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Assessing vaccine data recording in Brazil

Avaliação de dados vacinais no Brasil

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ABSTRACT: *Objectives:* Vaccines represent an important advancement for improving the general health of a population. The effective recording of vaccine data is a factor for the definition of its supply chain. This study investigated vaccine data recording relatively to data collected from vaccination rooms and data obtained from a government-developed Internet platform. *Methods:* The monthly recorded total number of diphtheria and tetanus toxoids and pertussis vaccine (alone or in combination with the *Haemophilus influenzae* type b conjugate vaccine) doses administered in a medium-sized city of the Southeast region of Brazil was collected for the period January/2006 through December/2010 from two sources: City level (directly from vaccination rooms, the study "gold standard"), and Federal level (from an Internet platform developed by the country government). Data from these sources were compared using descriptive statistics and the Percentage error. *Results:* The data values made available by the Internet platform differed from those obtained from the vaccination rooms, with a Percentage error relatively to the actual values in the range [-0.48; 0.39]. Concordant values were observed only in one among the sixty analyzed months (1.66%). *Conclusions:* A frequent and large difference between the number of diphtheria and tetanus toxoids and pertussis vaccine doses administered in the two levels was detected.

Keywords: Vaccines. Health planning. Statistics as Topic. Immunization. Statistics & numerical data. Diphtheria-Tetanus-Pertussis Vaccine.

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RESUMO: *Objetivos:* Vacinas representam um importante avanço para melhorar a saúde de uma população. O registro adequado dos dados vacinais é um fator crítico para a programação da distribuição de vacinas. Este estudo investiga os registros de uma vacina aplicada à população, de acordo com dados coletados nas salas de vacinação e dados obtidos a partir de uma plataforma governamental de Internet. *Métodos:* O número mensal total de doses aplicadas da vacina contra difteria, tétano e coqueluche (isolada ou combinada à vacina contra *Haemophilus influenzae* tipo b) de uma cidade de médio porte da Região Sudeste do Brasil foi coletado no período de Janeiro/2006 a Dezembro/2010, de duas fontes: a nível Local (diretamente de salas de vacinação, o "padrão ouro") e a nível Federal (a partir de uma plataforma governamental de Internet). Os dados dessas fontes foram comparados utilizando estatística descritiva e a Percentagem de erro. *Resultados:* Os valores dos dados disponibilizados pela plataforma governamental diferem daqueles obtidos nas salas de vacinação, com uma Percentagem de erro compreendida no intervalo [-0,48; 0,39]. Valores concordantes foram observados somente em um dentre os sessenta meses analisados (1,66%). *Conclusões:* Detectou-se uma frequente e acentuada diferença entre o número de doses aplicadas da vacina observada relativamente às duas fontes de dados da pesquisa.

Palavras-chave: Vacinas. Planejamento em saúde. Estatística como Assunto. Imunização. Estatística & dados numéricos. Vacina contra Difteria, Tétano e Coqueluche.

INTRODUCTION

By now, at least 25% of the world deaths are caused by infectious diseases, most of which in children between zero and five years of age; and more than 60% of these deaths could be avoided by effective immunization programs[1]. Therefore, vaccines arguably represent the most important advancement for improving the general health and the quality of life of a population[2,3]. They are a relatively cheap medical procedure with an excellent potential to control and even to eradicate infectious diseases.

Worldwide vaccine coverage has been increasing since the 1980s, showing the importance of the immunization programs currently under way, especially in developing countries[1,2]. However, in these countries, immunization programs suffer from the lack of technical and human resources, resulting in vaccine data quality problems and in poor data interchange between local level (vaccination rooms) and central government level (federal), hindering policies for health care planning[2-5]. These problems may result in an inadequate evaluation of vaccine supply chain and vaccine campaigns, with serious repercussions in immunization program strategies[3,6].

In Brazil, the National Immunization Program (NIP) was created in 1973, with the aim of coordinating national vaccine programs[7]. The expansion of these programs created the necessity to improve vaccine distribution logistics, so as to achieve a high vaccination coverage[8]. NIP data can be accessed via an Internet platform, the NIP/Datasus, which also makes available immunization data according to vaccines, age group and monitoring vaccination coverage in different target groups of immunization, according to health units, municipalities and states (the Information System of Evaluation of National Immunization Program – SIAPI)[9].

