Report of the meeting on Sustainable local production of influenza vaccines for pandemic preparedness

Synergies with other international efforts and improvement of the current tool

Geneva, Switzerland, 16–17 June 2017
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ACKNOWLEDGEMENTS

The GAP Secretariat and the Technology Transfer Initiative thank:

- the co-chairs Larry Kerr and William Ampofo, as well as facilitator Daniel Normandeau, for keeping the meeting lively, engaging and inclusive, as well as both on time and on topic.

- all the speakers and discussants who prepared presentations and took part in panel discussions to stimulate our collective thinking and identify key issues.

- all participants, who engaged in frank and open discussions and contributed a wealth of ideas and suggestions to inform our future work on the sustainability checklist.

A special mention to the US Department of Health and Human Services, Office of Global Affairs, Pandemic and Emerging Threats, for its continuous financial and technical support.
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AMR</td>
<td>Antimicrobial resistance</td>
</tr>
<tr>
<td>APPV</td>
<td>ASEAN price policy for vaccine</td>
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<tr>
<td>ASEAN</td>
<td>Association of Southeast Asian Nations</td>
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<tr>
<td>BARDA</td>
<td>Biomedical Advanced Research and Development Authority</td>
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<tr>
<td>BSL</td>
<td>Biosecurity level</td>
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<tr>
<td>CBD</td>
<td>Convention on Biological Diversity</td>
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<td>CDC</td>
<td>Centers for Disease Control &amp; Prevention</td>
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<tr>
<td>CT</td>
<td>Clinical trial</td>
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<td>CVV</td>
<td>Candidate vaccine virus</td>
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<td>DCVMN</td>
<td>Developing Countries Vaccine Manufacturers Network</td>
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<td>EU</td>
<td>European Union</td>
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<td>EMA</td>
<td>European Medicines Agency</td>
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<td>ERL</td>
<td>Essential Regulatory Laboratory</td>
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<td>GAP</td>
<td>Global Action Plan for Influenza Vaccines</td>
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<td>GHSA</td>
<td>Global Health Security Agenda</td>
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<td>GISRS</td>
<td>Global Influenza Surveillance and Response System</td>
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<td>GLP</td>
<td>Good laboratory practice</td>
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<td>GMP</td>
<td>Good manufacturing practice</td>
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<td>HEP</td>
<td>WHO Health Emergencies Programme</td>
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<td>HR</td>
<td>Human Resources</td>
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<td>IHR</td>
<td>2005 International Health Regulations</td>
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<td>JEE</td>
<td>Joint External Evaluation</td>
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<td>LSE</td>
<td>London School of Economics</td>
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<td>MoH</td>
<td>Ministry of Health</td>
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<tr>
<td>NAFTA</td>
<td>North American Free Trade Agreement</td>
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<tr>
<td>NGO</td>
<td>Nongovernmental organization</td>
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<td>NIC</td>
<td>National Influenza Centre</td>
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<td>NRA</td>
<td>National regulatory authority</td>
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<td>OIE</td>
<td>World Organisation for Animal Health</td>
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<td>PAHO</td>
<td>Pan American Health Organization</td>
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<td>PIP</td>
<td>Pandemic Influenza Preparedness</td>
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<td>PR</td>
<td>Public Relations</td>
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<td>PQ</td>
<td>WHO Prequalification</td>
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<tr>
<td>PVS</td>
<td>Performance Veterinary Service</td>
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<tr>
<td>R&amp;D</td>
<td>research and development</td>
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<tr>
<td>SMEs</td>
<td>Small- and medium-sized enterprises</td>
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<td>SMTA-2</td>
<td>Standard Material Transfer Agreement 2</td>
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<tr>
<td>SPF</td>
<td>Specific Pathogen-Free</td>
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<td>SPP</td>
<td>Strategic Partnership Portal</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WTO</td>
<td>World Trade Organization</td>
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<td>UN</td>
<td>United Nations</td>
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<tr>
<td>UNICEF</td>
<td>UN Children's Fund</td>
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<tr>
<td>UNIDO</td>
<td>UN Industrial Development Organization</td>
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<tr>
<td>USAID</td>
<td>United States Agency for International Development</td>
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SUMMARY

As part of efforts under the Global Action Plan for Influenza Vaccines (GAP) to increase vaccine production capacity, especially in developing countries, WHO’s Technology Transfer Initiative has supported 14 countries to establish or expand local production of influenza vaccines. The sustainability checklist is a tool developed to help those countries identify – and address – potential threats to the sustainability of their new production capacity. Divided into seven sections, the checklist provides a framework for discussion of topics ranging from policies, legislation, capacities and evidence to manufacturing, procurement and communication. It is not intended as a prescriptive list, but a way of sparking discussion and facilitating dialogue among the many stakeholders involved in local vaccine production.

In June 2017, the GAP secretariat convened a meeting of stakeholders and experts in Geneva, Switzerland, to review each section of the checklist, identify its strengths and weaknesses and suggest improvements. The key messages to emerge from this review are highlighted in Table 1.

Some suggested improvements cut across all areas of the checklist and relate to how WHO might frame the list as a whole. In particular, participants highlighted the need for WHO to:

- **Clarify objectives**, both for the list as a whole and for each subsection.
- **Revisit basic premises**, not least the assumed link between seasonal and pandemic preparedness.
- **Seek feedback** from checklist users as soon as possible, and use it to inform improvements.
- **Frame preparedness as insurance**, as a means to attract investment.
- **Consider a tiered approach** that distinguishes between producing and non-producing countries.
- **Think about a restructure** of the checklist to streamline it, and address finance and human resources education and training more effectively.

SPOTTING SYNERGIES

As well as improving the checklist itself, the June meeting aimed to highlight synergies with other preparedness initiatives and identify opportunities for collaboration. Throughout the two days, participants reflected on their experience and suggested ways they might work together. They highlighted five areas where closer cooperation among international initiatives could help countries improve their influenza preparedness and secure the sustainability of local vaccine production.

- **Identify dual-use activities.** Ensuring that capacity building addresses multiple goals and objectives across the health system.
- **Encourage self-assessment.** Promoting self-assessment as a learning tool, hand in hand with external support to analyse results and identify gaps.
- **Join the dots on messaging.** Making sure that all preparedness initiatives are clear about how they complement each other.
- **Take a holistic view.** Supporting countries to avoid duplications or standalone plans by looking across all initiatives.
- **Share data.** Encouraging the use of data across initiatives for knowledge exchange and learning.

At the close of the meeting, the GAP Secretariat outlined its next steps for work on the sustainability checklist. These include:
1. Revising the checklist in line with participants’ feedback.
2. Developing a comprehensive and coherent approach to financing and HR.
4. Creating a mechanism for immediate feedback.
5. Exploring the idea of framing investments in preparedness as buying insurance.
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Table 1. Key messages to emerge from the meeting for each section of the checklist.

<table>
<thead>
<tr>
<th>Checklist area</th>
<th>Key messages</th>
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| Healthcare systems & policies                     | • The checklist must be fit for purpose  
• We need to test the assumptions of the checklist  
• It’s important to maximise synergies and align health programmes  
• Properly used, the checklist can spark collaboration and provide transparency  
• The checklist must help policy-makers think about the technological future |
| Other policy areas that interconnect with health   | • Local production may be subject to international trade  
• Agreements health exceptions in trade agreements can help support local vaccine production  
• A cohesive industrial policy relies on building consensus and ownership in-country  
• A holistic approach can support and inform companies looking to start local production |
| Influenza-specific evidence                        | • Burden of disease data can point the way forward  
• For tropical countries, flu seasonality poses a problem  
• Pandemic preparedness isn’t the problem: seasonal vaccination is  
• A One Health approach relies on close and constant collaboration across sectors |
| Regulatory capacity strengthening                  | • Common documentation does not equal harmonization  
• Harmonizing regulations benefits multiple stakeholders  
• Having a mechanism for fast track approval is important  
• The checklist is not a prescriptive tool  
• The checklist should address concepts of reliance and recognition |
| Manufacturing                                      | • Individual manufacturers need a guaranteed income  
• At a company level, more can be done to attract investors and finance  
• Local production by a strong pharma sector benefits countries in many ways  
• The timing of a switch from seasonal to pandemic vaccine impacts multiple stakeholders  
• The implications of the Nagoya Protocol remain unknown |
| Procurement                                        | • Pooled procurement can be effective but it relies on engagement and shared purpose  
• Demand for seasonal influenza vaccines is negligible  
• Scaling procurement to meet pandemic demand deserves consideration in the checklist  
• Countries can adopt a range of approaches to improve supply and procurement |
| Communication & engagement                        | • Collaboration, cooperation, empathy and trust are created or destroyed in communications  
• Communication isn’t just about what you say; it’s about how you say it too  
• Mapping reasons behind vaccine hesitancy can help tailor communications  
• Tackling misinformation remains a key priority  
• Risk communications saves lives |
1. Introduction

All presentations available at:
http://www.who.int/influenza_vaccines_plan/objectives/Agenda_hyperlinks.pdf?ua=1

In 2006, the Global Action Plan for Influenza Vaccines (GAP) was launched to help address the expected shortfall in vaccines during times of need.

