Research Article

Vaccine Storage in Private Practice: A Community Trial

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Abstract

Aim: Vaccine storage practice in private practitioner clinics is poor, and concerted effort to improve practice at national level is lacking. This study sought to identify practices in private practitioner clinics and assess the effectiveness of an intervention.

Methods: A non-controlled community trial was conducted in four administrative regions. The intervention was implemented concurrent with the first baseline audit and reinforced in the subsequent 3 audits. We designed a comprehensive, multipronged intervention package to effect behavioral change. It consisted of training, enabling resources, educational materials and non-monetary incentives. Outcomes were assessed based on six essential criteria: temperature between 2-8°C, refrigerator type and placement, dedicated vaccine refrigerator, vaccine placement and temperature monitoring. Analysis was done at private practitioner clinics level and estimates pooled by meta-analysis.

Results: Of 467 clinics invited, 442 participated. One year later, 430 remained. At baseline, no clinic complied with the combined six criteria. Significant improvement was seen for the combined four criteria with drugs, 1.2% (0.0-2.3%) at baseline to 50.9% (37-64.7%) at 1 year. Improvement in five criteria were all statistically significant, most notably in the correct placement of vaccine [31.7% (27.3-36.0%) to 75.0% (62.9-87.0%)], maintenance of temperature between 2-8°C [56.9% (45.2-68.7%) to 88.2% (84.1-92.4%)] and daily monitoring of temperature [2.3% (0.9-3.7%) to 84.1% (74.1-94.2%)].

Conclusions: The intervention was able to improve practice, and this change was sustained at one year. This intervention package had been adopted for all private practitioner clinics in Malaysia, and could be implemented in other countries to improve practice.

ABBREVIATIONS

PPC: Private Practitioner Clinics; A1: Audit at baseline; A2: Audit at 1 month; A3: Audit at 3 months; A4: Audit at 1 year; MOH: Ministry of Health; WHO: World Health Organization

INTRODUCTION

Cold chain refers to a continuum of safe handling that maintains vaccines between recommended temperature ranges; else they risk losing potency [1-4]. Poor vaccine storage could lead
to increased morbidity or mortality for vaccination preventable diseases [5] and outbreaks have been reported linked to poor storage for measles and pertussis [6,7].

Current evidence shows good vaccine storage practices are lacking even in developed countries [2,8-11]. No uniformity of criteria currently exists for assessing vaccine storage practices, although the World Health Organization (WHO) and others have published guidelines [1,12]. Most studies used a combination of criteria to assess outcome, and did not rely on a particular measure. Of the various criteria used, maintaining internal refrigerators temperature within 2-8°C is the most crucial. For this criterion, there was a wide range in adherence reported, with rates of 1 to 83% [13,14].

In Malaysia, half of outpatient care occurs in the private sector, [15] and in 2006, 6-44% of the population obtained vaccination from private practitioner clinics (PPC) [16]. This is a concern, as it is internationally recognized that quality assurance systems for vaccine storage may not be in place in private practice [17]. Monitoring and compliance to guidelines in the private sector is minimal even in developed countries, [2,14,18-22] and this is unlikely to be different in Malaysia.

Few studies have assessed the effect of interventions in improving vaccine storage practices in PPC. Of those that did, outcomes and interventions studied varied [10,13,18,23,24]. Most adopted a multi-pronged approach and focused predominantly on internal temperature maintenance. Methods used included training of staff, feedback on practice, provision of thermometers and educational materials such as guidelines, videos, charts.

Hence, this study was designed to assess the situation in Malaysia, as faulty handling and storage was perceived to be high. This study aimed to obtain information on current vaccine storage practices in PPC and to assess whether an intervention could improve practice.

**MATERIALS AND METHODS**

A non-controlled community trial was conducted in four regions to assess storage practices in PPC in Malaysia. PPC are private sector stand-alone clinics, either single or group practices, with no hospitals. The trial consisted of four audits over 1 year: baseline (A1) and post intervention at 1 (A2), 3 (A3) and 12 months (A4). Intervention implementation was carried out during all audits. Public health nurses from the Ministry of Health (MOH) were trained and they conducted audits using a checklist and implemented the intervention package. This was completed in each region within a week to reduce possible contamination across clinics.