The present study aimed to assess the agreement between data sources for diphtheria and tetanus toxoids and pertussis vaccine (DTP) doses administered in a city of Brazil. To this end, the total number of DTP doses (alone or in combination with the *Haemophilus influenzae* type b conjugate vaccine) administered in the city vaccination rooms was collected and then compared with that from the federal level, obtained from an information system managed by the Ministry of Health of Brazil (NIP/Datasus)[10].

METHODS

RESEARCH SET UP

An observational, ecological study was performed, in which the monthly total number of DTP doses administered in the period January, 2006 through December, 2010 was obtained for a Brazilian city. The vaccine was introduced in the city in 1973; data were collected between January, 2012 and April, 2012.

As mentioned, data were collected from two sources: directly from the vaccination rooms in operation at the time of the study (City level, the study "gold standard") and from an information system (an Internet-available platform) developed by the federal government, the National Immunization Program/Datasus (NIP/Datasus) (the Federal level)[10]. This system offers access to consolidated vaccine data from all the cities of the country since 1991[11], and is openly accessible via an Internet platform. Data from the vaccination rooms were collected with the permission of the City Health Secretariat/Juiz de Fora (CHS-JF).

The research took place in a typical southeastern Brazilian city (Juiz de Fora, MG), a medium-sized city[12], located 275 km from the capital of the Minas Gerais State (Belo Horizonte city), 180 km from the city of Rio de Janeiro and 480 km from the city of São Paulo. The city is basically urban, with about 550,710 inhabitants[13] in an area of 1.435,664 km². Its Municipal Development Human Index (MDHI) is 0.828 (state average: 0.719, country average: 0.699); it has three schools of medicine, one public and two private[13]. Health care is provided by four public and seven private hospitals. The vaccination rooms offered the fourteen vaccines recommended by the Brazilian National Immunization Program (NIP) at the time of data collection. DTP was chosen for analysis since it is considered as one of the best indicators for the performance of a health system, as well as an indicator of vaccine coverage[14,15].

INFORMATION SOURCES, DATA FLOW AND ANALYSIS

Two variables were developed for the present study: the first indicates the "Number of doses administered at the city vaccination rooms" (CiDo) and the second the "Number of doses reported at the NIP/Datasus system" (NIPDo).

Vaccine data flow is basically the same as from other Brazilian cities and, in the vaccination rooms, the management of vaccine supplies and information recording is usually performed by nurses. Data are processed at the city level, sent to the regional level and finally to the federal level, as below (see also Figure 1):

1. City level: The vaccination room personnel write down, daily, in paper spreadsheets, data concerning the number of vaccine doses administered in each vaccination room. These doses are registered in a vaccination card (which remains in possession of the vaccinated person), and in a specific spreadsheet, in which the available vaccines of the Brazilian NIP are recorded. Still in the vaccination room, the number of doses
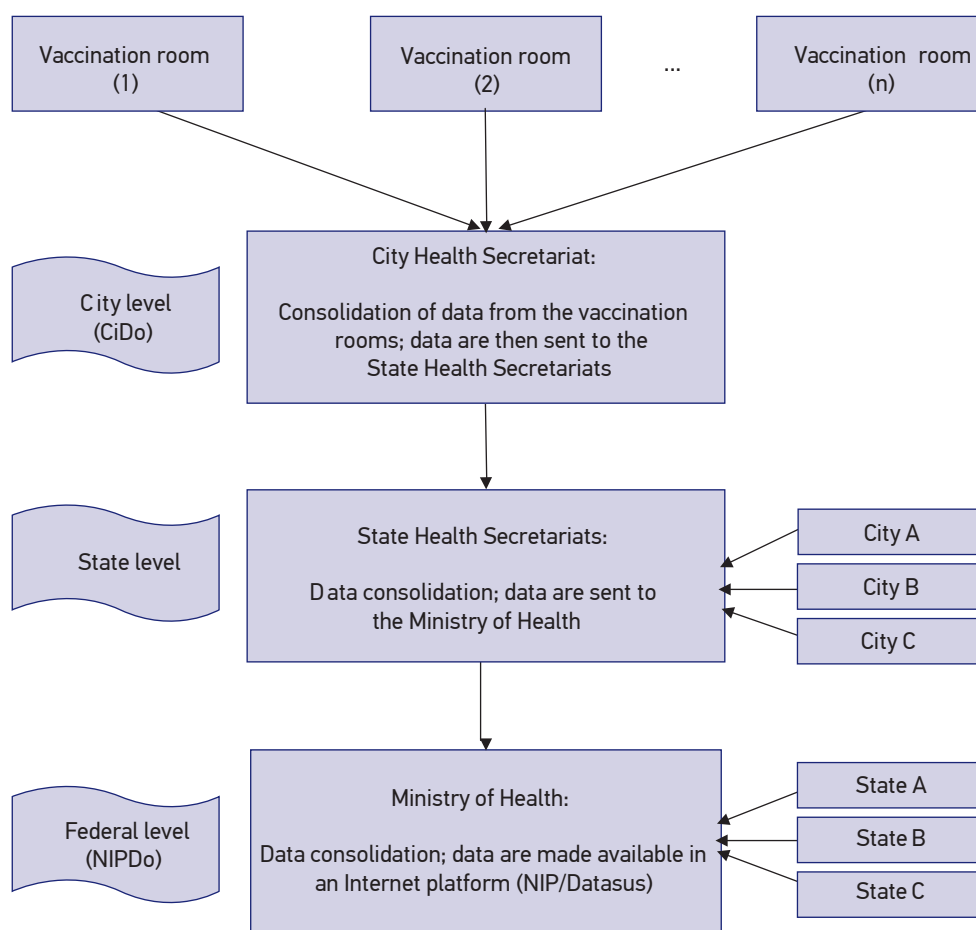
Figure 1. Data flow from the City level (CiDo) through the Federal level (NIPDo). Vaccine data are sent by Internet and made available for researchers, health planners and health professionals in a public available Internet platform (NIP/Datasus).

