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Validation of the 5-year tetanus, diphtheria, pertussis and polio booster vaccination in the Danish childhood vaccination database

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A B S T R A C T

Background: In Denmark, data from the childhood vaccination database are used to calculate vaccination coverage (VC) for childhood vaccinations. However, there may be under-reporting in this database. Accurate VC estimates are necessary for adjusting vaccination strategies and providing population-level protection.
Aims: The main purpose of this study was to validate the reporting of the tetanus, diphtheria, pertussis and polio (Tdap-IPV) booster in the childhood vaccination database, identify reasons a child was not vaccinated, for the unregistered vaccinations, identify where the vaccination was provided, and to adjust calculations of the VC accordingly.
Methods: Children registered in the Danish Civil Registry System (residing legally in Denmark) from the 2000 to 2003 birth cohorts without a recorded Tdap-IPV booster in the childhood vaccination database were randomly selected for this cross-sectional, questionnaire-based study. The adjusted VC in the population was calculated by adding the fraction of the study population registered with the Tdap-IPV booster in the childhood vaccination database to the fraction of the study population who reported being vaccinated on the questionnaire but who were not register according to the childhood vaccination database.
Findings: Of the 574 contacted parents, 386 (67%) completed a questionnaire; 272 (70%) reported that their child received the Tdap-IPV booster, with 121 (44%) providing the date of vaccination. Most commonly reported reasons for not receiving the booster included forgetting (37%) and not wanting the vaccination (16%). The majority (89%) of children who received the booster were vaccinated by their general practitioners (GPs); 6% abroad and <1% in a hospital. Using a conservative approach, considering only those who used a vaccination card to answer the questionnaire and who provided an exact data of vaccination, the adjusted Tdap-IPV booster VC was 85.6% (95% CI, 85.1–86.3%) compared to 82% from the childhood vaccination database.
Conclusion: We identified substantial underreporting of the Tdap-IPV booster in the childhood vaccination database, mainly due to GPs not registering given vaccinations. Validating data used for VC calculations is needed to obtain more precise estimates.

1. Introduction

The Danish childhood vaccination schedule recommends a booster against tetanus, diphtheria, pertussis and polio (Tdap-IPV) at the age of 5 years [1]. Childhood vaccinations are provided by general practitioners (GPs) who register and record immunizations both on a personal vaccination card kept by the parents of the vaccinated child and in a national database, the childhood vaccination database. This database contains information collected by the National Board of Health from the National Health Insurance. In order to obtain financial reimbursement, GPs are required to submit data to the National Health Insurance, including the code corresponding to a specific vaccine and dose number given, the date the vaccination was given and the personal identification number (CPR number) of the vaccine recipient. Electronic records of reimbursement codes are available starting from 1990 [2]. In Denmark, data from the registry of reimbursement codes are used to calculate vaccination coverages (VCs) for vaccines given in the childhood vaccination program. It is not known to what extent this approach to calculate VCs is affected by missing vaccination data in the childhood vaccination database.

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The main purpose of this study was to investigate the possible underreporting of the reimbursement code for the Tdap-IPV booster vaccine to the National Health Insurance and consequently to the childhood vaccination database. With an estimated coverage of 82%, this is the childhood vaccination with the lowest coverage in Denmark [3]. The study also aimed to identify reasons why a child was not vaccinated with the Tdap-IPV booster. In the case of unregistered vaccinations, we aimed to identify where the booster vaccination was provided and adjust the VC accordingly.

2. Methods

2.1. Study design, population, sampling and sample size calculations

For this cross-sectional study, we randomly selected and contacted individuals registered in the Danish Civil Registry System (legally residing in Denmark) [4], whose child did not have a recorded Tdap-IPV booster vaccination at the age of 5 or later. Parents who had previously declined that any researchers contact them ("forskerbeskyttelse") were not invited to participate (12.8% of the country's population). All selected children were between 7 and 10 years of age because it was not expected that these children would still be "catching-up" with the Tdap-IPV booster vaccination and because their birth cohorts (2000–2003) did not see any changes in the childhood vaccination schedule. We selected children to be equally distributed in the number of: (1) boys and girls, (2) children from each of the five Danish administrative regions (Capital, Central, North, South and Zealand) and (3) children born in the years 2000–2003. To account for difference in gender, population distribution among regions and birth years, specific weights were applied when calculating VC (see Section 2.3).

