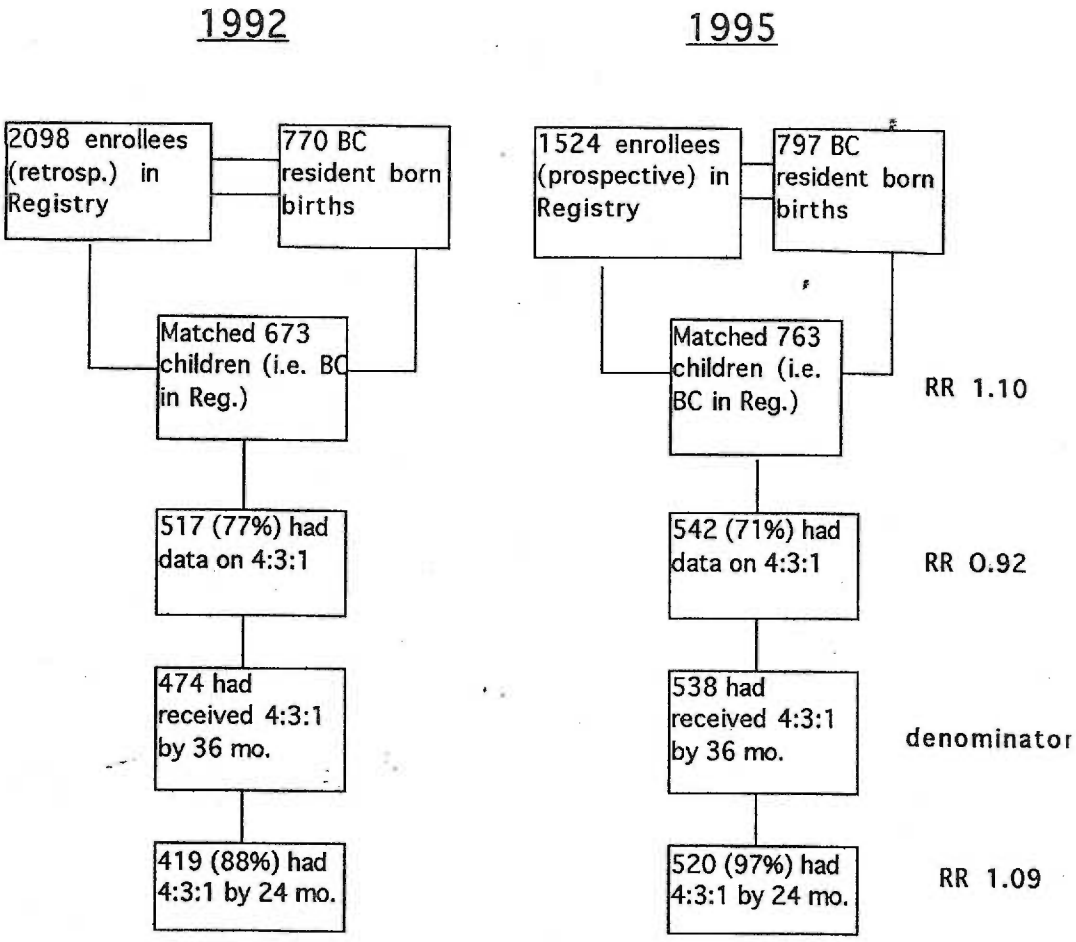

Figure 2. Flow sheet illustrating method used to define population.

