



Use of Hub Cutters and the Volume of Sharp Waste and Occurrence of Needle-Stick Injuries during 2011 Mass Immunization Campaigns against Yellow Fever in Ghana: A Cohort Study

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Abstract

Background: Current WHO best infection control practices for injections do not address the use of hub cutters due to insufficient evidence on safety and efficacy.

Objective: To assess the impact of the use of hub cutters on 1) the frequency of needle-stick injuries (NSIs) and other blood exposures among workers and 2) the volume of sharps waste in a mass vaccination campaign setting.

Methods: During yellow fever vaccination in Ghana, we conducted a cohort study on the use of hub cutters. We compared two groups—one group using hub cutters and a control group—for the occurrences of NSIs and the volume of sharp waste produced.

Results: In the control arm, vaccinators used 284 482 syringes in 825 vaccination sessions. In the group using hub cutter, vaccinators used 397 079 syringes in 1599 sessions. Among vaccinators, the rate of NSI was not significantly ($p=0.14$) different between the hub cutter users (0.15/10 000 syringes) and the control group (0.04/10 000). Factors such as workload, lack of organization and pressure seemed to have influence the occurrence of NSIs. With all the limitations of the work, the volume of sharp waste per 10 000 syringes was 0.24 m³ in the hub cutter users and 0.41 m³ in the control group—a reduction of 41.2%. Vaccinators found hub cutters easy to use and safe. Use of hub cutter was not associated with increased duration of work.

Conclusion: The use of hub cutters did not increase the risk of NSIs. More training is needed to facilitate its implementation in mass campaign setting.

Keywords: Safety; Injections; Medical waste disposal; Vaccination; Hub cutters; Infection control; Needle-stick injuries; Yellow fever vaccination

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Introduction

Waste management plays a key role in the quality of immunization programs. The lack of means to manage sharps waste is sometimes considered as an obstacle to the replacement of reusable devices by single-use injection devices. The inability to destroy on time the huge quantity of contaminated needles generated during mass vaccination campaigns in some settings can be an environmental threat.¹⁻⁶ Hub cutters have been proposed to improve waste management because they separate the needle from the syringe's hub. The needle is collected in a secured container; the isolated needles are the only products processed as sharp waste.^{7,8}

Current WHO best infection control practices for injections do not address the use of needle removers due to insufficient evidence on their safety and efficacy.⁹ In developing and transitional countries, there are lack of resources for appropriate collection and management of sharps waste. As a consequence, reported rates of needle-stick injuries (NSIs) among health care workers are ranging from 0.93 to 4.7 injuries/person/year in various WHO regions.^{3,4,6,10-13}

Ghana, as part of the Expanded Program of Immunization (EPI) policy, had planned the use of hub cutters to reduce the volume of sharp contaminated waste during the yellow fever mass immunization campaign in November 2011. The use of hub cutters could either decrease the frequency of NSIs (through facilitated waste management) or increase the frequency of NSIs (through adding a step in the collection of dirty needles).^{7,8}

The availability of hub cutters has limited the number of regions where we could provide such a device. A mass immunization campaign against yellow fever in November 2011 in Ghana provides the op-

portunity to test the effectiveness of this device. We conducted this study to assess the impact of using hub cutters on 1) the frequency of NSIs and other blood exposures among vaccinators and volunteers and 2) the volume of injection-associated sharps waste in the setting of a mass vaccination campaign.

Materials and Methods

Study design

In this cohort study the use of hub cutters was studied in field. The reference practice was the collection and disposal of sharps waste according to the WHO best practices: immediate collection of sharps in a safety box without recapping and without separating the syringe from the needle. One group used hub cutters to separate syringes from needles; the needles were then disposed in a container separately from the syringes which were disposed in a safety box.⁸

Setting

The yellow fever mass vaccination campaign targeted a population of 5 831 171 and had a supply of 6 239 400 auto-disposable (AD) syringes and 623 900 mixing syringes. Plans were made to use hub cutters in Greater Accra and Central regions only. Greater Accra and Central regions gather a target population of 1 388 376 which was compared to that of Ashanti region with a population of 1 325 201, where hub cutters were not used.