One of GAP’s objectives was to increase vaccine production capacity, especially in developing countries. To that end, under the GAP’s Technology Transfer Initiative, 14 countries were given funds and technical support to establish influenza vaccine manufacturers.¹ That support seems to have paid off: in the past decade, six of these countries have licensed locally produced influenza vaccines, of which three are now prequalified by WHO. Other countries are making progress towards this goal.

But is this increased capacity sustainable? Will it still be in place when the next pandemic strikes? To answer those questions, WHO engaged with governments and experts to understand the environment around local vaccine production and identify all the different elements that might challenge its sustainability. The results were summarised in a “sustainability checklist”.

1.1. About the checklist

The sustainability checklist covers seven areas (see Figure 1). It is not a prescriptive list; nor is it a tool for measuring performance or collecting data. Rather, it has been offered to governments and other in-country stakeholders as a device for sparking discussion and facilitating dialogue around the sustainability of local vaccine production and outline key issues to be aware of.

The checklist was initially created with a very targeted and narrow focus—aimed specifically at helping the 14 countries that received WHO support to highlight potential barriers and complexities to sustaining their newly established local vaccine production. But the checklist may also be helpful for other countries with, or looking to establish, local production capacity.

So far, the checklist has been used in six countries (Brazil, Indonesia, Mexico, South Africa, Thailand, Viet Nam). Each country has adapted the list to its own contexts and needs, and used it as a means to engage multiple stakeholders and assess the national policies, structures and resources available to sustain local production of influenza vaccines.

Figure 1. The sustainability checklist covers seven areas.

¹ Brazil, China, Egypt, India, Indonesia, Iran, Kazakhstan, Mexico, Republic of Korea, Romania, Serbia, South Africa, Thailand and Viet Nam.
1.2. Meeting aims and objectives

In June 2017, the GAP Secretariat hosted a meeting in Geneva, Switzerland, to review the checklist. The meeting was convened with an eye to the future and an overarching desire to make the checklist as good as it can possibly be. In particular, the secretariat wanted to make the checklist useful and relevant to the countries that might want to use it. It was also looking to futureproof the list so that it can continue to be used even though GAP (and the funding that came with it) has officially ended.

With that in mind, the June meeting had twin objectives:

- Bring together a wide range of experience and expertise to collectively examine each area of the checklist in detail, assess its strengths and weaknesses and suggest improvements.

- Listen to and learn from colleagues working in other initiatives to improve influenza preparedness and vaccination to identify synergies and highlight opportunities for collaboration and cooperation.

Beyond these stated objectives, meeting participants also had their own expectations and visions of success for the meeting. These ranged from getting clarity on the checklist’s intended use, to ensuring wide engagement of all stakeholders to understanding how countries can use the checklist in their planning (see Annex 5.1. for a visual summary of participants’ visions of success for the meeting).

2. Towards coherence

2.1. Identifying synergies

GAP (including the sustainability checklist) is just one of many international initiatives aimed at improving influenza preparedness. Indeed, an ongoing study commissioned by the GAP Secretariat identifies nearly 100 frameworks, initiatives and organisations that work on preparedness and vaccines or vaccination, and who share GAP objectives.

The study, which is being carried out at the London School of Economics (LSE), looks at 23 of these initiatives that meet more than two synergy mapping criteria to measure overlaps with the GAP sustainability checklist. The shortlist focuses on larger organisations that work in developing countries. It does not include private pharmaceutical companies; nor does it include organisations that focus solely on R&D.

The study aims to identify potential partners for the sustainability checklist, and highlight areas for coordination and collaboration. It began by developing a set of indicators across four fields (policy environment and healthcare systems; communications and human resources (HR); surveillance and information sharing; and product development etc.). Each initiative was scored against these indicators; overlaps and synergies were quantified using a “total synergy score”.

While the study is still under way, preliminary results suggest that there are seven initiatives and organisations that have significant overlap with the objectives of the sustainability checklist and that could prove valuable partners to take the checklist forward (see Figure 2).

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2 WHO Health Emergencies Programme, Global Influenza Surveillance and Response System (GISRS), Centers for Disease Control & Prevention (CDC), Global Health Security Agenda (GHSA), Pandemic Influenza Preparedness (PIP) Framework, United States Agency for International Development (USAID), Joint External Evaluation (JEE) Alliance.
Figure 2. Preliminary results suggest seven initiatives have significant synergies and overlap with the sustainability checklist.

2.2. A summary of key initiatives

Representatives from many of the programmes featured in the LSE study were at the June meeting and participants heard from some of them – as well as from other initiatives beyond the realm of influenza.

Pandemic Influenza Preparedness (PIP) Framework

The PIP Framework was adopted in 2011 to improve global pandemic influenza preparedness and response. It does this by promoting timely sharing and access to influenza viruses with human pandemic potential (through the WHO-coordinated network of public health laboratories, GISRS).

The framework includes two benefit sharing mechanisms. First, a Partnership Contribution, which is made up of annual payments to WHO from manufacturers that use GISRS. These funds are used to support capacity-building work in developing countries. Second, the Standard Material Transfer Agreements 2 (SMTA-2), which are contracts negotiated by WHO with manufacturers that use GISRS, and which secure predictable, equitable and real-time access to pandemic vaccines for use by countries in need.

Find out more at: [www.who.int/influenza/pip](http://www.who.int/influenza/pip)

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3 WHO coordinates the sharing of influenza viruses with pandemic potential through an international network of public health laboratories called the “Global Influenza Surveillance and Response System” (GISRS). Under the Framework, Member States are expected to share their influenza viruses on a regular and timely basis with GISRS. GISRS laboratories use the viruses for risk assessment, and to develop candidate vaccine viruses and other products that are provided on request to influenza product manufacturers and institutions.
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**WHO R&D Blueprint**

The R&D Blueprint is a global strategy and preparedness plan that allows the rapid activation of R&D activities during epidemics (excluding influenza). Its aim is to fast-track the availability of effective tests, vaccines and medicines that can be used to save lives and avert large scale crisis.

The blueprint focuses on three approaches:
1. *Improving coordination*: convening stakeholders to jointly address the global R&D agenda.
2. *Accelerating R&D*: defining priorities and creating R&D roadmaps for each priority disease.
3. *Developing new norms and standards*: ensuring adequate study design, incentivising data sharing and building tools for outbreak-affected countries.

Find out more at: [www.who.int/csr/research-and-development/en](http://www.who.int/csr/research-and-development/en)

**Global Health Security Agenda (GHSA)**

The GHSA is essentially an implementation vehicle to help countries achieve their 2005 International Health Regulations (IHR) core capacities. Launched in 2014, it engages a subset of IHR countries (on a voluntary basis) and works across sectors (health, agriculture, foreign affairs, defence, development) to address infectious disease threats through collaborative capacity building.

The initiative does this through a series of 11 action packages that outline milestone-driven actions to assess whether a country is meeting IHR core capacities. If it isn’t, GHSA supports the development of a five-year action plan to address gaps.

Find out more at: [www.ghsagenda.org](http://www.ghsagenda.org)

**IHR Monitoring and Evaluation Framework**

The IHR M&E Framework is made up of a series of activities used to assess a country’s effort to develop core public health capacities under the IHR. It includes annual reporting, after-action reviews, simulation exercises and Joint External Evaluation (JEE). Together, these activities build dialogue and appreciation across sectors and lead to the development of a five-year national action plan for health security. So far, five countries have completed their action plan; another 20 have plans in the pipeline.

The Strategic Partnership Portal (SPP) sits above the framework and exists to coordinate WHO support and help countries mobilize and track support for their national plans. The SPP aims to foster transparency, accountability and most importantly, donor alignment.

Find out more at: [https://extranet.who.int/spp/ihrmef](https://extranet.who.int/spp/ihrmef)

**A rapid review of planning and costing tools for Joint External Evaluations**

This rapid review, being conducted by LSE Health, examines 19 planning and costing tools and assesses their strengths and weaknesses when it comes to supporting the national action plans for health security that come out of JEEs. The study uses a quality assessment framework to evaluate the scope, methodological quality, relevance of each tool and includes evaluation criteria to assess both performance and economic costing.
The three tools that score most highly on scope and quality are: the SPECTRUM tool, the One Health Model by WHO et al, and the OIE Performance Veterinary Service (PVS) Gap Analysis tool. But the study concludes that several tools are comprehensive, adaptable and relevant, and there’s more work to be done to make any of them work for the JEE. It recommends developing a “unifying toolkit” for partner countries that draws on the best bits of different tools and provides guidance for how to use these to cost capacity building.

