Results from a Survey of Immunization Stakeholders in Vietnam Regarding the Presentation, Packaging, and Distribution of Human Papillomavirus Vaccines

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Overview

The purpose of this survey was to obtain input from stakeholders within the Expanded Programme on Immunization (EPI) in Vietnam about issues and perceptions related to the storage, distribution, and delivery of the current and potential options for human papillomavirus (HPV) vaccine presentation and packaging. The information obtained from EPI program managers, officers, storekeepers, and health care workers is intended to be utilized by the Vaccine Presentation and Packaging Advisory Group as part of a broader work program to help determine the optimal presentation and packaging options for second-generation HPV vaccine products.[1]

Methodology

Interviews were conducted to seek feedback on four formats under consideration for second-generation HPV vaccines, as well as programmatic information that may influence preferences for HPV vaccine formats in the future. Vaccine formats under consideration include the existing single-dose vials (from GlaxoSmithKline [GSK] and Merck & Co. [Merck]), two-dose vials with no preservative, multi-dose vials with preservative, and compact prefilled autodisable devices. Programmatic information assessed included the benefits and challenges of ambient temperature transport and storage of HPV vaccine and feedback on any issues (e.g., safety, cold chain constraints, time to prepare vaccine) that arose during the recent introduction of the single-dose vial format. Two separate yet similar questionnaires were developed for this study: one for interviewing health care workers (n=8) at the commune level (vice-head and head of commune health centers, EPI health workers, and commune health workers; see **Appendix 1**) and another for interviewing individuals responsible for procurement of vaccines (n=20) at the national, regional, provincial, and district levels (EPI managers, EPI officers, and storekeepers; see **Appendix 2**).

The questionnaires were conducted by two teams of local PATH staff members and National EPI (NEPI) employees. Drs. Huyen (NEPI) and Huong (PATH) conducted surveys in regional stores in Can Tho province; Mr. Tung (NEPI), Dr. Nga (PATH), and Ms. Hai (PATH) conducted surveys in Thanh Hoa province; and Drs. Huong and Nga conducted surveys at NEPI. Interviews were performed on a one-on-one basis with individuals involved in the ongoing HPV vaccine demonstration project. Data entry forms were created by Ahmar Hashmi and Le Hai (PATH), with Le Hai translating and entering the data. Preliminary analyses were completed by Ahmar Hashmi. Key findings are summarized in this report.

Given the qualitative nature of this survey, when descriptive feedback was solicited, many interviewees provided more than one comment for a question. As a result, the number of responses for a given question may exceed the number of subjects interviewed. If no response was given for a particular question, it was recorded as such in the results.

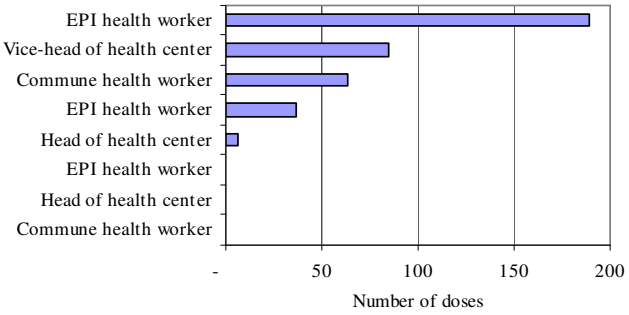
Results

General Immunization

1. Have you administered or procured HPV vaccine?

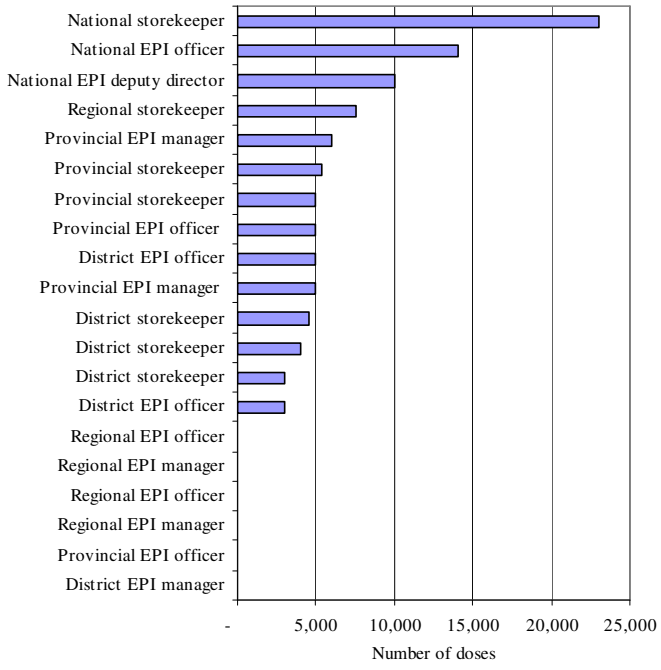
   Of the eight health care workers (HCWs) interviewed, five had administered HPV vaccine (also referred to throughout this report as "HCW vaccinator"), and three had not administered HPV vaccine (also referred to in this report as "HCW non-vaccinator"). Of those who had administered the vaccine, the number of doses delivered ranged from 6 to 189. (see **Figure 1**)

   Figure 1. HPV vaccine doses administered by health care workers



   Seventeen of the twenty procurement individuals interviewed (also referred to in this report as "Procurement") had procured between 3,000 and 6,000 doses each of HPV vaccine. The EPI deputy director, EPI officer, and storekeeper at the national level procured 10,000 to 23,000 doses each of HPV vaccine. (see **Figure 2**)

   Figure 2. HPV vaccine doses procured



2. Health care workers were asked: Have you or others experienced any safety issues when administering HPV vaccine?

   One of the five health care workers reported one patient responding to HPV vaccination with a rash that disappeared after two weeks. Apparently this individual had previously experienced allergic reactions to vaccinations. No other safety issues were reported by vaccinators.

3. Health care workers were asked: Do you find that the time it takes to prepare and administer HPV vaccine using single-dose vials is a problem?

   One health care worker found the vial cover to be difficult to open and therefore time consuming. Another health care worker found the delivery of HPV vaccine to be time consuming since it is a new vaccine and requires explanation prior to vaccination.

4. Have you experienced any problems with the volume or weight of HPV vaccine and supplies that need to be transported?

   Two procurement individuals at the national level experienced problems with the volume that HPV vaccine occupied during transport. One storekeeper at the provincial level expressed concern about the large size of the vaccine box.

   An EPI officer reported problems keeping vaccine cold during transport. It takes at least 30 minutes to receive a vaccine from the district level. A thermometer was placed in the icebox before transport, and in the time it took to reach the commune level the temperature inside the icebox had increased.