Power calculations, showed we needed a sample size of 380 respondents to conclude with 90% power that the underreporting of the Tdap-IPV booster by physicians is 15% or less (one-sided test, assuming that 10% of the unvaccinated children were vaccinated but not registered) among those not registered with a vaccination in the childhood vaccination database.

Underreporting in this study means the incorrect registration or a complete lack of registration of a vaccination into the Danish childhood vaccination database, so that a child who received a vaccination does not appear to have had the vaccination according to the database. In order to reach 90% power, we selected a total of 680 parents to whom we were able to send out questionnaires until we reached 380 responses.

2.2. Questionnaire and data collection

We asked parents about the Tdap-IPV booster, including whether the child ever received this vaccination, if yes, where and when the vaccination was provided; if no, why not, and whether a vaccination card or other documentation from the GP was used to answer these questions. Parents were also asked to provide the date of the Tdap-IPV booster vaccination. We pilot-tested the questionnaire before administering it in the main study.

All participants were sent a cover letter explaining the study, a consent form, a questionnaire and an addressed and stamped envelope for reply. Parents could complete the paper questionnaire and return it by mail, be interviewed over the telephone or complete the questionnaire online. Trained interviewers called parents who did not respond to the initial letter up to ten times to conduct a telephone interview. Parents who did not wish to answer the questionnaire themselves could give permission for direct contact with their GPs to verify their child's vaccination history. This GP provided vaccination information was received either verbally over the telephone or through a fax. The consent form also contained an option for complete refusal to participate, at which point all contact ceased. Written or verbal consent was obtained from all participants.

2.3. Data analysis

Two approaches were used for the VC calculations in the study population: the "most conservative" and "least conservative". In order for children to be considered vaccinated with the Tdap-IPV booster in the most conservative approach, parents had to use a vaccination card to answer the question and report a complete date of the Tdap-IPV vaccination. In the least conservative approach, children were considered vaccinated with the Tdap-IPV booster if their parents simply answered affirmatively to the Tdap-IPV booster question. These two approaches were used to construct the two extremes of how the data obtained from this study could be interpreted.

Additionally, the results of the most conservative approach were further split into two calculations, the first of which includes all contacted participants in the denominator, even if they were non-respondents or refusals, assuming these persons were not vaccinated. In the second calculation of the most conservative approach, non-respondents and refusals were not included in the denominator, assuming the same proportion of them were vaccinated as the proportion of the respondents.

The adjusted VC in the population was calculated by adding the fraction of the study population registered with the Tdap-IPV booster in the childhood vaccination database to the fraction of the study population who reported being vaccinated on the questionnaire but who were not registered according to the childhood vaccination database, e.g.

$$r + (1 - r) * q \quad (1)$$

where r is the VC calculated using the childhood vaccination database and q is the (estimated) fraction of vaccinated children among those not registered in the database. The 95% Wald confidence intervals (CIs) for q were calculated on the log(odds)-scale and transformed back into a proportion-scale. The 95% CIs of the vaccination coverage were calculated by using Eq. (1) on the confidence limits of q, e.g. $(r + (1 - r)^* q_{\text{lower}})$ and $(r + (1 - r)^* q_{\text{upper}})$.

To improve the applicability of the estimated coverage in the population of Denmark we calculated a weighted VC. In the calculation each child contributed a weight proportional to the size of the population which the child represents (with respect to gender, birth year, and region). Using these weights ensures that the estimated underreporting is a measure of the average underreporting across the country (otherwise, children from smaller regions would have been overrepresented compared to children from larger regions).

All descriptive statistics were performed using STATA (version 10.1; StataCorp, TX) and all VC calculations were performed using SAS (version 9.3; SAS Institute Inc., Cary, NC).

