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Rotavirus and Triple Viral Vaccine Losses in Vaccination Rooms: a Cross-Sectional Study

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OBJECTIVE: This study aimed to analyze Rotavirus (ROTA) and Measles, Mumps and Rubella (MMR) vaccine wastage in vaccination rooms of Juiz de Fora city, MG, Brazil, to identify factors related to this wastage.
METHODS: The study had a cross-sectional design, based on spreadsheets reporting monthly vaccine use in a year; and based on questionnaires applied to 45 urban vaccination rooms. A linear regression model was developed, endeavoring to predict vaccine loss rates using variables related to vaccination room infrastructure/operational conditions.
RESULTS: Statistical significance was detected for ROTA loss variables: vaccine knowledge, health unit type and number of personnel in the vaccination room (R2=0.33; p = 0.001). It was also found that 1,254 ROTA and 33,762 MMR doses were wasted during the period. Concerning ROTA, 331 (26.4%) were technical losses, and 923 (73.6%) miscellaneous losses; for the MMR vaccine, these numbers were 23,281 (68.96%) for technical losses and 10,481 (31.04%) for miscellaneous losses.
CONCLUSION: The percentage losses in the period were significant, which should induce the production of health protocols to facilitate the correction of weaknesses in the studied vaccine cold chain.

KEYWORDS: Rotavirus vaccine; MMR vaccine; Vaccine wastage.

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INTRODUCTION

Immunization is one of the most important health science discoveries; it is responsible for some of the greatest advances in health promotion and disease prevention.[1] Recent decades have witnessed a worldwide increase in the development and use of vaccines.[1,2] However, with their widespread use, losses related to their inadequate handling and application also became more frequent, calling for the implementation of measures to reduce such wastage.[3]

Vaccine wastage is defined as any non-used vaccine, and the World Health Organization (WHO) points to more than 50% of vaccine wastage worldwide.[4,5] Knowledge about this wastage is fundamental for estimating the amount of vaccines to be used in a community.[4,5] Thus, if vaccine losses are not correctly calculated, one may have either a lack or an excess of immunobiological products, leading, in the latter case, to further wastage. Although few studies have tried to quantify the amount of these losses in developing countries, it should be noted that physical damage, suspected contaminated vials, heat exposure, failures in refrigeration systems, losses during transportation and inventory losses are frequently mentioned among the causes of vaccine loss.[4,5]

In this work, we analyzed the vaccine losses of the monodose vaccine against Rotavirus and the multidose vaccine against Measles, Mumps and Rubella (Triple Viral - MMR) in vaccination rooms of the city of Juiz de Fora, (population: 500,000, HDI: 0.731), state of Minas Gerais, Brazil, with the objective of quantifying losses and identifying the relevant characteristics related to vaccine wastage. It will be seen that vaccine wastage rates were

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well above those deemed as "acceptable" by international agencies.

MATERIALS AND METHODS

The oral vaccine against Rotavirus and the Triple Viral injectable vaccine were chosen for this study, due to their extreme importance in the childhood immunization schedule and to their high immunization capacity. Data were obtained by means of spreadsheets with monthly vaccination records from January to December 2013; and by a questionnaire applied by the present research team in 45 vaccination rooms in the urban area of Juiz de Fora, MG, Brazil. The study was approved by the Ethics Committee of the University Hospital Clementino Fraga Filho of the Federal University of Rio de Janeiro (CEP/HUCFF-UFRJ) case # 707.490.

Data and variables. In order to assess losses, the following variables were obtained from the health units vaccination records: *Previous Stock* (number of doses of vaccines in each health unit), *Doses Received* (doses actually delivered to the vaccination room), *Applied Doses* (number of vaccines effectively administered), *Technical Losses* (losses due to error in application), *Miscellaneous Losses* (losses due to the expiration of the vaccine dose and other losses due to unidentified causes), *Missed Doses* (Technical Losses added to Miscellaneous Losses), and *Current Inventory* (stocks at the health unit at the time of the data collection).