2.3. Insights to inform future efforts

For each of the initiatives above, speakers and discussants described their experience and reflected on what works and what doesn’t for sustainability. They shared their insights and thoughts on synergies with the checklist and highlighted areas for greater collaboration and coordination.

Lessons learned from experience

I. Educate to basic principles

- When it comes to communicating about influenza, we must “go back to basics”.
- That means educating people about the principles of influenza – what it is, why it is a problem and what can be done about it – that the influenza community have known about and worked on for decades.
- It also means informing the authorities, the media and the public about the basic need to produce and distribute seasonal influenza vaccines as preparation for a pandemic.

II. Build a compelling case

“Value begins with a clear and coherent vision for investment.”

- Keeping a topic in the eye of government relies on being able to emphasise its importance – both socially and economically – in a clear and compelling way.
- Explaining how investments in healthcare can drive economic gains will help build a compelling case for the Ministry of Finance.

III. Make the checklist progressive over time

- Experience from the JEE suggests that in developing a plan of action, you need to keep your eye on the future and aim to deliver progressive, measurable results.
- Any activity that follows a self-assessment (such as the JEE or checklist) must not only respond to an immediate recommendation, but also develop over time, to ensure long-term results.
- Building an M&E framework into national/action plans is one way of achieving that.
- Working with parliamentarians, who are less transient and more connected to citizens, is another.

IV. From assessment to action: accurate costing is key

- Preparedness has a cost; and allocating adequate resources to achieve it is key.
- A clear and accurately costed plan enables governments and donors to prioritize actions, solicit partner engagement and assign budgets.
- It’s important to engage with finance and planning ministries at the earliest stages of development, and to align plans with national budgetary processes, to ensure domestic funding.

“It’s one thing to identify gaps in your own capacities, but the key is turning those gaps into a costed action plan.”
V. **Ensure country ownership across sectors**

- When it comes to developing a national action plan, country ownership and national leadership provide the foundation to long-term sustainability and engagement of all stakeholders.
- Each country is different so there is no one size fits all approach to country planning; but all countries require a strong multi-sectoral approach within and across sectors.

**Ideas for cross-fertilization**

I. **Identify cross-fertilization**

- Capacity building in each initiative needs to address multiple goals and objectives across the health system. For example, laboratory capacity may be built for one disease, such as for seasonal influenza, but have the capacity to also deal with other diseases or pandemic.
- How can GAP and PIP work together to get governments with domestic production capacity to allow companies to release some proportion of their vaccine supplies during a pandemic to support global as well as local demand?

II. **Encourage self-assessment as a learning tool**

- There is nothing less empowering and enlightening about doing a self-assessment than having an external team do it for you.
- But bringing in external experts afterwards, to help analyse results, can help identify gaps.

III. **Join the dots on messaging**

- All preparedness initiatives must be clear about how they complement each other.
- That includes providing clarity on availability of vaccine for procurement in order to manage expectations of non-producing countries, and clarity about access to vaccines donations through WHO PIP or possibly UNICEF if a pandemic strikes.
- It also includes communicating the need for countries to be able to accurately forecast demand and be clear about where they intend to get their supply of vaccines from, and how.

IV. **Take a holistic view**

*Many of the principles and ideas on the sustainability of influenza vaccines raised both on the checklist and within other initiatives are also relevant to routine immunization.*

*There are some states that don’t think they need to invest in seasonal production because of the PIP Framework, which some states think will act as a portal to access vaccines during a pandemic.*

- There is a need to ensure our approach is integrated across the vaccine spectrum to help countries sustain multiple vaccines within their national immunization programme.
- To avoid duplications or standalone plans, countries must look across all their initiatives, including for example, One Health, antimicrobial resistance initiative, pandemic preparedness plan, Sustainable Development Goals (SDGs) action plan, Sendai Framework etc.
V. Share data across initiatives

- Have we done all we can do to share data (or make use of shared data)?
- For example, there’s a lot of information on influenza infrastructure within JEEs because many countries use influenza laboratory data as the basis for demonstrating they have capacity for detection more widely. That means there’s significant potential for mining the JEEs to collect influenza data.

3. Reviewing the checklist

During the June meeting, participants reviewed each section of the checklist to suggest specific additions, amendments or deletions that might improve the checklist based on their experience. Each section review was informed by expert panels or speakers as well as lively table and plenary discussions – all designed to encourage a frank and open exchange among diverse participants.

Future framing

Some suggestions that came up again and again at the meeting cut across all areas of the checklist and relate to how WHO might frame the list as a whole going forward.

I. Clarify objectives

- Both countries and partners need to know exactly what the checklist is for and how to use it.
- That requires clearly stated objectives – both for the list as a whole and for each section.

II. Revisit basic premises

- The global health community has made an inextricable link between seasonal and pandemic preparedness as a norm for decades – but does it remain true? (The experience of some manufacturers suggests not.)
- The checklist could have a role to play in assessing the sustainability of using seasonal vaccine production as a platform for pandemic preparedness.

III. Seek feedback from checklist users

- There must be a way of collecting and incorporating immediate feedback from users.
- Such feedback could also serve as a useful data source, both within and beyond WHO.

IV. Frame preparedness as insurance

- How could investment in pandemic preparedness be framed as buying insurance?
- The World Food Programme insurance scheme for disaster preparedness offers an example of how to pitch investment in preparedness as insurance – and should be examined to explore how it might be adapted for pandemic influenza.

V. Consider a tiered approach

- The checklist should be applicable to all countries, both those that do, and do not, produce vaccines locally.
- The checklist is already designed to be customized to local circumstances and contexts.
- Making it relevant to non-producing countries may require a tiered approach: tier one aligning efforts with a central development and financing plan (producing countries); and tier two identifying challenges and opportunities to accessing vaccines (non-producing countries).

"Developing a user feedback mechanism would be a more sustainable approach than organising big meetings."
VI. Think about a restructure

- Participants agreed with most of the existing structure of the checklist. But, as a group, they suggested two structural changes:
  - **Take procurement out**: this section of the checklist was thought to be different enough that it deserved a parallel process (see section 3.6 below for more information).
  - **Mainstream finance and HR**: these two topics are relevant across all sections of the checklist and participants suggested that they should either be consistently included in each, or taken out of all existing sections and put into a new, separate section of its own.

- Some participants further argued that the checklist should be streamlined – that it should be made more compact, with the addition of an executive summary.
- One participant had more radical changes in mind, suggesting a complete restructure to better match the health system pillars. That means dividing indicators into six policy areas (surveillance, immunization, communication, regulatory aspects of pandemic preparedness and response planning, and vaccine development and manufacturing) and clustering them into policy, infrastructure, manpower and finance.

3.1. Healthcare systems and policies

**Overview**

Policies have a central role in strengthening the sustainability of any influenza programme. This section of the checklist is all about developing health policies that are based on the national and international body of evidence and vaccination recommendations. It encourages a multi-purpose approach that integrates influenza policies into other health strategies for greater cost efficiency and a larger positive impact on the health of the population. It is made up of 14 indicators, across six topics of interest (see Figure 3).
Key messages

I. The checklist must be fit for purpose

- The checklist’s objectives must be very clear.
- It’s not just objectives that need to be clear – the indicators themselves do too. Ensuring that these are not left open to interpretation, may require re-wording or additional explanatory notes.

II. We need to test the assumptions of the checklist

- Some checklist indicators make assumptions that need testing, or a more nuanced approach.
- For example, 50% of WHO Member States don’t have an influenza ‘position’, but that doesn’t mean there’s no political will: those countries may simply need different data for decision making in their contexts.

III. It’s important to maximize synergies and align health systems

- There are two sides to this:
  a) The idea that the checklist can, in itself, be a tool for maximizing synergies: experience from Brazil suggests that it’s harder to duplicate efforts if you use the checklist properly.
  b) The idea that we must be opportunistic about other needs in the country and ensure the checklist serves multiple uses – for example, tying it to the IHR framework or the JEE.

IV. Properly used, the checklist can spark collaboration and provide transparency

- In Brazil, use of the checklist was helpful in uncovering all the stakeholders in vaccine production and in creating some transparency in the roles and responsibilities across the supply chain.

V. The checklist must help policy-makers think about the technological future

- One obvious omission in the checklist is advances in technology – vaccine production is a fast-evolving field and the checklist should include one or more questions about the tech horizon and new approaches that could address or change infrastructure, because some vaccines could become inefficient very quickly.