3. Results

The questionnaire was sent to 574 parents, 386 (67%) of whom responded either by telephone interview (58%), a letter (32%), granting permission to contact their GPs (8%) or internet (3%). One hundred thirty-four (23%) persons did not respond and 54 (9%) refused to participate in the study.

Table 1 provides detailed information about Tdap-IPV booster vaccination questionnaire answers. Of the 386 individuals who responded, 272 (70%) reported that their child received the Tdap-IPV booster vaccination (though this was not registered in the Childhood Vaccination Database), with 136 (50%) providing this information from a vaccination card. Parents indicated that 89% of

Table 1
Tdap-IPV booster questionnaire answers provided by parents of children recorded as not having received the Tdap-IPV booster by the childhood vaccination database.

	Tdap-IPV booster	Vaccination card[a]
Vaccination		
Yes	272 (70%)	136 (50%)
No	70 (18%)	30 (43%)
Do not know	33 (9%)	6 (18%)
Missing	11 (3%)	3 (27%)
Where		
GP	242 (89%)	120 (50%)
Pediatrician	0 (0%)	
Hospital	1 (0.5%)	1 (100%)
Travel clinic	0 (0%)	
Abroad	17 (6%)	9 (53%)
Other	1 (0.5%)	1 (100%)
Missing	11 (4%)	
Why not vaccinated		
Forgot	26 (37%)	
Child cannot tolerate according to doctor	0 (0%)	
Do not want vaccination	11 (16%)	
Did not have time	1 (1.5%)	
Child sick at vaccination, not rescheduled	1 (1.5%)	
Other	21 (30%)	
Missing	10 (14%)	
Date of vaccination		
Day, month, year	121 (44%)	116 (96%)
Month, year	13 (5%)	2 (15%)
Year	15 (6%)	4 (27%)
Missing	123 (45%)	

[a] Percentages in "Vaccination card" column are of Tdap-IPV booster column numbers; describes parents who used a vaccination card to answer the specific questions.

the children were vaccinated at a GP's office, 6% abroad and 0.5% in a hospital. Seventy (18%) parents reported their child did not receive the Tdap-IPV booster; 26 forgot about the vaccination, 21 had "other" non-elaborated reasons, 11 did not want their child vaccinated, 1 did not have time to take the child to the GP, and 1 reported that the child was sick at the time the vaccination was to be given and a new date was not scheduled. One hundred twenty-one (44%) parents provided a complete date of the Tdap-IPV booster vaccination, 13 (5%) a month and a year, 15 (6%) a year only, and the remaining 123 (45%) did not provide any date information. The children whose parents reported a complete date of Tdap-IPV booster vaccination and who used the vaccination card to retrieve this information were treated as "definitely immunized" for the remainder of the analyses.

The adjusted VCs for the Tdap-IPV booster using information from this study are examined in Table 2. The results of the most conservative approach and including everyone contacted in the denominator give an overall vaccination in the participants of 20.2% or 19.8% after weighting with respect to gender, birth year, and region of the participants. After applying this VC as an adjustment to the VC calculated using the childhood vaccination database, the overall VC for the Tdap-IPV booster vaccination in Denmark is 85.6%. This is 3.6 percentage points higher than suggested by the childhood vaccination database. The adjusted VCs by region range from 83.8% in the Capital Region to 87.4% in the Central Region.

The second VC calculation uses the most conservative approach but did not include the non-respondents and refusals in the denominator. The overall VC in the participants is 30.4% or 30.5% after weighting. Applying this VC as an adjustment gives an overall VC of 87.5%. The adjusted VC rates for the regions range from 85.9% in the Capital Region to 89.4% in the Central Region.

The last part of Table 2 shows VC results obtained by using the least conservative approach. The overall VC in the participants is 71.2%, much higher than the coverages calculated with both the conservative approaches discussed above. After applying this VC as

Table 2
Estimated vaccination coverages from the childhood vaccination database, the study, and adjusted[a] in the population using data from participants who used the vaccination card and gave an exact date of the Tdap-IPV booster vaccination by region.

