

Appendix 1: Phase III Country consultations

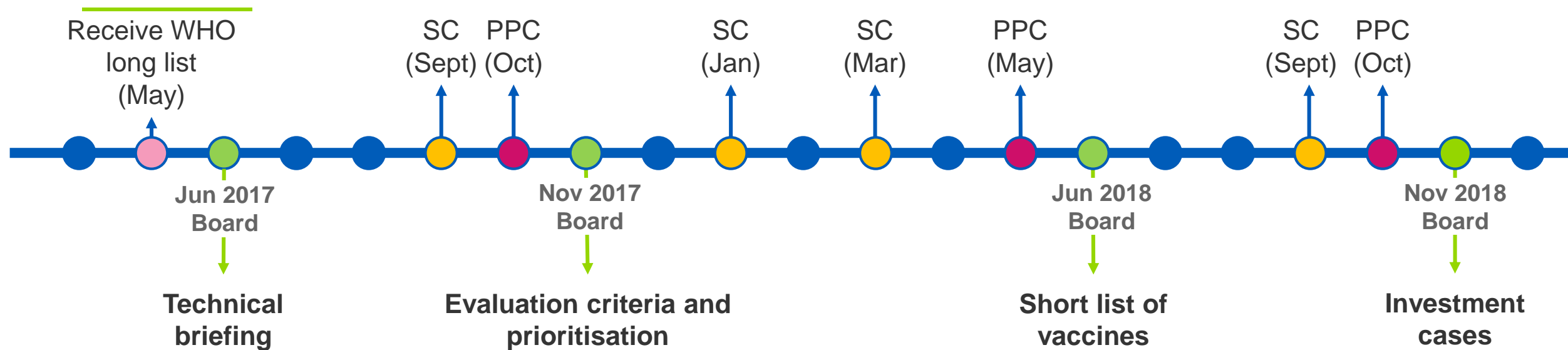
Vaccine Investment Strategy
Programme and Policy Committee Meeting
18-19 October 2018



Topics

1. Country consultations - focused interviews
2. Country consultations - survey

VIS consultation process



Phase: Evaluation Criteria

Decision Framework Survey
August- September 2017

- Countries & Board members
- To inform development of decision making framework

Phase: Vaccine Shortlisting

Vaccine Prioritization Consultations
January – February 2018

- Consultations with subset of Gavi Board members
- Survey with Country & Regional-level EPI, NITAGs, CSOs & Alliance Partners

Phase: Vaccine Investment Cases

Shortlisted Vaccine Consultations
June – August 2018

- Consultations with subset of Gavi Board members
- Focused interviews and survey with country & regional-level EPI, NITAGs, CSOs & Alliance Partners

1

Country consultations – Focused interviews

In-depth country interviews targeted specific stakeholders in a prioritised set of countries

Targeted participants

- Country and regional-level representatives
e.g. EPI, other MoH, WHO, UNICEF, NITAG members, CSOs
- Representative group of countries contacted for participation

Format

- 1hr in-depth discussion facilitated by a discussion guide
- Conducted in English, French or Russian

Questions

- Focused on:
 - Understanding the prioritisation and implementation feasibility of vaccines for endemic disease prevention
 - Perceptions around pandemic influenza preparedness
 - Perceptions around financing of IPV post-2020

Interviews

- 28 consultations with 17 countries, 2 regional WHO offices and 3 CSOs*
- Conducted over the phone or in person at WHA, AFRO RITAG or SEAR ITAG



Country consultations have raised several key cross-cutting insights

- Countries very focused on current and near-future introductions
- Gavi-support of vaccines is important factor for decision-makers considering new vaccine introductions
- Lack of burden data is a barrier to prioritising and introducing vaccines, and is required to generate political will
- Responses on benefits and challenges are very country-specific and point towards tailored approaches

Interviews with country stakeholders revealed that ease of implementation depends on existing systems

06a – Appendix 1

Priorities and approach

- Of mixed priority; in some countries, not yet introduced due to low due to lack of awareness and political will in some countries (and some boosters viewed as more important than others); in other countries, rising priority due to high burden of tetanus and diphtheria outbreaks
- Some countries already include one or more boosters
- WHO recommendations not disseminated clearly: some countries still boosting ever 10 years, some countries not clear on value of 2nd booster

Coordination and expanding to new platforms

- One respondent expressed difficulty in introducing any new vaccines after 12 months of age (including 2nd year of life; others noted that the 1st and 3rd boosters would be easier as those time points exist (measles 2nd dose and HPV)
- In some countries, 2nd and 3rd boosters are given in schools, while in other countries, vaccination is more feasible at the health care facility
- Some respondents noted that bringing vaccines to schools from health care facilities could carry additional operational costs and require additional training

Challenges

- Determining the optimal location and timing of vaccination of 2nd and 3rd boosters seen as a challenge (eg, health care facility vs schools)
 - One respondent said parents don't often bring children to health facilities over 1 year old except for illness
 - Unclear how to reach children who do not attend school, which in some countries can be significant number
- Lack of communication with communities to build awareness
- Mixed responses on whether the boosters would require additional costs: some respondents cited behaviour change, logistics and demand creation as costing more
- Some interest in using pentavalent for the 1st booster, but will need WHO guidance on what is preferred
 - One respondent said it might be confusing and seen as 'going backward' to use DPT, and there could be mix-ups in administration
- Some concern about cost – individually vaccine price less concern, but country costs are increasingly going up as more vaccines added and countries progress along transition and take up more co-financing

Interviews with country stakeholders revealed that reaching out of facility births would be challenging

06a – Appendix 1

Priorities and approach

- Regional priority (eg, Southeast Asian region countries), but some countries mixed without burden data
- Some countries exploring subnational introductions first, targeting high risk populations
- Not viewed as similar to BCG due to different time component (eg, longer time period for vaccination with BCG)
- Some countries using traditional vials out of cold chain, seeing improvement in coverage; other countries express interest in Uniject but cautious on price and cold chain requirements

Coordination and expanding to new platforms

- Leveraging antenatal care platform seen as feasible, but mixed views on costs
 - Some respondents noted training midwives could carry higher costs, others felt overall costs should be similar to other vaccine introductions as touchpoint already exists
- Coordination of supply will need to be addressed – should vaccine be stored in maternity wards or using EPI storage facilities?

Challenges

- Some confusion over use of vaccine, eg, administration after 24 hours (recommended time frame) or to babies born with low birth weight
- Out of facilities births seen as significant challenge to reach due to distance and lack of skilled birth attendants present
 - Some countries delaying introducing birth dose until institutional birth rate increases
 - Some respondents expressed desire for global guidance on how to access this population
- Midwives can be trained to give birth dose even for out of facility births, but sometimes difficult in administering within 24 hours if birth is unattended (midwife sometimes doesn't arrive for baby check within that timeframe)
- Single dose vials are preferred as midwives cannot carry multi-dose vials, but they would be more expensive presentation
- Some concerns about higher transportation costs to deliver vaccines to district facilities

Interviews with country stakeholders revealed that introduction dependent on additional cost vs. MenA

06a – Appendix 1

Priorities and approach

- Some countries still yet to introduce Meningococcal A (MenA) vaccine
- Where meningococcal disease occurs, respondents felt a vaccine would be a priority
- Multivalent vaccine preferred though not necessarily due to known disease burden of other serogroups beyond A
- Question whether approach would be to replace current MenA vaccine (MenAfriVac) with multivalent

Burden of disease and surveillance

- Most common serogroups are A and C; W, X, Y unknown burden
- Not always a national problem; meningococcal disease occurs regionally/ subnationally

Programmatic implementation

- Cost viewed as biggest barrier, based on pricing of current multivalent vaccines compared to MenAfriVac
- Could consider subnational approach but would be programmatically challenging and concerned about serogroup emergence and shift
- Campaigns at time of introduction viewed as appropriate initial step, followed by routine immunisation, for successful introduction
- Current experience has been that serogroups occur heterogeneously across areas with meningococcal disease burden (eg, some areas have NmA, others have other serogroups)
- Respondents felt additional training would be required

Interviews with country stakeholders revealed that campaigns are of high importance in endemic areas

06a – Appendix 1

Priorities and approach

- High priority for most countries where it is a disease of importance, though a few countries with high burden have not yet begun discussions on control
- Some respondents felt they could leverage epidemic/pandemic preparedness mechanisms as cholera is mainly viewed as outbreak disease, though interested in preventive approach

Burden of disease and hotspot identification

- Most respondents felt that they have some way of identifying hotspots, but the approach is not standardised
- Surveillance for cholera is mixed; some countries have diarrheal disease surveillance

Integrated disease control and coordination

- Respondents identified varying levels of coordination within government, but everyone recognised its importance
 - E.g., EPI not involved in cholera control in some countries; some felt oral cholera vaccine could be delivered through EPI, while others noted EPI cold chain being used at national level
 - In one country, EPI sits on a working group; in another country, there is a weekly meeting and data shared
 - Strong sense that EPI should be included as has the expertise of training vaccinators and conducting campaigns
- One respondent cited coordination as the reason why a recent outbreak was controlled successfully
- Respondents felt that cholera control would be most sustainable if led by strong government leadership
- WaSH is viewed as important but often a fragmented intervention that sits in a different sector and reliant on donor funding

Campaign challenges

- Respondents noted some difficulty in accessing cholera vaccine due to current supply mechanism (global stockpile) and limited supply
- Water, sanitation and hygiene activities are not always implemented during campaigns; some respondents felt it would not be difficult to do so but key would be to identify appropriate interventions
- Cost, access and security also highlighted as key challenges; hotspots are often inaccessible or located in conflict areas

Interviews with country stakeholders revealed that most countries have weak, fragmented programmes

06a – Appendix 1

Priorities and approach

- High priority for many countries as burden is significant or increasing in young children and results in death
- Many countries have weak and fragmented programmes mainly in the private sector resulting in high out of pocket expenditure for patients
- Some countries using non-PQ human rabies vaccine, though quality is not assured
- Mixed responses on prioritising dog vaccination, though might have other approaches to animal control

Integrated disease control and coordination

- Rabies post-exposure prophylaxis (PEP) is not coordinated through EPI
- Sometimes a separate cold chain, though at district 2 level could be same
- Animal control/dog vaccination housed in different ministry though some respondents unsure of which ministry
 - However one country highlighted existing One Health function to coordinate different components of comprehensive programme
- Some countries feel public rabies PEP programme could be built on existing public health system infrastructure (eg, integrated in primary health care)

Challenges

- Demand fragmentation and supply raised as significant challenges, leading to stockouts and lack of confidence in availability of the vaccine
- Animal control could be logistically difficult in terms of reaching all stray dogs, as well as coordination with another ministry
- Misalignment in roles and training: vaccinators not trained to give rabies PEP but have access to it; emergency department personnel trained to give rabies PEP but can't access vaccine
- Building community awareness would cost more than social mobilisation for traditional vaccine introduction
- Could be some challenges with switching to a prequalified vaccine and intradermal administration
- Logistics of vaccine storage unclear: vaccine needs to be made available at which level of health facility?

Interviews with country stakeholders revealed that RSV priority difficult to assess as burden unknown

06a – Appendix 1

Priorities and approach

- Respondents indicated RSV was low priority at national/government-level due to lack of information about disease and disease burden, however:
 - Respiratory illnesses are generally of concern among consulted in-country stakeholders
 - At clinical level, physicians/paediatricians see many suspected RSV-related bronchiolitis cases and would prioritise vaccine if made available
- Some respondents suggested diagnostics would help improve value proposition

Burden of disease and surveillance

- Country-level hospital and community disease burden not well understood by decision makers at national level
- Many countries have surveillance for respiratory infections, but not RSV specifically

Programmatic considerations and challenges

- Maternal immunisation overall not viewed as a challenge, because many countries already have tetanus toxoid (TT) or tetanus-diphtheria (Td) programmes for pregnant women
 - In some countries, TT/Td vaccine given during ‘immunisation day’ in local communities, so more easily accessible (and often free) vs during antenatal check when women travel to hospital or clinic
 - Some countries noted low coverage of maternal TT/Td due to gender barriers (e.g., sex of vaccinator)
- Need for demand generation and social mobilisation to improve knowledge of disease burden
- Some respondents cautioned that TT/Td coverage might not translate to RSV coverage because there is understanding that tetanus is untreatable; similarly other non-treatable infections higher priority (e.g., dengue)

Interviews with country stakeholders revealed that IPV will continue to be a high priority in most countries

06a – Appendix 1

Cost-sharing

- IPV seen as high priority; need to continue to protect people from re-emergence of polio and meet eradication goal
 - Particularly of concern to polio-endemic countries and neighbours
- Many countries expect to take up some co-financing; mixed views as to financial implications
 - Some expect fiscal space to increase so low risk for other vaccines, particularly as time-limited and OPV to be phased out (and will free up funding)
 - A few expressed concern about tightening fiscal space or increased costs due to increased co-financing of vaccines, could result in delays of other vaccine introductions
- One respondent noted that as IPV is global mandate, financing more of a global issue

Fractional IPV

- Acceptance is mixed; some are already implementing, others hesitate to go off label
- Some concern about high drop out for a second dose in certain populations

Hexavalent vaccine

- Many expressed positive of programmatic convenience of fewer injections (could also help increase coverage of all antigens contained), but would need to see prices to determine if higher price is offset by some systems savings

Interviews with country stakeholders revealed that countries had variable levels of pandemic planning

06a – Appendix 1

Priorities and approach

- Knowledge of pandemic preparedness plan variable; mixed information as to whether vaccination is a component
 - One respondent noted their country includes pregnant women in plan
- Many respondents noted they either do not have seasonal influenza or their country decision-makers do not see it as a problem
 - In some countries, flu vaccine available in the private market
 - Other countries said they only have it when there is outbreak or high risk
- Link between seasonal flu vaccination and pandemic preparedness unclear; need some systematic data collection and further awareness building for government officials

Surveillance

- Surveillance for severe acute respiratory illness (SARI) and acute lower respiratory illness (ALRI) exists in many countries
- Few countries have specific flu surveillance but some have lab capabilities; others can send sample to labs in other countries
- There is some hospital based or symptoms based surveillance
- Some countries through One Health approach have surveillance for emerging zoonotic infections

Priority groups

- Mixed views as to whether health care workers or pregnant women is the preferred priority group for routine vaccination
 - Some respondents suggested both
 - Health care workers were generally seen as easier to reach, and more relevant and carrying more weight in relation to pandemic preparedness
 - One respondent said health care workers could actually be more difficult as could require a mind shift for health professionals to think of themselves as patients vs not just caregivers; health facilities might not prioritise workers vs pregnant women who are seen as a vulnerable group and already have a vaccination touchpoint with TT/Td
 - Pregnant women also seen as a priority because health care workers receive training

Country focused interview questions (1/9)

Overarching questions

1. Have any of the vaccines under consideration for investment already been introduced or planned for introduction at present, or been discussed by the Interagency Coordinating Committee (ICC) or National Immunisation Technical Advisory Group (NITAG) or other decision-making or advisory body?
 - If yes: Please describe your experiences with the vaccines mentioned, level of priority in country, expected introduction date, coverage levels achieved or expected
 - If no: What are the reasons why these have not been considered? Probe specifically Hep B birth dose, DTP boosters, seasonal flu and rabies PEP.
2. Considering the cost of co-financing/ financing each of these vaccines, realistically, which of these eight would you prioritise for new vaccine introductions within the next ten years? Why?
PROBE: Opportunity costs of introducing new vaccines
3. Are there any vaccines which you would not consider for introduction? Why?