5. Have you experienced any problems with vaccine during storage?

   Health care workers reported that HPV vaccine is stored at the district or provincial health center but not the commune health center. Vaccination is conducted at the commune health center immediately after receiving vaccine. Any remaining vaccine is then brought back to the district or provincial center.

   Two procurement individuals at the national level experienced problems with the large amount of space HPV vaccine occupies during storage.

6. What do you perceive are the benefits of a single-dose vial? (see **Table 1**)

   Reduced wastage and ease of drawing vaccine into the syringe or general convenience were referenced as the top benefits of single-dose vials. Also of significance was the mention that single-dose vials ensure accuracy of measurement, ensure vaccine quality or reduced risk of infection, and allow vaccinees to feel confident in the quality and safety of the vaccination.

Table 1. Responses as to the perceived benefits of a single-dose vial

Benefits	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procurement (n=20)	Total (n=28)
No/reduced wastage	4	3	15	22
Easy to draw vaccine into syringe, convenient, and easy to use	4	3	9	16
Clients feel confident in quality/safety	1		6	7
Ensures accuracy of measurement	3	1	3	7
Ensures quality; reduces risk of infection	2		3	5
Saves time	1			1
No need for strict supervision			1	1
No need to wait for more than one vaccinee (prior to opening the vial)			1	1

7. What do you perceive are the challenges of a single-dose vial? (see **Table 2**)

   Over half of the interview participants perceive the space required for vaccine storage (18 of 28) and transport (16 of 28) to be a challenge with single-dose vials. Several also commented that additional cold chain equipment may be required which would ultimately increase the cost of vaccine delivery. Two individuals, however, perceive single-dose vials to only pose a challenge when session sizes are large; for example, outreach to schools with more than 15 eligible girls for vaccination.

Table 2. Responses as to the challenges of a single-dose vial

Challenges	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procurement (n=20)	Total (n=28)
Requires more space for storage	2	3	13	18
Requires more space for transport	2	2	12	16
Insufficient cold chain equipment, need additional iceboxes			3	3
Need to remove from box to transport	1		1	2
Insufficient storage at district level			2	2
Increased cost for transport			2	2
Transport difficulties if >15 eligible girls		1	1	2
Insufficient storage at regional level			1	1
Need to open vial cover for each injection		1		1
Increase in amount of rubbish			1	1
Higher price for vaccine			1	1
No challenges	1			1
No response	1		2	3

*For the next series of questions (#8-10), the interviewers showed a prototype multi-dose vial (see **Appendix 3**, **Figure 1**) with preservative and explained that this is a hypothetical HPV vaccine product that does not exist. This product could potentially be kept for use for up to 30 days if safe techniques are used to withdraw doses from the vial (i.e., a new syringe/needle is used to withdraw each dose).*

8. What do you perceive are the benefits of a multi-dose vial with preservative? (see **Table 3**)

   The majority of the interview participants (15 of 28) perceive that multi-dose vials save space during transport and storage. Five individuals specifically commented that multi-dose vials would be easy to store at the health-center level. Another perceived benefit of a multi-dose vial with preservative is reduction in vaccine wastage and extension of the duration of vaccine use, based on the World Health Organization (WHO) multi-dose vial policy (MDVP).[2] Several interview participants commented that this presentation is especially good for school-based vaccination or campaign settings; yet, due to the preservative, it is not necessary to wait until multiple vaccine recipients are present to deliver the vaccine.

   Table 3. Responses as to the benefits of a multi-dose vial with preservative

Benefits	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procurement (n=20)	Total (n=28)
Saves space in transport and storage	1		14	15
No/reduced wastage	3	3	3	9
Extends duration of vaccine use	2		4	6
Easy to store at health center	2	1	2	5
Good for school or campaign setting			3	3
No need to gather multiple vaccinees	1		1	2
Lower cold chain equipment cost			2	2
Ability to transport via variety of vehicles			1	1
Lower-price vaccine			1	1
Increases vaccine safety			1	1
No benefits	1		1	2
No response			1	1

9. What do you perceive are the challenges of a multi-dose vial with preservative? (see **Table 4**)

   Over half (15 of 28) of interview participants responded that vaccine in multi-dose vials leads to higher wastage when compared to one- or two-dose vials. Several respondents perceive multi-dose vials with preservative to be linked with adverse events associated with vaccination. In addition, four procurement officers believe that there is potential to introduce infection, two health care workers commented that safety is dependent on proper storage, and several others believe vaccine recipients do not want to receive vaccine from open vials.

Table 4. Responses as to the challenges of a multi-dose vial with preservative

Challenges	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procurement (n=20)	Total (n=28)
Higher wastage	2	1	12	15
Concern about reactions to injection	3		4	7
Vaccinees do not want vaccine from open vials		1	4	5
Potential to introduce infection			4	4
Safety is dependent on proper storage	1	1		2
Not easy to use	1		1	2
No significant benefit in transport and storage space versus single-dose vial	1		1	2
Difficult to measure dose accurately			1	1
Vaccinators don't want to wait for multiple vaccinees			1	1
Vial will be larger with preservative			1	1
No challenges	1	1	3	5
No response			1	1

10. Do you think there would be issues with transporting unused open vials of vaccine back to storage after outreach trips? (see **Table 5**)

Five out of eight health care workers said that there would be issues with transporting unused open vials after outreach trips. Thirteen out of twenty EPI managers and procurement officers agreed that it would be difficult to transport open vials back after vaccine outreach. Over half of the interview participants fear contamination of the transported vials. This was expanded upon with the comment that not all EPI staff members have the technical knowledge to properly store, label, and record open vaccine vials for transport. Several respondents believe that it would be difficult to control or monitor the temperature and properly store and protect vials during transport.

Table 5. Responses as to the issues with transporting unused open vials back to storage after outreach trips

Issues	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procurement (n=20)	Total (n=28)
Fear of contamination	2		13	15
Requires technical support and proper labeling and record keeping	1		5	6
Difficult to control/monitor temperature	1	1	3	5
Difficult to store/protect in transport	2	1	2	5
EPI staff lack knowledge to properly transport open vials	1		3	4
Inconvenient; staff may not plan to return to health center			2	2
Preservative may not be good			1	1
Cost of personnel to transport back to health			1	1

center				
No issues	1			1
No response		2	3	5

*For the next two questions (#11-12), the interviewer showed a two-dose vial prototype (see **Appendix 3**, **Figure 3**) and explain that this hypothetical HPV vaccine product does not contain preservative and therefore must be kept cold and discarded within 6 hours (like a measles vaccine that has been reconstituted). If the vaccine is kept for longer than 6 hours, the lack of preservative may allow bacteria to grow in the vial. Consequently, if a contaminated vaccine is administered to a patient, toxic shock may result.*

11. What do you perceive are the benefits of a two-dose vial with no preservative? (see **Table 6**)

    Health care workers perceive that a two-dose vial with no preservative would offer low wastage rates, would be easy to use, and easy to transport and store. Interview participants involved in vaccine procurement also believe a two-dose vial of vaccine would offer low wastage, would reduce space needed in the cold chain, and would be easy to transport and store. Five of twenty procurement individuals believe the vaccine will be safer and less likely to trigger an adverse reaction compared to a vaccine with a preservative.

