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HEALTH SCIENCES

Estimated quantification of residual volume in vaccines supplies and its impact on the Brazilian health system

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Abstract: Between 2017 and 2021, the Brazilian Unified Health System (BUHS) administered a total of 527,903,302 doses of immunizations. Each immunization results in the presence of a residual volume (RV) due to syringe dead space (DS). The International Organization for Standardization 7886-1 allows a DS of up to 0.07mL in sterile single-use hypodermic syringes with volumes less than 5mL. This study aims to quantify the DS of immunization devices used in Brazil, study the best combinations of needles and syringes to minimize RV, estimate the number of wasted doses from 2017 to 2021, and evaluate the impact on the BUHS. Pneumococcal 10 vaccine with a 25x6mm needle and a regular 1mL syringe exhibited a significantly higher average RV (0.0826mL) and waste rate (14.42%). It was observed that for some intramuscular vaccines, there is less waste when using a 20x5.5mm needle compared to a 25x6mm needle. The use of syringes with plunger stoppers that penetrate the syringe barrel, denoted as low dead space syringes, results in less RV and an estimated difference in the waste rate of approximately 10% compared to the regular syringe. The estimated number of wasted doses from 2017 to 2021 by BUHS is approximately 32 million doses.

Key words: Dead space, needles, residual volume, syringes, vaccine supplies.

INTRODUCTION

From 2017 to 2021, the Brazilian Unified Health System (BUHS) administered a total of 527,903,302 doses of immunizations (DATASUS 2022). Nevertheless, current immunization cannot fully administer the agent contained in the syringe/needle, which leads to the presence of a residual volume (RV) in the syringe/needle. The RV is caused by dead space (DS), a technical limitation of the syringe/needle that hinders complete expulsion of the vaccine/drug (ANVISA 2021a, Ministério da Saúde 2021).

The International Organization for Standardization 7886-1 allows for up to 0.07mL of DS in sterile single-use hypodermic syringes. It is known that the average volume of immunizations administered in Brazil is 0.5 mL. Therefore, the acceptable waste for immunizations under the National Immunization Plan (NIP) is up to 14%, as up to 14 doses may be wasted due to the RV for every 100 doses administered. Pharmaceutical industries recognize this RV and fill ampoules with overfill, which means they fill them with the volume of the dose plus the RV recommended by current standards (ANVISA 2021b, ISO 7886-1 2020, INMETRO 2020).

Vaccine wastage has always been a topic discussed in the literature (Karpuz & Özer 2016, Setia et al. 2002). Studies demonstrate various aspects that can result in wastage, such as the difference between single-dose or multi-dose vaccines, refrigeration, distribution chain, lyophilized or non-lyophilized vaccines, and geographic characteristics of the area where the vaccine will be applied (Parmar et al. 2010, Usuf et al. 2018). Another crucial consideration in vaccine wastage involves distinguishing between Low Dead Space (LDS) and High Dead Space (HDS) syringes, primarily based on the presence of a syringe with a plunger stopper that enters the barrel (PSTEB). This distinction substantially minimizes dead space, resulting in the use of LDS syringes (Shinozuka et al. 2021). In developing countries, the wastage rate can reach up to 50% when considering the entire logistics chain, resulting in a lower vaccination rate and higher expenditure on vaccines (WHO 2005, U.S. Government Accountability Office 1999).

However, the RV of syringes and needles, a factor that has been rarely considered in studies on vaccine wastage, gained prominence during the COVID-19 pandemic, particularly due to the limited availability of vaccine doses and the severity of the pandemic crisis (Smith et al. 2021, Strauss et al. 2006). Difficulties in obtaining the maximum number of doses per vial were observed in the Pfizer/BioNTech and Butantan/CoronaVac vaccines, mainly due to the use of syringes with high DS. In these cases, the number of obtained doses was 6 out of 7 possible for Pfizer/BioNTech and 9 out of 10 possible for Butantan/CoronaVac (ANVISA 2021a, Smith et al. 2021, Strauss et al. 2006).

