Prophylaxis at Outpatient Sites

Presentation to the Committee on Implementation of Antiviral Medication Strategies for an Influenza Pandemic

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Working Assumptions and Philosophy

The perceived best policy may change as the pandemic progresses and will depend on a number of variables.

- Attack rate, death rate
- Demographics of those most affected
- Natural history of individual infections and community outbreaks
- Availability and effectiveness of medication and vaccine

Working Assumptions and Philosophy

- An all hazards infrastructure is better than trying to anticipate every specific possibility or disease.
  - Build on seasonal influenza and all hazard preparedness infrastructures.
  - Use existing infrastructure of pharmacies, medical homes and safety net providers as much as possible.

Working Assumptions and Philosophy

- Federal, state and local health departments, physicians and other health care providers should all have a clearly defined role, spelled out in advance.

- Physicians will need guidance
  - Simple, concise, easy to use, authoritative
  - Should be consistent at all levels
    - Federal, state, local
    - Professional organizations
  - Needs to be timely as the pandemic progresses and changes

The Role of Physicians and Other Health Care Professional in a Pandemic

- Accurate diagnosis
  - Laboratory confirmation and use for surveillance
- Correct treatment
- Office infection control
- Community infection control
  - Isolation of cases, advice to contacts, PEP to contacts, reporting to LHD

- **<u>All require public health guidance.</u>**

- **<u>The approach to some will differ depending on the pandemic stage.</u>**

Early Pandemic-- Approach to Suspected Cases

- Implement infection control precautions
  - Hospital or home
- Contact the local public health department.
- Collect clinical specimens for confirmation
  - nasopharyngeal swab, nasal swab, throat swab and an acute serum specimen, using PPE and precautions
- Start antiviral treatment
  - As recommended by LHD
- Evaluate alternative diagnoses
- Assist in locating potentially exposed contacts, providing infection control advice and providing antiviral prophylaxis if recommended

Later in the Pandemic

- Preserve hospital resources for sickest
- Clinical specimens will probably be needed only on a subset of patients
  - To monitor the epidemiology
  - Unusual presentations
  - Failures of preventive therapy
- Report atypical cases, prophylaxis failures, and other abnormal cases
- Treatment and PEP as recommended by LHD

Antiviral Prophylaxis in the Outpatient Setting

- Outpatient staff
- Household and other close contacts of diagnosed cases

Outpatient Staff

- The case for prophylaxis:
  - Staff safety, patient safety, assure attendance at work
  - Decreased liability
  - Decreased community spread
- Once immunized, vaccine and infection control practices will suffice.

Staff Prophylaxis

- Issues to resolve
  - When to start? When to stop?
  - Who will prescribe?
  - Where will the medications be obtained?
    - To stockpile and dispense on site or not?
  - Who pays?
  - What if staff refuse?
  - Pre-Rx evaluation, medical records, communication with medical home

Cost of Stockpiling

- At non government rate it will cost $80 per 10-day regimen.
- Assume a staff of 6, pandemic lasting 12 weeks, no vaccine available.
- This is a $5000 expense and security issue
- No reason to do this if the pharmacy will have a supply

Compliance

- Always an issue for prolonged therapy
- Look at TLTBI compliance rates
- As with TB, Directly Observed Therapy (DOT) could be used

Other Measures to Protect Staff

- Office infection control, with strict adherence
- Immunization for other risks, including seasonal influenza
- Personal protective equipment
- Education regarding the need for multiple interventions
- Guidance

- All these issues can be resolved if thought out in advance.
- Each clinical site should have a plan in place to address the details.
- Guidance will be very helpful.