Suggested improvements: a taste

1. Do we need an oversight programme? Something from WHO – a policy for example – to make this checklist a priority and provide an incentive for countries to take it up.
2. Beware talking about target groups and pandemics–it’s hard to identify target groups before a pandemic.

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4 These select points represent just a very few of the comments and suggestions shared in plenary. It does not include significant discussion points already covered by previous sections of this document.
Report of the meeting on sustainable local production of influenza vaccines for pandemic preparedness

3. To help users, clearly separate questions that are policy or governance and those that are programmatic.
4. Addition: Is there a national preparedness plan in place?
5. Addition: Where does influenza rank compared with other public health risks in your country?

See Annex 5.2.1. for a full list of the suggested improvements to this section of the checklist.

3.2. Other policy areas that interconnect with health

Overview
The policies that impact influenza vaccination extend far beyond health, to cover industrial policy, national and international trade, workforce policy and others. This part of the sustainability checklist provides a bridging element between public health and industry. It focuses on promoting policy coherence and coordination, looking at things such as the interactions between academic institutions and local manufacturers, multilateral agreements, etc. across five areas (see Figure 4).

Figure 4. The sustainability checklist covers policies other than health in five areas.

Key messages

I. There are lots of different international trade agreements and policies that apply to local production

- These include multilateral, bilateral and regional trade agreements with public/governments procurement obligations (e.g. WTO’s government procurement agreement, EU directive 2014/24/EU on Public Procurement, ASEAN framework, NAFTA).
- To organise local production without breaching of an obligation under these trade agreements, governments and manufacturers must identify and understand their specific obligations on government procurement, preferential schemes and trades agreements rules.
- Some bilateral agreements could pose a threat to the 14 countries that have received WHO support for local vaccine production.
II. The health exception in trade policies can help support local vaccine production

- Many trade agreements or frameworks include a “health exception” that can allow countries to choose how to procure supplies needed to protect human (or animal or plant) life.
- That means countries wanting to support local vaccine production may be able to set up preferential procurement schemes to protect the health of their own citizens. But they must demonstrate that it was introduced to protect human health; and also show that it was necessary and proportional. The country should prove that a less restrictive measure would not suffice to achieve a selected level of protection. To evaluate whether this satisfies the requirements, its contribution will be weighed against its restrictiveness.

III. A cohesive industrial policy relies on building consensus and ownership in-country

- Achieving coordination and collaboration between stakeholders means understanding and taking account of the diverse roles and interplay between policy, regulation and business.
- It also means regular engagement through meetings and workshops, ongoing assessments of needs and priorities, appropriate training and managing expectations.
- Collaboration includes working with and across ministries: with ministries to ensure ongoing political will, and across ministries because policy coherence is important.

IV. A holistic approach can support and inform companies looking to start local production

- One approach to increasing the capacity for competitive local manufacturing – tried and tested by UNIDO – is to improve the operating environment for pharmaceutical companies, particularly small- and medium-sized enterprises (SMEs).
- A holistic approach needs to look across strategic components, including quality assurance, regulatory strengthening, finance, incentives, HR, and common support services, to identify elements that need strengthening and articulate a multi-year plan for making that happen.

Suggested improvements: a taste

1. Some of the questions in this section are very general and/or complex and should be broken down to make them easier to understand and answer.
2. We need to include something on shipping permits and licences in this section.
3. Is there a need to change title of section – perhaps to something about “interaction with”, or “harmonization”?  
4. Addition: Are there any policies to encourage investment and technology transfer?
5. Addition: What sort of governance or coordination mechanisms exist to ensure relevant stakeholders (such as ministries and investors) are cooperating?

See Annex 5.2.2. for a full list of the suggested improvements (edits, additions, deletions and comments) to this section of the checklist.

---

5 These select points represent just a very few of the comments and suggestions shared in plenary. It does not include significant discussion points already covered by previous sections of this document.
3.3. Influenza-specific evidence: strengthening surveillance systems

**Overview**
Without strong data on influenza burden, the transmission landscape and antiviral resistance, authorities can’t establish evidence-based policies to reduce the disease’s impact. Local data on mortality and morbidity are also essential to combat misperceptions that influenza is nothing more than a mild illness.

This part of the checklist looks at how information is generated; and assesses the relevance and strength of the data that underpin a country’s evidence on influenza and ultimately shape policy and public perceptions. It encourages governments to look at their own system in terms of sentinel sites, human resources and communication procedures, and to think about how data are collected and how they are aggregated, reported and used (see Figure 5).

**Key messages**

I. **Burden of disease data can point the way forward**
- Burden of disease data are particularly useful for policy-makers and other stakeholders in discussing new areas of work, vaccination policies and in framing new studies.

II. **For tropical countries, flu seasonality poses a problem**
- In tropical countries, both hemisphere’s strains of seasonal influenza are often present, all year round.
- For manufacturers in these countries, it is difficult to decide whether to produce the Northern or Southern hemisphere vaccine.

“…we have flu all year round, so if the government decides to adopt a vaccine then which vaccine do we use?”

III. **Pandemic preparedness isn’t the problem: seasonal vaccination is**
- In many countries, the case for pandemic preparedness has been made. But that doesn’t necessarily mean that the same is true for seasonal vaccination.
- In Ghana for example, despite various pandemic influenza preparedness plans in place and an active risk communications group, the country still has no policy for seasonal vaccination.
- Cost can be a significant barrier, especially among low middle-income countries, who can be reluctant to adopt a seasonal vaccination policy because they do not qualify for free vaccines.
IV. A One Health approach relies on close and constant collaboration across sectors

- Monitoring data submitted to a National Influenza Centre can be used to support an alert system for avian flu at the human-animal interface.
- But only if there is close collaboration and communication with veterinary groups; for example, through weekly updates on influenza cases in contact with dead or sick animals.

Suggested improvements: a taste

1. The indicators in this section seem to fall into one of three categories – surveillance, information sharing, and burden of disease – and should be clustered as such.
2. We need to include the perspective of non-producing countries here.
3. Clarify the use of burden of disease data here: it’s not enough to have the data, governments need to demonstrate that they are being used.
4. Addition: Is there collaboration between animal and human health systems and programmes?
5. Addition: Is influenza treated as a priority human disease?

See Annex 5.2.3 for a full list of the suggested improvements (edits, additions, deletions and comments) to this section of the checklist.

3.4. Regulatory capacities strengthening

Overview
Assessing, licensing, controlling and surveilling biological medicinal products can pose a major challenge to national regulatory authorities (NRAs) that are confronted with a growing number of novel products, complex quality concerns, and new technical issues arising from rapid scientific advances. It is not uncommon for a country to have local vaccine production before its NRA is fully functional.

This part of the checklist is designed to encourage governments to strengthen NRAs by building their capabilities and functionality; and to ease their burden by looking outside to collaborate and to harmonize their efforts with other NRAs in their region as well as exploring the WHO prequalification process (see Figure 6).

Figure 6. The checklist assesses functionality of NRAs as well as efforts in harmonization and prequalification.

6 These select points represent just a very few of the comments and suggestions shared in plenary. It does not include significant discussion points already covered by previous sections of this document.
7 http://apps.who.int/medicinedocs/en/d/Js21317en/
Key messages

I. Common documentation does not equal harmonization

- Experience from WHO’s Regulatory System Strengthening Group shows that harmonization is largely about harnessing political will and continuous support; and building a common vision and mission, with clearly elaborated roles and responsibilities.
- It also requires developing shared legal, regulatory and technical frameworks; as well as operational procedures for interpreting and implementing decisions.

II. Harmonizing regulations benefits multiple stakeholders

- NRAs themselves improve their capacity for timely and cost effective evaluation.
- Manufacturers (local and international) get faster approval and greater transparency.
- Donors get greater reach for their investment or support.
- Governments can potentially save money, better manage healthcare resources, and improve public health.
- Patients get quicker access to affordable vaccines and are better assured of their safety.

III. Having a mechanism for fast track approval is important

- The ability to fast track approval is a basic building block in robust preparedness planning and in ensuring an NRA can cope with a pandemic.
- It can also serve as a good incentive in attracting producers and investors.

IV. The checklist is not a prescriptive tool

The checklist is not there to assess whether or not an NRA meets a given set of functionality criteria.

The checklist is there to spark a dialogue among regulators to discuss in-country local production, and look at interactions with manufacturers and others and assess willingness to integrate and harmonize efforts.

V. The checklist should address concepts of reliance and recognition

- Reliance means basing decisions on the assessment of another agency.
- Recognition means following/adopting international treaties and frameworks and joining cooperation arrangements etc.
- In both cases, experience shows that it takes time to develop the trust, confidence and frameworks for sharing work and information required to harmonize regulations.