To improve participation, nurses showed an introduction letter from the regional health director and a flier that emphasized benefits of participation and confidentiality. For accuracy of data and accountability, the study required both research nurse and private practitioner to acknowledge audit results by signing on “value of study” during A2.

Fidelity testing on intervention implementation was conducted in the first two audits. Supervisors assessed extent of intervention implementation in terms of materials delivery and audit process. One third of PPC were interviewed, and care was taken to ensure no repetition of clinics at the second fidelity test.

**Participant selection and description**

The sampling frame was all PPC sending monthly vaccination feedback to MOH. We excluded private health facilities/hospitals with central pharmacy stores, as these may have centralized monitoring system for vaccines. Following exclusion, a convenient sample was selected based on accessibility.

Sample size was calculated based on difference in two proportions, assuming an improvement from 10 to 30%, a power of 90% and a significance of 0.05. The minimum number was 81 clinics per region. To account for a poor response, we targeted 100 per region.

**Intervention package**

In developing the intervention, the research team emphasized practicality and sustainability. The package consisted of training of PPC personnel, provision of enabling resources, educational materials and additional incentives.

**Training of PPC personnel**

Research nurses explained the recommended storage practices during the audit, gave immediate verbal and written feedback to accompanying personnel, and to reinforce learning, held a power-point presentation with a question and answer session.

**Enabling resources**

We gave all PPC a dial thermometer (bimetal model by Moller-Therm GmbH, Germany) for monitoring internal refrigerator temperature. This was selected instead of the min-max thermometer because it is more robust, long lasting and easier to read.

Temperature monitoring charts were provided, adapted from WHO [1] and MOH charts. This incorporated the safe range for storage (2-8°C) and action needed for out-of-range temperature. Research nurses verified the use of these charts during audits. We provided contact details of research nurse for troubleshooting.

**Educational materials**

A laminated “Six Essential Messages” card that summarized good storage practice was provided, to be attached to the front of the refrigerator door as a reminder (Figure 1). As reference material, a copy of the WHO manual [1] on vaccine storage was distributed. A bilingual power-point presentation CD-ROM, in English and Malay, was used, then provided to PPC for current and future training. Stickers stating “Open Me Only When Necessary” was pasted to refrigerator doors, to reduce unwarranted door opening. We provided a “To do” list for doctors, as a reminder.

**Additional Incentives**

A certificate of acceptable vaccine storage status, signed by regional health directors, and a sticker stating “My Refrigerator is Safe for Vaccines”, were awarded based on audit results.
Outcomes

Outcomes measured were adherence to six criteria, chosen based on WHO guidelines [1].

*Criterion #1: Type of refrigerator* - refrigerator used to store vaccines. Appropriate were top loading or one with a separate freezer compartment.

*Criterion #2: Dedicated vaccine refrigerator* - refrigerator that stores only vaccines. Refrigerators storing food, beverages, blood/urine/other specimens, reagents or drugs were considered inappropriate.

*Criterion #3: Placement of refrigerator* - Inappropriate placement include presence of either direct exposure to sunlight, evidence of frost, or distance of refrigerator surface to the nearest object/wall is less than 40, 30 or 20 cm from the top, sides and back respectively (Figure 1).

*Criterion #4: Placement of vaccine* - Inappropriate placement include storing vaccines in door shelves, freezer, immediately below the freezer (for single door refrigerator), in the vegetable/fruit compartment, reconstituted vaccines kept in syringes or vaccines found outside the refrigerator.

*Criterion #5: Temperature between 2-8°C* - measured using the research nurse’s dial thermometer, to be placed in the middle of the refrigerator for at least 15 minutes prior to reading. Research nurses verified accuracy of thermometers prior to audits by comparing the reading with calibrated MOH vaccine refrigerator thermometers.
**Criterion #6:** Monitor temperature - Temperature recorded daily for each working day over the last 5 working days.