Country focused interview questions (2/9)

Cholera

1. Please describe the current approach to cholera control in your country.
PROBE: Plans for future
Follow-up: What would be the impact of preventative cholera campaigns in your country? Are there any barriers to delivering cholera vaccine?
2. If Gavi were to support preventative cholera immunisation, it would be targeted at hotspots, which are relatively small areas where the cholera burden is most concentrated and that play a central role in the spread of cholera. What is the current status of cholera surveillance activities and how are cholera hotspots currently identified in your country? Do you have/ foresee any challenges in identifying cholera hotspots?
PROBE: Support required to identify hotspots
Follow-up: What other challenges exist or do you foresee in implementing preventative campaigns?
3. What is the current level of coordination between EPI and water and sanitation (WaSH) programmes for cholera (or other related diseases) and what are the challenges?
4. [Question for cross-cutting roles] If access to Gavi support for preventive campaigns depended on scale up of water and sanitation (WaSH) activities, would you be able to increase investment in water and sanitation (WaSH) activities?

Country focused interview questions (3/9)

D,T&P-containing boosters

1. *[If not introduced]* What are the main reasons why the full booster series has not yet been introduced? Are there plans to do so?
PROBE: financial barriers, political commitment, technical knowledge, immunisation system capacity
2. *If introduced:* What were/ are the main issues you face in introducing and scaling-up the use of D,T&P-containing boosters to achieve high coverage?
PROBE: What is required to mitigate the identified issues?
Follow-up if partial introduction: What are your plans regarding the other boosters? Why did you not implement all three concurrently?
3. Which systems (e.g., healthcare service delivery platforms) are in-place in your country that could be leveraged for the routine delivery of each of the 3 booster time points? How feasible would it be to integrate the booster into each of these existing systems?
NOTE: MCV2/2nd year of life, school entry (4-7 yr), HPV/adolescent health care platforms (9-15 yr)
4. Are there any other requirements to successfully establish the immunisation delivery timepoint and achieve high coverage?
PROBE: Platform requirements, system capacity, specific training, cold chain capacity etc.
5. Would D,T&P-containing boosters carry more systems costs than other routine vaccines to introduce or deliver? If yes, what might drive the costs higher?
PROBE: technical assistance, training, demand generation, microplanning delivery, waste management, monitoring and surveillance
6. WHO recommends that the first D,T&P-containing booster at 12-23 months could be delivered as either DTwP or pentavalent vaccine. Which of these two vaccine options would you prefer to deliver as the first booster? What would be the challenges and opportunities of using pentavalent vaccine vs. DTwP?
PROBE: Cost differential (DTP ~\$0.20; Penta ~0.60-0.75)

Country focused interview questions (4/9)

Hepatitis B birth dose

1. [If introduced] Please describe the process of introducing hepatitis b birth dose. What challenges have you experienced when scaling-up use and what are the barriers to increasing coverage?
PROBE: What aspects of the EPI/ MNCH platform have you leveraged?
PROBE: Risks and challenges of new platform (disruption of existing health services at this time point and resources allocated for other services, vaccine confidence at this time point among mothers and EPI and/or MNCH staff, mixed messages about facility delivery)
2. [If introduced] Do you have outreach programmes that deliver hepatitis b birth dose to babies born outside of health facilities? If so, how does this work in practice? If not, why not?
PROBE: What are the risks of vaccinating outside of facilities? What other programmes can be leveraged to reach these babies? Would you be interested in supporting novel delivery mechanisms (i.e. task shifting, training of community healthcare workers, promoting outside the cold chain use)
3. [If not introduced] What are the main reasons why hepatitis b birth dose has not yet been introduced? Do you have any plans to introduce hepatitis b birth dose vaccination without Gavi support? What would be required or would facilitate hepatitis b birth dose introduction?
PROBE: MNCH and EPI working together, cold chain facilities in maternity wards, financial considerations including external support
PROBE: Risks and challenges of new platform (disruption of existing health services at this time point and resources allocated for other services, vaccine confidence at this time point among mothers and EPI and/or MNCH staff, mixed messages about facility delivery)
4. If you were to introduce hepatitis b birth dose with Gavi support, based on your experience and existing policies, would you also aim to reach births not taking place in facilities and what would be the best approach to do so?
5. There are new delivery technologies which have been developed to be easier to use and have been piloted specifically for use in outreach. You may have heard of a specific product called Uniject, which is an autodisable pre-filled syringe. What is your perception of Uniject or other delivery innovations as an option for hepatitis b birth dose delivery? Would you use it if it was offered despite increased cost and potential implications on training & cold chain?
Follow-up: Do you perceive challenges in using such a product and allowing healthcare workers to administer the vaccine?
6. Does hepatitis B birth dose cost more than other routine vaccines to introduce and deliver? If yes, what drives the costs higher?
Follow-up: Does or would the introduction and operational costs to support out-of-facility delivery differ in significant ways from in-facility delivery?

Country focused interview questions (5/9)

Multivalent Meningococcal

1. We understand that you have already, or plan to introduce Meningitis A into routine immunisation with catch-up in year X, is that correct? Do you have any further plans regarding the introduction of multivalent meningitis vaccines?
2. Based on your country context, do you think there is value in a multivalent conjugate vaccine compared to Meningitis A vaccine? Which serogroups are the most important for a vaccine to contain?
PROBE: How much more would you pay for a multivalent vaccine vs. Men A? 0%? /50%/ 100% more? Why?
(Men A ten-dose costs \$0.52 per dose for routine and \$0.69 per dose for campaign)
3. What would you expect the greatest programmatic challenges associated with introducing a multivalent meningitis vaccine/ switching meningitis vaccine would be?
4. Assuming a recommendation of routine introduction with campaign, would the introduction and operational costs to support multivalent meningitis vaccines differ in significant ways from those of Men A?

Country focused interview questions (6/9)

Rabies

1. Is rabies a public health priority in your country? Why or why not?
Follow-up: Does the government have a specific documented elimination goal for rabies? If not, are there other policy commitments?
Follow-up: How would you assess the human and dog vaccination programmes?
2. *[Deprioritise for learning agenda countries]* What are the components of the rabies control programme in your country and what is the current status of this programme? How would you rate the current effectiveness of this programme?
PROBE: How would you assess the human and dog vaccination programmes? Which department is responsible for the rabies control programme, what is the access to vaccine (and RIG?) at urban vs. rural centres, is PrEP in place for specific sub-populations e.g. occupational exposures or other high risk groups
Follow-up: Please describe any changes in access to the rabies programme in recent years and how the system has adapted to accommodate those changes
3. What are the main challenges you face in implementing a rabies control programme?
PROBE: Correct PEP administration, vaccine or RIG supply including stock outs, reactive vaccine stock management, lack of financial resources, coordination between departments and administrative levels, mass dog vaccination, low awareness in at risk populations
4. *[Deprioritise for learning agenda countries]* How is the rabies PEP vaccine (+ RIG?) distributed from the central level to health facilities? How is vaccine need forecast?
PROBE: Distribution mechanisms (integrated with EPI, shared logistics with EPI, or other mechanism?), who delivers (EPI or other healthcare worker?)
5. What would be the additional investment (technical and/or budgetary) required to progressively implement the rabies programme and to improve access to PEP?
PROBE: technical assistance, training, demand generation, microplanning delivery, waste management, monitoring and surveillance
6. Are there mass dog vaccination and awareness campaigns about rabies in your country and are there any plans to scale them up?
Follow-up: If access to Gavi support for the human rabies vaccine depended on scaling up, would it be feasible for you to commit or increase more resources in mass dog vaccination?
Follow-up: What are the challenges associated with implementing mass dog vaccination?

Country focused interview questions (7/9)

RSV

1. How much is known about the burden of respiratory syncytial virus within your country?
PROBE: contribution to acute lower respiratory infection (ALRI) burden (it is typically most common aetiology), proportion of children infected with RSV before 2 years of age (usually between 75-100%), surveillance, knowledge of disease at higher ministry levels
 2. Are any vaccines currently delivered to pregnant women in your country (e.g., tetanus, influenza)? Is vaccination in pregnancy acceptable to women in your country?
PROBE: Who delivers these? Through which health service delivery platform(s)?
 3. What are the barriers to vaccinating pregnant women? Would it be feasible to deliver a vaccine to pregnant women through ANC?
PROBE: Task-shifting to ANC healthcare workers rather than EPI, current ANC delivery model (i.e. location, staff, type/quality of services provided), acceptability in target population
 4. Would the costs of introducing a vaccine administered to pregnant women (e.g. maternal RSV) be different than other EPI vaccines? Why might maternal RSV cost more than other vaccine introductions?
PROBE: technical assistance, training, demand generation, microplanning delivery, waste management, monitoring and surveillance
- 2nd tier questions**
5. *The RSV vaccine is currently in clinical trials.* Considering the vaccine's efficacy is still unknown, what would be the minimum efficacy that would encourage you to consider introducing the vaccine, regardless of price?
PROBE: same as maternal flu, other benchmark, cost-effectiveness analysis
 6. Does your country have existing systems in place to monitor background rates for birth outcomes (e.g. low birth weight, gestational age, congenital abnormalities etc.)?

Country focused interview questions (8/9)

IPV post-2020

1. If Gavi were to require co-financing for IPV, meaning that countries would have to contribute to costs, would it present a risk to continuation of the IPV programme in your country?
Follow-up: What trade-offs would you consider? Are there implications for other routine immunisation programmes?
Follow-up: How could the risk of discontinuation of polio programmes be mitigated?
Follow-up: [Nigeria & Pakistan] If your country's government was to commit financing towards the vaccine, what changes would you foresee in the programme and in progress towards the goal of elimination?
2. Assuming polio has been eradicated and Gavi required co-financing for IPV, would you maintain IPV in the routine schedule for as long as it is recommended by SAGE (currently 10 years, and longer/indefinitely if a country maintains a “polio essential facility”)?
3. What would you consider to be the most important challenge to adopt fractional dose IPV and what would be required to overcome the challenge? If Gavi required co-financing, would you be more likely to adopt fractional dose IPV?
4. Hexavalent vaccines, which contain all five pentavalent antigens as well as IPV, may become available in the coming years. However, uncertainties remain about hexavalent price and the cost to countries may be higher than that of pentavalent and IPV together. If Gavi were to offer hexavalent vaccine, would you prefer it to pentavalent vaccine and IPV separately? How would you weigh programmatic versus financial implications?
PROBE: What benefits would you expect from the use of hexavalent and how would you value them? How much more would you pay for hexavalent vs. pentavalent + IPV? 0%/ /50%/ 100% more? Why?

Country focused interview questions (9/9)

Pandemic influenza & other epidemic diseases

1. Do you have a national pandemic influenza preparedness plan? When was it last updated? Does it specifically include provisions for use of influenza vaccines as part of the pandemic national response? Does it identify high priority groups for immunisation in a pandemic?
PROBE: [If not completed a Joint External Evaluation] Are you planning to complete a JEE through the Global Health Security Agenda?
2. Do you currently deliver seasonal flu vaccination to any priority groups? What coverage is achieved? If introduced, what were/ are the main issues you face in introducing and scaling-up the use of seasonal flu vaccination?
PROBE: Have you previously, if it was stopped, why? Acceptability to patients.
3. To what extent do you think seasonal influenza vaccination can help prepare your country for a pandemic? In what specific ways?
PROBE: regulatory, demand promotion, microplanning, surveillance. Confirm relevance of these activities in seasonal immunisation setting vs. pandemic setting
4. What is the current status of influenza surveillance activities, both in terms of tracking influenza-like illnesses and circulating strains? Do you have/ foresee any challenges with surveillance activities?
PROBE: surveillance of emerging strains, impact of surveillance
5. WHO has identified 5 groups as high priority for seasonal influenza, including health care workers and pregnant women. If you had to choose between these two groups for seasonal immunisation, which would you select? Why?

2nd tier questions

6. Based on your country's experience of the 2009 H1N1 influenza pandemic, what was the greatest challenge you faced in pandemic flu response?
PROBE: specific challenges related to the use of vaccine in the pandemic
7. Thinking more broadly about epidemic diseases, do you have a list of national/ regional priority pathogens for epidemic preparedness?
Follow-up: What broader epidemic/ pandemic preparedness priorities do you have, and how important is pandemic influenza preparedness as part of these broader activities?