Given this scenario, this study aims to quantify the DS of immunization devices available in the NIP using syringes and needles provided by the Brazilian healthcare system. The study aims to identify the best combinations of needles and syringes to obtain a lower DS and, consequently, reduce waste. Subsequently, the study aims to estimate the number of wasted doses between 2017-2021 and evaluate the impact of this waste on the UHS.

MATERIALS AND METHODS

It is a quantitative descriptive study conducted at the Laboratório de Imunologia e Bioinformática da Universidade Federal do Triângulo Mineiro. The materials used consisted of vaccines, syringes, and needles that were past their expiration date, provided by the health department of the city of Uberaba-MG. The needles and syringes evaluated, as well as the application methodology - injection site, needle gauge, and syringe volume - followed the Manual of Norms and Procedures for Vaccination of the Brazilian Ministry of Health. The vaccines and their respective needles/syringes used are illustrated in Table I.

For single-dose vaccines, the entire contents of the vaccine vial were extracted, and for multi-dose vaccines only the recommended dose was extracted. Afterwards, air bubbles were removed, the plunger was set to the 0.5mL mark, the plunger was moved to the 0mL mark simulating injection, the plunger was then returned to the 0.5mL mark, and the RV was visually analyzed, and the data was collected. Vaccine vials were refrigerated and stored in accordance with the Ministry of Health's Cold Chain Manual.

The average residual volume (RV_a) as calculated for each vaccine using Equation 1.

$$RV_a = \frac{\sum RV}{N_d} \qquad (1)$$

Where,

RV_a= The average residual volume of the immunizing agent,

Table I.Description of vaccines, number of doses, needles, and syringes used in the study.

Vaccines	Doses	Needles	Syringes
P10	25	20x5.5mm	1 mL
P10	25	25x6mm	1 mL
P10	25	25x7mm	1 mL
VA	30	13x4.5mm	1 mL
YF	30	13x4.5mm	1 mL
HPV	30	20x5.5mm	1 mL
HPV	30	25x6mm	1 mL
HA	25	20x5.5mm	1 mL
HA	25	25x6mm	1 mL
MenACWY	30	20x5.5mm	1 mL
MenACWY	30	25x6mm	1 mL
Pentavalent	30	20x5.5mm	1 mL
Pentavalent	30	25x6mm	1 mL
Influenza	30	20x5.5mm	1 mL
Influenza	30	25x6mm	1 mL
DTaP	30	20x5.5mm	1 mL
MenC	30	20x5.5mm	1 mL
MMR	30	13x4.5mm	1 mL
MMR	30	13x4.5mm	1mL LDS

P10 = Pneumococcal 10; VA = Varicella; YF = Yellow Fever; HPV = Humam Papillomavirus; HA = Hepatitis A; MenACWY = Meningococcal ACWY; Pentvalent = DTaP + Haemophilus influenzae +Hepatitis B; DTaP = Diphtheria + Tetanus + Pertussis; MenC = Meningococcal C; MMR = Measles + Mumps + Rubella.

ΣRV = The sum of all residual volumes obtained by visual analysis of the vaccine,

N_d = Number of analyzed doses of the immunizing agent.

Waste rate (WR) was calculated for each vaccine using the Equation 2. Thus, we were able to estimate the percentage of waste of a particular vaccine for each application performed.

$$WR = \left(\frac{RV_a}{V_d}\right)*100 \qquad (2)$$

Where,

WR = Waste rate of the immunizing agent,

RV_a= The average residual volume of the immunizing agent,

V_d= Volume of the vaccine dose.

The amount of wasted doses (WD) from 2017 to 2021 was estimated through the calculation shown in Equation 3.

$$WD = WR * D \qquad (3)$$

Where,

WD= Estimated amount of wasted doses from the vaccine in the years 2017 to 2021.