Other variables, obtained through a questionnaire, referred to the infrastructure and operating conditions of the studied units, and concerned the type of *health unit* in charge of vaccination (Family Medicine or "Traditional" health unit); *Vaccine knowledge*; *Vaccine storage* conditions (in refrigerators and in thermal boxes)*; Refrigerator shelf temperature measured with a laser thermometer* and with a *regular thermometer; Thermal box temperature measured with a laser* and with a *regular thermometer* and *Preventive maintenance* of refrigerators and storage systems (see below).

The variable *Vaccine knowledge* was built from answers given to three questions asked to the professional in charge of the vaccination room. These questions concerned their ability to mention a live virus vaccine, their knowledge about the correct placement of vaccines inside a refrigerator and their capacity to correctly identify what is worse for a vaccine: "heating" or "freezing" (correct answer: worse is freezing). *Partial vaccine knowledge* meant that at least one question was correctly answered; *adequate knowledge* meant that all questions were correctly answered, and *inadequate knowledge* meant no correct answer.

Shelf and thermal box temperatures were measured with the (regularly used) health unit thermometer and also by the research team responsible for the present study, with the help of a calibrated laser thermometer. Temperatures were considered as adequate when inside the 2° - 8°C range, and inadequate otherwise. Maintenance was defined as adequate when it followed the Ministry of Health guidelines (at least biannual full maintenance procedures)[6].

Vaccine storage in refrigerators was assessed by means of a visual inspection at the time of the visit to the health units. Eight items were used to this end (positive characteristic when present): (1) thermogel storage in upright position, (2) storage of attenuated vaccines on the lower refrigerator shelf, (3) storage of inactivated vaccines on the second shelf, (4) placement of a thermometer in the center of the second shelf, (5) diluents and other stocked vaccines on the third shelf, (6) no shelves/support structure on the inside of the refrigerator door, (7) freezing compartment with door and support structure and (8) presence of 12 bottles of water with dye in the lower drawer of the refrigerator (to help stabilize temperatures)[6]. For this variable, "adequate" meant all positive characteristics were present. For the thermal boxes, adequate storage meant presence of a thermometer sensor in the center of the box and presence of plastic containers for vaccine inside the box[6].

Analysis. Wastage rates were estimated monthly and aggregated for all studied health units. We considered as vaccine loss any vaccine dose lost due to vial contamination, expiration, breakage or failures in the cold chain.[6] These losses were analyzed according to two procedures:

a) Estimation of vaccine wastage rates by means of the following equation:

Vaccine wastage rate = number of lost doses / number of doses received by the health unit

b) Modeling: Variables mentioned above as "obtained through a questionnaire" were considered as independent predictors in two multiple linear regressions, which had 1) ROTA and 2) MMR loss rates as dependent variables (significance level $\alpha = 0.05$). Binary variables were rated "0" for inadequate. "1" for "adequate". A stepwise-selection procedure was used for model building, and data were analyzed in the Statistical Package for Social Sciences (SPSS), v. 22.0.[7]

RESULTS

The studied city had 63 Primary Health Care Units, out of which 21 were "traditional" health units (12 urban and 9 rural) and 42 were Family Health units (36 urban and 6 rural). The 48 urban vaccination rooms were selected for analysis; two declined to participate and one was not operational at the time of the research. Therefore, 45 units effectively studied (12 "traditional" and 33 Family Health).

Table 1 shows that for the January - December 2013 period, there were 1,254 lost doses of ROTA, 331 (26.4%) of which were due to technical losses; for the MMR vaccine, 33,762 doses were lost, 23,281 (68.96%) due to technical losses.

Table 1 - Monthly consolidated data for Rotavirus and Triple Viral (MMR) vaccines, 45 studied vaccination rooms, Juiz de Fora, MG, Brazil, January-December 2013.