Case Contact Post Exposure Prophylaxis

- This is an important public health intervention.
- How will it be accomplished? At least 4 options:
  - At medical home of case patient
  - At medical home of the contact
  - At the local health department
  - OTC or BTC
- These are not mutually exclusive

Case Contact Post Exposure Prophylaxis

- Assumption is that an adequate medication supply is available.
- If not, guidance will be needed on how to prioritize it.
- There will be patient pressure to ignore prioritization.
- Pharmacies would be more secure and controlled environments for storing and dispensing

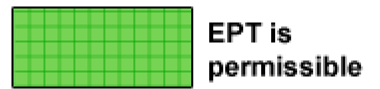
Case Contact Post Exposure Prophylaxis

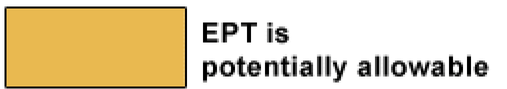
- Issues to consider
  - Legal*
  - Timeliness and practicality
  - Safety*
  - Liability
  - Experience with contact treatment*
  - Access/equity*
  - Cost*

Case Contact Post Exposure Prophylaxis

- Legal
  - Legality of prescribing without examining or establishing a relationship needs to be considered
  - 11 states allow, 13 prohibit, the rest are uncertain
  - This can be changed but should be considered in advance, and states need to do it

LEGEND :


EPT is permissible


EPT is potentially allowable

EPT is prohibited

Case Contact Post Exposure Prophylaxis

- Safety
  - Adverse effects of oseltamivir
  - Adverse effects of PEP
    - Contacts need to take other precautions and avoid a false sense of security
    - PEP should be part of comprehensive contact prevention strategy

Case Contact Post Exposure Prophylaxis

- Safety of oseltamivir
  - Contraindications
    - Allergy
  - Precautions
    - Pregnancy – category C
    - Breast feeding
    - Renal insufficiency – decrease dose
    - Possibly interferes with LAIV vaccine for seasonal influenza

Safety

- Oseltamivir
  - Adverse reactions
    - Nausea and vomiting 7%
    - Abdominal pain 2%
    - Serious ones are rare
      - SJS and other skin reactions rare
      - Delirium and self destructive behavior rare, all children to date
    - No significant drug interactions documented

Case Contact Post Exposure Prophylaxis

- Overall, influenza PEP conducive to expedited contact prophylaxis with
  - Easy to use pre PEP evaluation check sheets and patient handouts, electronic prescribing, pre filled out prescriptions, and;
  - If pharmacies have adequate supply
  - Guidance would be helpful

Experience With Expedited Partner Therapy

- Mostly STD's
  - Chlamydia, Gonorrhea, Trichomonas
  - Improved outcomes have been demonstrated
  - No proven harmful effects
  - Physicians are not accustomed to doing it

Infection control

- We should encourage social distancing and avoidance of places where sick are likely to be (medical facilities).
- Encouraging well contacts to visit medical facilities to obtain prophylaxis may not be a good idea.
- PEP prophylaxis at contact medical home could be completed by phone protocol, email, etc without requiring a visit.

- The uninsured and under insured need to be considered.
- It is in society's interest to provide access to medical care and preventive medicines.
- A safety net system is needed for diagnosis and treatment and for obtaining medications.

- Who will pay for the cost of preventive medicines?
- Cost should not be a barrier and initiatives to address cost should not be an administrative hassle.
- This should probably be worked out with commercial payers in advance.
- A safety net is needed.

	Case MH	Contact MH	LHD	OTC/BHC
Legal	+/-	+	+	+/-
Timeliness	+	_	+/-	+
Safety	+	++	+	?
Liability	+	++	+	?
Experience	+		++	
Community Infection control	++	+/-	+	?
Access/equity	+/-	-/-	++	+/-

Case Contact Post Exposure Prophylaxis

- Conclusions
  - Options are not mutually exclusive and some combination may be best
  - The best option depends on what values have highest priority
  - Early in the pandemic LHD or LHD collaboration with case MH may be the preferred
  - In full blown pandemic go to all options including possibly OTC/BTC or some version
  - Harms/benefits of any option are unproven at community level

References and Resources

- CDC. Expedited Partner Therapy. http://www.cdc.gov/std/ept/
- CDC. Legal Status of Expedited Therapy. http://www.cdc.gov/std/ept/legal/default.htm
- CDC. Expedited partner therapy in the treatment of STD's. Review and Guidance. http://www.cdc.gov/std/treatment/EPTFinalReport2006.pdf