CONSISE

CONSORTIUM FOR THE STANDARDIZATION OF INFLUENZA SEROEPIDEMIOLOGY

# CONSISE Epidemiology Working Group:

## *Summary discussions and future plans*

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CONSISE International Meeting

Cape Town, South Africa, 3-4 September 2013

# Aims of CONSISE's Epi Working Group

- **Overall aims**
  - Working together with laboratory working group: Recommend best practices and standardize influenza seroepidemiology studies for pandemic, epidemic, zoonotic influenzas and emerging respiratory viruses

  - Provide support to countries who wish to carry out seroepidemiology studies for, primarily flu, but also other emerging respiratory pathogens
    - Tools: protocol templates & questionnaires
    - Recommendations on which study to conduct when
    - Guidance on adaptation of tools to meet specific objectives and contexts
    - Guidance and support of implementation of study
    - Coordination of lab support if capacity does not exist in country
    - Analysis and writing up of findings

Epidemiology Working Group Session:

# PROTOCOL DEVELOPMENT

# Protocols fully drafted and reviewed

- **Influenza Protocol Working Drafts**
  - Prospective Longitudinal Cohort for Pandemic Influenza
    - Lead: Steven Riley
  - Household Transmission Study
    - Leads: Ben Cowling/Richard Pebody
  - Close Contact Serologic Investigation for Zoonotic influenza
    - Leads: Maria Van Kerkhove/Marianne van der Sande

- **Ready to be shared**
  - Assessment of Health Care Workers
    - Leads: Tony Mounts/Maria Van Kerkhove

# Protocols still under development

- **Influenza Protocol Working Drafts**

  - Serial Cross-sectional Seroepidemiological Investigation
    - Leads: Tony Mounts/Maria Van Kerkhove/Heath Kelly
  - Closed Setting Transmission study
    - Leads: Peter White/Vernon Lee
  - Routine/Residual Sera
    - Leads: Angus Nicoll/Olav Hungnes/Richard Pebody/Katja Hoschler

# Discussion Points

- **Sharing and open access**
  - CONSISE has adopted the Creative Common License

**LICENSE**

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  - Will add acknowledgement statement
- **Revision – how do we reach consensus?**
  - AGREEMENT: We don't. We revise and post. If required, post modifications from feedback later
- **What is the best way to provide these templates?**
  - Online as protocol templates

- **Validation needed: Strobe-like checklist**

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# QUESTION BANK

# Headings

- Demographics
- Health and vaccination history
- Exposures (animal, food, environment)
- Travel history and exposure
- Illness, diagnosis and management
- Access to care
- Health seeking behavior
- Care givers
- Health care workers

# Question Bank

- **Stage 1 Focus: Data Collection**
  - Finalize the list of questions under headings
    - Instructions, General Questions, Specific Questions
    - Include recommendations on translation/back translation
  - Recommendations on which studies to include for which protocols

| Protocol | | | | | | | Question |
|---|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | |
| | | | | | | | ***Background Demographics*** |
| x | x | x | x | x | x | x | Q1 |
| | | x | | | x | | Q2 |
| x | x | | | x | | | Q3 |
| | | | | | | | …. |
| | | | | | | | *Animal Exposures* |

- **Stage 2 Focus: Data Management**

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# FIELD VALIDATION – EXPERIENCE FROM THE FIELD

# Experience from the Field

- **South Africa:  NICD**
  - Modification of the household transmission study
  - Interaction with protocols lead (Ben Cowling) when developing their own study
- **Opportunities for further field validation**
  - MERS-CoV Protocols:  Bangladesh, Egypt
    - Protocols will be shared with CONSISE members and we will explore how to support implementation
  - Flu Protocols
    - Household Transmission Study –Hong Kong (on going); Kenya (possible to implement)
    - Longitudinal Study: Mongolia (planned), Hong Kong (several on going)

- **ADD FEEDBACK FROM LAB GROUP**

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# FIELD VALIDATION – ADAPTATION OF GENERIC PROTOCOLS FOR FLU/MERS-COV