WR = Waste rate of the immunizing agent,

D = Number of doses administered of the immunizer from 2017 to 2021.

RESULTS

The doses were administered, and after visual recording of RV, descriptive analysis was used to calculate the means and standard deviations of RV, the values of which are shown in Table II. We observed that the highest waste was P10 25x6mm with an average RV of 0.0826 ± 0.0083 mL and a waste rate of 14.42 ± 3.6%. The lowest waste was MMR 13x4.5mm LDS with an average RV of 0.0153 ± 0.0073 mL and a waste rate of 3.06 ± 1.46%.

To assess which syringe/needle set would have a lower mean RV in vaccines administered by the intramuscular route, we selected the P10 immunizer and, using a regular 1mL syringe, estimated the mean RVs with the different needles 20x5.5mm, 25x6mm, 25x7mm. After analysis, it was found that P10 with a 20x5.5mm needle has a significantly lower mean RV when compared to P10 with a 25x6mm needle. When compared to P10 with a 25x7mm needle, there was no significant difference, just as there was no difference between P10 with a 25x6 needle when compared to P10 with a 25x7mm needle, as shown in Figure 1.

Table II. Descriptive analysis of the RV.

Vaccine	RV (mL)	Waste (%)	CV (%)
P10 20x5.5	0.0721±0.0183	14.42±3.66	25.38
P10 25x6	0.0826±0.0083	16.52±1.66	10.05
P10 25x7	0.0763±0.0107	15.26±2.14	14.02
VA 13x4.5	0.0568±0.0108	11.36±2.16	19.01
YF 13x4.5	0.0464±0.0109	9.28±2.18	23.49
HPV 20x5.5	0.0627±0.0111	12.54±2.22	17.70
HPV 25x6	0.0613±0.0125	12.26±2.5	20.39
HA 20x5.5	0.0576±0.013	11.52±2.6	22.57
HA 25x6	0.0716±0.0094	14.32±1.88	13.13
MenACWY 20x5.5	0.055±0.0123	11±2.46	22.36
MenACWY 25x6	0.0617±0.0115	12.34±2.3	18.64
Pentavalent 20x5.5	0.062±0.0122	12.4±2.44	19.68
Pentavalent 25x6	0.0673±0.0114	13.46±2.28	16.94
Influenza 20x5.5	0.0473±0.0074	9.46±1.48	15.64
Influenza 25x6	0.0678±0.0067	13.56±1.34	9.88
DTaP 20x5.5	0.0634±0.0115	12.68±2.3	18.14
MenC 20x5.5	0.0467±0.0071	9.34±1.42	15.20
MMR 13x4.5	0.0663±0.0125	13.26±2.5	18.85
MMR 13x4.5 LDS	0.0153±0.0073	3.06±1.46	47.71

In RV, the average residual volumes plus standard deviation are shown. In Waste, the estimated waste rate plus standard deviation is shown. CV = Coefficient of Variation. P10 = Pneumococcal 10; VA = Varicella; YF = Yellow Fever; HPV = Human Papillomavirus; HA = Hepatitis A; MenACWY = Meningococcal ACWY; Pentavalent = DTaP + Haemophilus influenzae + Hepatitis B; DTaP = Diphtheria + Tetanus + Pertussis; MenC = Meningococcal C; MMR = Measles + Mumps + Rubella.

To evaluate whether different syringes could result in lower average residual volume (RV), we selected the MMR vaccine and using 13x4.5mm needles, compared regular 1mL syringes with LDS 1mL syringes. After analysis, it was found that the LDS syringe with 13x4.5mm needle has a significantly lower RV compared to the regular 1mL syringe with 13x4.5mm needle for the MMR vaccine, as shown in Figure 2.