    Table 6. Responses as to the perceived benefits of a two-dose vial with no preservative

Benefits	**HCW vaccinator (n=5)**	**HCW non-vaccinator (n=3)**	**Procurement (n=20)**	**Total (n=28)**
Low wastage		3	8	11
Easy to use, easy to measure dose	1	3	4	8
Reduces space needed in cold chain			5	5
Less likely to have reaction to injection, “aseptic guaranteed”			5	5
Easy to transport and store	1		3	4
Saves electricity, staff, maintenance costs			1	1
No benefits	2		2	4
No response	2		1	3

12. What do you perceive are the challenges of a two-dose vial with no preservative? (see **Table 7**)

    The perceived challenges expressed most by procurement officers and managers associated with a two-dose vial with no preservative were the space required for vaccine transport and storage relative to that required for multi-dose vials, and the high wastage compared to single-dose vials.

    Health care workers and procurement individuals perceive the challenges to be associated with accuracy of measuring one dose and convenience when compared to a single-dose presentation.

Table 7. Responses as to the perceived challenges of a two-dose vial with no preservative

Challenges	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procurement (n=20)	Total (n=28)
Requires more space for transport and storage than multi-dose vials		2	9	11
High wastage compared to single dose			10	10
Difficult to measure accurate dose	1	1	2	4
Not as convenient as single-dose vial			3	3
Need to wait for 2 vaccinees before opening	1		1	2
Can not store for a long time	1			1
More expensive than 10-dose vial			1	1
Need to test safety			1	1
No challenges			2	2

*For the next two questions (#13-14), the interviewer showed prototype BD Uniject® devices (See **Appendix 3**, **Figure 3**) in foil pouches and demonstrated how to remove the device from the pouch, activate the device, and inject the dose (into an orange or other appropriate item). The interviewer also explained that this is a hypothetical product. Some vaccines are currently available in Uniject, but HPV vaccine is not.*

13. What do you perceive are the benefits of Uniject? (see **Table 8**)

All of the health care workers interviewed perceived Uniject to be easy to use, as did the majority of procurement individuals. Low wastage and ease of transport and storage were also common perceptions. The assurance of vaccine safety, no vial breakage, and no need to use a separate needle and syringe were all benefits communicated about Uniject.

Table 8. Responses as to the perceived benefits of Uniject

Benefits	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procurement (n=20)	Total (n=28)
Easy to use (comfortable, convenient, simple)	5	3	15	23
Reduces vaccine wastage	3	2	15	20
Easy to transport, light weight	4	1	10	15
Easy to store, not bulky	2		5	7
Saves time	2	1	4	7
Ensures vaccine safety	1		6	7
No fear of breaking vial	1	1	4	6
No need for autodisable needle and syringe			4	4
Patient feels safer	1		1	2
No need to destroy needle			2	2

14. What do you perceive are the challenges of Uniject? (see **Table 9**)

Health care workers and procurement officers reported that the bulkiness of Uniject may pose challenges for storage or transport. One health care worker and five procurement individuals believed training would be necessary before use. Procurement individuals also perceived the vaccine would be difficult to push out, increasing wastage if operated improperly, or that Uniject was fragile and subject to being damaged during transport.

Table 9. Responses as to the perceived challenges of Uniject

Challenges	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procurement (n=20)	Total (n=28)
Bulky for storage or transport	1	2	11	14
Requires training of HCWs	1		5	6
Increased wastage if operated incorrectly			3	3
Fragile—may become damaged in transport			2	2
Difficult to push vaccine out/deploy			2	2
May be more painful for patient			1	1
No challenges	1		1	2
No response	2	1	3	6

15. How many doses per vial or per delivery device would you prefer to have for HPV vaccine? (see **Table 10**)

Six of eight health care workers and thirteen of the twenty procurement individuals prefer a single-dose container for HPV vaccine. Ease of use and low wastage were the most often cited rationale for the single-dose presentation preference. Reduced volume for transport and storage along with low wastage served as rationales for those preferring two-dose containers. The remainder of the respondents varied in their preferences and reasoning. Wording of this question should be improved for future surveys to ascertain whether those preferring a single-dose presentation would select vials or Uniject devices.

Table 10. Responses as to preferences regarding doses per container for HPV vaccine

Preferred # of doses container	Rationale (# of responses)	HCW-vaccinator (n=5)	HCW-non-vaccinator (n=3)	Procure-ment (n=20)	Total (n=28)
1-dose	Easy to use (10), low wastage (8), safe (3), exact dose (2), no rationale given (3)	4	2	13	19
2-dose	Reduce volume in transport & storage (4), low wastage (3)	1	1	2	4
10-dose	Less space, saves time in campaign setting (2)			2	2
2- or 5-dose	Reduce volume in transport & storage, saves time & cost (2)			2	2
5- or 10-dose	Less volume in transport & storage; low price			1	1

Storing/Transporting Vaccine at Controlled Ambient Temperatures

The interviewer showed the respondents a vaccine vial monitor (VVM) and VVM instructional color chart and provided the following explanation:

The center square of the VVM changes color from light to dark with exposure to heat over time. It changes more quickly at high temperatures and more slowly at low temperatures. When the color of the square is the same as the color of the reference ring or is darker than the reference ring, the vaccine vial has been exposed to too much heat and should be discarded.

Many studies have been successfully conducted transporting and storing vaccine (oral polio, hepatitis B, and tetanus toxoid) at ambient temperatures using the VVM and taking precautions to ensure that the vaccine is not exposed to excessive heat.[3,4,5,6] *The vaccine was transported and stored without refrigeration or ice, but kept as cool as possible and protected from sunlight.*

16. Assuming that HPV vaccines have VVMs attached, would there be a benefit to taking this vaccine out of the cold chain? If yes, what segments of the cold chain would best lend themselves to out-of-cold-chain storage or transport of the product? What would the benefits be? (see **Table 11**)

    The majority of respondents (20 of 28) believe commune health centers would benefit most from taking HPV vaccine out of the cold chain. The most common benefits listed include ease of storage and transport, reduction of wastage, and the lack of need for expensive refrigerators or electricity.