Suggested improvements: a taste

1. Questions here would be different for producing and non-producing countries.
2. The checklist needs to capture how facility itself is licensed, not just the vaccine.
3. We need to list specific criteria to define “effective working relationships”.
4. Addition: Does the country have an accelerated process for licensing during emergencies?
5. Addition: Is there political will for a strong NRA?

See Annex 5.2.4 for a full list of the suggested improvements (edits, additions, deletions and comments) to this section of the checklist.

8 These select points represent just a very few of the comments and suggestions shared in plenary. It does not include significant discussion points already covered by previous sections of this document.
3.5. Manufacturing

Overview
This part of the checklist, more than anywhere, acknowledges the need for a business eye in sustaining local vaccine production. It is where manufacturers are encouraged to look at their business plans based on evidence and market analyses and assess their sustainability.

Here, manufacturers are also asked to think about the international, regional and national contexts in which they operate. This includes assessing their own understanding of the many rules and requirements on commercialisation, as well as the extent to which they take advantage of relevant associations and networks, and whether or not they play a pro-active role with the government agencies that support the production process (see Figure 7).

Figure 7. Manufacturing components of the sustainability checklist.

Key messages

I. Political will is paramount to supporting local production

“\[The government plays a huge role in making or breaking local production efforts.\]

- Failure to recommend the influenza vaccine for high risk groups, or include it in routine immunization programmes, not only poses a public health risk but also threatens local production capacity.
- For example, the low uptake of vaccines produced last year at the Serum Institute in India is only partly due to the product’s presentation; it is more heavily associated with the lack of a government vaccination policy.
II. Individual manufacturers need a guaranteed income

- Companies wanting to move into vaccine production need a mechanism to guarantee enough income to keep their facility up and running.
- One option is paying companies to be ready to respond or to produce an annual stockpile.\(^9\)
- Another option is treating countries with a demonstrated pandemic response plan more favourably for investment.

Vaccine production is only sustainable if there is a fair price for both governments and manufacturers.

III. At a company level, more can be done to attract investors and finance

If companies can get some portion of cost at low rate and some at normal rate then combined, it becomes affordable.

- This includes demonstrating a well-run company with strong financial planning and robust technical and business plans.
- Governments have a role to play in providing low-cost capital (through, for example, mechanisms such as the Export Trade Agricultural and Development Fund in Ghana); and in demonstrating commitment to the sector (through local procurement preference, strengthening of national regulator, or lending incentives for banks).

IV. Local production by a strong pharma sector benefits countries in many ways

- UNIDO’s experience suggests that locally sourced medicines (and so, vaccines) deliver a range of social and economic benefits, including:
  - faster and easier access to medicines
  - more short- and long-term jobs
  - more money through tax revenues, payments and international investment in R&D.

V. The switch from seasonal to pandemic vaccine production impacts stakeholders

- The timeline for pandemic production is made up of a series of steps that are all potential bottlenecks.
- If everything goes well, it will take 20–24 weeks.
- That reality has implications for manufacturers (contracts, clinical trials, etc.); programme managers (no more seasonal vaccination, impacts on public health); communicators (getting the message out); WHO (developing country manufacturers and non-producing countries will look to WHO for guidance); affected populations: any vaccine developed for a pandemic will, in reality, only benefit second wave victims.

VI. The implications of the Nagoya Protocol remain unknown

- The Nagoya Protocol is a supplementary agreement to the Convention on Biological Diversity (CBD), which has one of its main goals the fair and equitable sharing of the benefits derived from the use of genetic resources. Viruses, including influenza viruses, are captured under the Nagoya Protocol and there is concern that the ability of manufacturers to access influenza strains (especially seasonal ones) may be affected.

\(^9\) For example, something similar to the EU mechanism, whereby every country has a contract with a pandemic manufacturer and commits to buying a certain amount of stockpile every year – anything between 50 to 200 million doses. These countries pay the manufacturer US$ 0.50 per dose, providing an assured income of US$ 25–100 million to keep the facility on and compliant with all requirements and regulations.
However the Nagoya Protocol will not apply to certain genetic resources, as long as they are covered by another specialized international instrument that is consistent with, and does not run counter to, the objectives of the CBD and the Nagoya Protocol (Article 4 of the Nagoya Protocol).

The CBD secretariat is conducting a study on the criteria that could be used to identify what constitutes a specialized international access and benefit-sharing instrument in the context of Article 4(4) of the Nagoya Protocol and what could be a possible process for recognizing such an instrument.

**Suggested improvements: a taste**

1. The indicators here need rearranging, regrouping and clarifying: for example, what does a “sustainable” business model look like?
2. Many of the points here deal with bringing procurement to a certain level but we also need to focus on improvements after a product has achieved WHO good manufacturing practices (GMP) and prequalification (PQ).
3. Environmental health and safety concerns need to be on list.
4. Addition: Does your business plan include elements of both pandemic preparedness and seasonal vaccination?
5. Addition: Does the educational infrastructure have the ability to provide the required skills and workforce for manufacturing?

See Annex 5.2.5 for a full list of the suggested improvements (edits, additions, deletions and comments) to this section of the checklist.

3.6. Procurement

**Overview**

Most countries don’t produce their own vaccines and rely on the import or donation of vaccines for both its seasonal vaccination as well as any pandemic. For non-producing countries, a strong procurement system with a solid network of suppliers is essential (see Figure 8).

This section of the checklist is aimed at non-producing countries and how their procurement policies and efforts can work for or against the sustainability of local production initiatives in the 14 countries supported by WHO. It can also serve as a tool for sparking dialogue within countries that do not have production capacity but are interested in supporting it.

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**Figure 8. Issues of procurement included in the sustainability checklist.**

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10 These select points represent just a very few of the comments and suggestions shared in plenary. It does not include significant discussion points already covered by previous sections of this document (e.g. the idea that pandemic preparedness should be sold as insurance).
Report of the meeting on sustainable local production of influenza vaccines for pandemic preparedness

Key messages

I. Pooled procurement can be effective but it relies on engagement and shared purpose

- Pooled procurement can increase a country’s negotiating and purchasing power.
- The ASEAN price policy for vaccine (APPV) and pooled procurement has been used effectively to: buy routine vaccines with a high risk of stock shortages, buy new vaccines that are very expensive; set up a regional stockpile of emergency pandemic supplies.
- It has worked in Southeast Asia because countries share a vision of vaccine security and are committed to stronger regional collaboration and integration, actively networking and sharing information and expertise across countries.

II. Demand for influenza vaccines is negligible

- Every year, UNICEF procures immunization supplies for around 100 countries, including around 2.5 billion doses of vaccines, worth US$ 1.64 billion.
- The demand for influenza vaccines through UNICEF is miniscule (less than 100 000 doses most years).

III. Scaling procurement to meet demand deserves consideration in the checklist

- Responding to a pandemic is not just about being able to develop a vaccine quickly and get local production and licencing sorted.
- It’s also about scaling up procurement to meet potentially massive demand.

IV. Countries can adopt a range of approaches to improve supply access and procurement

- UNICEF experience suggests procurement principles in five areas to support manufacturers and ensure governments can secure vaccine supplies (see Figure 9).

Figure 9. Five procurement principles to support manufacturers and governments.

Suggested improvements

The main suggestion that emerged from this session was that the role of non-producing countries in procuring influenza vaccines is so critical to sustaining vaccine production in developing countries (not least because demand is often very low here) that it deserves a parallel track that goes beyond the
sustainability checklist and is embedded in broader pandemic preparedness efforts. Participants agreed that this parallel track must be inclusive – developed in collaboration with international agencies and partners – and it should draw on major lessons learnt in terms of supply chain, product stability etc.

As a result of this collective conclusion, the individual indicators in the procurement section of the checklist were not reviewed by the meeting. Instead, it was decided that WHO’s Technology Transfer Initiative would begin thinking about what a parallel track for procurement might look like (see Next steps below).

3.7. Communication, community engagement and risk communication

Overview
To support local vaccine production countries must enable a wide uptake of influenza vaccines, which requires a comprehensive communication plan and well-developed infrastructure. That, in turn, means ensuring that everyone involved in vaccination (from governments to NGOs to companies) works together to deliver timely, meaningful and appropriate communication. It also means being able to develop risk communication and public campaigns during outbreaks, in the context of local and regional needs, and in concert with manufacturers.

This part of the checklist explores the conditions necessary to achieve that; and emphasises the approaches needed to build trust so that the general public takes health workers’ advice on both seasonal and pandemic vaccination (see Figure 10).

![Figure 10. Elements of communication and engagement explored in the sustainability checklist.](image)
Key messages

I. Collaboration, empathy and trust are created or destroyed in communications

- Communication is much more important and complex than we give it credit for: it’s both a bioactive process (that affects our health and body function) and a systemic one (that impacts our body and other people).
- We need performance measures for “different” areas of communication such as collaboration.