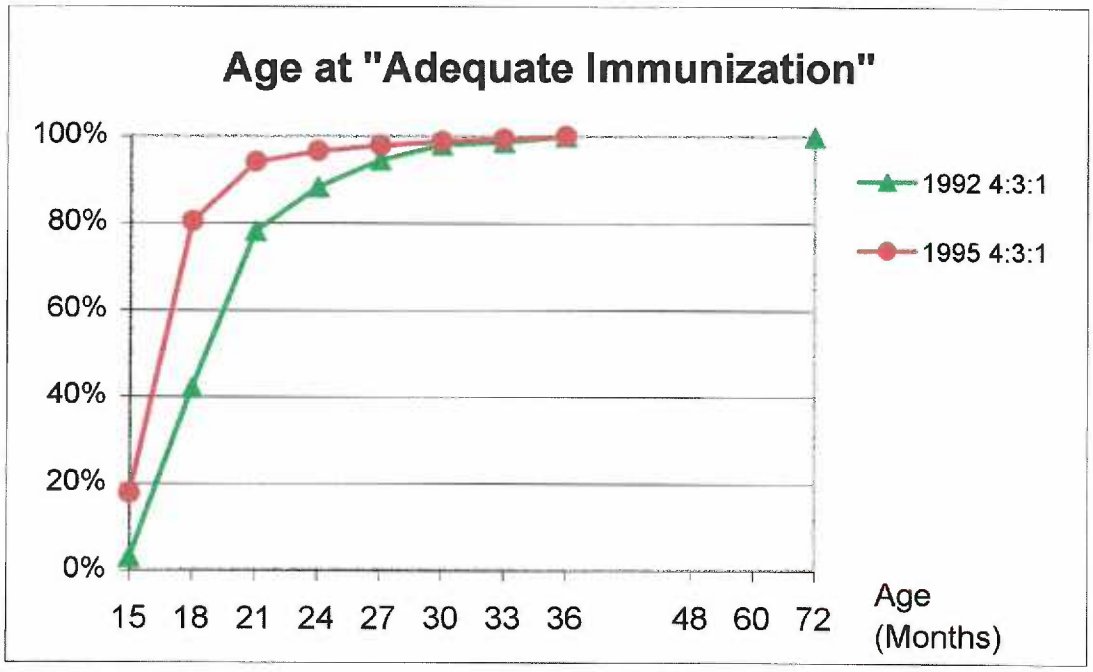

Figure 3. Percentage of Benton County children born in 1992 and 1995 who had received DTP 4, OPV 3, and MMR 1 (4:3:1) by 3 mo. interval after age 12 mos. of age until 36 mos. of age, and at 72 mos. for the 1992 cohort.