# Lessons learned

- Impossible to anticipant all of the questions in advance
- Preliminary questions change over time
- Not every critical question can be answered by serologic assays, but templates were helpful to have as tool to modify
- CONSISE network is a useful resource to call upon for advice

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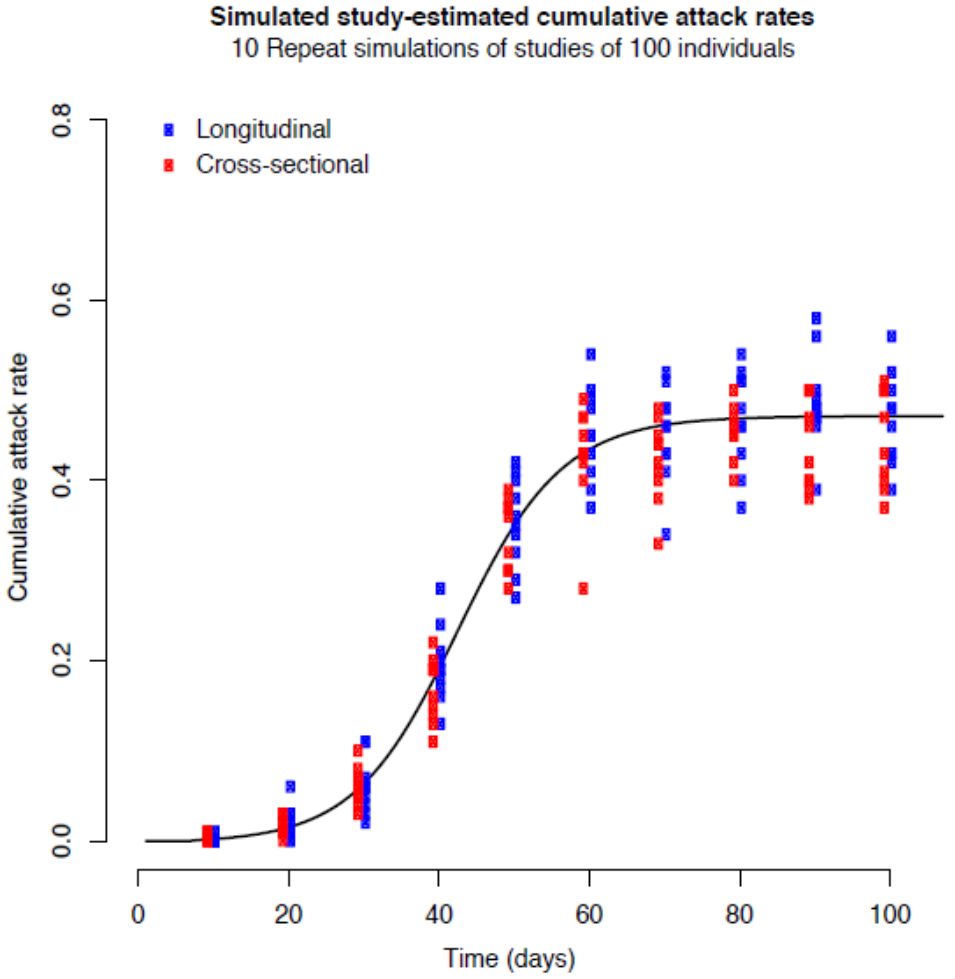
# SIMULATION STUDIES

# Simulation Studies

- Simulation permits accurate power calculations for seroepidemiology studies
- Incorporates baseline titre distributions and boosting on infection
- No real difference between cross-sectional and longitudinal for 2009 pandemic
- Likely substantial differences for seasonal strains, but subject of ongoing work