We observed through descriptive analysis that the difference in the average residual volume between the regular 1mL syringe and the LDS syringe is 0.051mL. This implies an estimated difference in the waste rate of approximately 10%. Thus, by opting for LDS syringes when administering MMR, compared to regular syringes, a savings of 10 doses can be estimated for every 100 applications. In the schematic design of the two syringes tested, Figure 3a, b, it is noticeable that the RV in the LDS syringes is reduced, where the retention plug has a shape that allows it to enter the barrel, resulting in greater expulsion of the administered vaccine and significantly reducing the RV.

To evaluate whether there is a difference in the average dead volume between the 20x5.5mm and 25x6mm needles as found in P10, we conducted tests with other intramuscularly administered vaccines, including HPV, Hepatitis A, MenACWY, Pentavalent, and Influenza. When we analyzed the results, we found that the average dead volume of the Hepatitis A, MenACWY, and Influenza vaccines was significantly lower in the regular syringe and 20x5.5mm needle set compared to the regular syringe and 25x6mm needle set. There was no statistical significance between the HPV and Pentavalent vaccines in the same comparison, as shown in Figure 4a-e. It is worth noting that the residual space of the tested syringes is the same for each tested dose. However, some factors may influence the dead volume, such as the viscosity of the agent and the pressure exerted on the plunger during injection, which may explain the appearance of significance in some vaccines and not others (Krisdiyanto et al. 2022, Karpuz & Özer 2016).

With the above finding, we conducted an evaluation of the distribution of average RV in different groups. It is noted that for subcutaneous vaccines with a regular 1mL syringe and 13x4.5mm needle, there is a heterogeneous distribution in

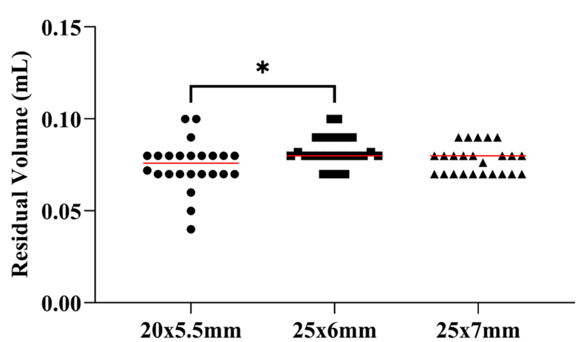

Figure 1. Analysis of needles 20x5.5mm, 25x6mm, and 25x7mm with a 1mL regular syringe for P10 vaccine. Kruskal-Wallis test with Dunn's post-test was used, where * equals p = 0.0091. Each symbol represents the quantification of an individual residual volume, with different symbols denoting different needles used.

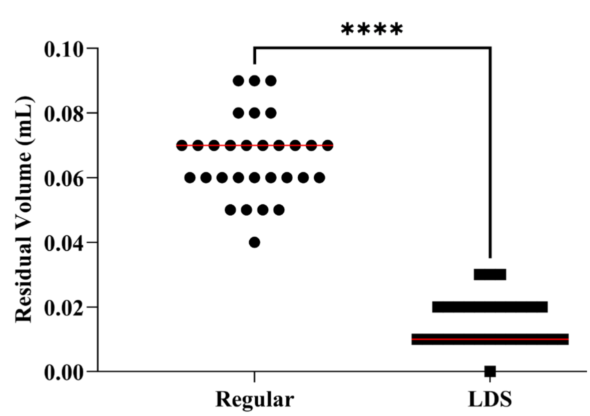

Figure 2. Analysis was performed on regular syringes and LDS syringes with a 13x4.5mm needle for the MMR vaccine. Statistical analysis using the Mann-Whitney test, where **** represents p < 0.0001. Each symbol represents the quantification of an individual residual volume, with different symbols denoting different syringes used.