II. Communications isn’t just about what you say; it’s about how you say it too

- Probably one of the most underused ways we have to improve vaccine uptake is to use communications in ways we haven’t done before.
- The concepts of risk and trust are as much a feeling as an intellectual assessment.
- Health workers must be able to address both – building trust is not about creating a particular message but about the way we interact with people.

III. Mapping reasons behind vaccine hesitancy can help tailor communications

- A mapping exercise of the influencing factors behind low vaccine use among doctors and nurses in Serbia revealed that the main barrier was not inconvenience but a perception that the vaccine was not safe or effective, or that natural immunity was better. This insight enabled the development of a tailored communications campaign.
- A few groups – such as the IUPUI Global Health Communication Centre – are trying to go one step further and tailor communications to individuals.

IV. Tackling misinformation remains a key priority

- There is a lot of misinformation going around – particularly on social media – that undermines efforts to talk about vaccine production or policy among decision-makers and the public.
- WHO’s Risk Communications group, among others, monitors traffic to address misinformation as soon as it is published.

V. Risk communications saves lives

- By addressing risky behaviours and informing the public, risk communications is one of the few public health dimensions at beginning of pandemic that can reduce mortality and morbidity before any other interventions.

Suggested improvements: a taste

1. Use trusted individuals – such as celebrities or religious leaders – to extend the reach of communications.
2. Some questions need clarification; for example, how do you achieve skilled communications staff?
3. There’s a need to check for consistent messaging across stakeholders, including government, medical associations and NGOs.
4. Addition: Are communication strategies tailored to specific groups?
5. Addition: Do manufacturers communicate effectively to the media during outbreaks?

See Annex 5.2.7 for a full list of the suggested improvements (edits, additions, deletions and comments) to this section of the checklist.

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11 These select points represent just a very few of the comments and suggestions shared during the meeting. It does not include significant discussion points already covered by previous sections of this document. (Please note that this section of the checklist was only covered by table discussion and was not reviewed in plenary.)
4. Looking ahead

At the end of the meeting, participants were asked to reflect on the checklist one last time and answer two questions to help direct the list’s future development; their answers are summarised below (see Table 2).

Table 2. Participants’ views on the future development of the checklist.

<table>
<thead>
<tr>
<th>Where should the checklist go from here?</th>
<th>How can the checklist be leveraged to its full potential?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clarify objectives</td>
<td>Formalise it at a government level</td>
</tr>
<tr>
<td>Mainstream finances and HR (skilled workforce)</td>
<td>Identify ways to make its output visible to policy-makers</td>
</tr>
<tr>
<td>Avoid a binary framework</td>
<td>Incorporate it into preparedness plans</td>
</tr>
<tr>
<td>Develop sustainability recommendations</td>
<td>Carry out an external assessment to put it through its paces</td>
</tr>
<tr>
<td>Create a parallel strategy for alternative options</td>
<td>Increase the frequency of review</td>
</tr>
<tr>
<td>Use it to define country- or region-specific objectives</td>
<td>Collect feedback from countries for ongoing improvement</td>
</tr>
<tr>
<td></td>
<td>Use it as a survey and collect information when the process is being carried out</td>
</tr>
</tbody>
</table>

4.1. Next steps

The GAP Secretariat outlined next steps for work on the sustainability checklist. These include:

- **Revising the checklist in line with participants’ feedback**
  This includes analysing all the comments and suggestions for improvement; and incorporating these into a revised checklist to be shared with participants. The aim is to arrive at a new version of the checklist that is better than it is now.

- **Developing a comprehensive and coherent approach to financing and HR**
  This involves discussion and analysis among WHO colleagues to decide whether to include the financing and HR strands as new, separate sections in the checklist; or mainstream them in a consistent way throughout every section of the checklist.

- **Kick-starting a process for tackling procurement of vaccines in preparedness efforts**
  This requires first clarifying internal WHO thinking before engaging broader audiences to discuss how to deliver a parallel process to the checklist focused on procurement. The aim is to produce a concept paper that can be shared with partners and others.

- **Creating a mechanism for immediate feedback**
  While WHO could not speak to the regularity of checklist reviews, the organisation did commit to finding a way of collecting and incorporating feedback from countries immediately after they have used the checklist.

- **Exploring the idea of “selling” pandemic preparedness as insurance**
  This begins with assessing the potential of framing investments in preparedness as buying insurance; it includes looking at the World Food Programme’s insurance scheme for drought, and thinking about how it might be adapted for use by WHO and others.
5. Annexes

5.1. Visions of success

![Success parameters diagram](image)

Figure 11. Some of the visions of success for the sustainability checklist meeting, as expressed by meeting participants.

5.2. Suggested improvements to the checklist

5.2.1. Healthcare systems and policies

Table 3. Participants’ suggestions and comments about the Healthcare systems and policies section of the checklist.

<table>
<thead>
<tr>
<th>Suggested edits (in blue)</th>
<th>Other suggestions and comments</th>
</tr>
</thead>
</table>
| **Demonstrable and ongoing** political will for in-country influenza vaccine manufacture | • What is political will and how is it measured?  
• Political will is fleeting and needs concrete commitment and expression (need follow up and action plan for each ministry). |
| **Demonstrable and ongoing** political will for pandemic influenza preparedness           |                                                                                                                                                            |
| **Awareness of** international influenza recommendations to shape national policies; and national policies having input into international recommendations |                                                                                                                                                            |
| Coherence among relevant national health policies and programs                           | • Not clear what coherence means in this case.                                                                                                            |
| Seasonal vaccination policies are based on the **local national** burden of disease, the vaccine effectiveness among at-risk groups and vaccination cost-effectiveness studies | • The issue is that national governments decide not to prioritize seasonal influenza programming.  
• Potential conflict: if you make indicator 5 absolute to meet, then you prevent indicator 6 from being met.  
• Move this indicator to Section 3 of the checklist (Influenza-specific evidence). |
| Seasonal influenza vaccination and control policies are developed also as means to sustain pandemic preparedness and national security | • Add that policies should be multi-sectoral.  
• Potential conflict: if you make indicator 5 absolute to meet, then you prevent indicator 6 from being met. |
<table>
<thead>
<tr>
<th>Question</th>
<th>Additional Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>The price of the vaccine is not a barrier for the government to provide it for free to the target groups</td>
<td>Does this indicator add much value? (price will always be barrier: rephrase or delete this one)</td>
</tr>
<tr>
<td></td>
<td>Complement to this: does the country have access to international organisation to buy vaccines?</td>
</tr>
<tr>
<td></td>
<td>Pandemic or seasonal?</td>
</tr>
<tr>
<td></td>
<td>Alternative question: Is the vaccine provided and delivered for free to target groups? (combine questions 7&amp;8)</td>
</tr>
<tr>
<td>Re-word: Is there sufficient funding for the government to provide vaccine for free to the target groups?</td>
<td>Seasonal influenza vaccination is included in health insurance schemes or directly provided by the public health sector</td>
</tr>
<tr>
<td>Vaccine Health system delivery infrastructure is in place and maintained</td>
<td></td>
</tr>
<tr>
<td>The vaccine health system distribution system is in place and efficient</td>
<td></td>
</tr>
<tr>
<td>There is adequate availability of the vaccine at the hospital, healthcare centers and pharmacies level</td>
<td>If you get hesitant people wanting vaccination and it’s not there, it is problematic: think of potential demand.</td>
</tr>
<tr>
<td></td>
<td>Possibly remove/reword since target groups are not defined prior to a pandemic.</td>
</tr>
<tr>
<td></td>
<td>(needs reword because process may differ depending on pandemic)</td>
</tr>
<tr>
<td>Target groups for pandemic influenza immunization have been established and are part of the pandemic preparedness plan</td>
<td></td>
</tr>
<tr>
<td>Reword: Risk assessment process is in place to identify target groups</td>
<td>The pandemic influenza preparedness plan takes into consideration the seasonal influenza vaccination policy and the local manufactured product</td>
</tr>
<tr>
<td>The pandemic influenza preparedness policy and plan is regularly updated, published and appropriately disseminated to all relevant agencies</td>
<td>Ensure the PIP plan is exercised regularly from a full health system perspective.</td>
</tr>
</tbody>
</table>

**Additional questions to include:**

- Are you aware of influenza pandemic preparedness?
- Is there a national policy/law to implement influenza vaccine programme?
- Is there a national pandemic preparedness plan? (Questions 12-14 assumes that there is)
- Are WHO influenza vaccine policies and/or resolutions being implemented?
- Is there policy coherence among all relevant government departments/ministries (e.g. health, trade, industry)?
- Is a monitoring system to measure uptake in place (for the identified risk groups)?
- Does the country have a fast mechanism to procure vaccine?