The study population included all the workers operating during the mass campaign. The number of vaccination teams was planned to be 991 in Greater Accra and Central regions and 947 in Ashanti region. Two types of workers were working: vaccinators who were involved in reconstituting and administering vaccines and volunteers who were responsible for waste handling,

transport and disposal.

Study sample

To calculate the sample size needed for the trial, we used the rate of 2.12 NSIs/person/year, an average of the rates reported in developing regions in the World Health Report 2002;¹³ and 4235 injections given/vaccinator/year, an average reported by interviewing vaccinators during rapid assessment of injection practices conducted in India, Mongolia and Albania.^{3,4,6} Therefore, five NSIs/10 000 injections was the baseline rate used in the calculation. For an estimation of 500 needles used per session, considering a 95% confidence interval, a power of 80% and a coefficient of variation between cluster of 50%, the study sample was calculated to be 200 vaccination teams. For quality monitoring purpose, the unit has been set as the district, considering that the number of teams in the district is proportional to the target population and to the number of needles used. Districts of the two arms have been matched to satisfy the sample size and one pair has been randomly selected among four to host the study. That pair comprised 246 teams for the control arm in Ashanti region (Asokwa district) and 258 teams for using hub cutters in Central region (Twifu district) and in Greater Accra region (Osu-Clotteh and Ashiedu Ketekeh).

The Study Group

Each team in the study group was provided with hub cutters individually assigned, one per vaccinator. The BD hub cutter[®] has been used for this campaign.⁷ Vaccination posts using hub cutters kept on using the same cutter day after day until it is full (450 to 500 needles) and then replaced it. All the used hub cutters were collected at the district health directorate for destruction. In case of failure of a hub cutter, syringes with needles were collected in safety boxes as in the reference practice until re-

placement of the hub cutter. Every safety box containing sharp waste was marked accordingly. One safety box was given for each 100 syringes and needles provided. The syringes without needles were to be autoclaved shredded and recycled into non-food items. The used syringe and needle sets were destroyed in incinerators at temperature above 800 °C.^{10,14}

A one-day training was provided to vaccinators, supervisors, and volunteers a week before the beginning of the immunization campaign. The training was conducted by the district health directorate and the supervisors for the hub cutters safety study. It addressed the best practices for the collection and disposal of syringes and needles after use, the correct use of the hub cutters (in the study group only), the disposal of syringes and needles after use, information on NSIs (common causes, frequency, what to do when one occurs and the value of reporting NSIs), the completion of the reporting forms and monitoring forms, and the standard operating procedures in case of device failure. The training was integrated in the routine training for the vaccination campaign conducted by the district health directorate.

Data collection

From November 22–23, 2011 where the

TAKE-HOME MESSAGE

- During a mass vaccination session, hub cutter is as safe as safety box alone.
- Adequate use of hub cutter could significantly reduce the volume of sharp waste produced during the vaccination campaigns.
- Adequate training is a prerequisite for the introduction of hub cutters in mass vaccination campaigns.
- Vaccinators have accepted hub cutter and are ready to implement it.

yellow fever vaccination campaign was conducted in the selected regions, the recorders at each vaccination post collected information on primary and secondary endpoints using a short, daily feed-back form. The daily feed-back form collected information on the number of vaccinators and volunteers in the team at the vaccination post, the number of working hours per day, the number of syringes used in a day, the occurrence of NSIs, the occurrence of other exposures to blood, the occurrence of device failures, the number of full sharps boxes produced per day.

Vaccinators filled specific reports in case of NSI or other exposures to blood or body fluids and in case of device failure. Particular attention was paid to needle-stick injuries related to the use of hub cutter. All injuries that occurred before or during the injection, were considered as not related to the use of hub cutter. Since the actions following the injections are to cut the hub and discard the syringe, the NSIs that occurred after the injection were considered to be related to the use of hub cutter.

Workers in charge of waste collection and handling outside of the vaccination post were counted neither as part of the team nor in the working hours, when completing the daily feed-back form. However, in case of NSI they had to fill a NSI form.