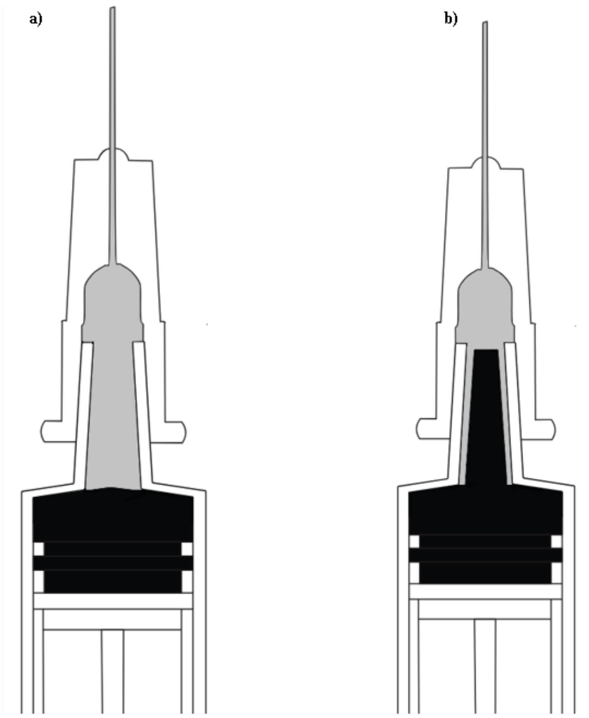

Figure 3. Schematic drawing of the syringes used is presented, where a) represents a regular 1mL syringe, in gray representing the DS of the syringe/needle, in black representing the retention plug, and b) represents a LDS 1mL syringe, in gray representing the DS of the syringe/needle, in black representing the retention plug.

the medians of MMR = 0.07mL, Varicella = 0.06mL, and YF = 0.05mL. In addition to factors that can influence this variance, considering that the DS of the syringes and needles used in this group was the same, another factor that can lead to this result is the limitation of RV observation by visual analysis. This variance is also observed in intramuscular vaccines with a regular 1mL syringe and 20x5.5mm needle, as demonstrated in Figure 5a, b.

We evaluated the estimate of the number of vaccine doses wasted by the Brazilian health system from 2017-2021 using equation 3. The estimate was made using the vaccines present in the NIP together with the most used syringes and needles in the health system (1mL regular syringes, 13x4.5mm needles for subcutaneous vaccines, and 20x5.5mm needles for intramuscular vaccines). The total estimated wastage, considering only the studied vaccine agents, is 32.149.202 doses, as shown in Figure 6. Among the vaccines with estimated wastage, the MMR vaccine showed the highest wastage of doses with a total of 7.427.933 doses, and the MenACWY vaccine showed the lowest wastage with 436.950 doses. It is worth noting that the latter vaccine is only applied to special groups within the Brazilian territory, with MenC vaccine (4.202.337 wasted doses) being used in vaccination against Meningococcus in individuals without comorbidities or outside the target population for MenACWY.

DISCUSSION

There are no studies in the literature that estimate the average wastage rate present in vaccines applied in the NIP. By quantifying the average wastage rate, it becomes evident that the result is very close to the limit established by ABNT. Thus, it is possible to estimate a wastage rate of up to 14% for the acceptable operational loss according to the current technical standards (ANVISA 2021a, ISO 7886-1 2017, INMETRO 2020).

Moreover, a study reported that when a batch of Pfizer COVID-19 vaccine vials was received for the vaccination of 1.242 healthcare workers, only 975 of them (78.5%) could be successfully immunized (Shinozuka et al. 2021). This finding is of particular significance as it demonstrates a substantial operational loss of 21.5%, considerably higher than the figures observed in our own investigation. It is worth noting that unlike the vaccine doses employed in our study (0.05 mL), the Pfizer COVID-19 vaccine administered to adults consists of 0.03 mL per dose. Accounting for the DS allowance stipulated by ISO 7886-1, which is 0.07 mL, results in a wastage rate of 21%. This underscores