2

Country consultations - Survey

Country consultations targeted a wide range of stakeholders from all 73 Gavi countries



- Country and regional-level representatives *e.g. EPI, other MoH, WHO, UNICEF, NITAG members, CSOs*
- Web survey sent through a link (Survey Monkey)
- Distributed at regional or country meetings
- Translated into French, Spanish & Russian
- 27 questions; ~30 mins to complete
- Surveys views of:
 - Prioritisation and implementation feasibility of vaccines for endemic disease prevention
 - Perceptions around pandemic influenza preparedness
 - Perceptions around financing of IPV post-2020
- 96 from all regions and stakeholder types

Vaccine Investment Strategy 2018 – Country Consultation

The Vaccine Investment Strategy (VIS), conducted every five years, is the formal process through which Gavi, the Vaccine Alliance, identifies new vaccines and other immunisation products for potential inclusion in its portfolio. Funding decisions consider the impact, cost, value, and programmatic feasibility of these vaccines. Any new or expanded vaccine investments in the VIS would be added to Gavi's existing portfolio of vaccines which includes: cholera (stool-plate only); Ebola (once vaccine is licensed and WHO recommended); human papillomavirus (HPV); inactivated poliovirus (through 2020); Japanese encephalitis; measles & measles-rubella; meningitis A; pentavalent; pneumococcal; rotavirus; typhoid; and yellow fever.

Three sets of vaccines are being considered for potential investment in the VIS 2018: vaccines for endemic disease prevention through routine immunisation; vaccines for epidemic preparedness (outbreak response); and inactivated poliovirus vaccine (IPV) support beyond eradication. This survey explores preferences of in-country stakeholders for new vaccine additions to Gavi's portfolio and implementation considerations. Your responses will inform the development of recommendations to the Gavi Board. The Board will endorse a set of prioritised candidate vaccines in June 2018 and will take final investment decisions in November 2018. Individual responses will be kept confidential.

Respondent Information

Name: _____

Country or Region: _____

Type of Organisation: (if multiple affiliations, please provide all)

Ministry of Health - EPI National Immunisation Technical Advisory Group (NITAG)
 Ministry of Health - not EPI Civil society/NGO
 Government - Other Research/Technical Institute/University
 WHO UNICEF

Other (please specify): _____

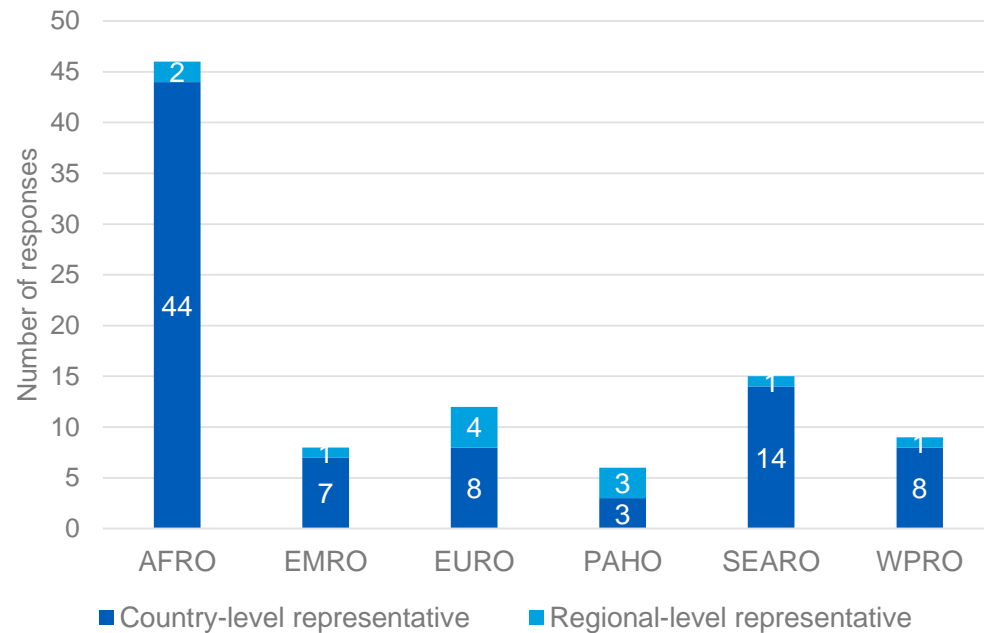
Vaccine candidates for Endemic Disease Prevention

1. Below are listed the vaccines for endemic diseases being considered in the VIS, including the specific vaccination strategies. Some of the vaccines are already available whilst others are still in development. Please indicate which are of highest importance for future introduction in your country or region by ticking the relevant boxes. (Malware RTS,S vaccine will be considered for an investment decision at another time, separate from the VIS, so Gavi-supported pilots are still ongoing.)

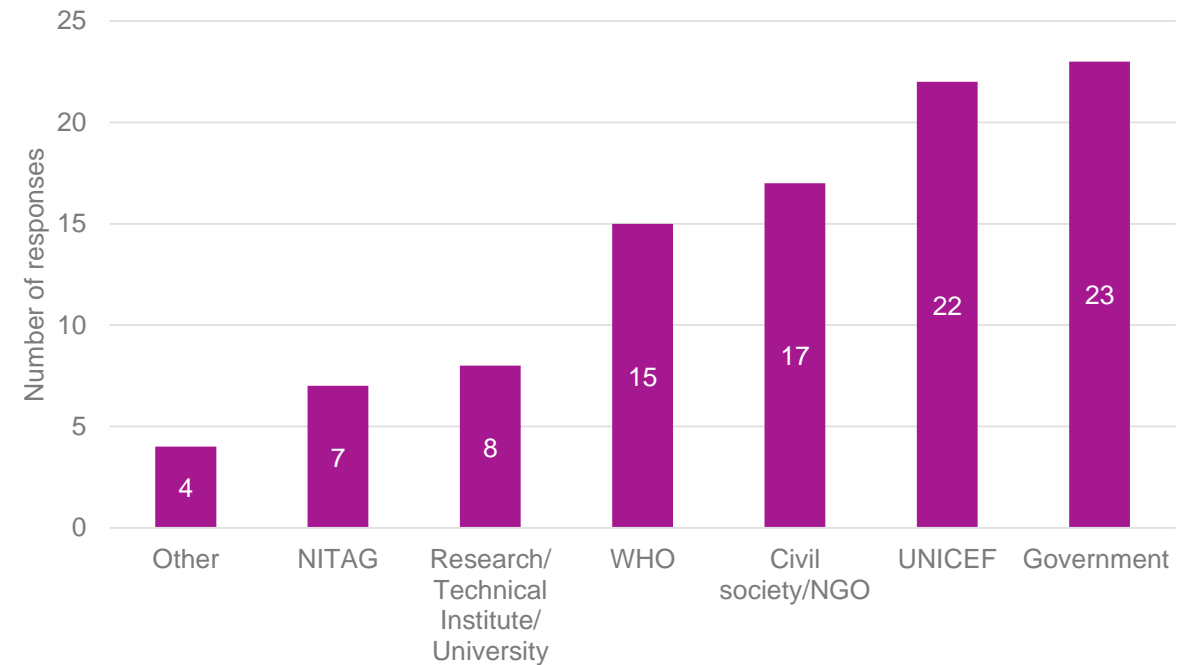
Vaccine/immunisation product	Vaccination strategy	Most important (choose up to 3 vaccines)	Important	Less important	No opinion
Cholera (oral)	Preventative campaigns in endemic settings				
Diphtheria, Tetanus & Pertussis	Routine immunisation with diphtheria, tetanus and whole-cell pertussis – containing booster (DTaP or DtaP) followed by two diphtheria and tetanus containing boosters (Tb)				
Dengue	Routine immunisation				
Hepatitis A	Routine immunisation				
Hepatitis B	Routine birth dose immunisation				
Influenza	Routine maternal immunisation against seasonal flu				
Meningitis ACWY or ACWY (conjugate)	Routine immunisation & preventive campaigns				

The survey was completed by individuals in all regions, with most input from AFRO & Government

Responses by WHO Region



Responses by Organisation

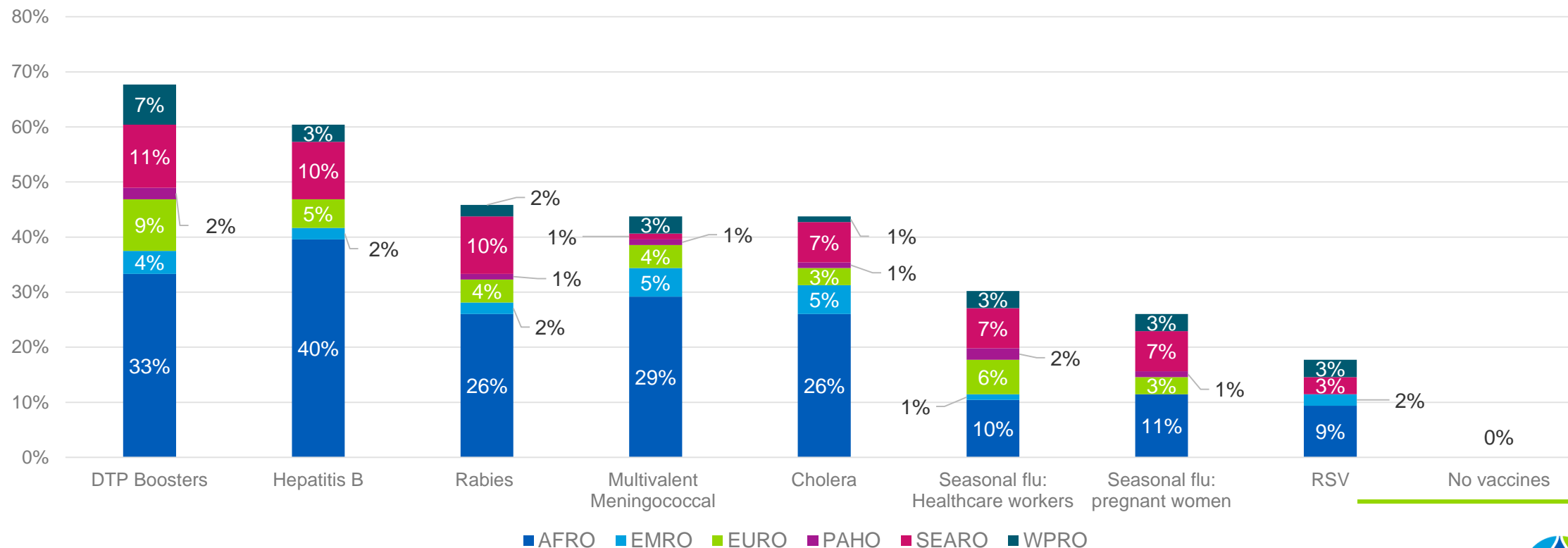


Represents respondents from 43 countries

DTP boosters and hepatitis B birth dose were prioritised by the majority of respondents

Taking into consideration the cost of co-financing/ financing each of these vaccines, the expected impact and your capacity to introduce new vaccines, which would you prioritise over the next 10 years?

% of respondents indicating they would prioritise each vaccine in next 10 years



Given limited or regional disease burden, not all vaccines are of relevance for all Gavi-supported countries

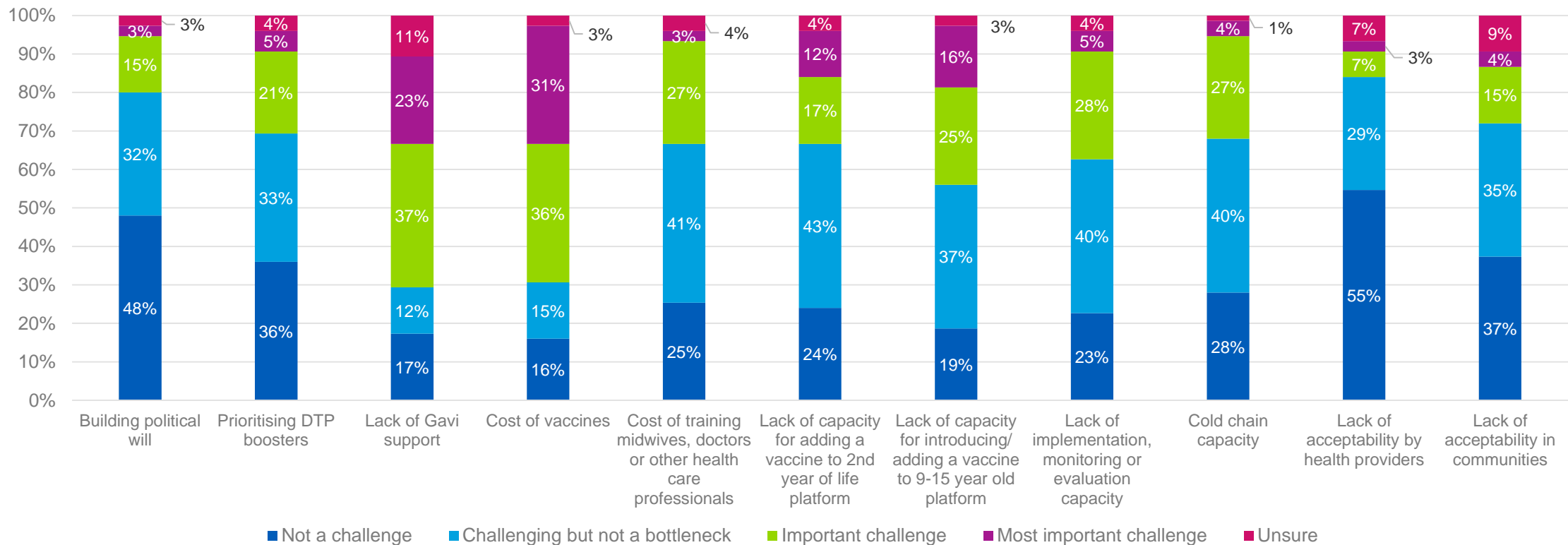


Cost of vaccines and lack of capacity for adding 9-15yo platform amongst challenges for introduction

06a – Appendix 1

WHO recommends three DTP-containing boosters at 12-23 months (DTP or pentavalent), 4-7 years old (Td) and 9-15 years old (Td). What are the main challenges faced in introducing and successfully scaling-up coverage of these vaccines?