**Criterion #2d:** Vaccine & drugs - Refrigerator that stores vaccines together with drugs only. This criteria was added to accommodate the reality of storing temperature sensitive drugs in the clinic. Most PPC were not able to accommodate two refrigerators in the clinic.

Criteria were analysed singly and in combination. We promoted all 6 criteria as the ideal vaccine storage practice. Two of the criteria, type and placement of refrigerator, were by nature more difficult to change as they involve financial and space constraints. Additionally, most PPCs had only one refrigerator. Hence, we analyzed additional combination criteria that allowed refrigerators to store vaccine and/or drugs.

**Statistical methods**

Analysis was done at PPC level, and applied only to refrigerators storing vaccines. PPC performance was deemed compliant if all refrigerators that stored vaccines in the clinic fulfilled the criterion. We used STATA SE10 and calculated pooled estimates across regions by meta-analysis.

**Ethical issues**

Permission was obtained from the Medical Research and Ethics Committee, MOH Malaysia. Written consent from private practitioners was obtained. All practitioners were required to sign the audit form after each audit to acknowledge they have been informed of the problems and suggested remedial action(s). Anonymity of individual PPC was ensured. No control arm was included as we considered it unethical not to intervene should the audit reveal defects in practice.

**RESULTS AND DISCUSSION**

**Response and clinic characteristics**

There were 726 PPC sending vaccine returns to MOH, from the 4 regions, of which 467 were invited to participate and 442 accepted. The number of clinics participating at 1 year was 430 (dropout rate 2.7%). Majority had been in operation for five years or more, only 5.0% was set up in the last 2 years. General practitioner clinics consisted 85.1%; 12.0% were specialist clinics. There were more solo practices (80.3%) than group (19.7%).

**Compliance**

At baseline, the percentage of PPC complying with any one criterion was low, except for criterion #5. At one-year, no significant changes were seen in the availability of the recommended refrigerator type. Only 13 clinics had changed their refrigerator. However, changes in the five other selected criteria were all statistically significant with a marked rise in compliance, most notably in the correct placement of vaccine, maintenance of temperature between 2-8°C and daily monitoring of temperature (Table 1).

At baseline audit, no PPC achieved all recommended 6 criteria. Space and financial constraints also hampered the PPCs' attempts to comply with criteria #1 and #3, refrigerator type and placement. Analysis without these criteria (fulfilled 4 criteria) showed statistically significant change from baseline to 1 year

| Table 1: Compliance with the Essential Criteria for Good Vaccine Storage, at baseline and subsequent audits. |
|-------|-------|-------|-------|-------|
|       | Audit 1 | Audit 2 | Audit 3 | Audit 4 |
|       | n=442   | n=442   | n=440   | n=430   |
| Criterion #1 | Type of refrigerator (%) | 21.8 (CI 14.3-29.3) | 21.8 (CI 14.3-29.3) | 24.1 (CI 17.1-31.1) | 25.5 (CI 17.5-33.6) |
| Criterion #2 | Dedicated vaccine refrigerator (%) | 8.8 (CI 6.1-11.4) | 27.6 (CI 21.0-34.1) | 31.5 (CI 24.2-38.8) | 39.4 (CI 20.6-58.3) |
| Criterion #3 | Placement of refrigerator (%) | 0.9 (CI 0.0-2.7) | 9.4 (CI 1.6-17.2) | 10.3 (CI 4.0-16.6) | 20.7 (CI 9.7-31.7) |
| Criterion #4 | Placement of vaccine (%) | 31.7 (CI 27.3-36.0) | 56.3 (CI 41.7-70.8) | 68.6 (CI 57.5-79.8) | 75 (CI 62.9-87.0) |
| Criterion #5 | Temperature between 2-8°C (%) | 56.9 (CI 45.2-68.7) | 87.3 (CI 84.2-90.4) | 88.8 (CI 85.9-91.8) | 88.2 (CI 84.1-92.4) |
| Criterion #6 | Monitor temperature (%) | 2.3 (CI 0.9-3.7) | 87.2 (CI 81.2-93.2) | 88.6 (CI 83.0-94.1) | 84.1 (CI 74.1-94.2) |
| Criterion #2d | Vaccine & drugs (%) | 44.8 (CI 40.1-49.4) | 70 (CI 62.6-77.4) | 72.8 (CI 64.2-81.4) | 79 (CI 72.9-85.2) |