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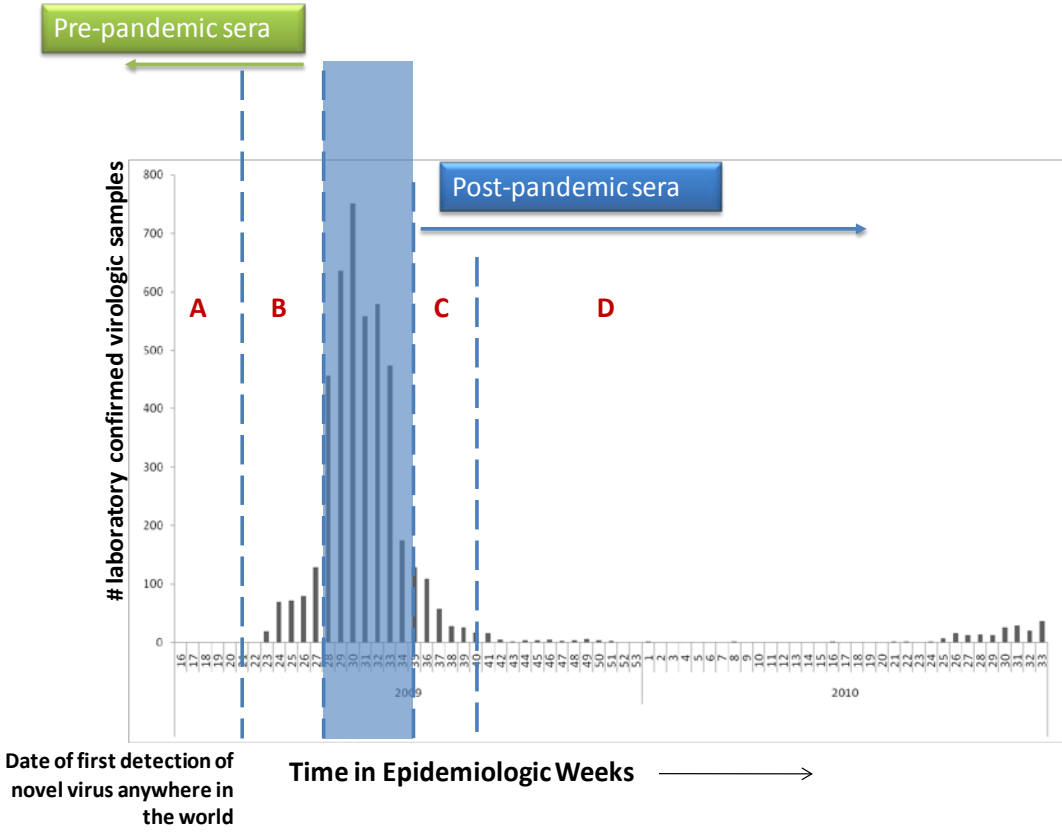
# TIMELINE OF PROTOCOL RECOMMENDATIONS DURING AN OUTBREAK