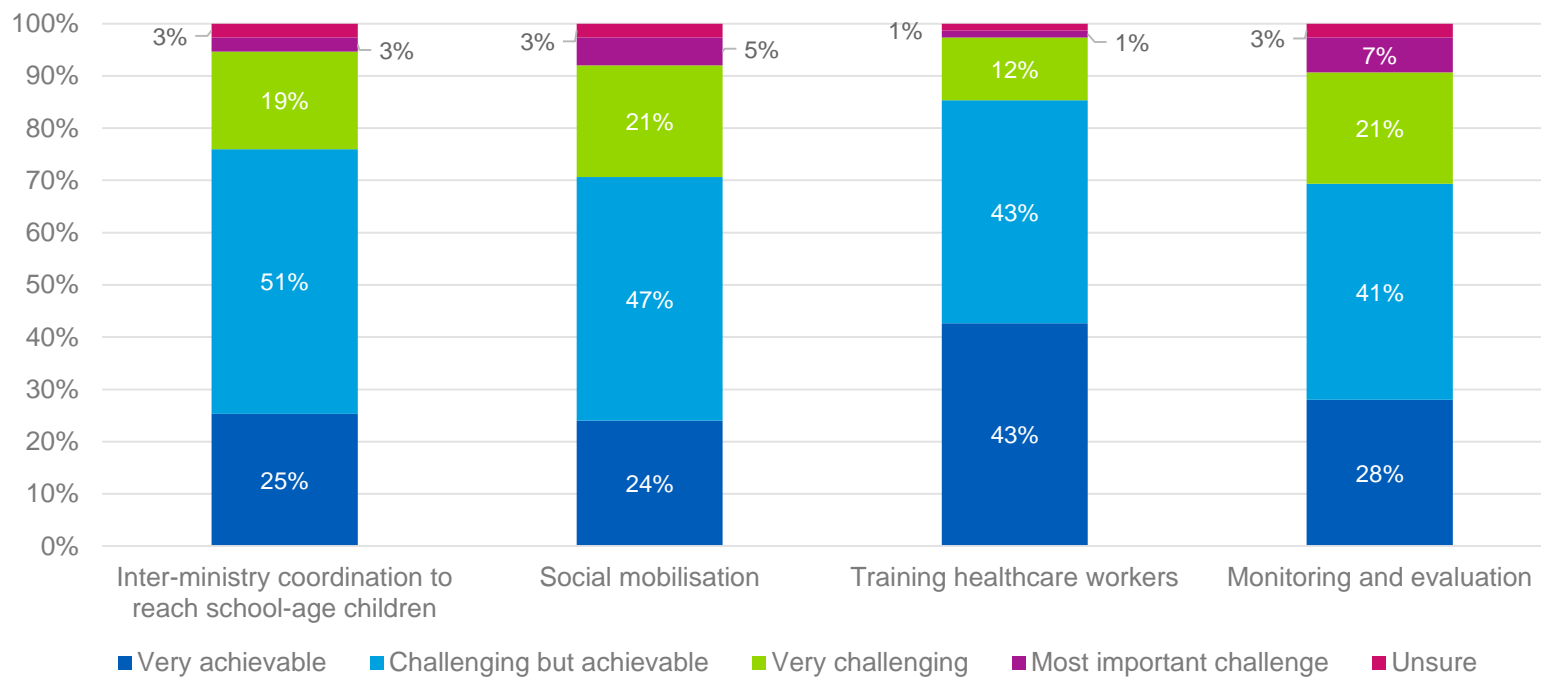
% respondents indicating level of challenge for each introduction-related activity



Most activities related to establishing 4-7yo platform generally viewed as achievable

How challenging are the following activities that have been/ could be required to establish a successful new vaccination time point at 4-7 years of age?

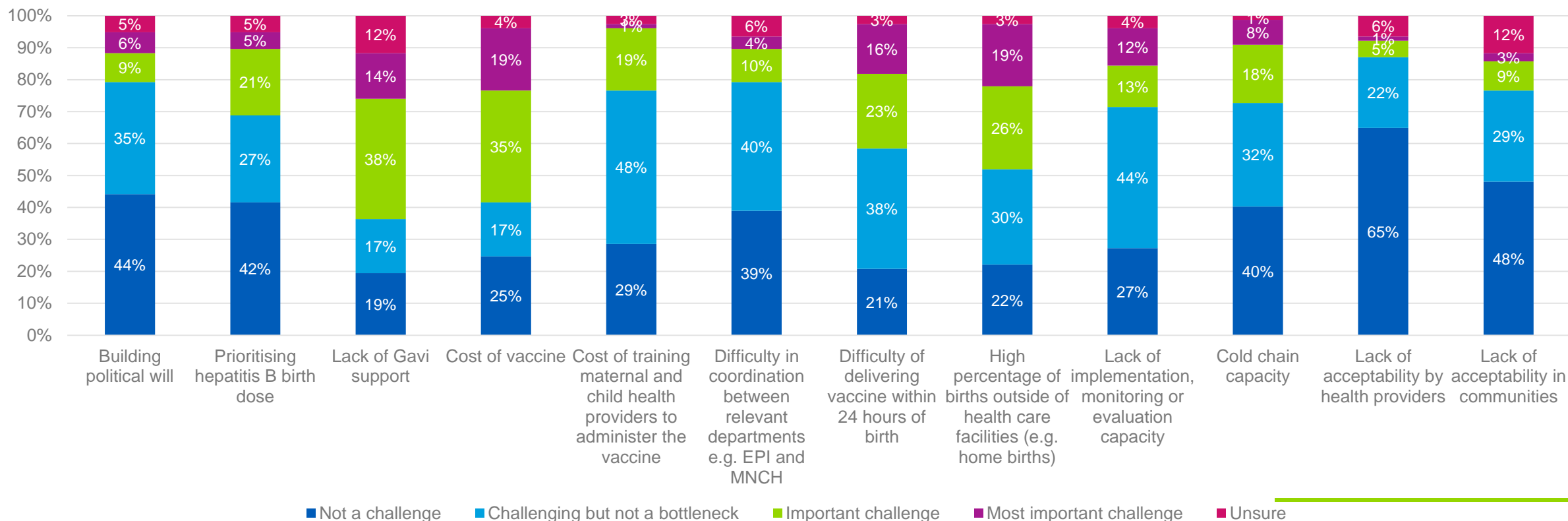
% respondents indicating level of challenge for each activity



Cost of vaccine, out of facility births and timeliness of administration amongst challenges for introduction

What are the main challenges faced in introducing and successfully scaling-up coverage of the vaccine?

% respondents indicating level of challenge for each birth dose-related activity

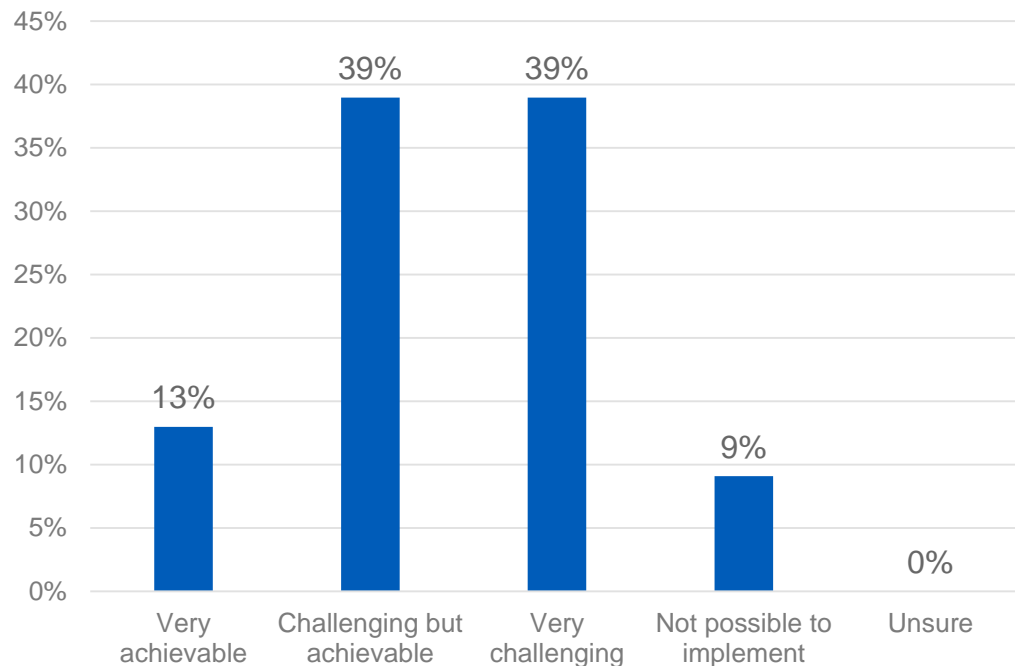


Most respondents indicate that reaching newborns born outside of facilities would be challenging

06a – Appendix 1

For newborns born outside of health facilities, would it be possible to conduct outreach to deliver hepatitis B birth dose within 24 hours?

% respondents indicating level of challenge to reach newborns outside of health facilities



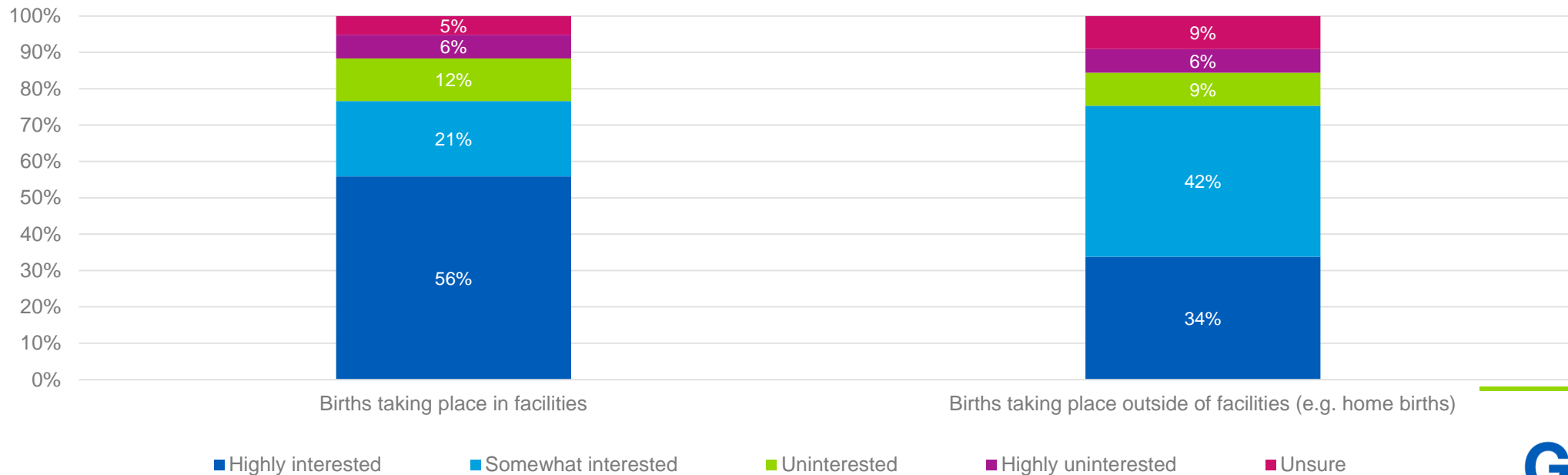
Comments regarding delivering birth dose outside of facilities

- Difficulty in reaching remote areas
- Could be integrated into routine outreach activities, but not within 24hrs of birth
- Lack of reporting of births
- Cost of transport for health care worker (HCW) or family
- Traditions that keep mother and baby at home for post-natal period
- Community HCWs not authorised to vaccinate
- Need for single-dose cPADs and controlled temperature chain to assist HCWs
- Outreach strategy likely expensive to implement, as well as security concerns
- Shortage of human resources
- Acceptability of parents
- Lack of integration between MNCH and EPI

Respondents are interested in using Uniject in facilities and for births taking place outside of facilities

Uniject is single-use auto-disposable delivery technology which has been pre-qualified for hepatitis B vaccine. Use has been shown to increase coverage, especially in outreach settings, and administrators have found it easier to use, however it is more expensive and requires more cold chain space than multi-dose vials. Would there be an appetite for this product to support hepatitis B birth dose administration if it was offered by Gavi under the usual co-financing arrangement?

% respondents who would be interested in using Uniject in different delivery settings

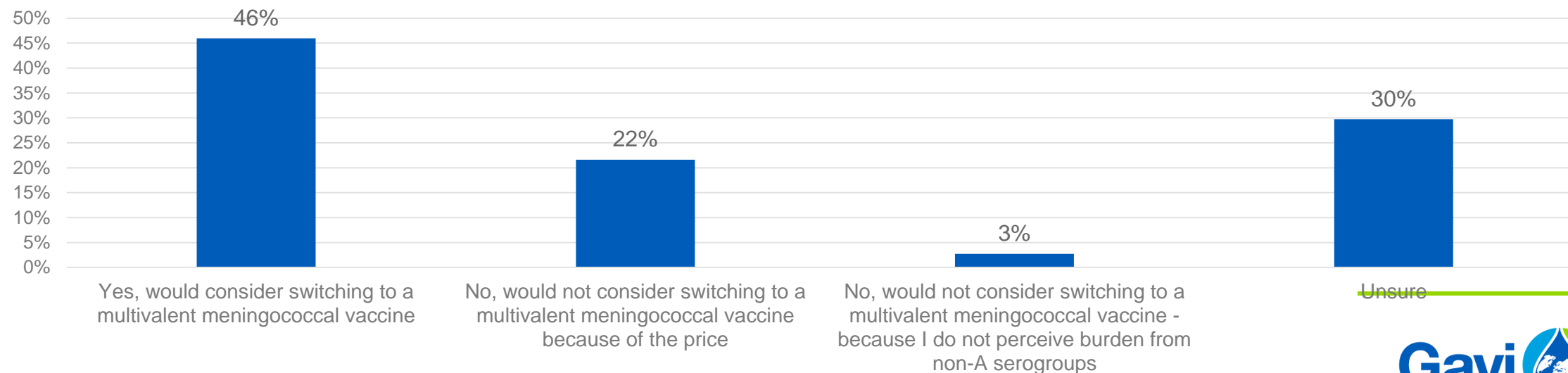


Many respondents see value in multivalent vaccines, others unsure about price

40/75 respondents indicated that meningococcal disease burden is important in their country, representing 27 countries¹ - only these respondents' answers included in analysis

Based on your country context and given the cost differential, do you think there is value in a multivalent meningococcal conjugate vaccine compared to meningococcal conjugate A vaccine? (Men A ten-dose costs \$0.52 per dose for routine and \$0.69 per dose for campaign and we expect multivalent meningococcal ACWY or ACWXY to cost ~\$1.00-5.00 per dose)