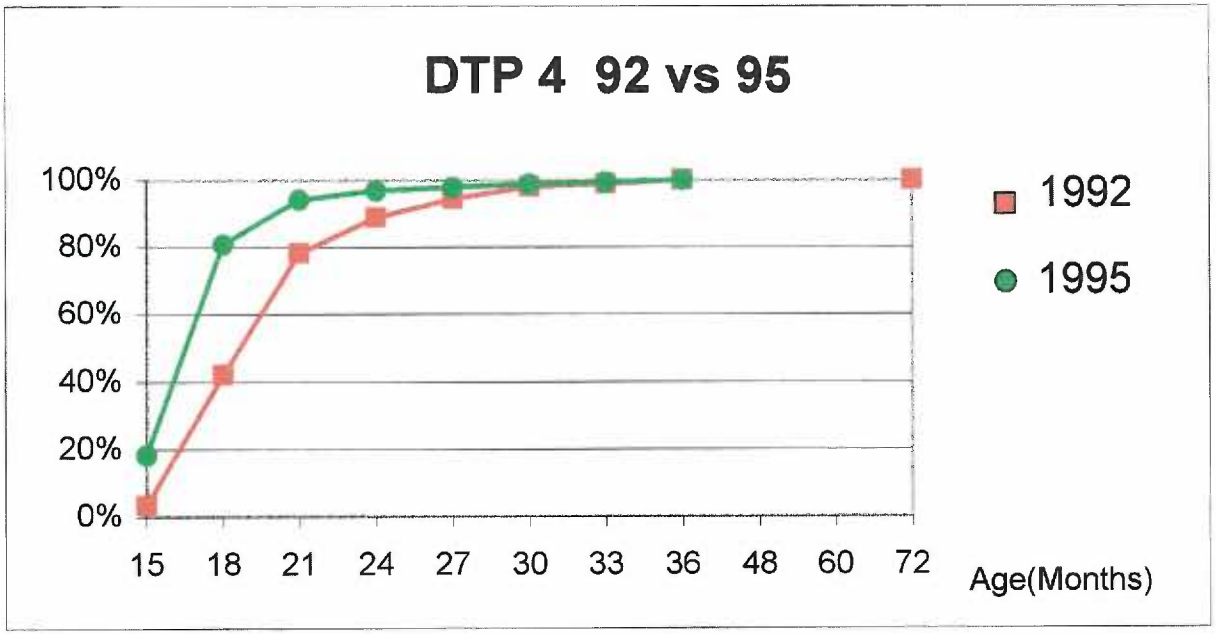

Figure 4. Percentage of Benton County children born in 1992 and 1995 who had received DTP 4 by 3 mo. interval after 12 months of age until 36 mos. of age, and at 72 mos for the 1992 cohort.

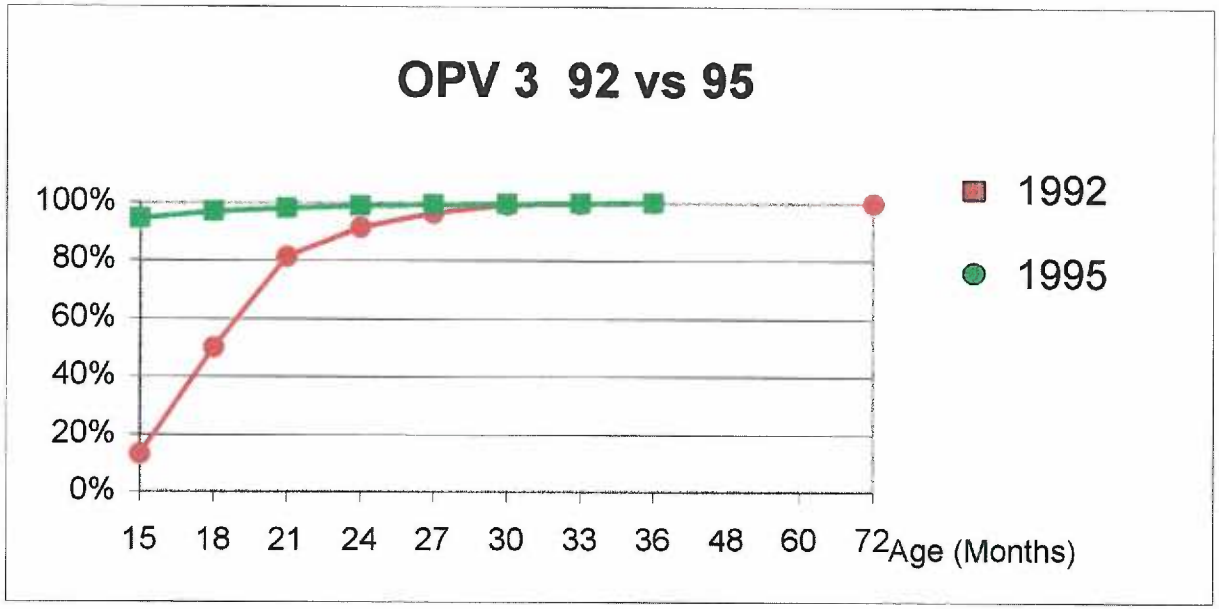

Figure 5. Percentage of Benton County children born in 1992 and 1995 who had received OPV 3 by 3 mo. interval after 12 months of age until 36 mos. of age, and at 72 mos. for the 1992 cohort.