administered is consolidated monthly (manually, with the help of an electronic calculator). The monthly DTP doses administered in each vaccination room is transferred to a paper spreadsheet, which is then sent to the CHS-JF. In the CHS-JF, vaccine data concerning all the city vaccination rooms are added up with the help of a computer information system, especially designed to this end. This process results in a database, the total city doses administered (CiDo), which is sent by e-mail to the next level, the SHS-JF;

2. State level: The SHS receives monthly vaccine reports from all State cities. The SHS is divided in different notification sections, according to government-defined geographical regions. Data sent to the SHS are consolidated and then sent, also monthly, to the Ministry of Health, at the federal level;

3. Federal level: Vaccination data from all states of Brazil are sent to the Department of Health, Ministry of Health. These data are then made available in an information system (the mentioned NIP/Datasus Internet platform), and may be consulted for each Brazilian city for the variables number of doses administered, vaccine coverage and month/year of vaccine administration. Around two and three months are necessary for the city data to become available in this system.

For this study, data were collected from maps of the monthly vaccine doses administered in each vaccination room, and then grouped into monthly totals for all vaccination rooms (CiDo). These values were compared with the data related by the NIP/Datasus (NIPDo) by means of the Percentage (or Percent) error (Pe)[16]. Pe indicates the inaccuracy of a measurement and is expressed as[16]:

$$Pe = [(\text{Estimated value} - \text{Actual value}) / \text{Actual value}] * 100\% \qquad (1)$$

In this paper the Estimated value = NIPDo and the Actual value = CiDo; and the equation above becomes:

$$Pe = [(\text{NIPDo} - \text{CiDo}) / \text{CiDo}] * 100\% \qquad (2)$$

A positive Pe indicates that the number of doses administered is overestimated, and a negative Pe that this number is underestimated. If Pe is zero, NIPDo is the same as CiDo (a concordance between the two data sources, a desirable situation). Pe was estimated monthly, given that this was the study smallest observational unit. 95% confidence intervals (95%CI) for Pe were also estimated using standard statistical formula:

$$95\%CI = [d - (1.96)s / \text{sqrt}(n); d + (1.96)s / \text{sqrt}(n)] \qquad (3)$$

Where d is the mean, s is the estimated standard error, 1.96 is the critical $\alpha = 5\%$ Normal distribution value and n is the sample size.

RESULTS

The staff of the vaccination rooms receives periodic training on the correct procedures for administering vaccine doses, especially before large immunization campaigns or before the introduction of a new vaccine in the immunization schedule. However, it was not possible to identify training specifically directed to the management of vaccine supplies or to the importance of adequate data reporting. Checklists, procedures for data quality control or information feedback systems were not used, and data input had little or no direct supervision.

Table 1 shows the monthly and yearly CiDo, NIPDo and mean Pe values. This table shows that the mean Pe among different years varies from -8.24 to 11.04. Thus, for

Table 1. Number of montly data regarding the DTP vaccine registered in the vaccination rooms and in the PNI/Datasus platform (NIPDo), Juiz de Fora, Brazil, 2006–2010.