¡	Previous stock	Doses received	Applied doses	Technical losses	Miscellaneous losses	Current stock
Rotavirus						
January	991	610	735	0	38	862
February	855	810	696	5	3	930
March	958	820	649	21	88	999
April	954	805	761	5	43	980
May	984	746	681	0	3	1027
June	1065	1118	730	18	115	1456
July	1444	620	701	22	12	1306
August	1319	825	804	3	109	1256
September	1255	1060	737	73	63	1427
October	1402	585	705	130	306	799
November	792	820	642	3	31	925
December	867	276	485	51	112	478
Triple Viral						
January	4231	3300	784	1909	1198	3765
February	3570	3970	804	2377	732	3494
March	3640	4040	662	2608	862	3390
April	3240	5310	1142	2313	1214	3783
May	3783	5030	942	2465	805	4185
June	4237	4190	2511	2314	1177	2397
July	2437	2950	992	1785	802	1613
August	1573	3570	1392	932	549	2315
September	2225	5190	1927	2682	1028	1574
October	1574	3560	623	1699	704	1700
November	1700	3170	484	1352	627	2400
November	2120	1180	377	845	783	1221

Variables collected through the questionnaire are presented in Table 2. Large differences were detected for temperature measurements with the regular health unit thermometer and with the calibrated laser thermometer, both for refrigerators and thermal boxes. In addition, 75.6% of the units did not correctly follow the standards for refrigerator vaccine storage, while 38.9% did not correctly follow the standards for thermal box vaccine storage.

The following variables achieved statistical significance when used as predictors in the linear regression model with ROTA as the dependent variable: *Vaccine knowledge* (p-value=0.001), *Type of unit* (p-value=0.009) and *Number of employees working in the vaccination room* (p-value=0.046). This model had $R^2 = 0.33$; p-value = 0.001; with equation:

ROTA loss rate = 12.47 + (16.76)[Vaccine knowledge] – (12.48)[Type of unit] – (2.45)[Number of employees in vaccination room]

DISCUSSION

Among the vaccines offered by the Brazilian National Immunization Program (PNI), the oral vaccine against Rotavirus and the Triple Viral injectable vaccine were chosen for this study, due to their extreme importance in the childhood immunization schedule and to their high immunization capacity.

The present study detected high rates of vaccine wastage in Juiz de Fora - MG, both for ROTA and for MMR vaccines, with percentages higher than those defined as "tolerable" by WHO (5% and 25%, respectively)[3]. This information adds to the body of knowledge showing high vaccine wastage rates for developing nations. For instance, an analysis of the distribution and wastage of vaccine doses in a municipality in the metropolitan region of Curitiba, PR, Brazil showed that the Triple Viral vaccine had an extremely high 91.13% wastage rate; in contrast, the Rotavirus vaccine reached a quasi-tolerable rate of 6.23%.[8]

Table 2 - Infrastructure variables with their respective frequencies, 45 vaccination rooms, Juiz de Fora, MG, Brazil; January-December 2013. n: number of health units. All temperatures were considered as adequate when inside the 2° - 8°C range.

Variable	Categories	Percent (%) / n
Health unit type	Family Medicine	73.3 (33)
	Traditional	26.7 (12)
Vaccine knowledge	Adequate	13.6 (6)
	Partial	82.2 (37)
	Inadequate	4.4 (2)
Vaccine storage (refrigerators)	Adequate	24.4 (11)
	Inadequate	75.6 (34)
Vaccine storage (thermal boxes)	Adequate	61.1 (58)
	Inadequate	38.9 (37)
Refrigerator shelf temperature, regular thermometer	Adequate	77.8 (35)
	Inadequate	22.2 (10)
Refrigerator shelf temperature, laser thermometer	Adequate	64.4 (29)
	Inadequate	35.6 (16)
Preventive maintenance	Adequate	2.2 (1)
	Inadequate	97.8 (44)
Thermal box temperature, regular thermometer	Adequate	50.5 (59)
	Inadequate	49.5 (47)
Thermal box temperature, laser thermometer	Adequate	62.1 (59)
	Inadequate	37.9 (36)

A discrepancy may be noticed in Table 1 concerning the registered monthly stocks, that is, stocks do not always "match" after considering losses and applied doses. This discrepancy, due to stock control deficiencies (manual control), was typically below 5% and did not have a preferred direction of variation (changes fluctuate up and down the registered values). Therefore, the differences could be thought of as random noise and were not considered to influence models and lead to evaluation losses.

Regarding the infrastructure of the studied health units, Table 2 shows that most vaccination rooms did not follow the recommended procedures for vaccine storage recommended by the Ministry of Health cold chain guidelines.[6] There were also important differences between the thermometer routinely used by the health units and the research team laser thermometer measurements, both for the refrigerators and for the thermal boxes.