Footnote: CI Confidence Intervals

† This allowed the refrigerator to also store drugs together with vaccines

‡ Pooled estimates across 4 regions using meta-analysis
Value of study and intervention

Majority of PPC reported that the study helped them improve practice. Items rated most helpful, in descending order, were the 6 essential messages card (Figure 1), dial thermometer, temperature monitoring chart and WHO booklet. Only 8 (2.3%) reported the intervention was not helpful, while 35.3% and 31.0% reported it not practical to change the refrigerator type or to have dedicated vaccine refrigerators respectively. Recommended refrigerator location was considered not practical by 19.2%.

Response rate in this study was good, comparable elsewhere [24,25]. Prior to intervention, 45.2 - 68.7% of PPC in Malaysia met the recommended temperature criteria, while 27.3-36.0% had appropriate placement of vaccines. Less than 4.2% met the four combined criteria. These results confirmed that vaccine storage practices may not be in place in PPC in Malaysia, as noted elsewhere [13,17,24].

The designed intervention package was able to improve vaccine storage practices, with significant improvement seen for five of six criteria. Percentages of practitioners that maintained refrigerator temperature and monitored temperature rose significantly. Compliance to all four combined criteria, with or without refrigerators that also stored drugs, improved. The intervention had improved practice, and this was sustained after 1 year.

Internal and external validity

We measured internal refrigerator temperature once during each audit. Hence, results obtained did not reflect temperature fluctuations over time. In addition, we did not measure the minimum/maximum temperature nor did we do continuous recording. Verification of thermometers used in the research was rudimentary, with comparison done with calibrated thermometers currently in MOH vaccine refrigerators. Additionally, sampling of regions and PPC were convenient, with region participation based on the interest shown by managers. However, we audited more than half of the PPC providing vaccines in each region.

On fidelity of intervention implementation, all PPC received the intervention items, except for 2 that did not get a thermometer during baseline audit, due to delayed supply. All PPC received a copy of audit results and were shown how to use a temperature monitoring chart. Only 4 were not given verbal feedback. The fidelity tests conducted in both audits showed no obvious differences between audits and regions, confirming that the intervention was implemented as designed in all regions equally well.

There was no control group in this trial as it would not be ethical to not intervene if discrepancies were noted in vaccine storage.

Table 2: Compliance with the Essential Criteria in Combinations, at baseline and subsequent audits.

<table>
<thead>
<tr>
<th>Essential Criteria</th>
<th>Combined</th>
<th>Audit 1</th>
<th>Audit 2</th>
<th>Audit 3</th>
<th>Audit 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfilled all 6 criteria (Criterion #1 to #6) (%)</td>
<td>0</td>
<td>2.3</td>
<td>2.5</td>
<td>3.9</td>
<td></td>
</tr>
<tr>
<td>Fulfilled all 6 criteria &amp; drug† (%)</td>
<td>0</td>
<td>2.3</td>
<td>2.7</td>
<td>5.6</td>
<td></td>
</tr>
<tr>
<td>Fulfilled 5 criteria‡ (%)</td>
<td>0</td>
<td>4</td>
<td>5.7</td>
<td>9.5</td>
<td></td>
</tr>
<tr>
<td>Fulfilled 5 criteria &amp; drug† (%)</td>
<td>0</td>
<td>5.5</td>
<td>7.8</td>
<td>14.3</td>
<td></td>
</tr>
<tr>
<td>Fulfilled 5 criteria§ (%)</td>
<td>0</td>
<td>4.2</td>
<td>6.9</td>
<td>7.5</td>
<td></td>
</tr>
<tr>
<td>Fulfilled 5 criteria &amp; drug† (%)</td>
<td>0</td>
<td>6.5</td>
<td>11.8</td>
<td>12.2</td>
<td></td>
</tr>
<tr>
<td>Fulfilled 4 criteria¥ (%)</td>
<td>1.8</td>
<td>16.1</td>
<td>22.4</td>
<td>28.4</td>
<td></td>
</tr>
<tr>
<td>Fulfilled 4 criteria &amp; drug† (%)</td>
<td>1.2</td>
<td>32.8</td>
<td>44.4</td>
<td>50.9</td>
<td></td>
</tr>
</tbody>
</table>

