The South-East Asia Region

- Bangladesh, Bhutan, DPR Korea, India, Indonesia, India, Maldives, Myanmar, Nepal, Thailand, Timor Leste, Sri Lanka

- Significant differences in size, climate, political & organizational structures, socio-cultural norms

- Changing context, i.e. increasing travel, trade and industrialization (and effects of climate change)
Seasonal Influenza in the SEA Region

- Bangladesh, Bhutan, DPR Korea, India, Indonesia, India, Maldives, Myanmar, Nepal, Thailand, Timor Leste, Sri Lanka

- Good data on burden of disease from some countries (and no reason to believe patterns of disease are likely to be very different in neighboring countries)

- Most countries do not have programmes for Influenza Vaccination

- Capacity for influenza vaccine manufacture being established in some countries
Burden of Influenza in Thailand 2004

- Hospitalized Influenza Pneumonia
  - 10% caused by influenza virus infection
  - Average LOS all ages 6.6 days (range 1 to 26 days)
  - Up to 51,788 influenza pneumonia hospitalizations

- Outpatient Influenza
  - 23% of all ILI is influenza positive
  - Average lost work if adults ill = 4.46 days
  - 84% of influenza cases were children <15 years
  - 924,478 OPD visits nationwide
  - 3,121,562 lost work & 1,701,450 lost school days
Avian Influenza in the SEA Region

![Bar chart showing the number of cases over years from 2003 to 2012 for the SEA Region and Other Regions.](chart.png)
Avian Influenza in the SEA Region

The diagram shows the number of cases of avian influenza in Indonesia, Thailand, Myanmar, and Bangladesh from 2004 to 2012. The highest number of cases was in Indonesia in 2006, followed by Thailand in 2008. Myanmar and Bangladesh had much lower numbers of cases during the same period.
April 2009: reports of sustained human to human transmission with a new influenza A (H1N1) virus in Mexico and USA

Virus had spread in all regions in less than 9 weeks

SEA Region Countries affected relatively late...

All countries already had pandemic plans

Formal reviews of pandemic response undertaken in several countries

Many now being revised
• In line with the provisions of the IHR, a committee was established to provide an objective overview of the response to the influenza pandemic
• The report was finalised in March 2011
• Several recommendations focus on WHO and some relate primarily to WHO Headquarters
Recommendation 1

- Accelerate implementation of core capacities required by the IHR
  - Most countries not ‘on track’ to achieve full implementation by June 2012 (all SEA Region countries have said they will apply for an extension)
  - Identify and focus support to most needy countries
  - Secure funding partners
  - Raise IHR National Focal Point (IHR) and political level awareness
Recommendation 2

- Enhance the WHO Event Information Site
  - User survey completed
  - Plan for both IT and content review

  In the Asia Pacific Region

  Advocacy with National IHR Focal Points

  Development of guidelines and training materials for a structured approach to ‘all hazards’ risk assessment
Recommendation 3:

- **Reinforce evidence-based decisions on traffic and trade**
  -- Meeting to review the public health measures implemented during the pandemic
  -- Technical consultation on IHR Implementation and public health measures in response to public health emergency at ports, airports and ground crossings, December, 2009
  -- Review of public health measures taken at international borders during early stages of pandemic influenza A (H1N1) 2009: preliminary results

Recommendation 4

- **Ensure necessary authority and resources for all NFPs**
  -- Recommendation is addressed to States Parties
  -- WHO HQ is reviewing and updating IHR training materials
Recommendation 5

- Strengthen WHO’s internal capacity for sustained response
  -- Global WHO team (common processes, tools, people)

Recommendation 6

- Improve practices for appointment of an Emergency Committee
  -- Review and expansion of Expert Roster
  -- Experts to complete new Form D that includes potential interest information
  -- Pre screening of experts on basis of Form D
Review Committee Recommendations and WHO Actions

**Recommendation 7**
- **Revise pandemic preparedness guidance**
  -- Consultations with WHO Regional Offices have taken place
  -- Systematic review of pandemic measures including cost-effectiveness completed

**Recommendation 8**
- **Develop and apply measures to assess severity of illness**
  -- Internal consultations undertaken and a proposal for severity assessment is under development

**Recommendation 9**
- **Streamline management of guidance documents**
  -- WHO HQ ‘information products’ working group has been established
Recommendation 10

• Develop / implement a strategic, organization-wide communications policy

  -- Organization-wide communication policy being developed.

Recommendation 11

• Encourage advance agreements for vaccine distribution and delivery

  -- Global Action Plan for Influenza Vaccines Objectives 1 & 2
Recommendation 12

• Establish a more extensive global, public-health reserve workforce

-- Reviewed in a series of GOARN Steering Group Meetings

-- In the Asia Pacific Region

  Strengthening Field Epidemiology Training

  Building Capacity for Regional Outbreak Response (SEARO held an informal consultation of outbreak response partners early this year)

  Training on international outbreak response
Review Committee Recommendations and WHO Actions

**Recommendation 13**

- **Create a contingency fund for public-health emergencies**
  -- Already exists in SEARO – Follow up at global level.

