Aim

To develop a core outcome set that should reasonably be reported in pandemic research studies examining natural history, policy measures, and interventions be they preventative or therapeutic.

Background

ISARIC

The International Severe Acute Respiratory and Emerging Infection Consortium (ISARIC) is a global initiative of over 70 networks and individuals whose aim is that researchers have the open-access protocols and data-sharing processes needed to facilitate a rapid clinical response to emerging diseases with epidemic and pandemic potential.

ISARIC’s desire for Common Outcome Measures

- Allow aggregation of data from independent studies
- Allow comparison of disparate interventions in different settings
- Consensus process means community ownership

Method

The ISARIC group (~100 policy makers, clinicians and scientists) is conducting a three-round Delphi consensus process to identify a core outcome set. A long list of candidate outcomes has been identified in round 1 by email requesting six outcomes of interest to investigators. Outcomes were be categorised by domains by two moderators (KC & CS). The core outcome set will be selected over subsequent rounds. In contrast, reflecting the small numbers of investigators in FLU2, two moderators (KC & CS) will run an informal consensus process.

Emergence of two novel health threats

H7N9 – 132 deaths 37 deaths = “situation evolving”

MERS-CoV – 61 cases 34 deaths = “situation evolving”

Interim Results

32 participants from 44 networks (73%), n=221 responses, i.e. 7 per participant

<table>
<thead>
<tr>
<th>6 Domains appear</th>
<th>Mortality</th>
<th>Acute Disease</th>
<th>Long term Sequelae</th>
<th>Resource Use</th>
<th>Functional Status</th>
<th>Adverse Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>27</td>
<td>47</td>
<td>25</td>
<td>98</td>
<td>5</td>
<td>21</td>
</tr>
</tbody>
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Mortality explored

- All responses i.e. put by least once by most
- Unspecified
- Landmark (status @ time X)
- Combined (death or Critical Care)
- Epoch Survival (days alive during time Y)

Resource type

- All responses
- Hospital
- Critical Care
- Ventilation
- Oxygen
- ECMO
- Cost

Resource explored

- Oxygen duration
- Admission to Hospital
- Admission to Critical Care
- Duration of ventilation
- Duration of mechanical ventilation
- Duration of oxygen
- Duration of ECMO

Conclusions

ISARIC Delphi first round poll: Common Outcome Measures are identifiable for studies on emerging infections with pandemic potential.

For ISARIC some outcomes will be rejected as not suitable for use in various settings

Death is important and not a good outcome, neither is it a good outcome measure.

We should probably focus less on death and think more about the resources used in sustaining life.

Funding

CS has received support from ISARIC and APHLS CDC to attend meetings in Europe and USA to facilitate the development of the ISARIC core outcomes.