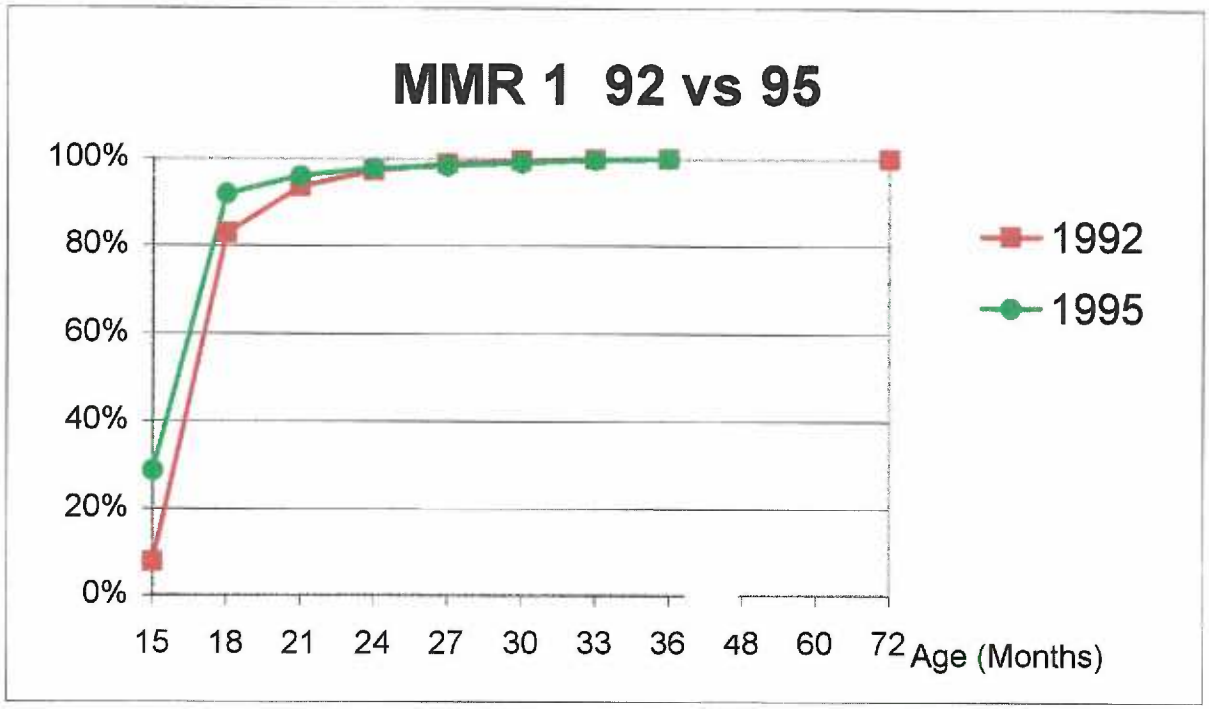

Figure 6. Percentage of Benton County children born in 1992 and 1995 who had received MMR 1 by 3 mo. interval after 12 months of age until 36 mos. of age, and at 72 mos. for the 1992 cohort.