**Other suggestions and comments:**

- There’s a need to organise elements a little more logically:
  - e.g. divide countries into groups: 1) producers, 2) non-producers; 1) national vaccine policy, 2) no national vaccine policy; 1) national manufacturer, 2) no national manufacturer.
  - e.g. to help users, clearly separate policy/governance indicators from programmatic ones.
- Develop a separate checklist for countries that want to produce or are considering producing.
- We need an ongoing (or rolling) review of documents instead of a yearly or set time.
- Greater effort for coherence at an international level.
- Risk characterisation: influenza placed within a broader risk matrix.
5.2.2. Policies other than health

Table 4. Participants’ suggestions and comments about the Policies other than health section of the checklist.

<table>
<thead>
<tr>
<th>Suggested edits (in blue)</th>
<th>Other suggestions and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efforts are made to overcome possible bureaucratic obstacles to establish and sustain vaccine manufacturing</td>
<td>• This is not a yes/no question; and it needs to be broken down into two parts.</td>
</tr>
<tr>
<td><strong>Reword: are there policies or practices in place that encourage multi-sectoral coordination and overcome bureaucratic obstacles…</strong></td>
<td>• What steps are being taken to establish local production?</td>
</tr>
<tr>
<td>• Identify specific obstacles.</td>
<td>• The term “bureaucratic” is negative and should be removed or replaced</td>
</tr>
<tr>
<td>• Should the word “efforts” be strengthened or replaced with “a binding strategy”?</td>
<td>• Should the word “efforts” be strengthened or replaced with “a binding strategy”?</td>
</tr>
<tr>
<td>National and regional procurement and distribution policies to promote <strong>and sustain</strong> in-country production and sourcing of materials are developed</td>
<td>• The development of regional blocks of countries to leverage regional production.</td>
</tr>
<tr>
<td>Policies and implementation plans are created to generate skilled local workforce for local vaccine production, also through facilitation of exchanges at national and international level and government grants to further education</td>
<td>• Split into three sub-questions.</td>
</tr>
<tr>
<td>Interactions between academic institutions and local manufacturers are encouraged and facilitated for the development of useful curricula for the vaccine manufacturing sector and for exchange and on the job trainings</td>
<td>• ( &amp; next indicator) Is there access to training outside the region if necessary, e.g. lab training at ERL, National control lab or industry.</td>
</tr>
<tr>
<td>Policies are created to influence the development and size of the GMP bio-manufacturing environment</td>
<td>• Raise the biosecurity level (BSL) up to 3 or 4 (this because of the issue of timing—need for timely action).</td>
</tr>
<tr>
<td><strong>Reword: Incentives are created to influence infrastructure to support development of size of the GMP bio-manufacturing environment</strong></td>
<td>• Nagoya protocol: treaties (not just agreements) that may not be traditionally thought of as important may impact flu.</td>
</tr>
<tr>
<td><strong>Identifying and understanding of how the multilateral and bilateral agreements affect commercialization and local procurement, import and export of products</strong></td>
<td></td>
</tr>
<tr>
<td>Additional questions to include:</td>
<td></td>
</tr>
<tr>
<td>• Are there any policies to encourage investment and technology transfer?</td>
<td></td>
</tr>
<tr>
<td>• What sort of governance/coordination mechanisms are there to ensure relevant stakeholders are cooperating? (e.g. ministries, investors)</td>
<td></td>
</tr>
<tr>
<td>• Shipping permits for CVVs (candidate vaccine viruses)?</td>
<td></td>
</tr>
<tr>
<td>Other suggestions and comments:</td>
<td></td>
</tr>
<tr>
<td>• Add the financing indicators to a new, separate section of the checklist.</td>
<td></td>
</tr>
<tr>
<td>• There is an assumption that this whole section is only for vaccine producing countries.</td>
<td></td>
</tr>
<tr>
<td>• Is there a need to change title of section: perhaps something about “interaction with” or “harmonization”?</td>
<td></td>
</tr>
<tr>
<td>• One health approach.</td>
<td></td>
</tr>
<tr>
<td>• Think about supply of eggs.</td>
<td></td>
</tr>
<tr>
<td>• Licensing policies among countries (pandemic).</td>
<td></td>
</tr>
</tbody>
</table>
### 5.2.3. Influenza-specific evidence

Table 5. Participants’ suggestions and comments about the Influenza-specific evidence section of the checklist.

<table>
<thead>
<tr>
<th>Suggested edits (in blue)</th>
<th>Other suggestions and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surveillance system for virological surveillance in place (sentinel cites, technology and human resources)</td>
<td>• Is there (for surveillance): policy? infrastructure? HR? funding? up-to-date methods?</td>
</tr>
<tr>
<td></td>
<td>• Is there an in-country WHO NIC?</td>
</tr>
<tr>
<td>There are clear and well-functioning procedures for communication of alerts from sentinel sites to central level (information transmission chain tested and updated)</td>
<td>• Communication of alerts needs to be linked to risk assessment, and risk assessment to action.</td>
</tr>
<tr>
<td></td>
<td>• Combine and rephrase this indicator with the next one.</td>
</tr>
<tr>
<td>Accurate and timely surveillance reporting</td>
<td>• Is the surveillance information provided to a WHO collaborating centre?</td>
</tr>
<tr>
<td></td>
<td>• The term “timely” needs clarification (surveillance reporting needs to meet timeline outlined in NIC agreement if country has an NIC).</td>
</tr>
<tr>
<td>Design of data collection driven by surveillance objectives.</td>
<td></td>
</tr>
<tr>
<td>Annual surveillance reports with risk factor data produced</td>
<td>• Risk factors include: animal risk assessments/ under surveillance guidance</td>
</tr>
<tr>
<td>Data aggregated and reported on international data sharing platforms</td>
<td>• Indicate consolidated under WHO flu web.</td>
</tr>
<tr>
<td>The health and economic burden of influenza is known in the country</td>
<td>• Add a sub-question: Is burden of disease data used in discussions with national entities involved in developing vaccination policy?</td>
</tr>
<tr>
<td></td>
<td>• Combine this with indicator 4: data collection &amp; surveillance go hand in hand.</td>
</tr>
<tr>
<td>Cost-effectiveness studies of seasonal influenza vaccination in target groups is known</td>
<td>- This indicator is about financing–move it.</td>
</tr>
<tr>
<td>Data on impact of influenza is expressed in a way that resonates with priorities of policy-makers</td>
<td>• Use simpler language for this element--e.g. Is language clear enough for policy-makers to understand?</td>
</tr>
<tr>
<td><strong>Reword:</strong> Burden of disease and cost-effectiveness data are communicated in a way that resonates with priorities of policy-makers</td>
<td>• Clarify this question, particularly re genetic surveillance–point mutations to decide that to use for vaccine and clarify “resonates with priorities”.</td>
</tr>
<tr>
<td></td>
<td>• This is more of a communications issue</td>
</tr>
</tbody>
</table>

**Additional questions to include:**
- Is there reference to One Health approach: surveillance in animals and monitoring of humans exposed to animals?
- Is there collaboration between animal and human health systems, with a One Health approach?
- Is there the capacity for continuous improvement in surveillance (including a place to learn about surveillance tools)?
- Is influenza treated as a priority human disease?
- Is influenza surveillance data included in the countries infectious disease reports?

**Other suggestions and comments:**
- We need a regular evaluation process for surveillance.
- The checklist should cross reference other relevant checklists–can we harmonize?
- Change the overall title of this section to: Influenza surveillance, early detection and evidence.
### 5.2.4. Regulatory capacity strengthening

Table 6. Participants’ suggestions and comments about the Regulatory capacity strengthening section of the checklist.