Table 11. Responses as to the benefits of taking HPV out of the cold chain

Segment of cold chain	Benefits (# of responses)	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procurement (n=20)	Total (n=28)
Commune	Cold chain is inadequate (2), no need for expensive refrigerator (6), no icepacks (5), easy transport (9), easy store (9), reduces wastage (7), ensures vaccine quality & safety (4), not dependent on cold chain (3), no need for electricity (4), saves time	5	2	13	20
District	Saves space, easy to manage, no need for expensive refrigerator, no need for electricity			2	2
Transport	Simplifies, no cold chain storage needed			1	1
Without electricity	Simplifies, no cold chain storage needed, reduces wastage		1		1

17. Would there be challenges to keeping the vaccine out of the cold chain? (see **Table 12**)

The perceived challenges amongst health care workers and procurement individuals of keeping HPV vaccine at ambient temperatures included: finding a suitable space for storage of the vaccine, lack of knowledge of the duration that a vaccine could be stored under these conditions, and the need to carefully check VVMs.

Table 12. Responses as to the challenges of taking HPV out of the cold chain

Challenges with out of the cold chain	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procurement (n=20)	Total (n=28)
Finding suitable space for storage	3		3	6
Unknown storage duration		1	4	5
Need to carefully check VVM		2	3	5
Difficult to control/monitor temperature			3	3
Not accepted by community			3	3
Easily broken			1	1
May be easily contaminated			1	1
Increased wastage			1	1
May lose vial on outreach			1	1
Need to carefully train HCWs			1	1
No response	1		2	3

*For question #18, the interviewer provided the interviewees with a copy of the Coldpack™ "Antifreeze Backpack" (See **Appendix 3**, **Figure 4**) Assembly Guide and demonstrated how to open, assemble, and fill the Antifreeze Backpack with vaccine samples[7]. The interviewees then tested the weight and feel of the pack.*

18. Do you think the Antifreeze Backpack would meet your needs as a vaccine carrier to outreach settings? Is it comfortable and easy to carry? What are you general thoughts on the backpack? (see **Table 13**)

Overall feedback on the backpack vaccine carrier was not positive. Respondents commented that the backpack was not comfortable or easy to carry; it was bulky, heavy, and too large. Over half of the procurement individuals perceived that the backpack would not be sufficiently durable. Several individuals commented that it contained too many parts and was complicated to assemble. However, Coldpack has indicated that the backpack is not meant to be assembled and disassembled between outreach sessions. Therefore, assuming there is room at the health center to store the assembled backpack, there should not be a need for enduring the complicated assembly more than once, although the liners may need to be re-inflated between uses. Future surveys may consider seeking the feedback of interviewees with an assembled backpack as well as other novel vaccine carriers.

In contrast, two individuals commented that it was comfortable, two reported it was easy to use and operate, and several thought the backpack was attractive and liked the color.

Table 13. Responses as to whether Antifreeze Backpack will meet needs as vaccine carrier

Backpack characteristics	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procure-ment (n=20)	Total (n=28)
Comfortable/easy to carry?				
No	3	1	8	12
Yes		1	1	2
If 10-dose packaging			3	3
No response		1	8	9
Form				
Nice color	2	2	4	8
Bulky	2		5	7
Attractive	1		6	7
Okay		1	5	6
Untidy, unattractive	1		1	2
Weight				
Too heavy, especially for females	5	3	18	26
Acceptable			2	2
Volume				
Too large	5	3	15	23
Redundant			3	3
Sufficient			2	2
Too small			1	1
Other comments				
May not be durable			11	11
Too many parts	1	1	4	6
Too complicated	1	1	2	4
Easy to use and operate	1	1	2	4
Difficult to transport	1	1		2
Difficult to clean	1		1	2
Difficult to put together and take vaccine out		1	1	2
Backpack does not meet needs as vaccine carrier			9	9

Labeling and Packaging

*For questions #19-21, the interviewer showed the respondents existing boxes containing Merck and GSK HPV vaccine vials (see **Appendix 3**, **Figures 5 and 6**) with packaging and labeling in Vietnamese.*

19. Are there any problems with the packaging or labeling of the box? If yes, what recommendations do you have to improve this?

    Several interview participants commented that the Merck HPV vaccine labeling includes too many words that are small in size making it difficult to read the important information, such as the vaccine name and expiry date (see **Table 14**). A few individuals requested that the original label be visible in English, with translation provided in Vietnamese. This is because the recipients of the vaccine tend to have a higher regard for imported products. Two health care workers interviewed also requested that a VVM be placed on the box.

Table 14. Merck HPV vaccine box packaging/labeling:

Problems	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procurement (n=20)	Total (n=28)
Too much information, wordy	1	1	6	8
Should read "box for 10 vials of 0.5ml"			4	4
Name of vaccine small			3	3
Original label should be in English with translation in Vietnamese—people like imported products	1		1	2
Lack of VVM	2			2
Place expiry date on front, using same size font			2	2
Box is too big			2	2
Add "vaccine for EPI, not for sale"			2	2
Add illustration		1		1
No response	1	2	6	9

The general feedback on GSK's HPV vaccine box (see **Table 15**) is that the box is too large and labeling is too wordy. This particular vaccine was not available with Vietnamese translation.

Table 15. GSK HPV vaccine box packaging/labeling:

Problems	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procurement (n=20)	Total (n=28)
Box is too big	5	2	13	20
Need full Vietnamese translation	4	1	14	19
Too wordy			3	3
Easy to understand		1	1	2
Words are too small		1	1	2
Easy to store and transport		1		1

20. Are there any problems with the packaging or labeling of the vial? If yes, what recommendations do you have to improve this?

    Interview respondents commented that the Merck HPV vial (see **Table 16**) was too big, had too much information about vaccine ingredients, and lacked information on the number of doses and issue or expiry dates. It was suggested that the lid be a different color to easily differentiate the top of the vial and that the vial not be as difficult to open.

Table 16. Merck HPV vaccine vial packaging/labeling

Problems	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procurement (n=20)	Total (n=28)
Vial is too big		2	3	5
Use different colors for lid	1		3	4
Too much ingredient information			4	4
Vial difficult to open	2			2
Add information about # of doses & issue date			2	2
Original label in English with translation in Vietnamese	1			1
Vial is too small			1	1
Add "vaccine for EPI, not for sales"			1	1
No response	2	1	7	10

Only a few procurement interviewees responded to this quesiton and they commented that GSK's HPV vaccine vial (see **Table 17**) was too large and short. The available vial did not have Vietnamese translation and labeling in English was too small.