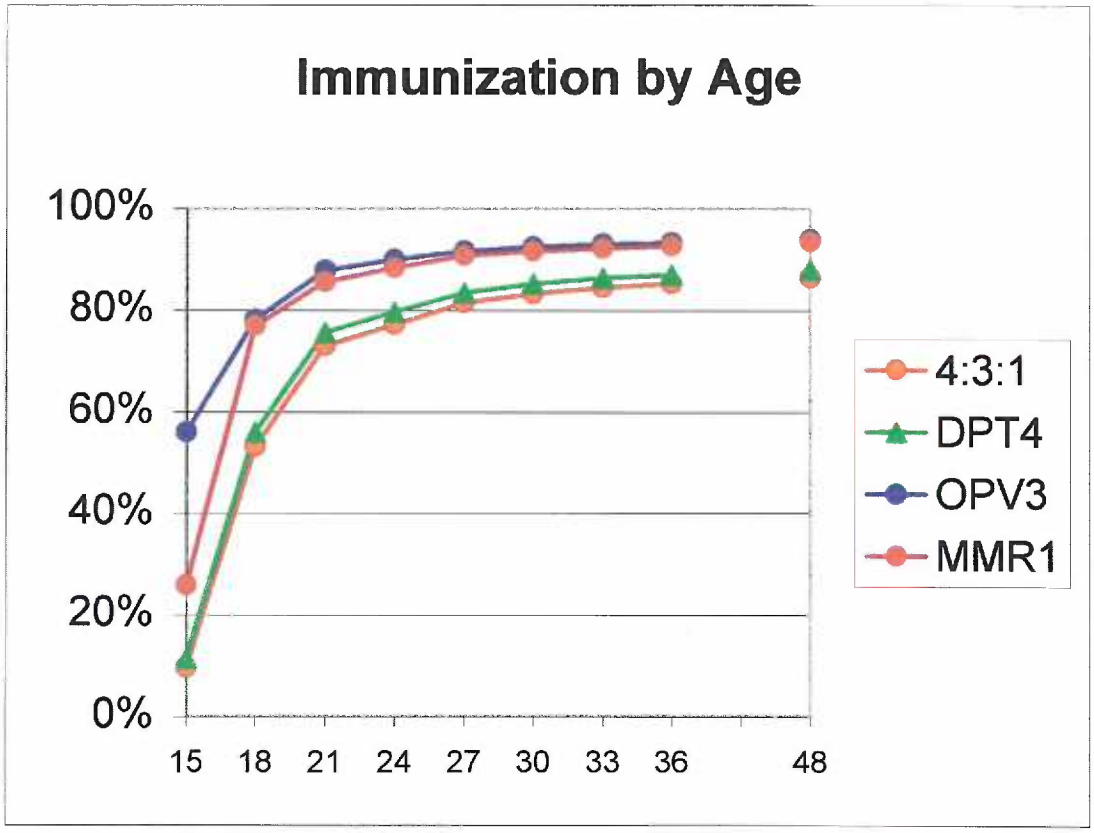

Figure 7. Percent of children surveyed by OHD (N=2285) who had received 4:3:1 and DTP 4, OPV 3, and MMR 1 by 3 mo. interval after age 12 mos. until 36 mos., and at 48 mos.

APPENDIX 1

The Benton County Registry

At this time, Benton County is the only county in Oregon with a functioning immunization registry. In 1992, Benton County began planning an immunization registry for all children in the County age 5 and under. The signing of Senate Bill 965 in July of 1993 allowed physicians to share confidential immunization information with health departments. Each Registry record includes a personal identification or client number, name, street address, city, state, and zip code, (note that county has only recently been included), phone number, date of birth, sex, ethnic group, the vaccine, number in series and date given, provider it was given by, and an activity code. The activity code for each child, which may change as additional information is received (or not received), is entered as follows:

A: Active and living in Benton County.

O: Active and lives outside of Benton County, but sees a Benton County provider.

I: Inactivated after 6 monthly reminder notices because moved out of Benton County or lives outside of Benton County and no longer sees a Benton County provider.

IA: Inactivated after 6 monthly reminder notices and do not have a good address.

IP: Parent requests no reminder/recall postcards be sent.

D: deceased

CS: Postcards are sent to Children Services Division.

PH: A letter has been sent to the parent requesting history.

R: A request has been made to the provider for missing data or for clarification.

Prospective Data Entry (1994 to Present)

Benton County Health Department began prospectively entering all new births into the Registry in January, 1994. Records of births are collected from the nursery of the only hospital in the County on a weekly basis by Registry personnel.

Each child is assigned a personal identification number, and demographic information is entered from the birth record. Home births are reported when the parents apply for a birth certificate from Vital Statistics. Out-of- county births are reported from the state. It is not possible to determine the Registry enrollment date for a child.

Demographic data ensures that a child is not entered more than once. To check for a match, names and birth dates are checked by the computer. Duplicates do occur, especially in the Hispanic population where mother's maiden name may mistakenly be confused for the surname, or due to misspelling or name change, and attempts to merge corrected records may require manual input and the use of other demographic data. No data is deleted, though data under different names for the same child is merged, at least until age 25.

If not entered at time of birth, any visit by a child born after 1990 to a health care provider for an immunization also triggers an entry.

