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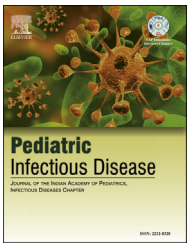

Immunization Update

Prefilled syringes versus vials: Impact on vaccination efficiency and patient safety in Indian private market

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ABSTRACT

Background and aim: Considering the proportion of unsafe injection practices in India, an evaluation of the potential improvement in vaccination with prefilled syringe (PFS) compared to SDV and MDV (single and multidose vials) in Indian private market is the objective of this paper.
Method: An observational, open label, randomized 2-phase time and motion study involved comparison in terms of efficiency associated with the vaccine administration process (preparation, injection, and disposal) and rate of handling errors with safety implications.
Setting: Five Indian pediatric vaccination centers.
Participants: Forty vaccinators (8 per center). 10 observers.
Main outcome measures: Time taken for each activity cycle; frequency of errors observed (Phase 1); time for 10 consecutive injections (Phase 2).
Results: The mean time required to perform a vaccination with PFS was 47.6 ± 11.7 s and was twice as fast as with vials ($p < 0.0001$). The mean number of handling errors with PFS was 1.1 ± 1.7 and was 3 times fewer than with vials ($p < 0.0001$).
Conclusions: Compared with vials, PFS are productivity enhancers, as they decrease time required to perform vaccinations and reduce wastage. PFS are also risk reducers, as they reduced the occurrence of handling errors and associated health hazard risks by a factor of 3.

Actual cost comparison was not part of the study. But this study has shown that use of PFS is associated with cost reduction in terms of saving time correlated with man hours and reducing wastage.

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1. Introduction

Globally, vaccines are distributed in three main presentations: vials, which can be single dose vial (SDV) or multidose vials (MDV), and prefilled syringes (PFSs). In India, predominantly MDVs are used, but PFSs have gained market share over the last few years in the private market.

Comparing MDV, PFS offer advantages in speed, disposal, wastage and patient safety, owing to premeasured accurate doses that reduce dosing errors and risk of microbial contamination.[1–3]

PFS vaccines come without preservative with minimal overfilling unlike MDV. The limitations of PFS are in terms of large storage space in cold chain maintenance and slightly high cost per dose. Use of MDV is cheaper, but using MDVs can be more time consuming for the healthcare worker, leading to higher administration costs with more potential for dosing and handling errors and contamination.

Here, we study the vaccine presentation globally with various study data. Considering the proportion of unsafe injection practices in India, to evaluate the potential improvement in vaccination with PFS compared to SDV and MDV in Indian private market is the objective of this review article. This is an attempt to improve injection practices in India.

2. Global data of evaluation of vaccine presentation (vial versus PFS)

Prior studies comparing MDVs and PFSs have been conducted in other countries. A study conducted by Scheifele and colleagues[4] in Canada demonstrated that PFSs could save nurses' time in mass immunization clinics. In this Canadian study, for 1000 vaccine doses, vials took 36 nurse hours as against 27 nurse hours of syringes. This study clearly demonstrated that, compared with multidose vials, pre-filled syringes reduced nursing service time by 9 person-hours per 1000 doses, reducing labor costs by 25–33%.[4]

The observational study conducted by Johns Hopkins University, USA has found vaccinating with MDVs took 37.3 s longer than with PFSs.[5]

As per study conducted by Pellissier et al,[6] total nurse time associated with vaccine administration decreased by 2.4 and 1.7 min per shot eliminated in the examination room setting ($P = 0.006$) and in the injection room setting ($P < 0.001$), respectively. Significant time savings were realized for activities associated with vaccine preparation, vaccine injection, and administrative duties.[6]

Study conducted by Szilagyi et al, documented 1–2 min directly related to preparing and administering vaccines, as estimated by nurses or physicians.[7]

2.1. The Indian time and motion study

The study which was done in 2011/12 at five Indian pediatric vaccination centers with forty vaccinators and 10 observers, demonstrated advantages of PFS versus vials. The key advantage of this investigation over these studies lay in directly observing vaccinators rather than asking practitioners to estimate times via interviews or questionnaires.[7,8]

3. Materials and methods

3.1. Design

The study included 2 phases. In Phase 1, for each of the 9 injections (3 with each vaccine delivery system performed on dummy arm & in a randomized crossover order), an observer manually recorded the duration of the activity cycles with a stopwatch and noted potential handling errors. In Phase 2, observers recorded the time taken to perform 10 consecutive injections with each kind of vaccination delivery technology. The time required for vaccine delivery was divided into activity cycles depending on the vaccine delivery device used (Table 1).

The health hazard risk (HHR) evaluation tool was built by BDM- PS (Becton Dickinson Medical – Pharmaceutical systems) and validated by the principal investigator. The HHR score was calculated, for each activity cycle and in total, by multiplying the observed error frequency by a theoretical severity score (determined in the study protocol).

3.2. Vaccinators

The study was conducted at 5 centers (Mumbai, Hyderabad, Bengaluru, Delhi and Kolkata). Forty vaccinators (8 at each center), of both genders, with at least two years of professional experience delivering vaccines in children and/or adults, were recruited. Vaccinators were not centers employees. The study also included observers whom were met for the first time. There was a potential influence of observation to vaccinator behavior but logically equivalent for the three compared systems (PFS, SDV, and MDV).

3.3. Waste weight

Waste management is a significant part of cost evaluation; therefore, vaccine dose wastage with MDVs was measured after Phase 2 by counting the number of doses obtained per MDV. Supplementary MDVs were provided, if necessary, to allow vaccinators to prepare 10 doses.

3.4. Ethics

All participants were volunteers and agreed to participate in the study. Oral informed consent was taken.

3.5. Statistics

To have a margin in case of non-evaluable injections, a final sample size (observed injection) of 1560, i.e. 520 for each delivery system option, was targeted. Statistical analysis was performed using SAS 9.2. The significance level was 0.05 (2-sided). *Descriptive statistics were calculated for all continuous and categorical data.*