In addition, 60 intervention sites were visited to assess the acceptability of hub cutters by health care worker at the end of the study.

To assure quality data collection, field investigators were assigned to every approximately 65 teams. They went round the teams and supervisors daily to collect, verify and correct data.

Data analysis

Rates of occurrence of NSIs, exposure to blood, and device failure were calculated using the relevant denominators in each

cluster and then compared between the study group and the control group. The rates were then compared using Fisher's exact test. Primary outcomes were the needle-stick injuries and the exposure to blood per working hours and per number of syringes used; Another primary outcome was the volume of sharp waste per syringes used. Secondary outcomes were the failure rate of hub cutters (per hub cutters used, and per number of syringes used) and the duration of work. Kruskal-Wallis test was used to determine whether the duration of work per session influenced differently the occurrence of NSI from one arm to the other. Study data were subjected to an intention-to-treat analysis.

Rates of NSIs and exposures to blood were stratified according to the type of work in the team (vaccinator or volunteer). The number of filled safety boxes per 100 syringes used was also calculated for each arm of the study, clustering by vaccination post. In addition, the volume of needle waste was calculated using the volume of needle containers collected centrally.

Quality Assurance Procedures

The procedures to collect the data as well as the quality of the collected data were guaranteed as follows: a) Pre-test data collection forms among target audiences for comprehension; b) Standardization in data collection procedure, as presented in the training course; and c) Every day each field supervisor (3 per arm) visited 10 teams selected at random to validate data collection procedures, with a particular attention to the completion of the forms.

Ethical considerations

The present protocol template was cleared by WHO's SCRIHS ethical committee. Ghana having decided on the use of the hub cutters already, this study was only observational and did not need further clearance. Since the use of hub cutter came