When an immunization is given in the County, a private immunization form with shot type(s) and series number

checked off is filled out, usually by the nurse, for the Registry employee to pick up. The provider's office also provides the child's current demographic information on a separate piece of paper. This information is collected on a weekly basis by a Registry employee who goes to the provider sites as well as to the nursery.

On this occasion, the Registry may also leave any questions regarding immunizations for the provider. Registry staff may also write to or call the parent or provider to request any missing immunization history.

The State, which receives information concerning health department services from all county health departments (Infant Tracking and Recall System or ITARS), also sends the Registry any input it receives regarding immunizations given to Benton County children in other county health departments.

In 1997, Registry personnel requested from providers a list of children born after 1990 who were seen in 1996 to ensure that all children were entered in the Registry.

Registry data is entered only by trained data entry staff.

Retrospective Data Entry

Benton County retrospectively entered any child born after 12/31/90 who was seen by an immunization provider in order to have a pre-Registry comparison group. In addition to the request for names of children seen in 1996 described above, in 1994, the registry asked providers to give them names of any child born after 12/31/90 who was given an immunization. This data was downloaded from discs or manually entered from hard copy immunization records into the registry. To complete the immunization record the provider's immunization history and/or the parent was consulted. In 1997, providers were asked to provide the names and birth dates of any child born after 12/31/90 who was seen in 1996 for any reason as an additional check on complete inclusion of all children in the Registry.

Reminder and Recall

When a newborn is entered into the Registry, a card is mailed to the parents to tell them about the Registry, give them the ideal immunization schedule specific to their baby's

birth month, and to ask them to advise of any changes of address. The card also reminds them of upcoming immunization need(s). A shot date is entered for each individual immunization. There is an ideal schedule (forecast) for childhood immunization based on the child's date of birth. For example, the first DTP, polio, and Hib shots are recommended for 2 months of age (DOB + 60 days). The second hepatitis B shot should also come at this age, as long as a month has elapsed since the first. At this time, the parent receives a reminder postcard from the Benton County Registry. Reminder postcards go out as of the 15th for immunizations due the 16th through the 15th of the following month. If there is no immunization event by the age of 2 months and the immunization is past due on the date delinquent notices go out (the 15th of the month), the parents receive another postcard recalling the child for the listed immunizations. A child can be a late starter and not meet the age-appropriate criteria, but still be up-to-date on his own schedule. For example, for a child born March 16th, a mailing with his ideal schedule will be prepared on April 15th. He will get a reminder notice as of

May 15th saying he is due for his first shots beginning May 17th. If he doesn't get immunized by June 15th, the first of a series of 6 monthly recall notices will go out. If he comes in and only receives one of a number of immunizations he is due for, he will continue to get recall notices for the other indicated immunizations. If there is still no response after 6 months of recalls, an audit is conducted, requesting information from the provider (R code) and/or the parents (PH code). If there is still no response, the record is manually inactivated.

The reminder and recall dates are based on the schedule recommended by the Advisory Committee on Immunization Practices (ACIP) except for the MMR shot. Though recommended at 12 months with reminders going out in the 11th month, recall notices do not begin until the 19th month, since the Registry, after considering input from local providers, does not consider them delinquent until after 18 months of age. In the Registry's first year of operation, 1994, there were only two mailings. In 1995, there were five

mailings of reminder/recall postcards. Notices now go out every month.

In the case of a parental request, or if a philosophical exemption to immunization is requested, the postcard reminder system can be inactivated, though the Registry continues to track the child's immunizations and will consider him delinquent if they do not occur.

The data, or collections of observations about children, includes both text and numerical data, since demographic information about the patient must be given, as well as space for comments, if for example there is a contraindication or adverse reaction to a shot, or a philosophical exemption. The Registry was having difficulties with the comment section. When a shot was not given and a comment was recorded (eg. no stock, allergy, contraindication), the Registry erroneously indicated that the shot was given. Programming has corrected this problem, and comments no longer read as "shot given".