Footnote: CI Confidence Intervals
† This allowed the refrigerator to also store drugs together with vaccines
‡ The type of refrigerator was excluded from the criterion list.
§ The placement of refrigerator was excluded from the criterion list.
¥ The type of refrigerator & placement of refrigerator were excluded from the criterion list.
£ Pooled estimates using meta-analysis

later, both with and without drugs (Table 2).
storage practice. Additionally, the audit process itself would influence behavior in the control group.

Interpretation of outcomes

Prior to Intervention: We could find no similar studies that looked at the combinations of criteria as in our study. For individual criteria, rates varied greatly with location. The most studied outcome was temperature maintenance. In this study, 48.2 – 68.7% of PPC met the recommended temperature of 2-8°C at baseline. Reported rates ranged widely, from 1 to 83%, with differing methods and timelines [13,14,24,26].

We found that 14.3-29.3% of PPC used the recommended refrigerator type. Studies that mentioned refrigerator type reported the use of domestic refrigerators in the majority of cases, but did not specify details of type [5,9,24,25]. Only 9.0% of PPC in this study had dedicated vaccine refrigerators, compared to 2.7 to 90% elsewhere [5,24,26].

Most did not adhere to WHO placement of refrigerator requirements, [1] and we could not find studies on this for comparison. For placement of vaccines, at baseline 31.8% had met this criterion, compared to 22 to 84% reported elsewhere [5,13,26]. Internationally, monitoring of internal refrigerator temperature ranged from 1.25% to 46% [5,13,25,27] and this study had similar results.

Besides actual practice, differences in rates could be due to variation in time when studies were conducted, definitions, and methods.

With intervention: We demonstrated a significant improvement in the recommended practices, with absolute percentage improvements of 81.8% for temperature monitoring, 31.1% and 43.3% for temperature maintenance and vaccine placement respectively. Of the five interventional studies found for vaccine storage practices, most differed in definitions and methodology employed. In New South Wales, Australia, a change of approximately 20% was seen for the following criteria: dedicated refrigerator, temperature maintenance and monitoring for their intervention package; [23] while in Western Australia, another study reported an increase of 40% for temperature monitoring. [10] Other interventional studies did not report the degree of improvement [13,18,24].

Four studies provided a min-max thermometer [10,13,24] or a data logger [23] with instructions on use, while two gave advice on actions to be taken if discrepancy was noted [10,23]. One employed an audit incorporated with formal feedback session to respondents, gave a CD-ROM and a copy of the CDC guidelines on vaccine storage, [18] but no thermometer was provided. In comparison, the strength of our intervention was the adoption of most of the approaches used in other studies, in addition to incorporating multiple approaches to enhance behavior change. These included temperature charts with instructions on safe range and required documentation of action that was taken, nurse contact detail for technical support and reminder cards. The audit process also reinforced recommended practice, verified areas lacking and incorporated feedback.

Though our intervention package addressed all essential criteria selected, improvement was least achieved for refrigerator placement and type, most likely because this involve space and financial demands.

Questions for Future Research: Vaccines ruined by poor refrigeration had been reported to result in revaccination [28]. This study did not address storage conditions that warranted revaccination, vaccine spoilage, potency testing nor was the study designed to address other issues in preserving cold chain, such as temperature maintenance during transportation, a problem noted before [29]. Future research addressing vaccine storage could consider these issues.

CONCLUSION

Our study findings strongly indicate a crucial need to improve quality of vaccine storage in PPC in Malaysia. The intervention package was able to improve practice significantly, and Malaysia had adopted this intervention package for use nationwide. This intervention package could be implemented in other countries to make change possible to improve vaccine storage practices in PPC.

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