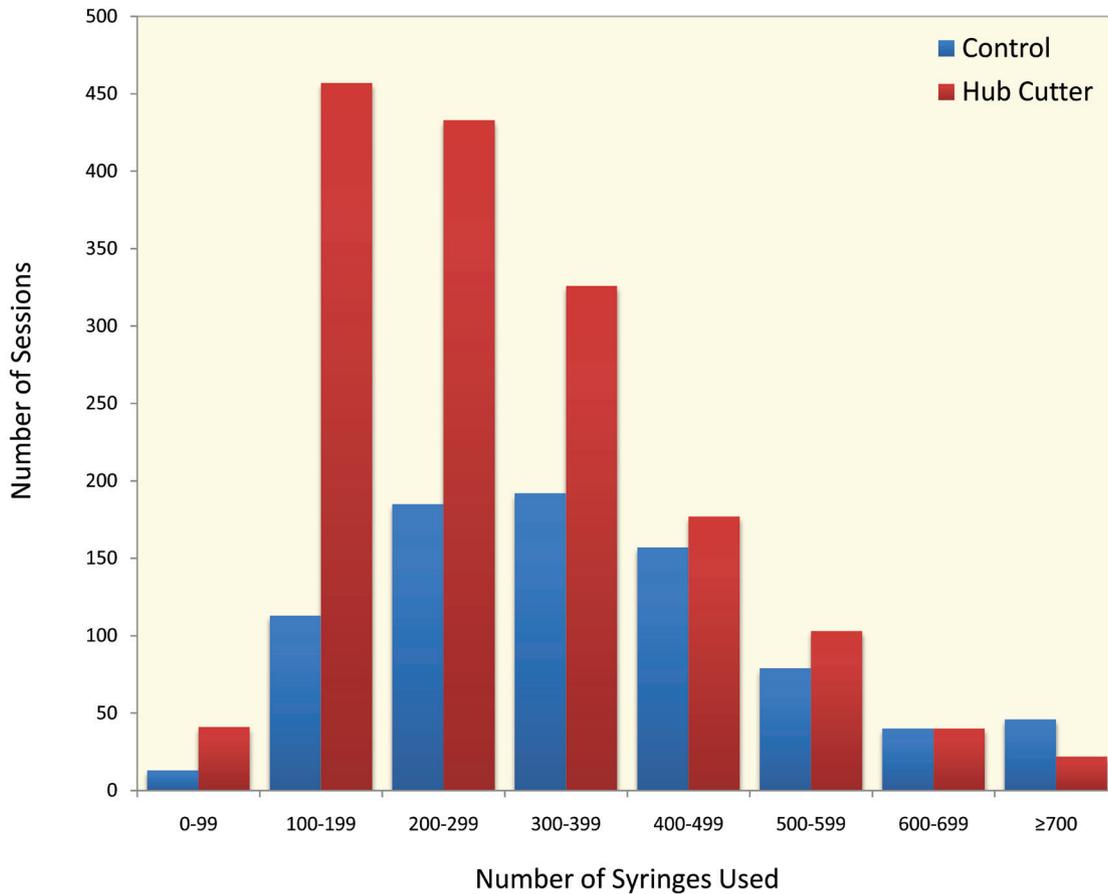


Figure 1: Number of syringes used

from a national policy, no informed consent was required from vaccinators or volunteers. However, specific training was provided.

Confidentiality of data was assured at all steps of the study including data collection, data management, access to data and use of the information. An identification numbering was developed with no reference to individual's names.

Workers exposed to sharp waste were oriented to the National HIV control program which manages NSIs. NSIs led to a case report specifying the circumstance of the injury.

Results

A total of 825 teams-days (sessions of vac-

ination) operated in the control arm and 1599 in the study group. Over the whole period of vaccination, they used 681 555 needles including AD syringes and mixing syringes. The number of syringes used was 397 073 in the study group and 284 482 in the control arm.

Among vaccinators, we have recorded 18 NSIs (0.26/10 000 needles) which occurred in 12 teams. One team encountered three injuries, two teams encountered two injuries and all others encountered one each. One of the 18 injuries (0.04/10 000 needles) occurred in the control arm. Of the 17 injuries recorded in the intervention arm, six were reported as related to the use of hub cutter (0.15/10 000 needles) and 11 having occurred even before the injection or while restraining the patient. The oc-

currence of injury was higher in the study group (0.15/10 000) than in the control arm (0.04/10 000) but the difference was not statistically significant (RR=4.29; 95% CI: 0.52–35.63).

Among volunteers, only one injury was recorded, in the intervention arm (0.02/10 000 needles). There was no significant difference for the volunteers between the studied groups (p=0.66). Neither vaccinators nor volunteers were exposed to blood or body fluid.

Number of syringes used

The median number of syringes used per session was 240 (IQR: 147–365). We grouped the number of syringes used per intervals of 100 syringes. For the vaccinators, we considered that the occurrences

could depend on the number of syringes per team and the number of syringes per vaccinator in a team.

Figure 1 presents the number of syringes used per session. Most of the sessions used 100 to 599 syringes in both the study (93.6%) and the control arm (88.0%). The NSI that occurred in a volunteer occurred in a group that used 400 to 499 syringes per session.

The number of syringes per session was used to describe the occurrence of NSIs among the volunteers (waste handlers). Among vaccinators, we considered the number of syringes per vaccinator per session.

Most of the vaccinators used 100 to 599 syringes per session in both the study group (88.0%) and the control arm (81.0%). In