	Jan	Feb	Mar	Apr	May	June	July	Aug	Sep	Oct	Nov	Dec	Total
2006													
NIPDo	2,503	2,277	2,498	2,168	2,256	4,503	2,143	2,063	3,659	2,208	1,997	2,127	30,402
CiDo	2,547	2,302	2,502	1,749	2,510	4,487	2,116	1,963	3,901	2,174	2,003	2,088	30,342
2007													
NIPDo	2,211	2,193	2,470	2,643	2,229	4,598	1,664	3,663	1,504	1,645	1,997	1,480	28,297
CiDo	2,168	2,185	2,470	2,625	2,050	4,449	1,620	3,627	1,459	1,674	1,833	1,627	27,787
2008													
NIPDo	2,161	2,256	1,881	1,604	2,514	4,514	2,521	3,129	1,675	1,767	1,961	1,890	27,873
CiDo	2,265	2,156	1,909	2,289	1,967	4,693	1,810	2,884	1,689	1,802	1,891	1,792	27,147
2009													
NIPDo	2,056	2,269	2,330	2,479	2,076	4,576	1,693	1,979	3,848	1,626	2,307	1,868	27,917
CiDo	1,821	2,321	2,556	2,403	2,078	4,443	1,576	1,977	3,520	1,680	2,168	1,664	28,207
2010													
NIPDo	2,157	1,993	2,690	2,326	1,512	3,734	1,883	3,382	1,592	1,860	2,174	1,760	27,063
CiDo	1,649	1,995	2,752	2,195	2,929	3,355	1,796	3,302	1,609	1,859	2,037	1,826	27,304
Mean													
NIPDo	2,218	2,198	2,374	2,244	2,117	4,385	1,981	2,843	2,456	1,821	2,087	1,825	28,549
CiDo	2,090	2,192	2,438	2,252	2,307	4,285	1,784	2,751	2,436	1,838	1,986	1,799	28,157
Pe	6.12	0.27	-2.63	-0.36	-8.24	2.33	11.04	3.34	0.82	-0.92	5.09	1.45	

CiDo: city doses; NIPDo: National Immunization Program doses; Pe: percent error.

May, the mean of the DTP vaccine doses notified in the NIP/Datasus Internet platform was 8.24% lower than the number registered in the vaccination rooms, and for July the NIP/Datasus number was 11.04% higher than the number at the vaccination rooms. Figure 2 shows the NIPDo juxtaposed to the CiDo (x axis: Months; y axis: Number of doses); the peaks observed in Figure 2 correspond to well-publicized mass vaccination campaigns, when Poliomyelitis vaccine and DTP are, if necessary, administered at the same time. Figure 3 shows that Pe had, monthly, values from -0.48 to 0.39 (x axis: Months; y axis: Pe). In one of the sixty observed months (March/2007) Pe was zero (CiDo = NIPDo), resulting in an agreement between the two data sources of 1.66%. Overestimation was present in 37/60 months (61.66%) and underestimation in 22/60 months (36.66%). In Figure 3, a 95%CI was plotted (Mean = 2, Standard deviation = 11.86); Pe values in April/2006, May/2006, April/2008, May/2008, July/2008, Jan/2010 and May/2010 were not included in the CI.

DISCUSSION

In 2008, WHO estimated that 1.5 million of deaths among children under 5 years of age (17% of global total mortality in this age) were due to diseases that could have been prevented by routine vaccination[17]. Immunization is, therefore, one of the most effective strategies for preventing illnesses in children[18].
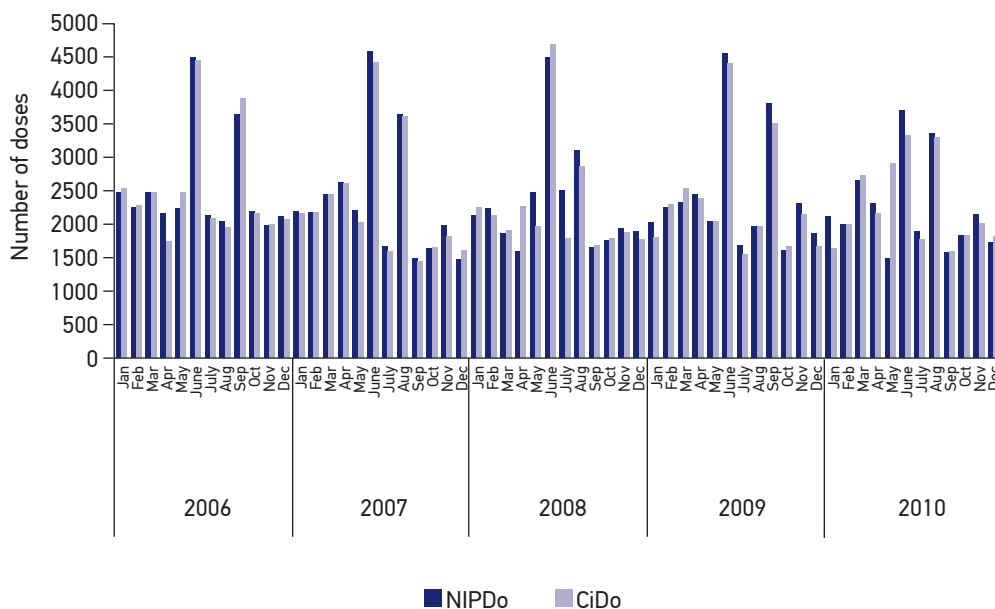