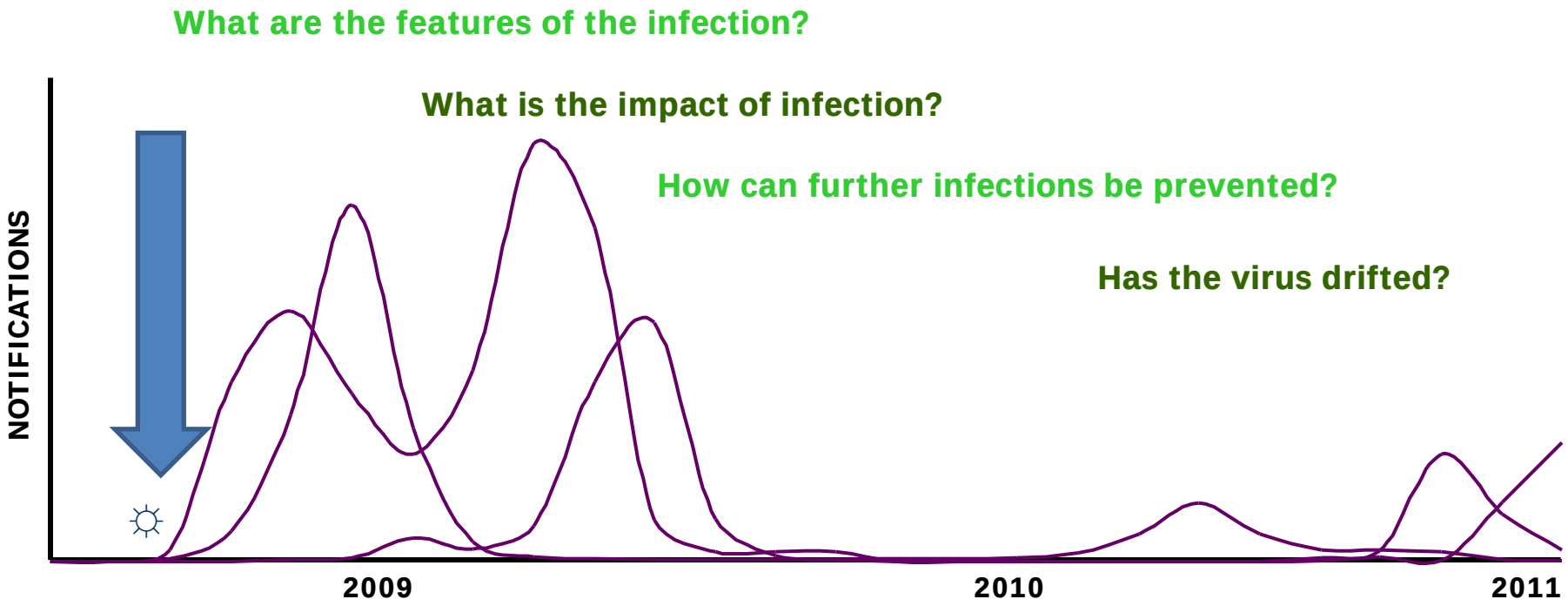
# Background

- **Each Protocol has specific objectives and an ideal timing to be implemented with respect to an epidemic**
  - Will be virus specific
  - Will be context specific
  - Feasibility
- **Recommendations needed**
  - Timing vs public health question or both
- **Links with ISARIC**