Table 17. GSK HPV vaccine vial packaging/labeling

Problems	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procurement (n=20)	Total (n=28)
Vial is too big			2	2
Need Vietnamese translation			1	1
Letters are too small			1	1
Vial is too short			1	1
No response	5	3	15	23

21. In your opinion, what recommendations do you have to improve the presentation and packaging of HPV vaccine for use in your region? (see **Table 18**)

    General recommendations for improving the presentation and packaging of HPV vaccine include decreasing the size of the box so the vials fit snugly inside and striving for single-dose vials, Uniject, or the fewest doses per vial. Finally, ensuring the essential information, including instructions for use, expiry date, and VVM, are legible and in the local language.

Table 18. HPV vaccine presentation and packaging recommendations

Presentation and packaging recommendation	HCW vaccinator (n=5)	HCW non-vaccinator (n=3)	Procure-ment (n=20)	Total (n=28)
Decrease box size to fit vial	1		4	5
1 dose like Uniject		2	3	5
Essential information on vial; expiry date easy to read			4	4
1-dose vials, 10 vials per box	1	2		3
Fewest doses per vial		1	2	3
Box and instructions in Vietnamese	1		2	3
Include VVM	1	1		2
Pack multi-dose (5-10 doses/vial, 10 vials per box)			2	2
Improve shape/form of vial & box			1	1
80 vials per box not convenient; should be 100 vials per box			1	1
No response	3		5	8

Vaccine Price

22. Procurement workers were asked: In your opinion, which is more important vaccine price or vaccine cost-effectiveness? (see **Table 19**)

    Eighteen out of twenty procurement individuals believe that cost-effectiveness is more important than price of a vaccine. Most of the respondents' rationale was based on the fact that effectiveness of the product, not the price of the product, drives the decision to purchase a vaccine. Price, however, was stated as more important than cost-effectiveness for public-sector EPI vaccines which serve poor populations.

    Table 19. Importance of price vs. cost-effectiveness

More important	Procurement (n=20)	Rationale
Cost-effectiveness	9	Prevention is more important
Cost-effectiveness	7	If not effective, there is no need to purchase the vaccine
Price	2	For EPI and poor people
Cost-effectiveness	1	Important for those with money

23. Procurement workers were asked: In your opinion, would you be willing to pay slightly more for a vaccine presentation that offered the following benefits? (see **Table 20**)

    a. Minimizes wastage so that less vaccine needs to be purchased?

       The majority of the procurement individuals interviewed expressed a willingness to pay slightly more for a vaccine presentation that minimizes wastage. However, two individuals commented that wastage associated with multi-dose vials is sufficiently low and often is available at a lower price per dose than single-dose vials.

b. Minimizes space in the cold chain if space were a constraint?

Only 8 of 20 procurement individuals interviewed said they would be willing to pay more for a vaccine presentation that minimizes space in the cold chain if space were a constraint. One individual felt this could be resolved by procuring multi-dose versus single-dose vials.

c. Improves safety, such as a multi-dose vial that contains preservative?

Paying a premium for a presentation that improves safety, such as a multi-dose vial with preservative was considered a possibility by 15 out of 20 respondents. However, 5 of 20 respondents said they would not pay more, most because there is a perception that preservatives may increase the incidence of adverse events.

d. Improves safety and convenience, such as a compact prefilled autodisable device?

Sixteen of twenty respondents expressed a willingness to pay a slightly higher price for a presentation that improves both safety and convenience, such as a compact prefilled autodisable device. Of the four who were not willing to pay more, one commented that Uniject was difficult to use, and two felt it would be a burden on storage and transport for campaigns. However, one of those individuals commented "if cold chain capacity is sufficient, Uniject will be the best choice."

Table 20. Willingness-to-pay by benefits

Benefit	**Procurement (n=20)**	**Rationale**
Minimizes wastage so that less vaccine needs to be purchased		
Yes	18	
No	2	Wastage with multi-dose vial is not a big issue
Minimizes space in cold chain if space were a constraint		
Yes	8	
No	12	Capacity of cold chain is sufficient or could be resolved by multi-dose vials; need to understand additional cost
Presentation that improves safety, such as a multi-dose vial that contains preservative		
Yes	15	
No	5	Difficult to understand community perception of open vaccine vial; preservative could be cause of increased adverse events
Improves safety and convenience, such as a compact prefilled autodisable device		
Yes	16	If capacity of cold chain is sufficient
No	4	Campaign strategy-Uniject burdens storage and transport; Uniject is difficult to use

Summary

General Immunization

In general, health care workers did not report any significant problems with safety or preparation time of the existing HPV vaccines in single-dose vials. Health care workers did not comment on transport of HPV vaccine and do not store HPV vaccine at the commune clinics. Only a few procurement individuals had difficultly with the size that the current HPV vaccine vials occupied in transport and storage. (see **Table 21**)

Table 21. Summary of general immunization feedback

Any safety issues when administering HPV vaccine	**Total (n=5)**
Yes-A rash that disappeared after two weeks	1
Experience problems with the time it takes to prepare and administer HPV vaccine using single-dose vials	**Total (n=28)**
Yes-vial cover is difficult to open and therefore time consuming	1
Yes-delivery of HPV vaccine is time consuming since it is a new vaccine and requires explanation prior to vaccination	1
Experience problems with the volume or weight of HPV vaccine and supplies that need to be transported	**Total (n=28)**
Yes-national level experienced problems with the volume that HPV vaccine occupied during transport	1
Yes-problems keeping vaccine cold during transport	1
Yes-concern about the large size of the vaccine box	1
Experience problems with vaccine during storage	**Total (n=28)**
Yes-large amount of space HPV vaccine occupies during storage at the national level	2

Most health care workers and the majority of procurement individuals interviewed prefer a single-dose presentation. Despite the challenges voiced about space required for storage and transport, single-dose vials and Uniject were considered easier to use and were perceived by procurement officers as safer and of higher quality. Uniject, in particular, was well liked by all health care workers and most procurement officials. The ease of use, wastage prevention, and light weight of Uniject were cited as advantages by nearly all respondents. However, challenges were voiced about space required for storage and transport, and several procurement individuals feared the Uniject device may be too bulky and fragile to easily transport or store. Future surveys should seek more clarity from respondents who favor single-dose presentations on whether they prefer Uniject or single-dose vials.