Figure 2. "Number of doses administered at the city vaccination rooms" (CiDo) and "Number of doses reported at the NIP/Datasus system" (NIPDo), monthly, DTP vaccine, 2006 – 2010.
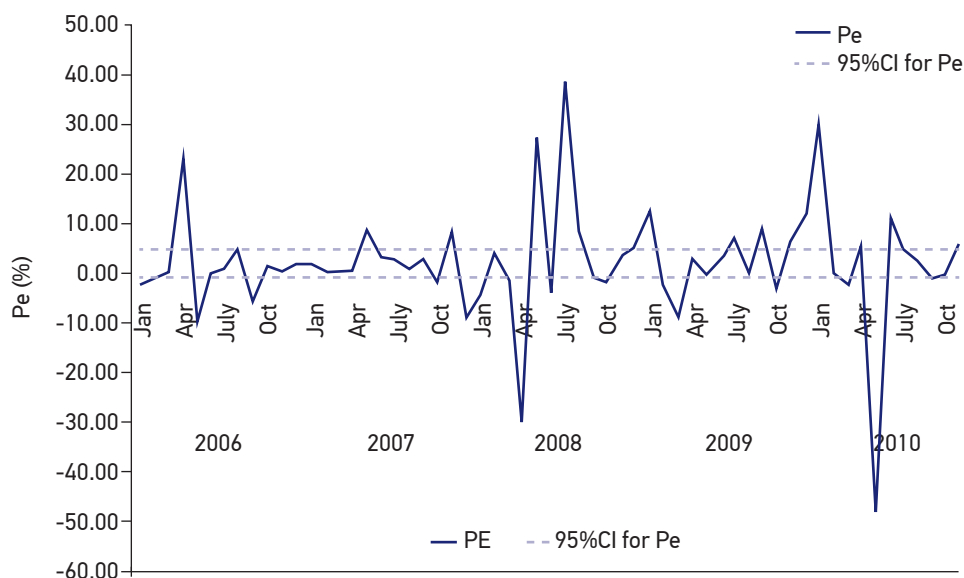
Figure 3. Percentage error (Pe) between the "Number of doses administered at the city vaccination rooms" (CiDo) and "Number of doses reported at the NIP/Datasus system" (NIPDo), monthly, DTP vaccine, 2006 – 2010, and 95% confidence intervals for Pe.

However, despite its importance, studies on the effective recording of vaccine data are not common, with few studies performed in Latin America[19]. Without adequate recording, it is to be expected that the planning and evaluation of immunization campaigns is seriously hindered[6]. Logistic planning for vaccine distribution should be based on solid and well-defined information, including previous supply and wastage values, so that future vaccine needs can be estimated with less error[20,21].

The Brazilian NIP began in 1973 with the purpose of coordinating vaccination policies at the national level. At first, only seven vaccines were made freely available by NIP: Poliomyelitis, Measles, Smallpox, Tuberculosis, DTP, Yellow fever and Tetanus vaccine[7]. Eventually, NIP was expanded and now includes fourteen vaccines, which are freely administered in about 30,000 vaccination rooms[22].

The choice of DTP to evaluate data concordance was based on the fact that this vaccine requires a minimum of three intramuscular shots, demanding a high degree of commitment by both the vaccination team and the target population[15]. The Global Alliance for Vaccines and Immunization (GAVI) finances children vaccination in 52 developing countries taking into account the results of DTP doses administered[15].