% respondents who see value in multivalent meningococcal vaccine



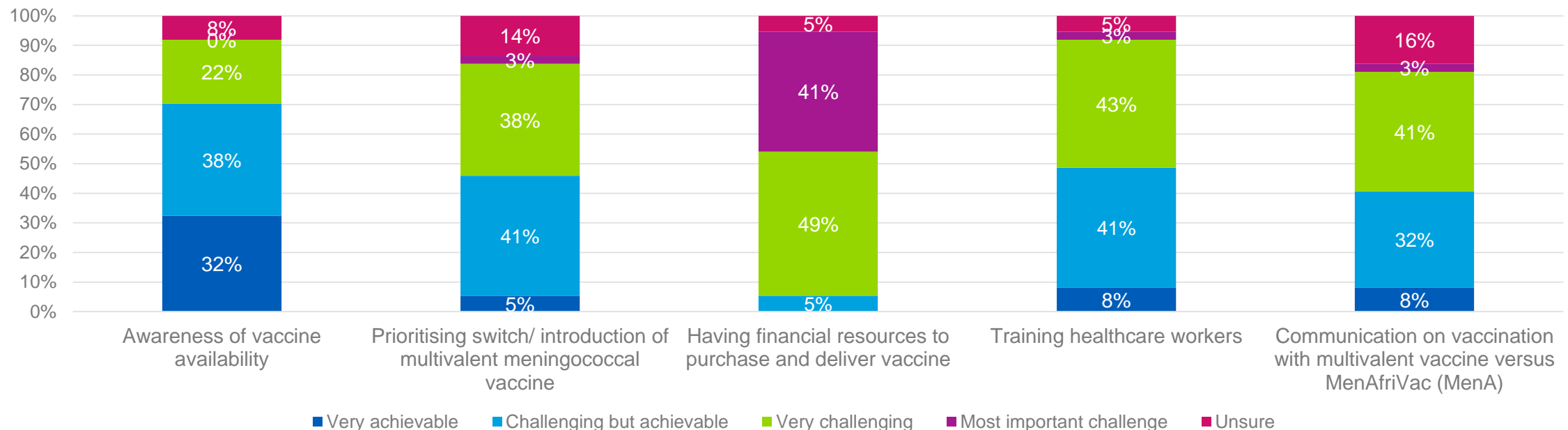
Respondents consider finding financial resources to fund vaccine to be the most challenging activity

06a – Appendix 1

40/75 respondents indicated that meningococcal disease burden is important in their country, representing 27 countries¹ - only these respondents' answers included in analysis

The table below lists several activities associated with introducing or switching to a multivalent meningococcal vaccine. Please rate the degree to which each activity would be challenging.

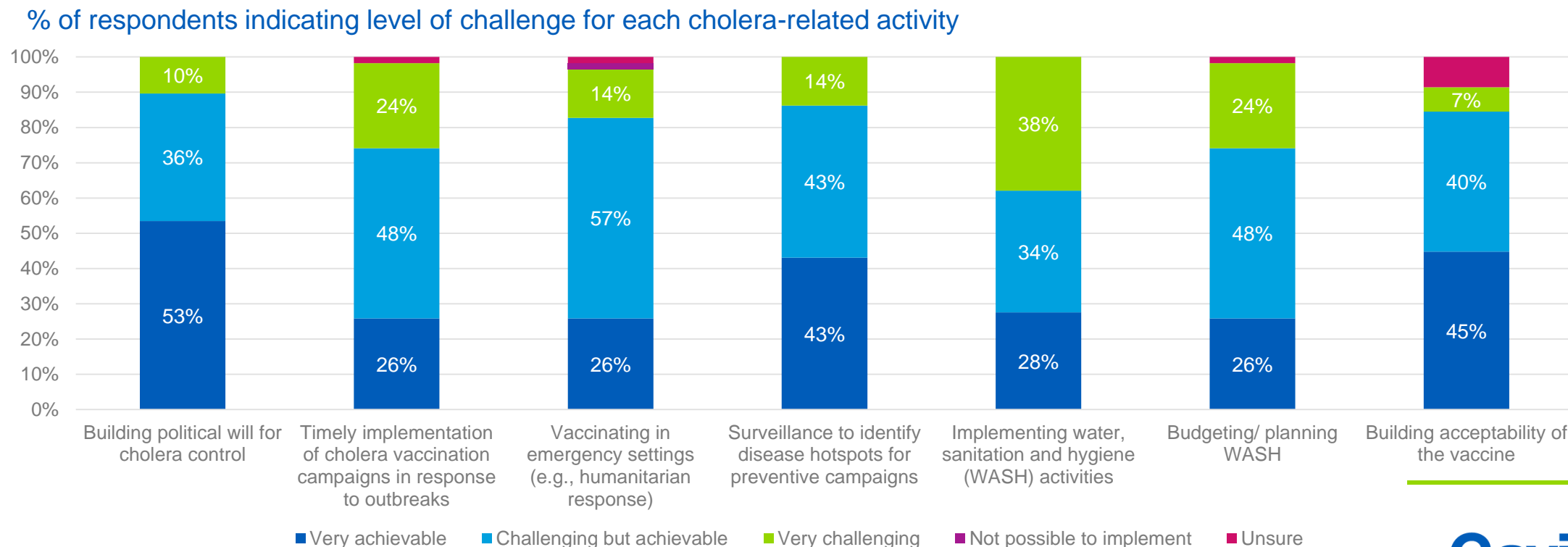
% respondents indicating level of challenge for each introduction-related activity



Respondents view identifying hotspots and timely vaccination of at risk populations achievable though still with challenges

59/85 respondents indicated that their country experiences cholera outbreaks, representing 27 countries

How challenging do you find each of the following activities related to cholera control?

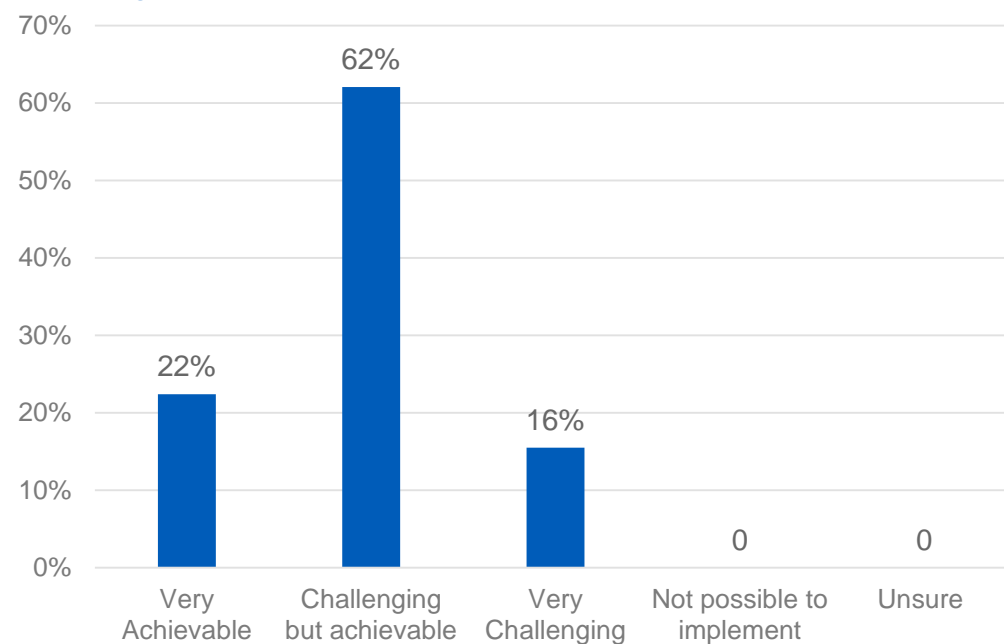


The majority of respondents would find WASH scale up challenging but achievable

59/85 respondents indicated that their country experiences cholera outbreaks, representing 27 countries

If Gavi support for oral cholera vaccine for preventative campaigns were contingent on having up to date, comprehensive national cholera control plans that include WASH activities, how challenging would you find this to be?

% of respondents indicating level of challenge for scaling up WASH



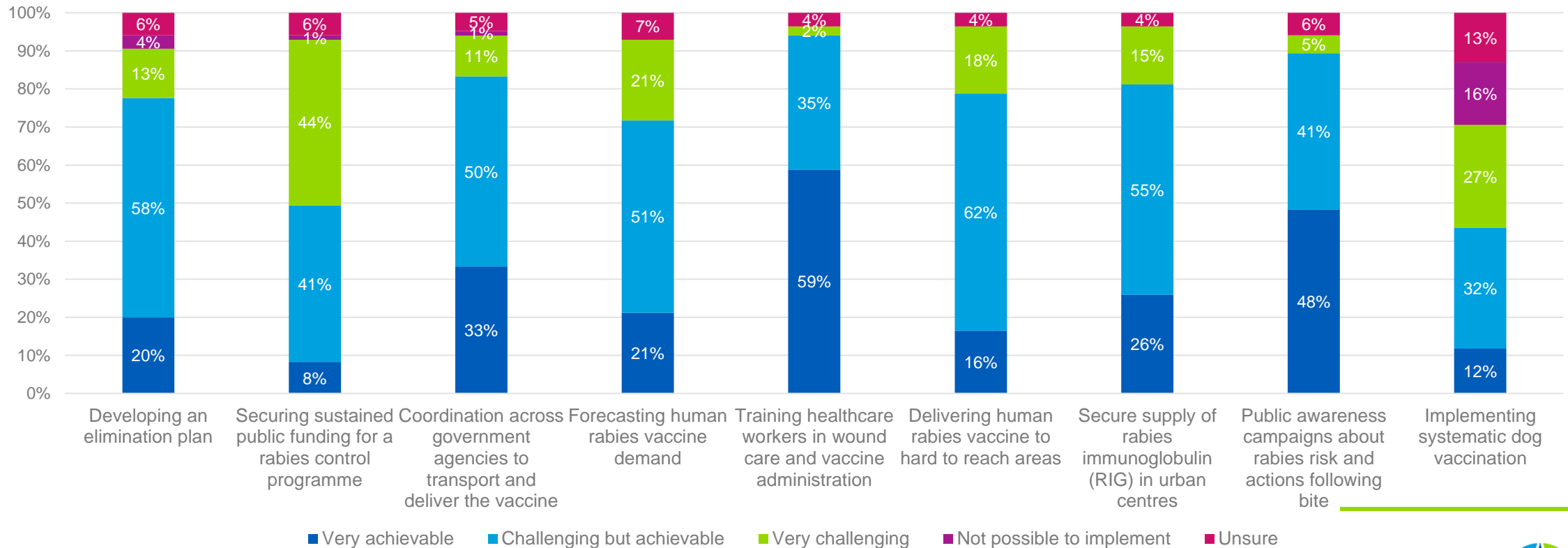
Challenges highlighted by respondents

- WASH is often solely donor-funded, and there is a lack of donor alignment regarding support, with need for greater investment
- Coordination with other government ministries is challenging
- Lack of political will
- Shortage of human resources
- Frequent displacement of population due to security issues
- Rapid urbanisation with high populations
- Illiteracy & difficulty in communicating to communities

Public funding a particular challenge, but multisectoral coordination could help achieve success

In your opinion, how challenging do you think each of the following activities related to rabies elimination are?

% of respondents indicating level of challenge for each rabies-related activity



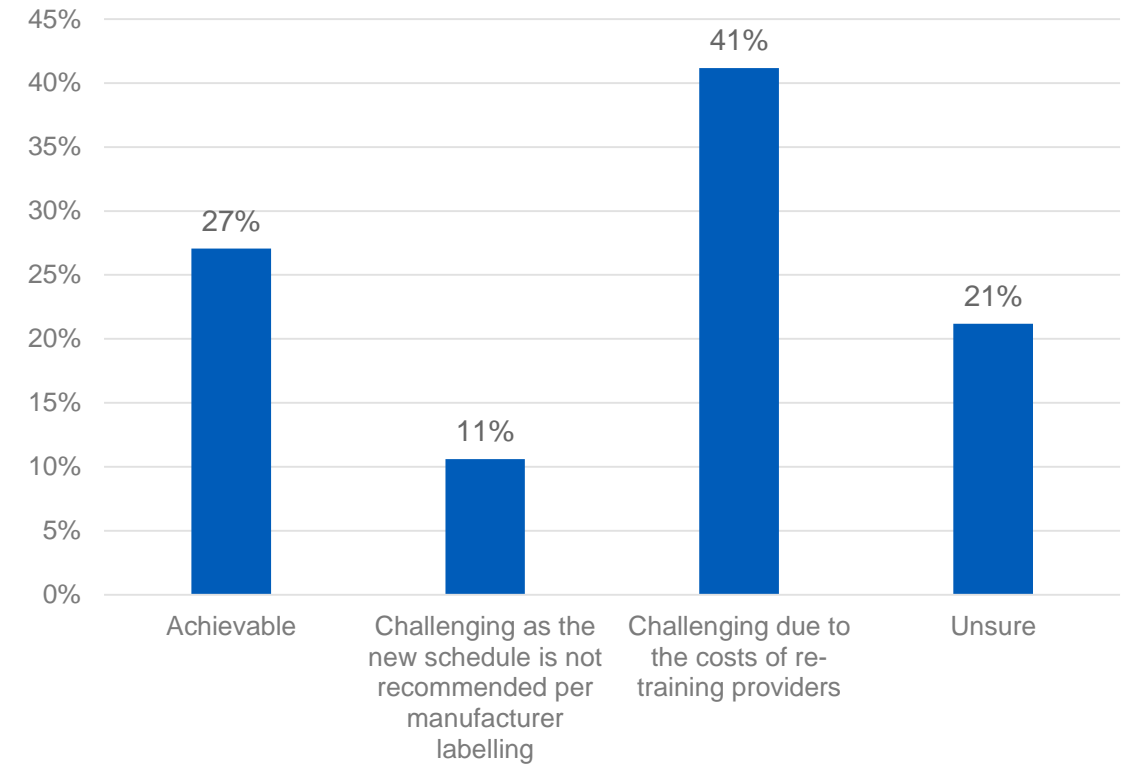
Respondents would find implementing the new WHO recommendations challenging due to costs of training

06a – Appendix 1

The updated WHO recommendation is to administer a 1-week, 2-site intradermal post-exposure prophylaxis schedule (2-2-2-0-0), of a total 6 doses of 0.1 ml vaccine injected intradermal vaccination during 3 visits over the course of 7 days, rather than a 5 dose intramuscular post-exposure prophylaxis schedule of a total of 5 ml vaccine injected during 5 visits over 28 days.