**Recommendation 14**

- **Reach agreement on sharing of viruses and access to vaccines and other benefits**
  -- PIP framework completed and now implementation of the workplan

**Recommendation 15**

- **Pursue a comprehensive influenza research and evaluation programme**
  -- Public health research agenda for Influenza
  -- Global Action Plan for Influenza Vaccines
Implementing the Pandemic Influenza Preparedness Framework: Regional Perspective

- A Regional Consultation on implementation of the PIP Framework was held 5-6 March, 2012
- Consensus reached on the following:
  - Advocacy should be undertaken for laboratories that are part of GISRS, in consultation with policy / decision makers to adopt the ToRs defined by the Framework.
  - Concerned laboratories should continue to share influenza viruses in a timely manner, including those with pandemic potential
Implementation of the PIP Framework: Regional Perspective

– Review the process for prioritisation of benefits through the Partnership Contribution to allow input from Member States

– The process for negotiation of SMTA type 2 should be accelerated

– Consideration should also be given to developing a mechanism to allow Member States to provide input into the process of negotiation of SMTA type 2 arrangements for non financial contributions, e.g. ‘in kind’ benefits / technology transfer
Current Challenges in the SEA Region

- Standardizing and expanding the scope of influenza surveillance to make data more valid and representative
- Better information on disease burden (to inform discussion about national policies on vaccination)
- Integration of influenza surveillance with programmes for (other) vaccine preventable diseases?
Initiatives in the SEA Region

- Establishment of NICs in the remaining three countries (Bhutan has formally declared its intention to start the process)
- Providing support to the establishment of a WHO Collaborating Centre in Indonesia for influenza at the animal-human interface
- Workshop on influenza data management in Bangkok 14-18 August, organized in collaboration with new WHO CC for epidemiology in Prince Songkla University and supported by US CDC
- Joint WHO / OIE / FAO / Ministry of Health / Ministry of Agriculture initiatives for Avian Influenza in Bangladesh and Indonesia
Initiatives in the SEA Region

• Please let us know what else we can do to support your work..!
• Thank you...
The PIP Framework: Background

• Since 1957, influenza viruses have been shared by Member States through the WHO global influenza surveillance network (GISRS).

• In 2007 important issues were raised about how such virus sharing might be linked to access to vaccines and other benefits.

• To resolve these issues, resolution WHA 60.28 recommended the Director General (DG) to:
  – develop a framework and mechanism for benefit sharing
  – establish an international stockpile of influenza A (H5N1) vaccine

prepare guidance on vaccine distribution
In response, an ‘Open-Ended Working Group on Pandemic Influenza Preparedness (OEWG) was convened to facilitate agreement between concerned parties.

The resulting document, the “Pandemic Influenza Preparedness Framework (PIP Framework)” was adopted through WHA Resolution 64.5.

According to PIP Framework, countries are requested to provide PIP Biological Materials from all influenza viruses with human pandemic potential to a WHO Reference Laboratory of their choice in a timely manner.
• In return, genetic sequence data and related analyses must be shared in a timely manner with the laboratory in the country of origin, and with WHO GISRS laboratories.

• It is expected that this PIP Benefit Sharing System will:
  - Provide information and build capacity for pandemic surveillance, risk assessment and early warning purposes.
  - Ensure prioritization of benefits, including antiviral medicines and vaccines to developing (especially...
The framework urges countries to share all influenza viruses with potential to cause pandemic

– So viruses can be used to help inform risk assessment

– So viruses can be used to develop vaccines

– So the world is as prepared as possible for next pandemic
Framework calls for Tools, revised Terms of Reference and new SMTAs

- **Influenza Virus Traceability Mechanism**
  - Internet based tool to *track* movements of PIP Biological Materials
  - In operation since 2008

- **The Framework also defines revised Terms of Reference for all GISRS labs**

- **SMTA1 & SMTA 2**
  - *Establish terms & conditions for GISRS labs receiving PIPBM (SMTA type 1) and for ‘third parties’ receiving viruses (SMTA type 2)*
Standard Material Transfer Agreement 1 ("SMTA1")

- Should be incorporated into all GISRS lab Terms of Reference & applied 'as is' (as detailed in the PIP Framework document)

- Establishes rights & obligations of GISRS labs when transferring PIP biological materials within GISRS & to parties outside GISRS

- Also address
  - Use of Influenza Virus Traceability Mechanism
  - Participation of originating labs in research
  - Acknowledgments in publications
  - Intellectual Property Rights
  - Dispute resolution
Standard Material Transfer Agreement 2 ("SMTA2")