Although the worldwide number of vaccinated people increased in recent decades, information on the actual number of doses administered has been questioned, with

reports on large discrepancies between data at vaccination rooms and data notified by government information systems[2,14,23]. This is a serious problem, especially for developing countries, and such discrepancies have been identified, for instance, in Tunisia and Myanmar[2,14].

Besides mis-recording and over-reporting, sometimes registering errors may arise from the need to overestimate the number of doses administered, in order to fulfill governmental planning targets[24]. However, the probability of these errors in the Brazilian case is small, since, as mentioned, vaccine doses are registered in a specific spreadsheet. Additionally, recording takes place at the moment of vaccination, and each vaccination room manages a relatively small amount of information, so that it is expected that under (or over) estimation is not to be a great concern in the present case.

The results showed important differences in the city level data relatively to the federal level. These differences are especially visible when data are considered monthly — a necessary information, for instance, for vaccine purchasing, stocking and administering[25]. Thus, for instance, in May, 2010 it can be seen that NIPDo = 1,512 and CiDo = 2,959, and in April, 2006, NIPDo = 2,168 and CiDo = 1,749.

A lower number of doses administered was reported by the federal level in 36.66% of the months, while overestimation was present in 61.66% of them. Thus, in 59/60 (98.33%) of the months data disagreed between the two levels (Figures 2 and 3). This disagreement suggests the existence of serious errors in the data information flow, and implies in a severe problem for vaccine demand estimation, since the city level data are "lost" for planners. Although these errors cannot be expected to seriously affect coverage estimation (which is based on longer periods of time) errors in monthly vaccine data may hinder the construction of mathematical and epidemiological demand models[26]. These models, already widely used in some countries, depend on data as disaggregated as possible (for example, city level, weekly). Other concerns refer to disease outbreaks, demanding a rapid response and a good knowledge of the available vaccine supply and the mentioned need for an adequate balance of vaccine purchase and supply[25].

It follows from the above that studies relying on federal data probably incurred in large errors[27]. This is also a problem, since the federal level data is easy to access, is endorsed by the Ministry of Health and has a very wide coverage (all the cities of the country). An additional concern is that data inconsistency was detected in a typical southeastern city (one of the most developed regions of the country). Under these conditions, one could only fathom the degree of discrepancy that would have been found if the study had been performed in regions with less reliable information systems, such as the North-east and the North (Amazon). Unfortunately, these are the regions where this type of information is the most critical, since inaccurate estimation of vaccine needs can result in inadequate vaccine distribution and coverage, with the generation of preventable disease foci.

On the other hand, demand overestimation will most probably cause vaccine wastage and monetary losses[28].

Variations in recorded data also may be due to inconsistent data checking routines and lack of specialized training[2, 24]. Since 2010, the Ministry of Health of Brazil is developing an Internet platform, the Brazil´s Nominal Information System of the National Immunization Program[29], with the purpose of registering individual vaccination data for all residents in Brazil. This platform, to be installed in all vaccination rooms of the country, will be able to transmit data directly to the managers of the National Immunization Program[29]. However, although computers are already in use for the processing of vaccine administrative data in most of the world, for the most part procedures and routines for data transfer are still far from adequate[6,19,30]. Thus, the implementation of computerized tools for public health data processing is indeed necessary, but that this endeavor also requires a high commitment to the improvement of human resources, towards an effective management of information systems[31-34].

Another problem resulting from inadequate data recording is that international comparisons of vaccination rates and population coverage are hindered if no standardization can be expected in data collection[25]. Surveys can be used for such comparisons, but these are not equivalent to good quality administrative data, since the information provided by surveys pertains only to limited cohorts, which do not allow for consistent and reliable information flow[6,20]. Regarding the improvement of data collection and transmission systems, an ongoing effort concerns the implementation of the Information System of the National Immunization Program (SINIP), with the objective of facilitating vaccine demand planning and stock control[10].

A limitation of the present study is that the data collection concerned only one Brazilian city and one vaccine type. Although a rationale was offered for this approach, it would be interesting to obtain a more complete picture of the global situation of vaccine data recording in Brazil. However, as argued before, at the present time it is not possible to have an optimistic view about this situation, and higher degrees of discrepancy are to be expected in more rural areas of the country.

CONCLUSION

This study investigated the discrepancies between the monthly total number of DTP doses administered at vaccination rooms and that reported by the federal government. The large differences are, most probably, due to errors in the vaccine information transmission chain, which did not have the help of adequate backup and support systems, and thus, could not prevent human errors. The implementation of tools for vaccine data processing and analyzing is recommended.

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