The new recommendation requires fractionating intramuscular doses as the volume per dose delivered is lower. How challenging do you think it would be to implement this new recommendation?

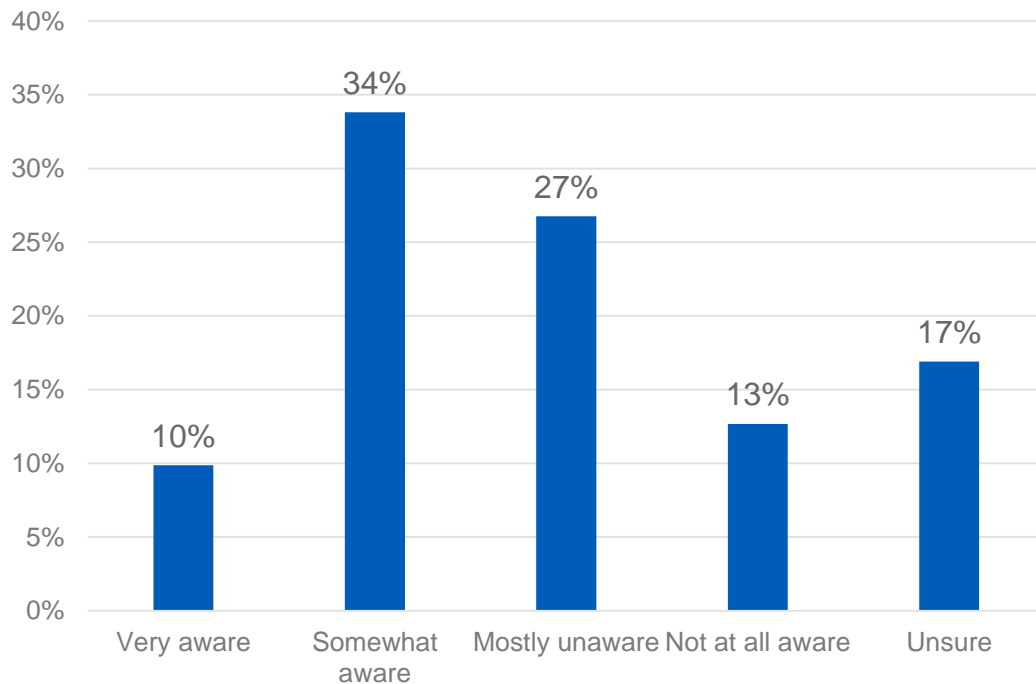
% respondents answers regarding new WHO recommendation



RSV remains an unfamiliar disease in many countries but acceptability is likely high

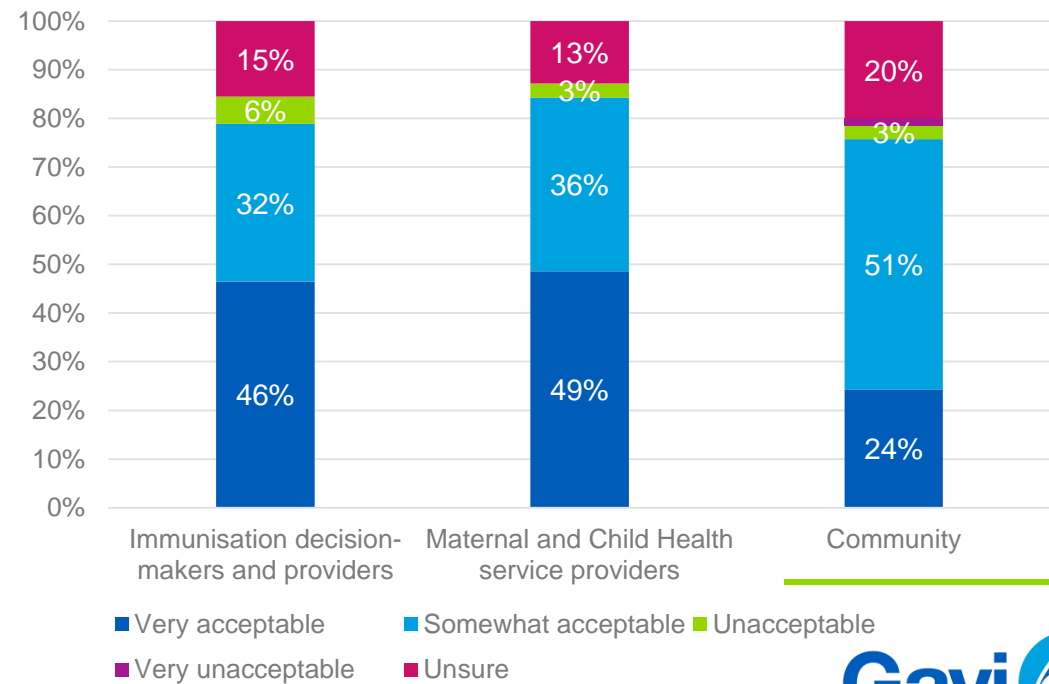
How familiar is the public health community in your country with respiratory illness (pneumonia, bronchiolitis) caused by respiratory syncytial virus (RSV)?

% respondents who say public health community is familiar with RSV



How acceptable is vaccination in pregnancy among the following groups of stakeholders in your country?

% respondents regarding level of acceptability of vaccination during pregnancy

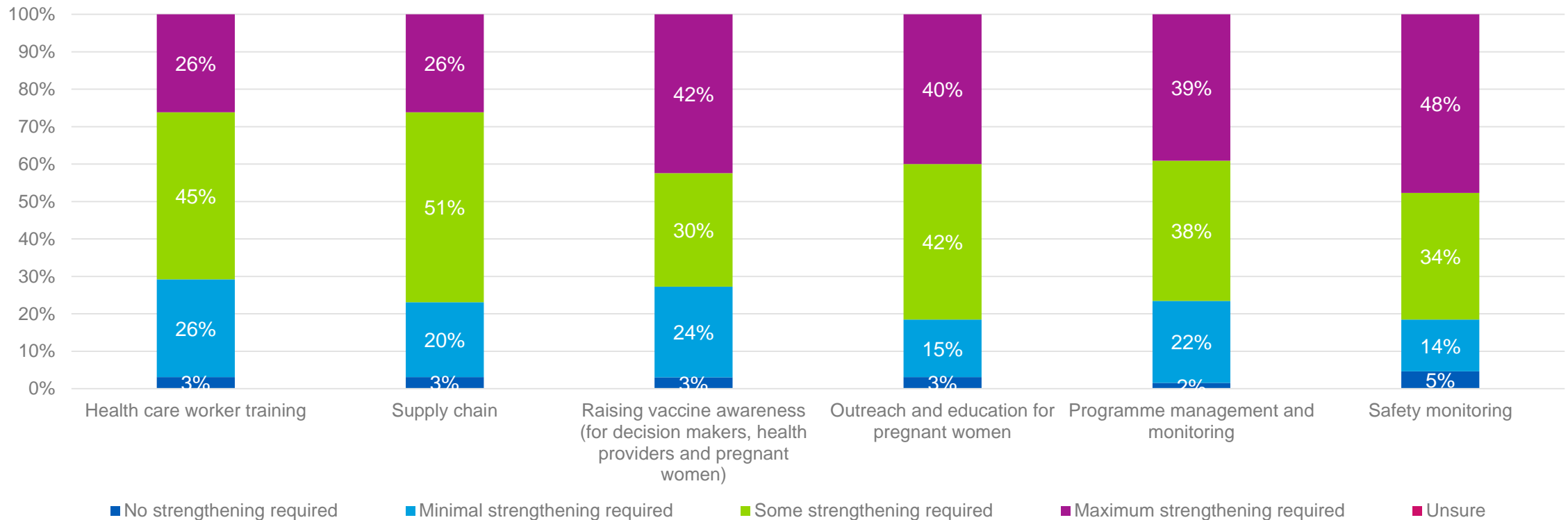


According to most respondents, some or a lot of strengthening is required across all activities

06a – Appendix 1

What is the extent to which each of the following would need to be strengthened to optimally deliver maternal RSV vaccine via antenatal care in your country?

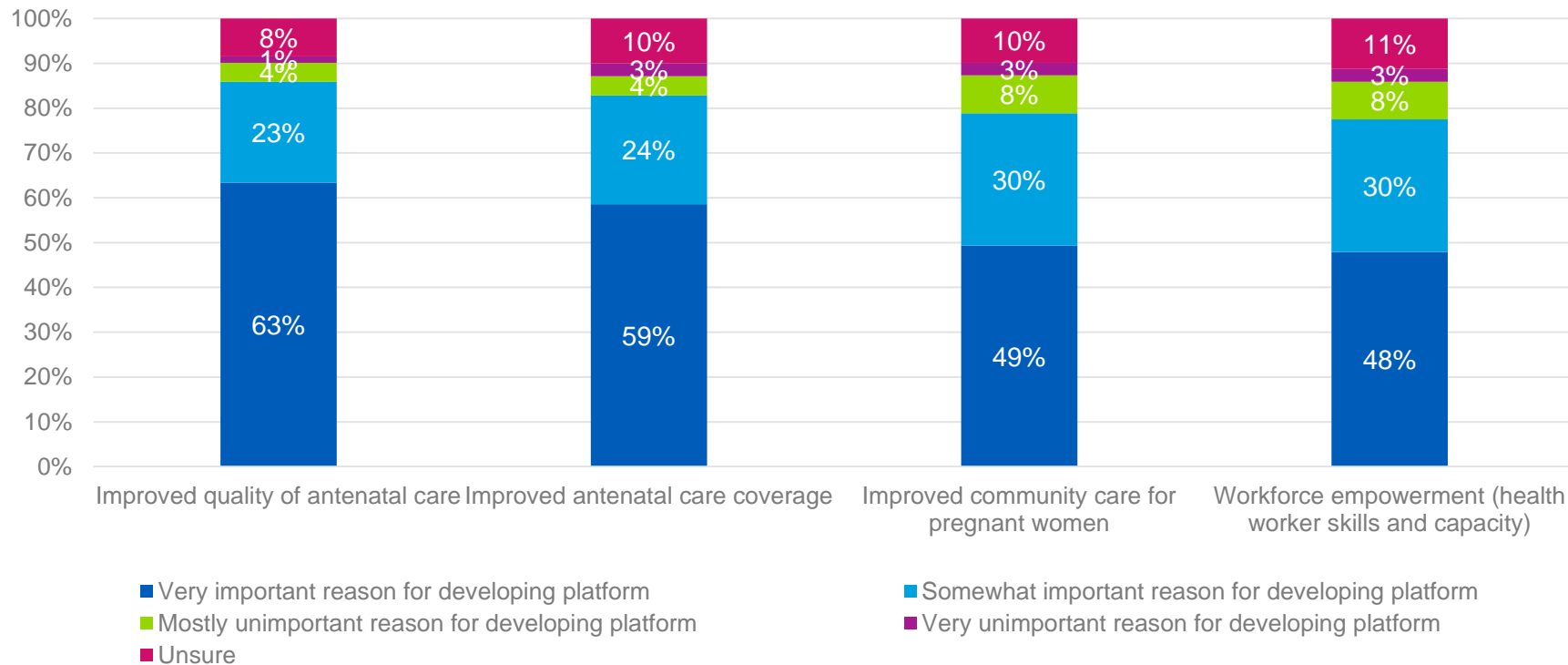
% respondents regarding level of strengthening required to deliver RSV vaccine



All benefits of maternal vaccination are viewed equally amongst respondents

The table below lists several supplemental benefits associated with introducing a vaccine for pregnant women through a maternal immunisation platform incorporated in antenatal care. Please rate the degree to which they could influence a decision to develop a maternal immunisation platform.

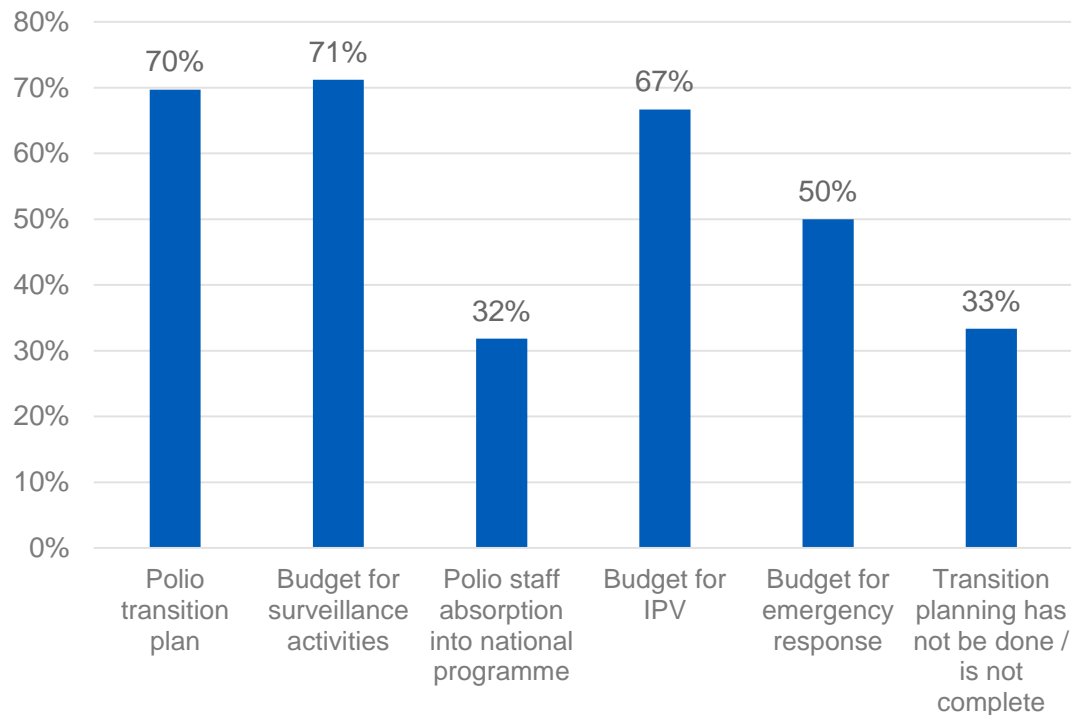
% respondents regarding the degree to which each benefit might influence the decision to introduce maternal immunisation



Most countries are prioritising surveillance, transition plans and budget to prepare for transition

To the best of your knowledge, which of the following activities are being prioritised to prepare for polio transition in your country? Please choose as many as you wish.