Regions of Denmark	Estimated coverage from childhood vaccination database	Most conservative (card and exact date) including non-responders/refusals[b]			Most conservative (card and exact date) NOT including non-responders/refusals[c]			Least conservative (ONLY answer yes) NOT including non-responders/refusals[c]		
		Vaccinated/total	Vaccination coverage in study	Adjusted vaccination coverage in population	Vaccinated/total	Vaccination coverage in study	Adjusted vaccination coverage in population	Vaccinated/total	Vaccination coverage in study	Adjusted vaccination coverage in population
Capital	81.0%	17/117	14.5% (9.2%, 22.1%)	83.8% (82.8%, 85.2%)	17/66	25.8% (16.7%, 37.6%)	85.9% (84.2%, 88.1%)	45/66	68.2% (56.1%, 78.2%)	94.0% (91.7%, 95.9%)
Central	83.1%	30/118	25.4% (18.4%, 34.0%)	87.4% (86.2%, 88.9%)	30/80	37.5% (27.6%, 48.5%)	89.4% (87.8%, 91.3%)	56/80	70.0% (59.1%, 79.0%)	94.9% (93.1%, 96.5%)
North	82.0%	24/115	20.9% (14.4%, 29.3%)	85.8% (84.6%, 87.3%)	24/81	29.6% (20.7%, 40.4%)	87.3% (85.7%, 89.3%)	57/81	70.4% (59.6%, 79.3%)	94.7% (92.7%, 96.3%)
Zealand	81.5%	20/107	18.7% (12.4%, 27.2%)	85.0% (83.8%, 86.5%)	20/81	24.7% (16.5%, 35.2%)	86.1% (84.6%, 88.0%)	54/81	66.7% (55.8%, 76.0%)	93.8% (91.8%, 95.6%)
South	82.5%	25/117	21.4% (14.9%, 29.7%)	86.2% (85.1%, 87.7%)	25/74	33.8% (24.0%, 45.2%)	88.4% (86.7%, 90.4%)	60/74	81.1% (70.5%, 88.5%)	96.7% (94.8%, 98.0%)
Total	82.0%	116/574	20.2% (17.1%, 23.7%)	85.6% (85.1%, 86.3%)	116/382	30.4% (26.0%, 35.2%)	87.5% (86.7%, 88.3%)	272/382	71.2% (66.5%, 75.5%)	94.8% (94.0%, 95.6%)
Weighted total	–	–	19.8% (16.8%, 23.3%)	85.6% (85.0%, 86.2%)	–	30.5% (26.1%, 35.3%)	87.5% (86.7%, 88.4%)	–	71.2% (66.5%, 75.5%)	94.8% (94.0%, 95.6%)

[a] Adjusted by subtracting childhood vaccination database estimated coverage from one, multiplying the result by the vaccination coverage rate from the study, multiplying by 100 and adding to the estimated coverage from the database.
[b] Denominator consists of all participants regardless of response status ($n = 574$); assumes that non-responders and refusals are unvaccinated.
[c] Denominator consists of respondents only ($n = 382$); assumes that non-responders and refusals have the same vaccination coverage at the responders.

an adjustment, the overall VC for the Tdap-IPV booster vaccination in Denmark is 94.8%. The adjusted VCs by region range from 93.8% in Zealand to 96.7% in the South Region.

4. Discussion

The results of this study show that underreporting of the Tdap-IPV booster in the childhood vaccination database does exist. The extent of this underreporting among those not registered in the childhood vaccination database with the Tdap-IPV vaccination is conservatively estimated to be 20.2%, but may be as high as 71.2% if all affirmative responses to the Tdap-IPV booster question are considered accurate. If this underreporting were to be corrected in the VC estimate calculated using data from the Childhood Vaccination Database, coverage would, in conservative scenarios, increase between 3.1 and 4.3 percentage points, to somewhere between 85.1% and 86.3%. Both scenarios would meet the 85% critical VC needed to block transmission of diphtheria and polio [5]. However, this VC is still not high enough to block transmission of pertussis (92–95%) [5].