Two-dose vials with no preservative were valued by health care workers and procurement individuals for the space-saving quality. However, the concerns about accurately measuring the first dose and the possibility that the second recipient might perceive an open vial negatively ranked the two-dose vial presentations below single-dose presentations for most individuals interviewed. Multi-dose vials with preservative were perceived to be beneficial for large campaigns and easy to store and transport, but the perception of using an open vial even when complying with the WHO MDVP guidelines

is that the vaccine is subject to contamination. Additionally, the reported perception amongst vaccine recipients and several individuals interviewed is that a preservative is associated with higher incidence of adverse reactions.

Surveys in other countries with recent experience introducing HPV vaccine could provide additional perspective. Consideration should also be given to the possibility of interviewing vaccine recipients to assess their perceptions related to HPV vaccine packaging and presentations.

Table 22. Summary of vaccine presentation feedback

	Perceived Benefits (+) or Challenges (-) (n=28)													
Presentation	**Accuracy**		**Function-ality**		**Safety/ Quality**		**Storage**		**Storage/ Transport**		**Transport**		**Wastage**	
	+	-	+	-	+	-	+	-	+	-	+	-	+	-
1-dose vial	7		16		7 5			18		3		16	22	
Uniject			23 7	6 3	7 6 4		7	14	15				20	
2-dose vial with no preservative		4	8	3	5		5		4	11			11	10
10-dose vial with preservative			3 6			7 4 5	5		15				9	15

Note: If more than one unique rationale was mentioned for a given presentation's benefit or challenge, the number of responses is listed in a row of the corresponding cell.

Table 23. Summary of preferred number of doses per container

Preferred # of doses container	**Rationale (# of responses)**	**Total (n=28)**
1-dose	Easy to use (10), low wastage (8), safe (3), exact dose (2), no rationale given (3)	19
2-dose	Reduce volume in transport & storage (4), low wastage (3)	4
10-dose	Less space, saves time in campaign setting (2)	2
2- or 5-dose	Reduce volume in transport & storage, saves time (2)	2
5- or 10-dose	Less volume in transport & storage; low price (1)	1

Storing/Transporting Vaccine at Controlled Ambient Temperatures

The majority of those interviewed believed that ambient temperature storage and transport would be tremendously helpful, especially at the commune level. However, the concept raised questions about the duration that a vaccine could remain safely at ambient temperatures, the temperature range allowed, and monitoring needs under these conditions.

Table 24. Summary of feedback on benefits and challenges of storing/transporting vaccine at controlled ambient temperatures

Benefits	Total (n=28)	Challenges	Total (n=28)
Easy to transport, store & manage	13	Finding suitable space for storage	6
No need for expensive refrigerator	8	Unknown storage duration	5
Reduces wastage	8	Need to carefully check VVM	5
No need for electricity	6	Difficult to control/monitor temperature	3
No need for ice packs	5	Not accepted by community	3
Not dependent on cold chain	5	Easily broken	1
Ensures vaccine quality & safety	4	May be easily contaminated	1
Cold chain is inadequate	2	Increased wastage	1
Saves time	1	May lose vial on outreach	1
		Need to carefully train HCWs	1

Feedback on the backpack vaccine carrier was not positive. The carrier was perceived to be too large, heavy, and complicated for the needs of these workers. However, future surveys using an assembled backpack may alter the feedback on this product.

Labeling and Packaging

Existing HPV vaccine packaging was perceived to be too large, the font on the label was too small, and some essential information was absent from the label according to most of the health care workers. English with Vietnamese translation was requested for the box and vial label.

Table 25. Summary of labeling and packaging feedback

Problems with HPV vaccine packaging/labeling (n=28)		
Box	**Merck**	**GSK**
Too much information, wordy	8	3
Should read “box for 10 vials of 0.5ml”	4	
Name of vaccine small	3	2
Original label in English with translation in Vietnamese	2	19
Lack of VVM	2	
Place expiry date on front, using same size font	2	
Box is too big	2	20
No response	9	
Vial	**Merck**	**GSK**
Vial is too big	5	2
Use different colors for lid	4	
Too much ingredient information	4	
Vial difficult to open	2	
Add information about # of doses & issue date	2	
Original label in English with translation in Vietnamese	1	1
No response	10	23

Vaccine Price

The question posed to procurement individuals regarding the importance of price versus cost-effectiveness appeared to be confusing to this group; perhaps the intended meaning was lost in the translation. The primary response was that a vaccine's effectiveness needs to be high to warrant procurement of the vaccine. It is likely that there was confusion about the term "cost-effectiveness."

The majority of the procurement individuals interviewed expressed a willingness to pay slightly more for a vaccine presentation that minimizes wastage. Less than half of those interviewed said they would be willing to pay more for a vaccine presentation that minimizes space in the cold chain if space were a constraint, as there are a variety of avenues one can take to mitigate this problem. Paying a premium for a presentation that improves safety, such as a multi-dose vial with preservative, was considered a possibility by 15 out of 20 respondents. Similarly, paying a slightly higher price for a presentation that improves both safety and convenience, such as a compact prefilled autodisable device, was a possibility for 16 out of 20 respondents. However, in the case of multi-dose vials, presence of a preservative remains a concern for some. In the case of Uniject, the potential for overburdening storage and transport space remains an issue.

Table 27. Summary of feedback on willingness to pay

Willingness to pay by benefit	Procurement (n=20)	Rationale
Minimizes wastage so that less vaccine needs to be purchased		
Yes	18	
No	2	Wastage with multi-dose vial is not a big issue
Minimizes space in cold chain if space were a constraint		
Yes	8	
No	12	Capacity of cold chain is sufficient or could be resolved by multi-dose vials; need to understand additional cost
Presentation that improves safety, such as a multi-dose vial that contains preservative		
Yes	15	
No	5	Difficult to understand community perception of open vaccine vial; preservative could be cause of increased adverse events
Improves safety and convenience, such as a compact prefilled autodisable device		
Yes	16	If capacity of cold chain is sufficient
No	4	Campaign strategy-Uniject burdens storage and transport; Uniject is difficult to use

It would be interesting to perform similar studies in other countries with recent experience introducing HPV vaccines to learn about the issues and perceptions in immunization programs with different infrastructures and distribution systems.

Appendix 1. HPV Vaccine Product Presentation Questionnaire for Health care Workers

The objective of this questionnaire is to better understand the product presentation and packaging issues that are important for effective and efficient delivery of human papillomavirus (HPV) vaccine. This questionnaire was presented verbally to interviewees.

Background Information

- Designation/title: _____
- Province: _____
- Health center: _____

General Immunization

1. Have you administered HPV vaccine?

   Circle one: Yes No

   If yes, approximately how many doses have you administered?