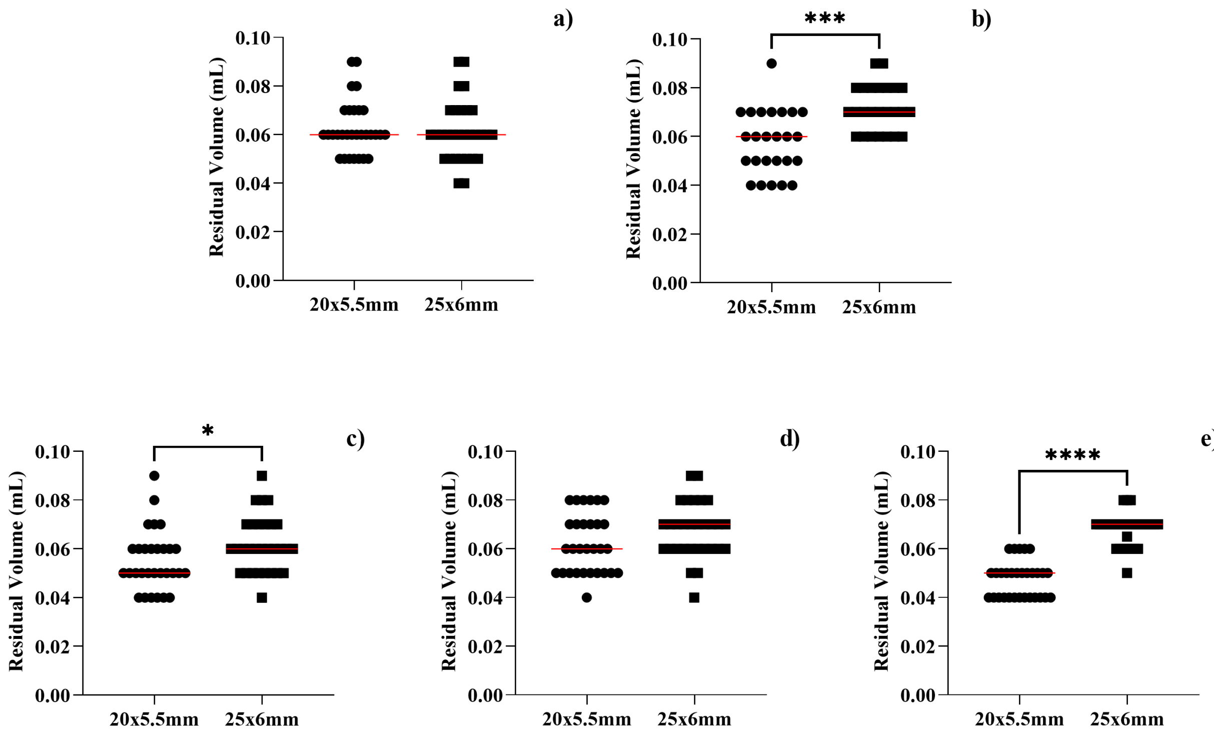

Figure 4. Analysis of different intramuscularly administered immunizations comparing 20x5.5mm and 25x6mm gauge needles with 1mL regular syringes. a) HPV, b) Hepatitis A, c) MenACWY, d) Pentavalent, and e) Influenza. Statistical analysis using the Mann-Whitney test, where *, *, and **** indicate $p < 0.05$. Each symbol represents the quantification of an individual residual volume, with different symbols denoting different needles used.**

the fact that the volume of the vaccine dose administered inversely correlates with the wastage rate of doses.

On the other hand, one way to overcome this wastage has been described as the Air-Filled Technique, which involves filling part of the syringe with air that occupies the dead space, allowing the proper extraction of the immunization without it remaining within the syringe/needle system after the application. Researchers have pointed out that this technique can extract 12 out of the 10 recommended doses of the ChAdox1-n CoV Vaccine (Prueksaanantakal et al. 2023).

Additionally, an important factor to be noted is the predicted operational loss due to syringe dead space at immunizations leads to overfill, exceeding the recommended dose, and increasing the cost of obtaining sufficient doses. As pointed out in other studies, if there were enough adequate supplies, the overfill would be lower, and there would be greater availability of immunobiological to produce a greater number of doses, resulting in a lower impact in UHS (Shinozuka et al. 2021, Smith et al. 2021, Strauss et al. 2006).