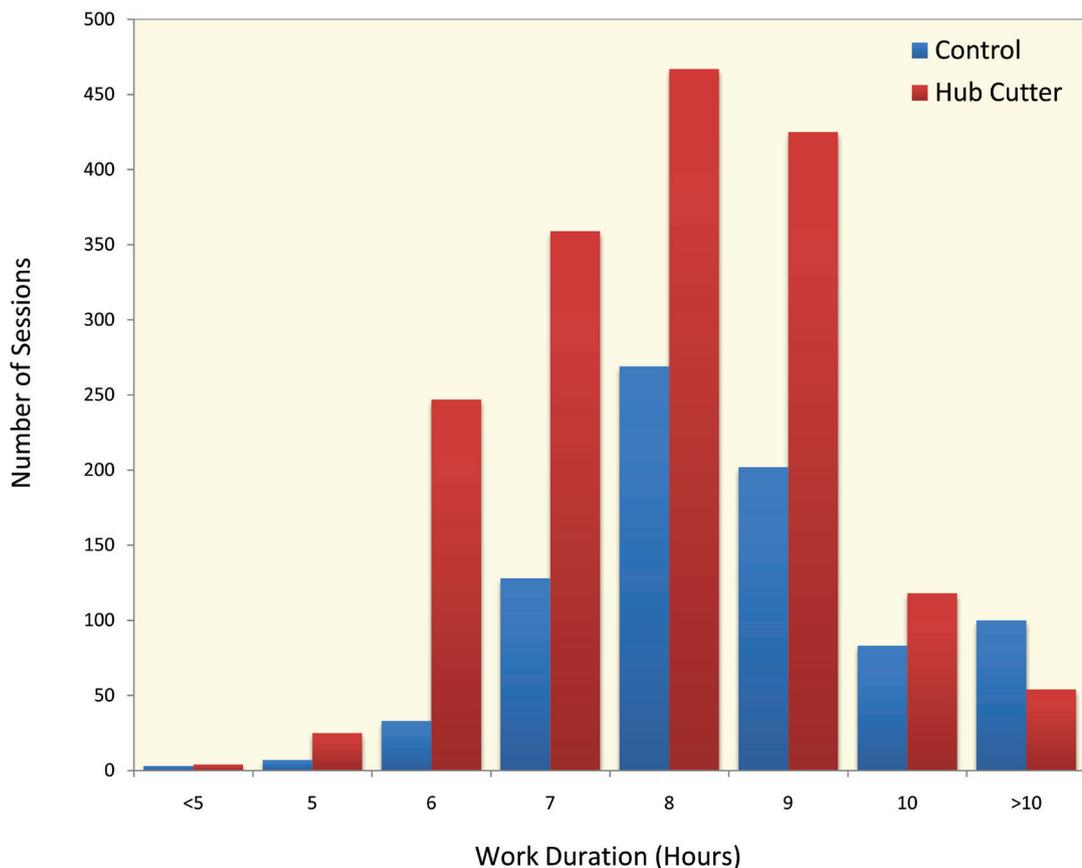


Figure 2: Distribution of work duration

the control arm, the needle-stick injury occurred in a team where a vaccinator used 100 to 199 (0.75%) syringes per session. In the study arm, needle-stick injuries occurred in teams where a vaccinator used 100 to 199 syringes (0.22%), 200 to 299 syringes (0.92%) and 300 to 399 syringes (0.61%) per session. No injury was recorded in the teams where a vaccinator used more than 400 syringes.

Number of vaccinators per session

Sessions operating with one vaccinator were 736 (89.2%) in the control arm and 1531 (95.7%) in the study group. Some sessions in the control arm had more than four vaccinators. In the control arm, the injury occurred in a session which had four vaccinators. In the study arm, all injuries occurred in sessions with one vaccinator.

Duration of work

The sessions lasted for a mean±SD of 8.53±1.38 (range: 4–11) hours in the control arm and 8.07±1.35 (range: 4–16) hours in the study group. Figure 2 shows the duration of work per team and the rate of NSIs per duration of session.

In those study group sessions with needle-injury, one session had 7 hours of daily work, five had 9 hours and one had 10 hours of daily work. In the control arm, NSI occurred in a session with eight hours of daily work. There was a positive correlation between the frequency of needle-stick injury and the length of the session. There were no significant ($p=0.65$) difference in the mean daily work hours between the control arm and the study group.

Quantity of sharp waste

The 1599 sessions of the study arm produced 1767 safety boxes (a mean±SD of 1.11±0.38 per session) while the 825 sessions of the control arm produced 2354 safety boxes (a mean±SD of 2.85±2.9 per session). There was a linear correlation

($r=0.26$) between the number of safety boxes and the number of hub cutters used in the study arm. In the study group, almost all sessions (96.3%) used one hub cutter a day, 3.8% used two and one session used four hub cutters. The volume of waste in the intervention arm was 9.67 m³ (1767 five-liter safety boxes and 1661 half-liter hub cutters). In the control arm, it was 11.77 m³. After adjustment for the number of syringes used, using hub cutter resulted in 41.2% reduction in the volume of sharp wastes. If all safety boxes were void of needle, the sharp waste could have been 0.83 m³ in the study arm where, the reduction of sharp wastes could have been 94.9%.