% respondents indicating activities as being prioritised

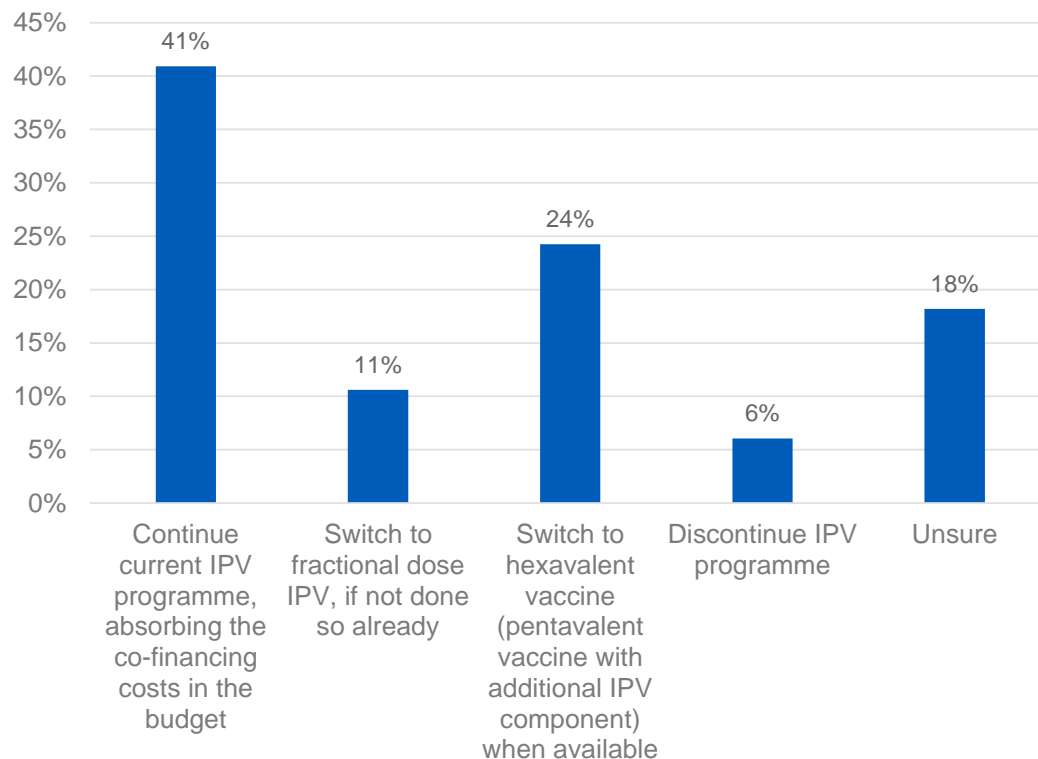


If IPV co-financing required, some countries see value in fractional IPV dosing or hexavalent vaccine

06a – Appendix 1

If governments had to share the cost of procuring IPV, what impact would you expect this to have on the IPV programme within your country?

% respondents regarding how governments might react to co-financing of IPV



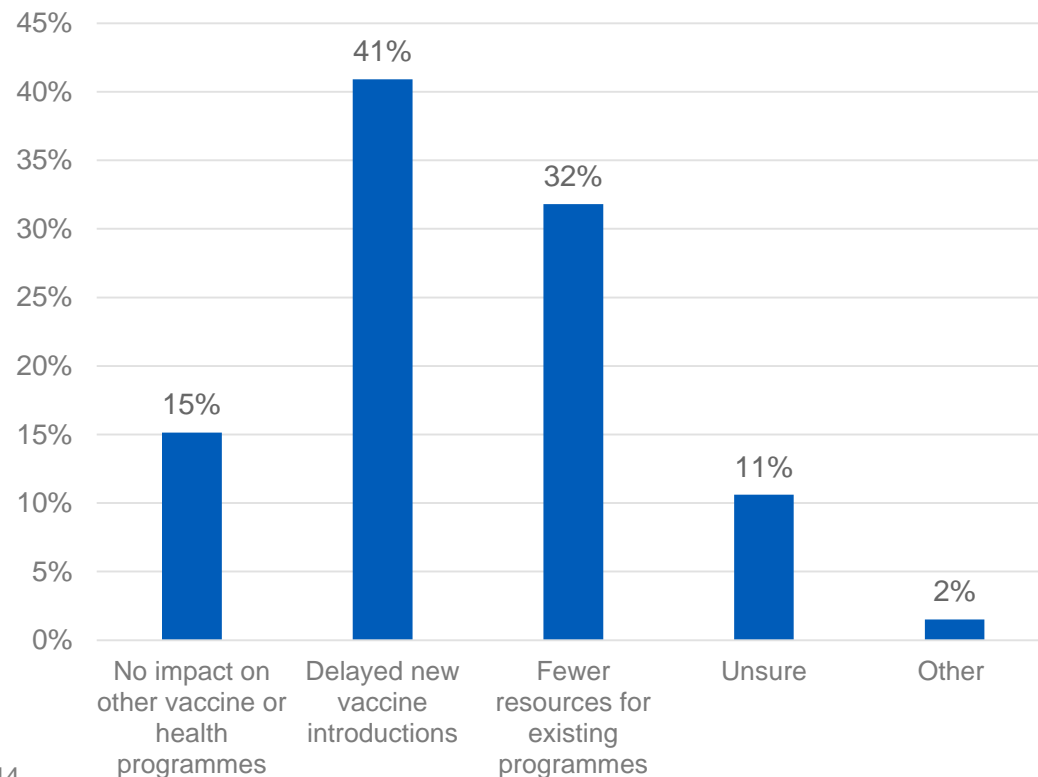
Comments regarding co-financing IPV

- Highly dependent on the countries future economic situation and cost – currently, budgets have not taken into consideration IPV procurement post-2020
- Border areas where outbreaks occur are a high priority
- Some countries note that there are health budget deficits and they struggle to honour existing co-financing commitments on time
- IPV is considered to be a critical programme
- Some governments do not currently finance any immunisation activities and would rely on other donor funding so co-financing could not be ensured
- Switch to hexavalent dependent on price, but attractive as reduces number of injections
- Difficult to implement fIPV due to training needed
- Any strategy that minimises cold chain capacity is attractive

Respondents suggest IPV co-financing would likely impact existing programmes and new vaccine introduction

If governments had to share the cost of procuring IPV, what impact would you expect this to have on other vaccine or health programmes within your country?

% respondents indicating likely impact on other vaccination programmes due to co-financing IPV



Comments regarding co-financing IPV impact on other programmes

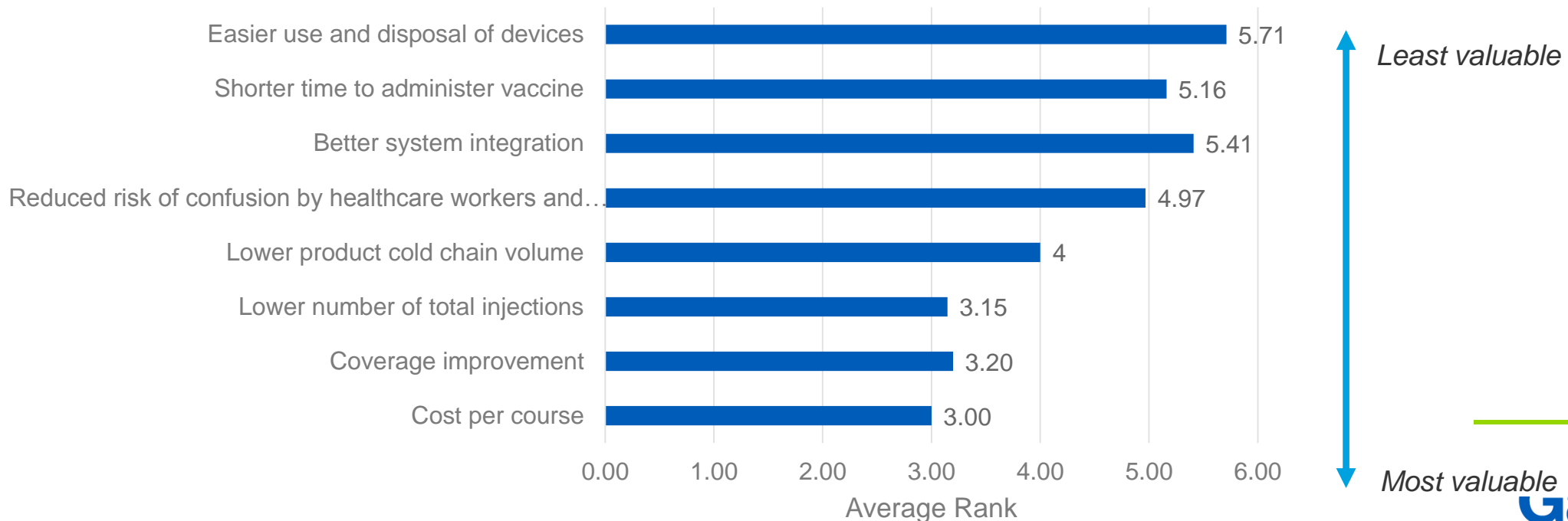
- Already limited funding to introduce any new vaccine, likely to exacerbate this problem
- Limited health budgets that need to be prioritised
- Dependent on the level of co-financing expected
- Concern that it will draw funding from other vaccination programmes and impact their coverage

Cost, coverage implications and fewer injections are the most valuable attributes of hexavalent vaccine

06a – Appendix 1

Hexavalent vaccines, which contain all five pentavalent antigens as well as IPV, may become available in the coming years. If Gavi were to support the procurement of hexavalent vaccine and governments had to co-finance it, which parameters would you use to evaluate it compared with existing vaccines, i.e. pentavalent and IPV? Please rank the following from the highest value to lowest value.

Importance of hexavalent vaccine attributes

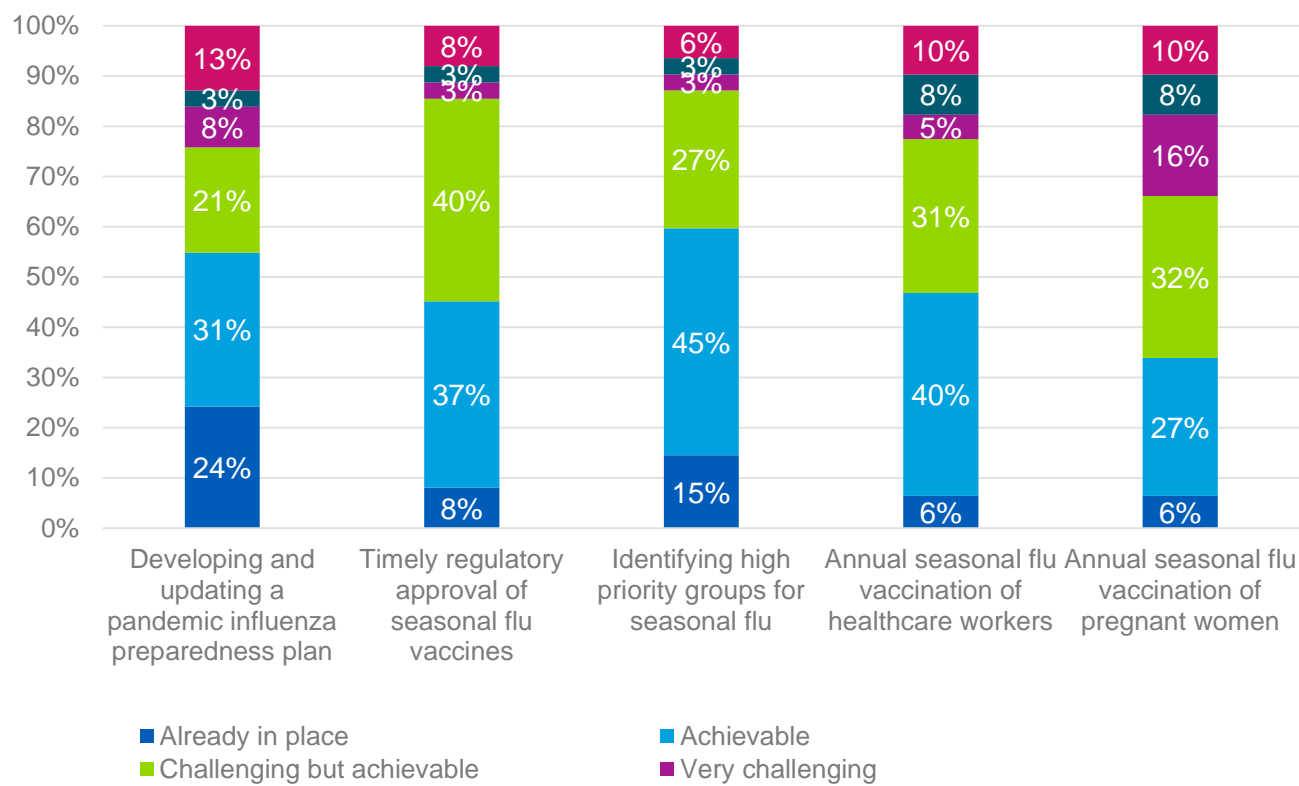


Most respondents have limited confidence in supply in a pandemic and would find regulatory approval and annual vaccination challenging for seasonal flu

06a – Appendix 1

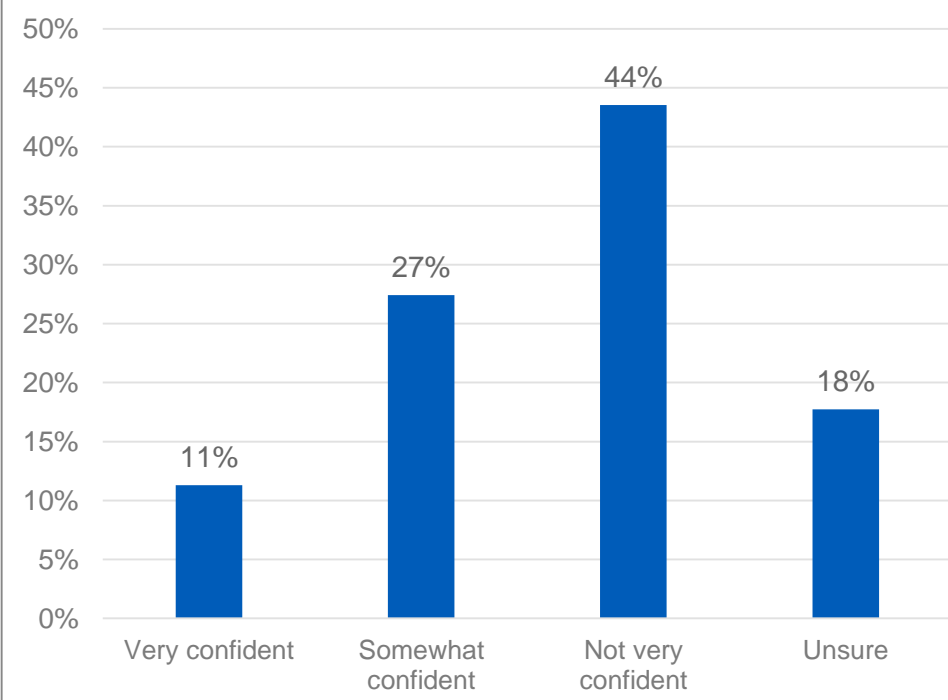
Currently, how achievable is implementation of the following activities in your country?