   Answer: _____

2. Have you or others experienced any safety issues when administering HPV vaccine?

   Circle one: Yes No

   If yes, what were the safety issues?

   Answer: _____

3. Do you find that the time it takes to prepare and administer HPV vaccine using single-dose vials is a problem?

   Circle one: Yes No

   If yes, please describe the problem.

   Answer: _____

4. Have you experienced any problems with the volume or weight of HPV vaccine and supplies that needs to be transported?

   Circle one: Yes No

   If yes, please describe problem and where the problem occurred.

   Answer: _____

5. Have you experienced any problems with vaccine during storage?

   Circle one: Yes No

   If yes, what was the problem?

   Answer: _____

   If yes, where (at what level of the health system) did the problem occur?

   Answer: _____

Show a single-dose vial of HPV vaccine

6. What do you perceive are the benefits of a single-dose vial?

   Answer: _____

7. What do you perceive are the challenges of a single-dose vial?

   Answer: _____

Show a prototype 10-dose vial with preservative and explain that this is a hypothetical product that does not exist. This product could potentially be kept for use for up to 30 days if safe techniques are used to withdraw doses from the vial (i.e,. a new syringe/needle is used to withdraw each dose).

8. What do you perceive are the benefits of a multi-dose vial with preservative?

   Answer: _____

9. What do you perceive are the challenges of a multi-dose vial with preservative?

   Answer: _____

10. Do you think there would be issues with transporting unused open vials of vaccine back to storage after outreach trips?

    Circle one: Yes No

    If yes, please describe the issues.

    Answer: _____

Show a two-dose vial prototype and explain that this product does not contain preservative and therefore must be kept cold and discarded within 6 hours (like a measles vaccine that has been reconstituted). If the vaccine is kept for longer than 6 hours the lack of preservative may allow bacteria to grow in the vial. Consequently, if a contaminated vaccine is administered to a patient, toxic shock may result.

11. What do you perceive are the benefits of a two-dose vial with no preservative?

    Answer: _____

12. What do you perceive are the challenges of a two-dose vial with no preservative?

    Answer: _____

Show two prototype Uniject devices in foil pouches—one for you and one for the respondent. Show them how to remove the device from the pouch, activate the device, and inject the dose into an orange or other appropriate item. Explain that this is a hypothetical product. Some vaccines are currently available in Uniject, but HPV vaccine is not.

13. What do you perceive are the benefits of Uniject?

    Answer: _____

14. What do you perceive are the challenges of Uniject?

    Answer: _____

15. How many doses per vial or delivery device would you prefer to have for HPV vaccine?

    Answer: _____

Usefulness of Out of Cold chain

Show a vaccine vial monitor and instructional color chart.

Explain: The center square of the vaccine vial monitor (VVM) changes color from light to dark with exposure to heat over time. It changes more quickly at high temperatures and more slowly at low temperatures. When the color of the square is the same as the color of the reference ring or is darker than the reference ring, the vaccine vial has been exposed to too much heat and should be discarded.

Many studies have been successfully conducted taking vaccine (oral polio, hepatitis B, and tetanus toxoid) out of the cold chain. The vaccine was transported and stored without refrigeration or ice, but kept as cool as possible and protected from sunlight.

16. Assuming that HPV vaccines have VVMs attached, would there be a benefit to taking this vaccine out of the cold chain?

    Circle one: Yes No

    If yes, what segments of the cold chain would best lend themselves to out-of-cold-chain (now referred to as controlled temperature chain) storage or transport of the product?

    Answer: _____

    What would the benefits be?

    Answer: _____

17. Would there be challenges to keeping the vaccine out of the cold chain?

    Circle one: Yes No

    If yes, please describe.

    Answer: _____

Provide the interviewee with a copy of the Coldpack "Antifreeze Backpack" Assembly Guide. Demonstrate: Open, assemble, and fill the Antifreeze Backpack with vaccine samples. Place it on the back of the interviewee to test the weight and feel of the pack.

18. Do you think the Backpack would meet your needs as a vaccine carrier to outreach settings?

    Circle one: Yes No

    Is it comfortable and easy to carry?

    Answer: _____

    What are you general thoughts on the Backpack?

    Answer: _____

Labeling and Packaging

Show an existing box of Merck or GlaxoSmithKline (GSK) HPV vaccine with packaging and labeling in Vietnamese

19. Are there any problems with the packaging or labeling?

    Circle one: Yes No

    If yes, what recommendations do you have to improve this?

    Answer: _____

Show an existing vial of Merck or GSK HPV vaccine with packaging and labeling in Vietnamese

20. Are there any problems with the packaging or labeling?

    Circle one: Yes No

    If yes, what recommendations do you have to improve this?

    Answer: _____

General

21. In your opinion, what recommendations do you have to improve the presentation and packaging of HPV vaccine for use in your region?

    _____

Thank you very much for your time and assistance!

Appendix 2. HPV Vaccine Product Presentation Questionnaire for Procurement/Logistics Managers and Officers

The objective of this questionnaire is to better understand the product presentation and packaging issues that are important for effective and efficient delivery of human papillomavirus (HPV) vaccine. This questionnaire was presented verbally to interviewees.

Background Information

- Designation/title: _____
- National EPI/Regional EPI/Province: _____
- Area of Expertise: _____

Note: EPI= Expanded Programme on Immunization

General Immunization

1. Have you procured HPV vaccine?

   Circle one: Yes No

   If yes, approximately how many doses have you procured?

   Answer: _____

2. Have you experienced any problems with the volume or weight of HPV vaccine that needs to be transported?

   Circle one: Yes No

   If yes, where (at what level of the health system) did the problem occur?

   Answer: _____

3. Have you experienced any problems with vaccine during storage?

   Circle one: Yes No

   If yes, what was the problem?

   Answer: _____

   If yes, where (at what level of the health system) did the problem occur?

   Answer: _____

Show a single-dose vial of HPV vaccine

4. What do you perceive are the benefits of a single-dose vial?

   Answer: _____

5. What do you perceive are the challenges of a single-dose vial?

   Answer: _____

Show a prototype 10-dose vial with preservative and explain that this is a hypothetical product that does not exist. This product could potentially be kept for use for up to 30 days if safe techniques are used to withdraw doses from the vial (i.e., a new syringe/needle is used to withdraw each dose).

6. What do you perceive are the benefits of a multi-dose vial with preservative?

   Answer: _____

7. What do you perceive are the challenges of a multi-dose vial with preservative?

   Answer: _____

8. Do you think there would be issues with transporting unused open vials of vaccine back to storage after outreach trips?