Previous studies have shown that vaccination card data, along with parental recall of a child's vaccination status can be useful in correcting VC estimates. A validation of the MMR vaccination in the Child Health Computer System in the North Cheshire, South Cheshire and Wirral areas of the United Kingdom also found underreporting [6]. After examining vaccination records for a selected birth cohort and adjusting the coverage, the VC increased by 2.1 percentage points to 92.6%. Similarly, the Australian Childhood Immunization Register (ACIR) has been shown to underestimate VC in children at the 12 and 24 month milestones [7]. Overall, 46% of incompletely immunized children met the study definition of "definitely immunized" at 12 months and 62% at 24 months by reporting a date of vaccination from a written record. These data were used to adjust the immunization coverage by 2.7 percentage points for the 12 month milestone and 6.5 percentage points for the 24 month milestone [7]. The main reasons for discrepancies between the ACIR and written records were a failure to register the vaccination, migration, and vaccinations administered abroad [8]. A Baltimore based study showed the percentage of vaccinated children was 17.4–18.4 percentage points higher when comparing parental recall data with medical record data for vaccinations given by the age of two [9]. On the other hand, vaccination card data compared with medical record data increased the percentage of vaccinated children between 2.3 and 10.9 percentage points [9]. Most likely the true VC estimate is somewhere between the two sets of results.

Top reasons reported for a child not receiving the Tdap-IPV booster vaccine included forgetting, not wanting the vaccination, and "other" non-elaborated reasons. Considering that 26 respondents forgot to take their child to a GP for the Tdap-IPV booster, one idea to increase VC is to send a reminder to parents. The reminder could be targeted to parents who do not come for a Tdap-IPV booster related scheduled appointment or who never made an appointment for the vaccination. The reminder can be sent in the form of a post card, a telephone call, SMS, or an email [10]. This sort of reminder system has previously been shown to be effective, with 50% of children who were not vaccinated up to date receiving vaccinations after outreach to parents [11].

Direct contact with 30 GPs to obtain information about a child's vaccination status (after obtaining permission from the parents to contact the GPs), enabled us to identify a specific reason for under-vaccination with Tdap-IPV booster: children were less likely to receive the recommended vaccination when parents switched their child's GP. Such record scattering has been previously examined and shown to occur in 22% of children in the United States [12]. Record scattering has been associated with increased difficulties by clinicians in identifying the vaccination status of their patients. In order to insure this occurrence is minimized in Denmark, it is recommended that GPs who receive a new child patient should both ask about the child's vaccination status the first time they see the child and check the childhood vaccination database for the child's vaccination status.

The main limitation of the study is the possibility of misclassification of unvaccinated children as vaccinated based on the answer provided by their parents. However, our conservative definition of Tdap-IPV booster vaccination (use of vaccination card and the exact date Tdap-IPV booster was administered) was specifically used to minimize this possibility. Vaccination cards have been shown to have better agreement with provider-reported vaccination rates compared with parental recall [13]. It is also possible that the results of this study may be an underestimate of the true Tdap-IPV booster vaccination status due to the strictness of our definition. Parents may not have always brought their child's vaccination card to the GP and consequently not all vaccinations were recorded in the card. In our study, such a scenario would prevent the child from being counted as vaccinated and would not be used in the adjusting of the VC estimates. Nonetheless, we feel that it is better to underestimate rather than to overestimate VC.

One of the main strengths of this study is the variety of ways parents could participate; whether by physical mail, telephone, internet, or even by granting permission to contact their GP. The study was also very thorough in the number of times parents were attempted to be contacted, resulting in a fairly high response rate (76%).

Accurate surveillance of VC is needed to decrease missed opportunities for vaccination, identify under-vaccinated populations and monitor progress in achieving coverage goals. An important lesson learned from the results of this study is that registry based data should be trusted with caution. Validation studies of databases and/or registries are recommended to make certain that data is of the highest quality and to locate problems and areas for improvement as soon as possible [14]. Merely, the presence of a vaccination database does not guarantee better VC; rather timely analysis and interpretation of data leading to action can improve both data quality and VC.

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