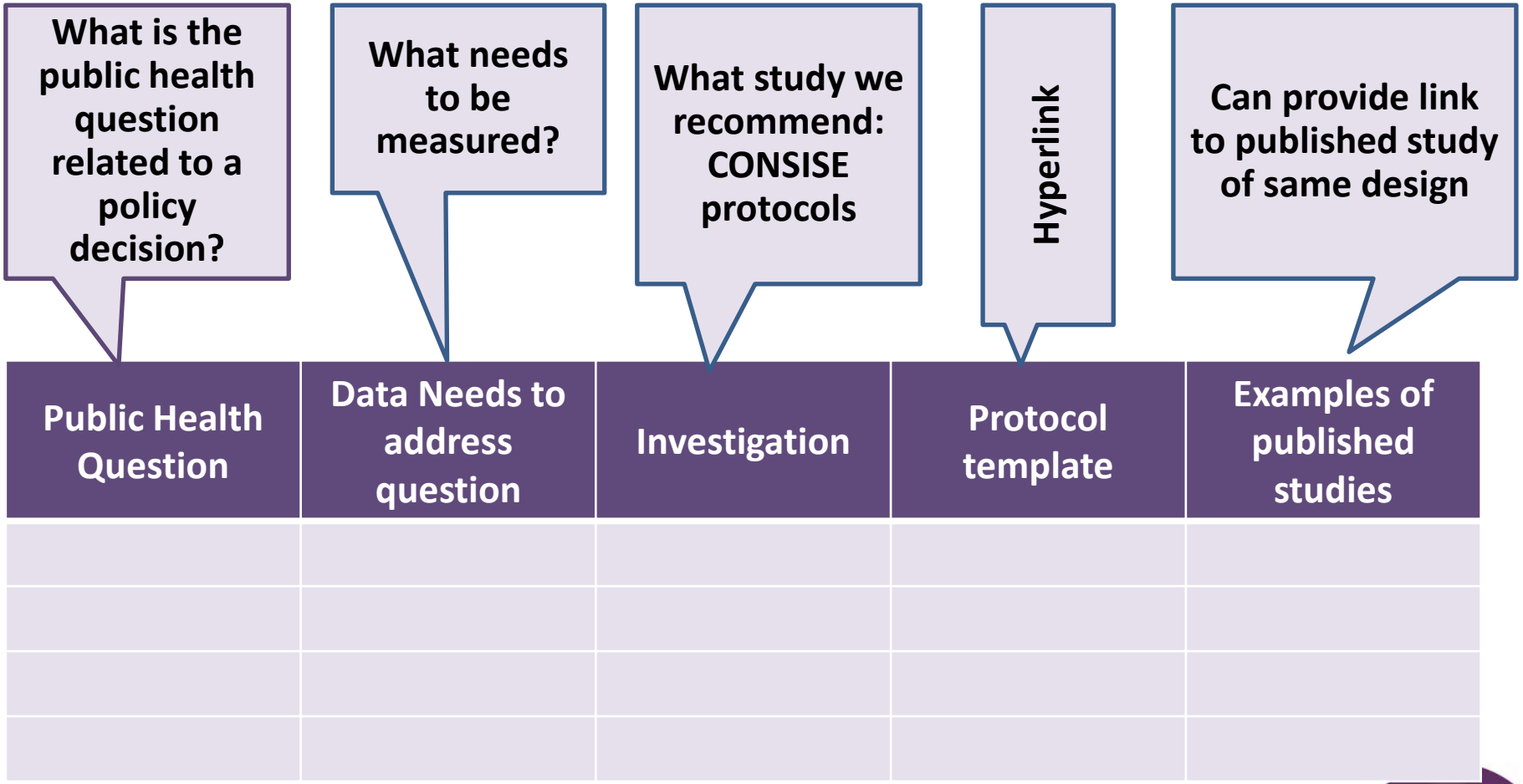


# Timing is critical

- During  a pandemic/severe epidemic, the availability of data will not match the information needs of policy makers, meaning key decisions will be made using limited data



# How do we illustrate our recommendations?




But does not address recommendation on WHEN study should be conducted

| Research Question | Study Design | | | | |
|---|---|---|---|---|---|
| | Longitudinal Study | Serial cross-sectional study | Transmission studies: Households | Transmission studies: Schools | Transmission studies: Others* |
| **What is the age-specific prevalence of cross-reactive antibodies?** | x (pre-pandemic sera) | x (pre-pandemic sera) | somewhat | no | |
| **What is the age-specific cumulative incidence?** | x (ideal - est from paired sera) | x (good, est by taking difference in pre and post sero+) | yes (but in limited numbers) | somewhat | |
| **What is the age-specific infection severity (e.g., IFR, infection: hospitalization)** | x (if can match population with severe cases) | x (more difficult) | x (quick, not necessarily adequate sample size, but informative) | x (potentially useful but limited to school age children) | |
| **What proportion of cases are asymptomatic?** | very difficult | very difficult | x (ideal study methodology) | x (potentially useful but limited to school age children) | |

*will depend on epidemiology of new virus and country settings

This table was based on a 2009-like virus; but could and should be developed for a more severe scenario

# Solution?

- **Decision to focus on table format, that timing wasn't that critical for all protocols**
  - Is for population based protocols

- **Two Tables will be drafted**
  - Recommendations on study designs to address research questions
  - Feasibility of each study design

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|---|---|---|---|---|---|
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# ETHICAL PRE-APPROVAL

# Discussion and Decisions

- **Support users to obtain pre-ethical approval?**
  - **Yes**

- **WHO ethical approval for templates?**
  - **Yes**

**Thank you!**