<table>
<thead>
<tr>
<th>Suggested edits (in blue)</th>
<th>Other suggestions and comments</th>
</tr>
</thead>
</table>
| National Regulatory Authority (NRA) “functional” in WHO – Pre-Qualification for vaccine prequalification and encourages vaccine manufacturers to prequalify products | • Does the NRA accept a mock-up/similar licence?  
• Does the NRA have a well-established fast-track process? |
| NRA staff trained and re-trained continuously                                               | • Trained in which areas?  
• How are training needs identified?                                                         |
| Effective working relation between domestic manufacturers and NRA, including workshops held to encourage effective relations | • Is there a clear road map for relations between manufacturers and NRA?  
• “Effective working relations” is not clear–what does “effective” mean in this context? This needs to be defined or detailed in a footnote or other explanation mechanism. |
| Effective exchanges among NRA staff and other governments and international organization  | • “Effective exchanges” is not clear–what does “effective” mean in this context? This needs to be defined or detailed in a footnote or other explanation mechanism. |
| Domestic manufacturer’s full awareness of regulatory requirements for the product in the country |                                                                                             |
| Domestic manufacturer’s full awareness of the requirements to submit a dossier for WHO Prequalification (PQ) |                                                                                             |
| Regional regulatory approvals harmonized and integrated                                    | • The term “regional” needs to be defined, globalised or deleted.  
• This deserves more than one question–e.g. is NRA participating in harmonization/regional programmes or efforts? |
| **Reword**: Regional regulatory assessments/processes harmonized                            |                                                                                             |

Additional questions to include:

- Is there a mechanism in place for fast-track or pre-pandemic licensing?  
- Are guides for all parties regularly updated for all stakeholders?  
- Does NRA update knowledge continuously?  
- How does NRA ensure that manufacturers are clear about requirements?  
- Is there political will to establish a strong NRA?  
- Is a country able to accept pandemic vaccine?  
- Has the NRA participated (is participating) in the process from facility design, preclinical and clinical development planning?  
- Is there a mock-up approval EMA?  
- Is there harmonized regulatory release (especially for pandemic)?  
- Are there requirements/guidelines on seasonal strain changes?  
- Is the facility licensed for: production/formulation/filling?  

**Other suggestions and comments:**

- This section refers to training and re-training, and to financing but these are concerns for all sections so should either be a) mainstreamed into all sections or b) in separate section  
- Here is where we need a different checklist for producing and non-producing countries.  
- We need to be able to encourage NRA to discuss pandemic vaccine with manufacturers and MoH early on in process.  
- Benchmarking of NRA can help identify improvements.
### Table 7. Participants’ suggestions and comments about the Manufacturing section of the checklist.

<table>
<thead>
<tr>
<th>Suggested edits (in blue)</th>
<th>Other suggestions and comments</th>
</tr>
</thead>
</table>
| Business plan based on analysis of production costs, price of product and return on investment | • Business plan needs to include both seasonal vaccine and pandemic preparedness.  
• Business plan needs to ensure self-sustainability.  
• Business plan needs to include sustainability over the long term: alternative procurement, insurance, alternative buyers.  
• Does business plan include private market opportunities?  
• Is there sufficient market data to be fed into the seasonal business plan?                                                                                                                                                        |
| Reliable and **stable uninterrupted** supply of utilities                                   | • ISO certification/ plus BSL 3 capability                                                                                                                                                                                                 |
| A proportion of the revenues is planned to be re-invested in R&D                            | • This indicator should be last on this list because only established companies can fund R&D.  
• Target revenue investment = 20%                                                                                                                                                                                                  |
| Reliable supply chain for all components **from CVV to final packaging**                    | • Streamline, consolidate, ensure cost efficiencies e.g. SPF eggs.                                                                                                                                                                   |
| Technologies selected based on cost-benefit analysis of initial investment, operating costs, time to market and product approval | • Risk manage through macro-environment market assessment.                                                                                                                                                                                                                     |
| More than one **compatible** product manufactured in the vaccine manufacturing facility  | • Other products made at the same facility should be compatible  
• Advise manufacturers that they should have more than one product, facility or other services requirement (e.g. a vaccine facility could also do quality control assays for other products).                                                                                           |
| Access to and retention of skilled workforce                                               | • What incentives are there for trained staff to stay?  
• Does the educational infrastructure have the ability to provide the required skills for manufacturing?                                                                                                                                 |
| Complies with and is certified for Good Manufacturing Practice (GMP) and other governmental regulations for environmental, health and safety. | • GMP and other local/regional legislation.                                                                                                                                                                                                                       |
| In-house skills—to design and administer clinical trials, provide quality oversight, produce, maintain and market-for vaccine product | • CT skills “in place with manufacturer”.                                                                                                                                                                                                                     |
| A **PV** system is in place at the **with manufacturing or and governmental level** to monitor adverse events after product commercialization | • Move this indicator to section 1 of the checklist (healthcare systems and policies) as clinical trial/post-market license with clinical trial is a medical affair.                                                                                                      |
| **Domestic** animal and development facility for the conduction of preclinical studies is available and under GLP | • It is important that this capacity is domestic but it should not be required to be in-house as you can also outsource this… (although you do require a small animal facility for toxicity studies  
• Animal facility or preclinical R&D skills to manage at Contract Research Organisations (manufacturers shouldn’t need to have the animal facility themselves (which is very expensive) but they do need the people and skills to be able to contract preclinical trials out to contract research organisations and manage those relationships). |
Partnerships with public or private entities (such as academic organisations, universities and financing institutes) to acquire know how and technology, conduct clinical trials, conduct post marketing surveillance, distribute the product, etc.

- This requires investment – product revenue and/or multiple sources of funding.

Participation in local and global manufacturers’ networks or associations for advocacy, exchange experience, training etc.

**Additional questions to include:**
- Has a marketing strategy been developed? Does marketing experience exist? And is there a marketing budget?
- Is a product being considered for WHO prequalification programme? (if regulator is considered to be functional)
- Is seasonal influenza vaccination recommended at least for at risk groups?

**Other suggestions and comments:**
- If we want to sell the idea that investment in pandemic preparedness is like buying insurance but we need two business models: 1) insurance vs pandemic; 2) seasonal market.
- Many of the points in this section deal with bringing procurement to a certain level BUT there is also a need for greater focus on improvements after have achieved GMP and WHO PQ.
- We need a global solution–so we need to shift paradigm to a global coordination mechanism (an insurance scheme?)
- Group some of these criteria together because they are related: e.g. indicator 1 (business case) should be followed by indicator 5 (selection of technologies) then GMP.
- Why are certain GMP requirements highlighted?
- Access to CVV and Ref reagents.

### 5.2.6. Procurement

Individual indicators in the checklist were not reviewed in the meeting (see Next steps above for more information).

### 5.2.7. Communication, community engagement and risk communication

Table 8. Participants’ suggestions and comments about the Communication, community engagement and risk communication section of the checklist.

<table>
<thead>
<tr>
<th>Suggested edits (in blue)</th>
<th>Other suggestions and comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>key functions established and strong relationships among stakeholders with a public communication role</td>
<td>Inter-/infra-agency communication</td>
</tr>
<tr>
<td>Well-trained and skilled communication staff</td>
<td>How do you achieve skilled comms staff? You produce risk comms specialists through academic/public health programmes, with a curriculum designed to produce graduates with these skills.</td>
</tr>
<tr>
<td>Operational research and metrics for influenza communication outcomes</td>
<td></td>
</tr>
<tr>
<td>Mechanisms for ongoing listening/feedback to update communication strategies and tactics</td>
<td>Is there ongoing engagement through local organisations, and a sustained approach? Communication is going both ways.</td>
</tr>
<tr>
<td>Integrated communication strategy with other policies (with clear behavioral objectives for priority groups)</td>
<td>Also need to integrate past experience from other events (e.g. Ebola, Zika etc)</td>
</tr>
<tr>
<td>Routine use of sound communication methodologies, tools and scientific expertise</td>
<td>• Is there an understanding of the effects of the communications cultural context (e.g. through the use of Bollywood stars or religious leaders)?</td>
</tr>
<tr>
<td>Regular evaluation of public campaigns and feedback to stakeholders</td>
<td></td>
</tr>
<tr>
<td>There is awareness among the public and the healthcare workers of the benefits of seasonal influenza vaccination</td>
<td>• Active promotion of influenza vaccination.</td>
</tr>
</tbody>
</table>

**Additional questions to include:**
- Is there a consistent messaging across relevant stakeholders, including governments and others?
- Is the messaging going through relevant associations? (i.e. medical associations, NGOs)
- Are communication strategies tailored to specific groups? (taking into account cultural beliefs and practices)
- Do manufacturers communicate effectively to media in case of events?
- Add an indicator on getting front line healthcare workers to deliver the communications message effectively during patient visits.

**Other suggestions and comments:**
- What about: mass media relations; PR departments; scientific reporting; community engagement; social media.
- Are there specific communication mechanisms to mitigate myths about influenza vaccine, like adverse events, or ineffectiveness?
- There is a need to (re)build trust in public health.
- Use trusted individuals like celebrities or the dalai lama.
- Campaigns on vaccine days need to use a mix of traditional means alongside modern communications (brochures + social media?)
- To protect people at mass, what measures need to be taken on reaching out for higher impact?
- Training is important: both targeted training for healthcare workers on vaccines (to improve uptake); and training of trainers, cascade trainers.
5.3. List of participants

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5.4. Further reading

All presentations from the meeting are available at:
http://www.who.int/influenza_vaccines_plan/objectives/Agenda_hyperlinks.pdf?ua=1

For more information on the sustainability checklist, see:

- Creating the environment for sustainable production of influenza vaccines in developing countries. Geneva: World Health Organization. (www.who.int/phd/sustainability_presentation.pdf?ua=1)