Our study estimates a waste of approximately 32 million doses in the NIP with only the evaluated vaccines in the years 2017-2021. There is a need to explore strategies to minimize the residual volume. Our findings suggest that using the LDS syringe can decrease waste by up to 10% due to its modified plunger stopper, this is consistent with findings from other studies (Shinozuka et al. 2021, Smith et al. 2021, WHO 2005). Moreover, the use of 20x5.5mm gauge needles for intramuscular vaccines results in lower average wastage compared to 25x6mm

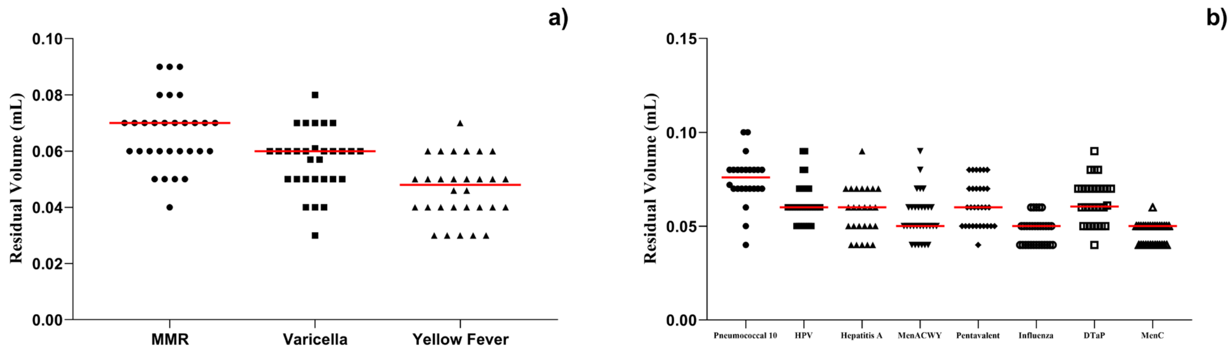

Figure 5. **Distribution of average RV in the various vaccines tested, with different median RV values highlighted in red. a) Subcutaneous vaccines, regular syringes and 13x4.5mm needles, b) Intramuscular vaccines, regular syringes and 20x5.5mm needles. Each symbol represents the quantification of an individual residual volume, with different symbols denoting distinct types of vaccine used.**