Model results indicated that vaccine discarding increased with increased knowledge about vaccines, with the type of health unit ("Family Medicine" units discarding less) and with the number of employees in the vaccination room (the higher the number, the lower the losses). Other studies also show inadequate knowledge of professionals in vaccine rooms, for example in relation to immunobiological conservation, indicating the need of continuous updating on vaccine and immunization practices.[9-11]

The possible causes for the high losses observed are not detailed here, but the international literature points to the importance of vaccination conservation and shelf life, the exposure of vaccines to freezing temperatures in storage, and transportation-related problems.[12,13] Also mentioned are the lack of refrigerator temperature monitoring and the inappropriate placement of vaccines (such as in refrigerator doors);[14,15] all of these problems are in agreement with the present results, which detected inadequate monitoring procedures in a large proportion of the studied health units. In this respect, an important observation was made in India, where a reduction of approximately 50% in wastage rates was achieved by means of the implementation of an 'open vial' policy (discarding all open vials at the end of a vaccination session, regardless of the number of remaining doses).[16]

The literature also shows that the physical structure and infrastructure of vaccination rooms strongly influence the quality of service and the occurrence of vaccine losses. The Ministry of Health guidelines for physical structure and architecture in health units[17] defines appropriate parameters for these rooms, such as "...presence of sinks; water taps that do not require the use of hands; use of paper towel holders and liquid soap dispensers; trash cans with lids and pedals; 260 liter-refrigerators, minimum area of $9m^2$ for the vaccination rooms and prevention of sunlight inside vaccination rooms".[17] The disregard for these

recommendations may be one of the factors leading to high vaccine losses observed in this study.

CONCLUSION

We identified a high percentage of vaccine wastage in the studied vaccination rooms. The study also stresses the relevance of vaccine handling knowledge for the professionals involved in vaccine administration. It also draws attention to the need of developing protocols that could allow for the elimination of fragile links in vaccine application chains at city level. As a limitation, the present study was not able to identify the specific problems related to the high vaccine wastage rates that were detected.

AUTHOR CONTRIBUTION

BD collected data, contributed to the statistical analysis and wrote the manuscript; RA designed the study, contributed to the statistical analysis and wrote the manuscript.

CONFLICTS OF INTEREST

The authors declare no conflict of interests pertaining to the present work.

PERDA DE VACINA ANTI ROTAVÍRUS E VIRAL TRIPLA EM SALAS DE VACINAÇÃO: ESTUDO TRANSVERSAL

RESUMO: Este estudo analisou as perdas vacinais das vacinas contra o Rotavírus (ROTA) e contra o Sarampo, Caxumba e Rubéola (VTV) em salas de vacinação de Juiz de Fora, MG, a fim de identificar os fatores relacionados a essas perdas.

MÉTODO: Tratou-se de um estudo transversal, baseado na análise dos movimentos mensais das vacinas estudadas durante um ano, por meio de planilhas e de questionários aplicados em 45 salas de vacinação urbanas. Um modelo de regressão linear foi desenvolvido, tentando prever perdas vacinais por meio de variáveis de infra-estrutura e funcionamento das salas.

RESULTADOS: Foi detectada significância estatística para o modelo ROTA, variáveis: *conhecimento sobre vacinas, tipo de unidade* e *número de funcionários que atuam na sala de vacina* (R^2=0,33; p = 0,001). Constatou-se 1254 doses perdidas de ROTA e 33762 de VTV durante o período pesquisado. Das 1254 doses perdidas de ROTA, 331 (26,4%) foram devidas a *Perdas Técnicas*, e 923 (73,6%) a *Perdas Diversas*. Para a vacina VTV, das 33762 doses perdidas, 23281 (68,96%) foram por *Perdas Técnicas*, e 10481 (31,04%) por *Perdas Diversas*.

CONCLUSÃO: Conclui-se que as perdas percentuais, no período, foram significantes, podendo instigar a produção de protocolos de saúde para auxiliar a eliminação dos pontos frágeis na cadeia de aplicação das vacinas.

PALAVRAS-CHAVE: Vacina contra Rotavírus, Vacina contra sarampo/caxumba/rubéola, Perdas vacinais.

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