- Applies to all recipients outside of GISRS requesting PIP Biological Materials

- Requires agreement between WHO (as secretariat) & the recipient

  "Recipients"

  - Include influenza vaccine, diagnostic & pharmaceutical manufacturers as well as biotech firms, research & academic institutions (defined in Article 1 Footnote 1)

  - Must assess benefits they can contribute based on their nature & capacity

  - Must sign an agreement with WHO to receive PIP Biological Materials
The obligations of 3rd parties who receive PIP Biological Material fall into one of 3 categories:

- **Category A:** For manufacturers of influenza vaccine & antiviral medicines
- **Category B:** For manufacturers of other products relevant to pandemic influenza preparedness & response ... (including diagnostic kits)
- **Category C:** For all others (such as researchers, academia) who shall consider contributing, in addition to other commitments, additional benefits ....

Need to be negotiated on a ‘one by one’ basis with every recipient.
Where do influenza viruses currently go..?

Number of PIPBM shipments by virus subtype
24 May 2011 – Feb 2012 (Source IVTM)
Categories of Recipients
(Recipients counted once regardless of number of shipments)
(Source: IVTM 24 May 2011 – Feb 2012)

Categories of recipients
- Categories of Non-GISRS recipients (per SMTA2 – see Framework Annex 2)
  - Vax AV: Influenza vaccine and antiviral medicines manufacturers (Art 4.1.1A)
  - Diagnostics: Manufacturers of other products relevant to pandemic influenza preparedness and response (Art 4.1.1B)
  - Academic & others: Incl. biotech firms, research & academic institutions (Art 4.1.1C)
Benefits from SMTA type 2: the Partnership Contribution

- An annual payment to WHO by influenza vaccine, diagnostic and pharmaceutical manufacturers using GISRS

- Annual contribution ~ US $28 million (50% of GISRS running costs - estimated at 56.5 million in 2010)

- First contribution to be received in 2012 (but may be late in 2012)
How will the Partnership Contribution be shared between countries?

• There are a number of indicators that can be used
  – World Bank gross national income (WB GNI)
  – Human Development Index
  – GAVI Alliance
  – United Nations Least Developed Countries (LDC)

• Other potentially relevant indicators
  – H5N1 Affected Countries: Countries that have had outbreaks of A/H5N1 - can be further refined to show countries with animal infections, human infections or both
  – Low and Middle income countries with pandemic influenza vaccine production capacity
  – Countries with populations less than 1 Million
How will the Partnership Contribution be used (what technical areas of work will benefit)?

- **It is proposed** to direct:
  - 70% (approx US $20M per year) to pandemic preparedness activities
  - 30% (approx US $8M per year) to pandemic response activities
- **Responds** to IHR Review Committee key finding: "...world is ill-prepared to respond to a severe influenza pandemic..."
Proportional Distribution of the Partnership Contribution

- It is proposed to fix this ‘overall’ proportional split for an initial period of 5 years because
  - Preparedness activities entail long-term capacity building and training
  - Fixed flow of resources over defined period of time would facilitate achievement of concrete results

- The proportional split will be reviewed after 5 years
Partnership Contribution for Pandemic Preparedness

• The proposal is to split this contribution into the following technical areas

  • 70% for surveillance and laboratory capacity building
  • 10% for disease burden studies
  • 10% for risk communications
  • 10% for activities to enhance capacity for future access and effective deployment of pandemic vaccines and antiviral medicines.
Partnership Contribution for Pandemic Response

- It is proposed to reserve approx US $8 million per year to for ‘response’ activities and procurement at the time of a pandemic.

- This response ‘reserve’ is likely to increase over time.
  - As global preparedness capacity increases, we can expect a decrease in need to build capacity.
  - May also receive donations and in-kind contributions from Member States and other stakeholders.
Implementation of the PIP Framework: Regional Perspective

• A Regional Consultation on implementation of the PIP Framework was held 5-6 March, 2012

• Consensus reached on the following:
  – Advocacy should be undertaken for laboratories that are part of GISRS, in consultation with policy / decision makers to adopt the ToRs defined by the Framework, including, if required, additions to SMTA type 1 to ensure alignment with existing arrangements
  – Concerned laboratories should continue to share influenza viruses in a timely manner, including those with pandemic potential
Regional Perspective (continued)

– In order to reflect national / regional priorities, consideration should be given to reviewing the process for prioritisation of benefits for different technical areas through the Partnership Contribution to allow input from MS: for example inclusion of additional technical areas such as healthcare facility preparedness, influenza research.

– The process for negotiation of SMTA type 2 should be accelerated.

– Consideration should also be given to developing a mechanism to allow MS to provide input into the process of negotiation of SMTA type 2 arrangements for ‘non financial’ contributions, e.g. ‘in kind’ benefits / technology transfer.