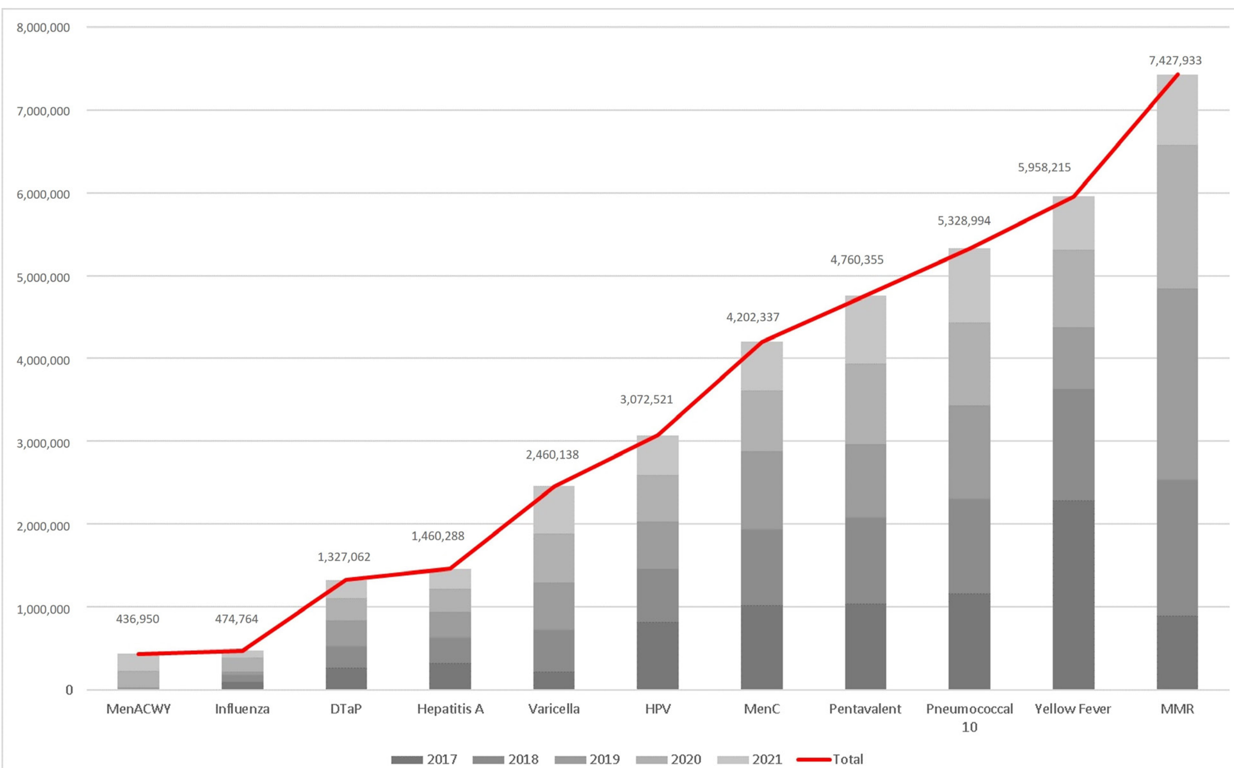

Figure 6. **Analysis of the estimated amount of wasted doses due to RV from the years 2017 to 2021 in the Brazilian health system. The grayscale represents the years and the number of estimated wasted doses each year, and the solid red line represents the total estimated wasted doses.**

gauge needles. This discrepancy can be primarily attributed to the internal diameter and size of the needle, which influences dead space due to its intrinsic characteristics. Smaller needles with reduced internal volume inherently translate to less residual vaccine, ultimately minimizing wastage (ISO 7886-1 2020).

This waste generates significant repercussions, as reported in other studies, especially in the face of health crises such as the coronavirus and influenza pandemics (Smith et al. 2021, Strauss et al. 2006). When estimating, as noted in our study, a waste rate close to 14%, as specified by ABNT, and considering that during the COVID-19 pandemic, approximately 500 million doses of coronavirus vaccines were administered in Brazil until January 2023 (VACINÔMETRO 2023), we can estimate a waste of approximately 70 million doses. In Brazil, the expenditure on the acquisition of vaccines and supplies against COVID-19 is estimated at 9.06 billion Brazilian reais (Tesouro Transparente 2023), with the waste rate found in our study, it is possible to predict a strong impact on the UHS accounts.

CONCLUSIONS

When calculating RV of vaccines in the NIP, a high waste rate was observed, especially when analyzing the supplies of needles and syringes provided by the Brazilian healthcare system. Combinations of needles and syringes that lead to lower waste rates were identified, presenting a viable short-term alternative to overcome this issue. Additionally, a significant estimated quantity of wasted doses from 2017 to 2021 was noted. Furthermore, as observed during the NIP, in pandemic crises such as COVID-19, this problem is extremely pronounced, generating high public spending and a strong socioeconomic impact.

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Y.M.P.G, A.L.G.J, H.C.P.C, C.S.D, R.O.T, and W.G.B contributed to conceiving and designing the analysis; Y.M.P.G, H.C.P.C, C.S.D, R.O.T, and W.G.B contributed to collecting the data; Y.M.P.G, C.S.D, and W.G.B contributed to data and analysis tools; C.S.D performed the analysis; Y.M.P, H.C.P.C, and C.S.D wrote the paper; M.V.S and C.J.F.O reviewed the manuscript and supervised the study.