Coded data is used whenever possible, since it is less subject to ambiguity (eg. each practice/provider is assigned a number). This is easier for computers to deal with and

provider-specific data, such as which of their patients are not up-to-date, can be generated. Benton County providers supported the Registry in part for this feature, since they wanted to have practice-specific information. Benton County's Registry therefore includes children from neighboring counties, who receive medical care in Benton County. This creates a problem when trying to analyze County-specific data, since County of residence was not one of the fields, and zip codes and cities may cross county lines. Attempts to correct this problem over the last 3 months (ie. there is now a specific field for County of residence) have not been satisfactory since people do not always know what county they live in, and the forms we receive do not generally have the county recorded.

Updates and Forecasts

The Registry employee exchanges information with providers in the course of weekly rounds, as described above. When a Benton County provider sees a new patient, he can also call the Registry directly to get an update and a forecast of

needed immunizations. Similarly parents can access this information for their children. This information is generally obtained via telephone. Registry employees believe that providers find the telephone to be a quick and easy way to get the information they need, however providers cannot obtain this information after regular working hours.

APPENDIX 2

The Oregon Health Division's Two-Year-Old Immunization Survey

An initial sample of 3149 children born in Oregon between November1, 1993 and March 31, 1995 was selected from birth certificates using SPSS' random sample option. The 48 children born to non-Oregon resident mothers were eliminated, as were the 26 adoptees and 26 deaths identified through a match of adoption and death certificate data by the Oregon State's Center for Health Statistics. Therefore, the parents and guardians of 3058 children received an initial mailing. Of these, 10 were eliminated (2 deaths and 8 adoptions or foster care) for a final sample size of 3048.

Survey participants were initially selected using a stratified random sample scheme. The state was divided into six regions (detailed below) to replicate the sampling scheme of the 1994 Survey of Two-Year-Olds. In this method, a larger

proportion of children born in regions with few births was selected than from regions with more births. Then African American, Asian/Pacific Islander, Hispanic and Native American children were oversampled. This construct was designed to enable researchers to perform analyses for those demographic groups whose relatively few births, if chosen through a simple random sample, would otherwise be too few to yield any generalizable data for that subgroup.

The regions employed in oversampling were:

I) Multnomah

II) Clackamas, Washington

III) Benton, Clatsop, Columbia, Lincoln, Linn, Marion, Polk, Tillamook, Yamhill

IV) Coos, Curry, Douglas, Jackson, Josephine, Klamath, Lane

V) Baker, Crook, Grant, Harney, Lake, Malheur

VI) Deschutes, Gilliam, Hood River, Jefferson, Morrow, Umatilla, Union, Wallowa, Wasco-Sherman, Wheeler

Survey Administration

A pre-survey postcard was mailed to the birth certificate address, to the parent or guardian of the child, more than a month before the survey packet was first mailed. This postcard was designed to allow correction of invalid addresses before the survey mailing, and to prepare parents for their impending receipt of the survey. Of the 3048 postcards sent, 69.0% were not returned to the Health Division and thus seemed to arrive at their intended destinations. Nearly a third of respondents, however, did not receive the postcard at the address provided on the birth certificate. The U.S. Post Office provided forwarding information for 10.9% of the postcards mailed, but other methods were employed to find addresses for the remaining 20.1%.

The first resource used was the National Change of Address Database (NCOA). NCOA services are provided by licensees of the U.S. Postal Service (USPS), who retain permanent changes of address filed with the USPS for 36 months (versus 18 months retention by the USPS). Over a thousand new addresses

were generated using this service, to which second postcards were mailed in early December of 1996.

Finally, late in December of 1996, survey packets were mailed to the approximately two-thirds of the sample for whom the addresses seemed correct. Of these 2001, 41.5% returned the survey by mail in the business reply envelope without further prompting. Most of the remaining surveys were first mailed in mid-January using data collected from the second postcard mailing.

Response to the survey was overwhelming at first, with 36.8% of the sample responding by the end of February. The final count was 2311. Records were verified with either the parent and/or the provider if they appeared incomplete or unusual. In about 60 cases, providers could not be located or identified or were not able or willing to provide the information.