% respondents regarding the degree to which each activity is implementable



In the event of a severe influenza pandemic, are you confident that you would be able to access sufficient and timely vaccine supply?

% respondents indicating confidence in ability to access supply in event of a pandemic

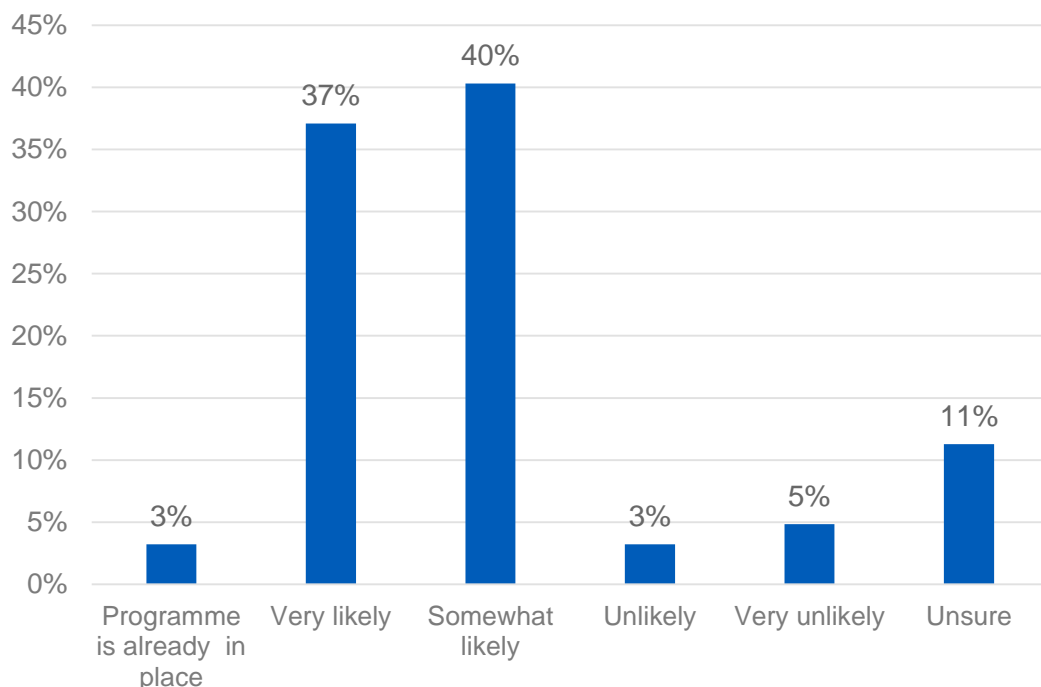


Seasonal influenza not considered a priority, but potential appetite to introduce if Gavi supported

06a – Appendix 1

WHO has identified both health care workers (HCWs) and pregnant women as high priority groups to receive seasonal influenza vaccine. If Gavi were to offer seasonal flu vaccine support for high priority groups (health care workers or pregnant women) how likely would you be to introduce?

% respondents indicating likelihood of introducing flu for high priority groups



Comments regarding likelihood of implementing seasonal flu vaccine for high risk groups

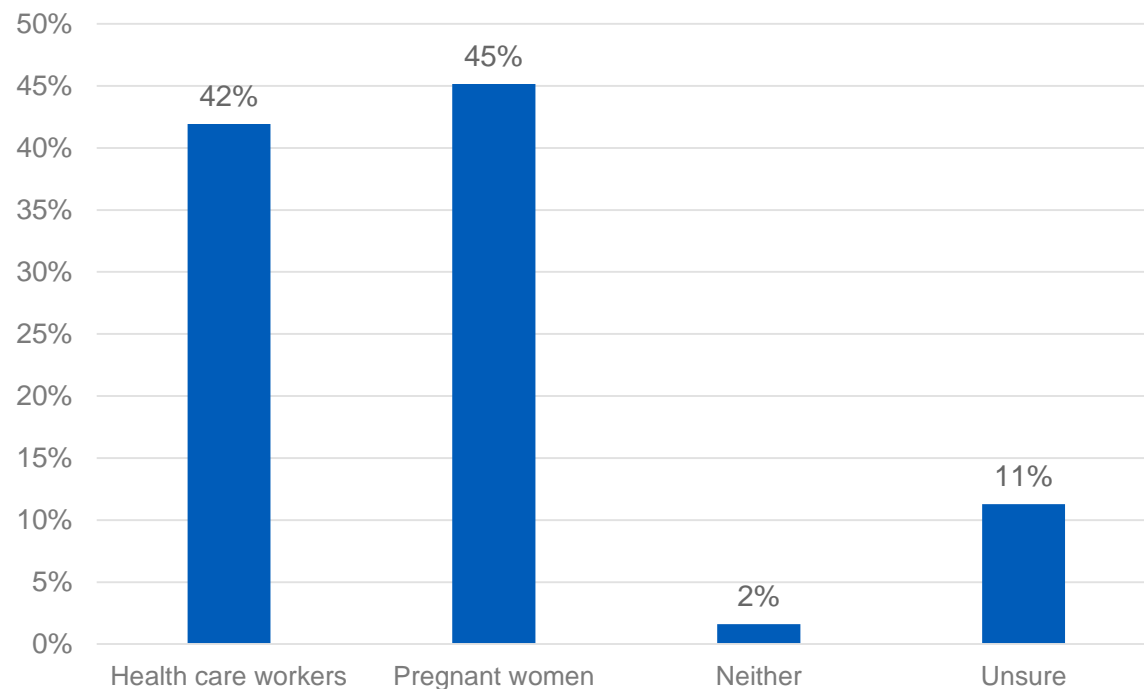
- Influenza is not considered a public health priority in many countries
- Little demand for the vaccine within the country
- Not a priority vaccine compared to others
- Concerns over acceptance in communities
- Requires a good understanding of epidemiology and investment case for introduction
- Vaccinating pregnant women should be folded into existing tetanus vaccination time points

There is an almost equal split between respondents prioritising pregnant women and HCWs for vaccination

06a – Appendix 1

If you had to choose between these two groups for seasonal immunisation, which would you select?

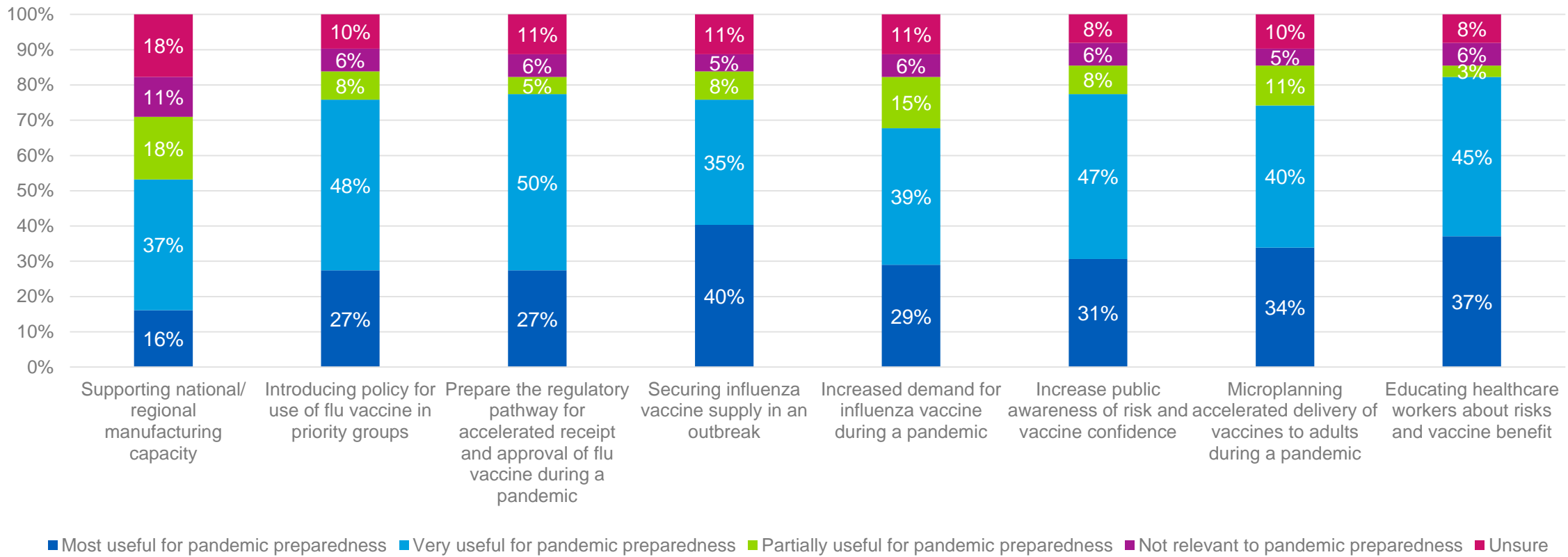
% respondents choosing between groups to for which to introduce seasonal flu



Supporting local manufacturing capacity has less value, however other pandemic preparedness activities considered useful

In what specific ways do you think seasonal influenza vaccination of high priority groups (health care workers or pregnant women) can help prepare your country for a severe influenza pandemic?

% respondents indicting the level to which each activity can help prepare for a severe flu pandemic

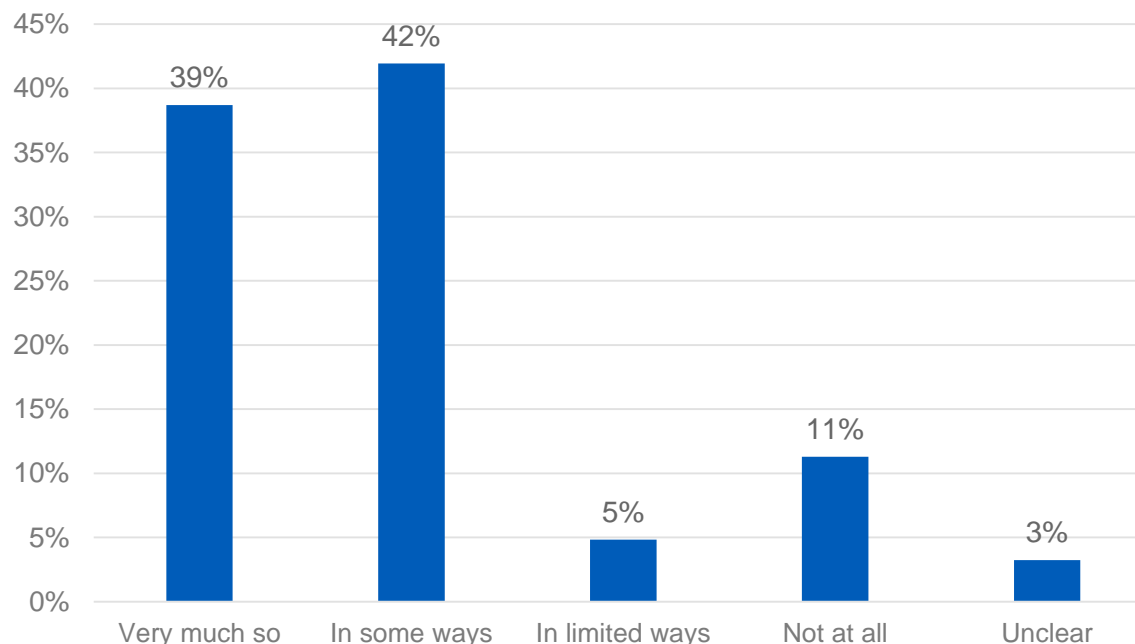


Source: VIS Phase III country survey

The majority of respondents think seasonal flu vaccination would help prepare for other epidemics

Looking beyond pandemic influenza preparedness, would seasonal influenza vaccination of high priority groups (health care workers or pregnant women) help prepare your country for delivery and use of vaccines for other epidemic diseases (e.g., Ebola)?

% respondents indicating whether seasonal flu vaccination would help to prepare for delivery of vaccines against other epidemic diseases



Comments regarding impact of seasonal flu vaccination on helping to prepare for use of vaccines against other epidemic diseases

- Raises awareness about the risks of influenza and availability of vaccines for epidemic diseases
- Identification of high risk groups and plans to reach them are helpful, however they are unlikely to be the same for other epidemic diseases
- Likely to strengthen existing systems for vaccination
- Preparations for PIP also help facilitate preparedness for epidemics