   Circle one: Yes No

   If yes, please describe the issues.

   Answer: _____

Show a two-dose vial prototype and explain that this product does not contain preservative and therefore must be kept cold and discarded within 6 hours (like a measles vaccine that has been reconstituted). If the vaccine is kept for longer than 6 hours, the lack of preservative may allow bacteria to grow in the vial. Consequently, if a contaminated vaccine is administered to a patient, toxic shock may result.

9. What do you perceive are the benefits of a two-dose vial with no preservative?

   Answer: _____

10. What do you perceive are the challenges of a two-dose vial with no preservative?

    Answer: _____

Show two prototype Uniject devices in foil pouches—one for you and one for the respondent. Show them how to remove the device from the pouch, activate the device, and inject the dose into an orange or other appropriate item. Explain that this is a hypothetical product. Some vaccines are currently available in Uniject, but HPV vaccine is not.

11. What do you perceive are the benefits of Uniject?

    Answer: _____

12. What do you perceive are the challenges of Uniject?

    Answer: _____

13. How many doses per vial or delivery device would you prefer to have for HPV vaccine?

    Answer: _____

Usefulness of Out of Cold Chain

Show a vaccine vial monitor and instructional color chart.

Explain: The center square of the vaccine vial monitor (VVM) changes color from light to dark with exposure to heat over time. It changes more quickly at high temperatures and more slowly at low temperatures. When the color of the square is the same as the color of the reference ring or is darker than the reference ring, the vaccine vial has been exposed to too much heat and should be discarded.

Many studies have been successfully conducted taking vaccine (oral polio, hepatitis B, and tetanus toxoid) out of the cold chain. The vaccine was transported and stored without refrigeration or ice, but kept as cool as possible and protected from sunlight.

14. Assuming that HPV vaccines have VVMs attached, would there be a benefit to taking this vaccine out of the cold chain?

    Circle one: Yes No

    If yes, what segments of the cold chain would best lend themselves to out-of-cold-chain storage or transport of the product?

    Answer: _____

    What would the benefits be?

    Answer: _____

15. Would there be challenges to keeping the vaccine out of the cold chain?

    Circle one: Yes No

    If yes, please describe.

    Answer: _____

Provide the interviewee with a copy of the Coldpack "Antifreeze Backpack" Assembly Guide. Demonstrate: Open, assemble, and fill the Antifreeze Backpack with vaccine samples. Place it on the back of the interviewee to test the weight and feel of the pack.

16. Do you think the backpack would meet your needs as a vaccine carrier to outreach settings?

    Circle one: Yes No

    Is it comfortable and easy to carry?

    Answer: _____

    What are you general thoughts on the backpack?

    Answer: _____

Labeling and Packaging

Show an existing box of Merck or GlaxoSmithKline (GSK) HPV vaccine with packaging and labeling in Vietnamese

17. Are there any problems with the packaging or labeling?

    Circle one: Yes No

    If yes, what recommendations do you have to improve this?

    Answer: _____

Show an existing vial of Merck or GSK HPV vaccine with packaging and labeling in Vietnamese

18. Are there any problems with the packaging or labeling?

    Circle one: Yes No

    If yes, what recommendations do you have to improve this?

    Answer: _____

Vaccine Price

19. In your opinion, which is more important vaccine price or vaccine cost-effectiveness?

    Why?

    Answer: _____

20. Would you be willing to pay a slight price premium for a vaccine that minimizes vaccine wastage so that less vaccine needs to be purchased?

    Circle one: Yes No

21. Would you be willing to pay a slight price premium for a vaccine that minimizes space in the cold chain if space were a constraint?

    Circle one: Yes No

22. Would you be willing to pay a slight price premium for a vaccine presentation that improves safety, such as a multi-dose vial that contains preservative?

    Circle one: Yes No

23. Would you be willing to pay a slight price premium for a vaccine presentation that improves safety and convenience, such as a compact prefilled autodisable device?

    Circle one: Yes No

General

24. In your opinion, what recommendations do you have to improve the presentation and packaging of HPV vaccine for use in your region?

    _____

Thank you very much for your time and assistance!

Appendix 3. Figures

Figure 1. Multi-dose vial prototype

Photo credit: PATH Vietnam

The Institute of Vaccines and Medical Biologicals' (IVAC) tetanus toxoid vaccine in a 20-dose vial with preservative served as the sample multi-dose vial.

Figure 2. Two-dose vial prototype

Photo credit: PATH Vietnam

Berna Biotech's Hepavax-Gene 1 ml in a 2-dose vial.

Figure 3. BD Uniject® prototype

Photo credit: PATH Vietnam

Uniject in foil pouch.

Figure 4. Antifreeze Backpack

Photo credit: Coldpack System

Coldpack's Antifreeze Backpack Vaccine Carrier with vaccine storage capacity of 3 liters and empty weight of 1.2 kg (packaged as a kit comprising a foldable backpack, 3 coldpack Airliner®, a T-Zone tray, manual air pump, aluminum bag, valve protection clip, and Thermometer Grid indicating the number of icepacks required based on ambient temperature).

Figure 5. Merck's Gardasil

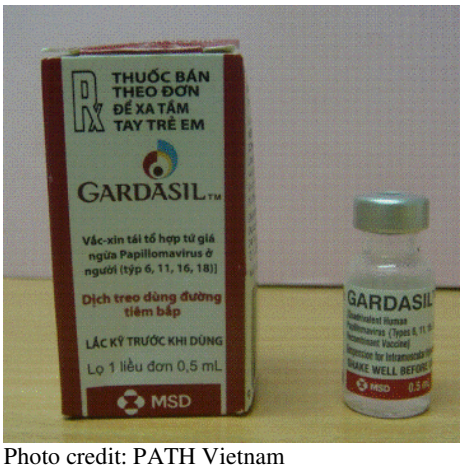


Photo credit: PATH Vietnam

Merck's Gardasil in a 0.5-ml suspension in a vial (type 1 glass) with stopper (FluroTec-coated or Teflon-coated chlorobutyl elastomer) and flip-off plastic cap (aluminum crimp band) in a pack size of 1, 10, or 20. The photo represents the box and labeling of Gardasil for distribution to Vietnam.

Figure 6. GSK's Cervarix

Photo credit: PATH

GSK's Cervarix in a 0.5-ml suspension in a vial (type I glass) with a stopper (rubber butyl) in pack sizes of 1, 10, and 100.

Photo credit: PATH Vietnam

At the time of the survey, a Vietnamese version of Cervarix was not available. Instead, a small label with Vietnamese translation was attached to the box.

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