Acceptability of the hub cutter

In the study arm, 62 sessions were interviewed on the acceptability of the hub cutter. The interviews took place from the third day of use so that the vaccinators had a minimum perspective. Of the sessions interviewed, 96.8% cut the needle from the syringe immediately after the injection; in one session, the syringes were kept in the safety box before cutting the needles later. During its use, 100% placed it within arm reach; 32.2% used two hands while cutting the needle with the hub cutter. None emptied the used hub cutter.

On the usage of hub cutter, 11.3% mentioned difficulties in general, and 1.6% reported problem in transporting the device; 46.2% kept the hub cutter on a table, 23.1% placed it nearby the vaccinator, 3.9% held it in hand, and 17.3% kept it in a polythene bag.

Failure occurred in 12.9% of hub cutters. In 19.4%, it failed to cut completely the needle from the syringe; 42.9% of teams encountered the problem more than once. In 8.1%, the needle was cut at the level of the barrel. None experienced liquid leak or needle escape from the hub cutter.

Overall, 96.8% of participants found the hub cutter easy to use and 100% judged it

safer. On the occurrence of NSIs, 80.3% thought that using a hub cutter would reduce NSIs. About two-thirds (66.1%) of participants believed that use of hub cutter does not increase the immunization time, 22.6% reported the time may increase slightly, 8.1% believed it would increase moderately, and 1.61% reported a significant increase in the time. The performance of the hub cutter was rated “excellent” by 48.4%, “very good” by 35.5% and “good” by 16.1% of participants.

Discussion

We observed very low rates of NSIs, 0.15/10 000 incidents in the study arm and 0.04/10 000 in the control arm, which is lower than the rates reported by Bari, *et al*, in Bangladesh (1.38/100 000 in the study arm and 1.64/100 000 in the control arm).¹⁵ The rate was not significantly different between the two arms. In the study arm, the injuries occurred more frequently with a higher number of syringes used per day. However, in both arms, increasing the number of syringes used per vaccinator beyond 400 did not have any influence on the occurrence of needle-stick injury. Because in the study group, all injuries occurred in sessions with one vaccinator, workload is probably an important risk for NSI. This hypothesis is also supported by the fact that duration of work is also seemed to be higher in those teams where NSI occurred more frequently. We reported only one NSI among the volunteers, as in the study of Bari, *et al*.¹⁵ We did not have any exposure to blood or body fluid.

The hub cutter failure rate (12.9%) was lower than that reported by Bari, *et al* (25%).¹⁵ In our series, most of the failures were attributed to wrong usage of the device by the operator. In fact, in the first days, some participants were pressing the cutter on the needle instead of the hub. This reflected inadequate training that was

corrected after a few days.

The reduction of volume of waste (41.2%) was higher than that reported from Bangladesh (9.6%).¹⁵ This would have been even higher (94.9%) if no needle was discarded at all in safety boxes in the study arm, and even more if the number of failed hub cutters was fewer.

The primary objective of the current study was to assess the safety and ability of hub cutters to reduce sharp waste. The main constraint to its implementation was the preparation time. The number of vaccination teams that operated in the districts selected was less than the planned number and it could have affected the power of the study. A correction has been done in the results since some injuries occurred even before the injection and in some settings, there were repeated injuries in the same session that could be staff related. We thus, discarded the injuries which were obviously not related to the use of hub cutter for the comparison of the two arms. To the best of our knowledge, this study is the second on the use of hub cutters in mass immunization campaigns and sets the pace for a systematic follow-up of its introduction to generate evidence-based data on the safety and efficacy of the hub cutters with respect to the current WHO protocols.

Regarding the kind of difficulties in use of hub cutter reported here and there, more training would be needed to facilitate the implementation of hub cutters in campaign setting. The stakeholders of vaccination campaigns should facilitate a progressive introduction of the hub cutter and support it with quality training on the correct use of the device.

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Conflicts of Interest: None declared.

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