ALTERED STANDARDS OF CARE DURING AN INFLUENZA PANDEMIC

IDENTIFYING THE ETHICAL, LEGAL AND PRACTICAL PRINCIPLES TO GUIDE DECISION-MAKING

DONNA E. LEVIN
GENERAL COUNSEL
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

COLLABORATION

- HOWARD K. KOH,MD,MPH HSPH
- REBECCA ORFALY CADIGAN,MS HSPH
- PAUL D. BIDDINGER, MD, FACEP MGH, HSPH
- SUZANNE K. CONDON, ASSOCIATE COMMISSIONER, MDPH
- MDPH/HSPH MEMBERS OF JOINT MDPH/HSPH ADVISORY GROUP
- OTHER PARTICIPANTS AT DPH, HSPH

HSPH/MDPH JOINT ADVISORY GROUP

- Bruce Auerbach, MD
- Dan Brock, PhD
- Jonathan Burstein, MD
- Harold Cox, MSSW
- Norman Daniels, PhD
- Alfred DeMaria, MD
- Priscilla Fox, JD
- Matthew Gordon, MPH
- Benjamin Moulton, JD, MPH
- Gilbert Nick
- Nancy Ridley, MS
- Eric Schneider, MD, MSc
- Lisa Stone, MD, MPH
- Vish Viswanath, PhD
- Daniel Wikler, PhD

OVERVIEW

I. WHY DEVELOP ALTERED STANDARDS OF CARE?

II. PROCESS:

WORKING GROUP
SCENARIOS

III. DRAFT GUIDELINES:

GOALS
PRINCIPLES
PROCESS

IV. NEXT STEPS

I. WHY?

INFLUENZA PANDEMIC

- POSSIBLY 30% POPULATION ILL
- DEMAND FOR RESOURCES WILL EXCEED SUPPLY: MEDICAL STAFF, HOSPITAL BEDS, ANTIVIRALS, VENTILATORS
- DELIVERY OF CARE WILL NOT MEET CUSTOMARY, USUAL COMMUNITY STANDARD OF CARE HEALTH CARE PROVIDERS ROUTINELY PROVIDE

QUESTIONS

- WHAT STANDARDS WILL HEALTH CARE PROVIDERS BE HELD TO DURING AN INFLUENZA PANDEMIC?
- HOW DO HEALTH CARE PROVIDERS MAKE HARD DECISIONS CONCERNING ALLOCATION OF CARE AND RESOURCES?
- CAN THESE RESOURCES BE ALLOCATED IN AN EQUITABLE MANNER?
- CAN THERE BE PRINCIPLES/GUIDANCE PREPARED IN ADVANCE TO ADDRESS THESE QUESTIONS?

ALTERED STANDARDS OF CARE (ASC)

SET OF PRINCIPLES/CONSIDERATIONS WHICH SERVE AS A GUIDELINE FOR THE PROVISION OF CARE AND ALLOCATION OF SCARCE EQUIPMENT, SUPPLIES AND PERSONNEL

Sources:

Mehta S. Disaster and mass casualty management in a hospital: How well are we prepared?. J Postgrad Med 2006; 52: 89-90

Altered Standards of Care in Mass Casualty Events AHRQ Publication No. 05-0043

II. PROCESS: MASSACHUSETTS EXPERIENCE

- JOINT ADVISORY GROUP - PURPOSE
- REVIEW OF RELEVANT LITERATURE
- REVIEW OF APPLICABLE STATE AUTHORITY IN PUBLIC HEALTH EMERGENCY SITUATIONS
- BASIC AGREEMENT ON NEED FOR:
  - ADVANCED GUIDELINES ON ASC
  - CONSULTATION WITH STAKEHOLDERS AND PUBLIC
  - TRANSPARENCY AND TRUST

SCENARIOS

- 5 SCENARIOS TO ILLUSTRATE ISSUES RAISED BY POTENTIAL ASC GUIDELINES:
  - ALLOCATION OF SCARCE RESOURCES
  - PRIORITIZATION OF CRITICAL CARE
  - GOVERNMENT SEIZURE OF PRIVATE ASSETS
  - PROVIDER SAFETY VS. DUTY TO CARE
  - PRIORITIZATION OF CRITICAL CARE: PROVIDER PERSPECTIVE

STAKEHOLDER GROUP MEETINGS

- FACILITATED DISCUSSION OF SCENARIOS
- TWO GROUPS OF 12-15 PARTICIPANTS
- #1: PRIMARILY CONSUMERS WITH HEALTH CARE PROVIDERS TO PROVIDE SUBJECT MATTER EXPERTISE
- #2: PRIMARILY HEALTH CARE PROVIDERS WITH TWO REPRESENTATIVES OF CONSUMER PERSPECTIVES

SCENARIO #1: ALLOCATION OF SCARCE RESOURCES

ACCESS TO OSELTAMIVIR ("TAMIFLU")

4 DIFFERENT PROTOCOLS TO USE ANTIVIRALS

- HOSPITAL A: EXPOSED HEALTH CARE STAFF
- HOSPITAL B: MOST ACUTELY ILL
- HOSPITAL C: MOST LIKELY TO BENEFIT (WITHIN 48 HRS OF SYMPTOMS)
- HOSPITAL D: EXPOSED STAFF AND ALL PROBABLE AND CONFIRMED CASES

STAKEHOLDER REACTIONS

- CONSUMERS – MOST LIKELY TO BENEFIT
- PROVIDERS – NO CONSENSUS EXCEPT THAT HEALTH CARE PROVIDERS AND FIRST RESPONDERS GET PRIORITY
- BOTH GROUPS – DECISIONS SHOULD BE CONSISTENT AND MADE AT STATE LEVEL
- BOTH GROUPS – TO BE SUCCESSFUL, MUST BE AGGRESSIVE COMMUNICATION OF DECISIONS TO HEALTH CARE PROVIDERS AND PUBLIC

SCENARIO #2: PRIORITIZATION OF CARE

SCHEDULED, ELECTIVE OPERATIONS FOR DIAGNOSTIC/ PALLIATIVE CARE FOR THOSE WHO WOULD DIE WITHIN 2 WEEKS WITHOUT THIS INTERVENTION

- HOSPITAL A: KEEP THE SCHEDULE/ FIRST COME, FIRST SERVED
- HOSPITAL B: PROVIDE CRITICAL CARE ONLY FOR THOSE WITH 6+ MONTHS SURVIVAL

STAKEHOLDER REACTIONS

- CONSUMERS AND PROVIDERS - OPPOSED TO MAXIMIZING LIFE-YEARS SAVED USING 6 MONTH CUT-OFF
- PROVIDERS - TRIAGE ON CASE-BY-CASE BASIS MORE REALISTIC/ETHICALLY SOUND
- CONSUMERS – STRONGLY OPPOSED TO MODEL OF LIMITING CRITICAL CARE INTERVENTIONS
- PROVIDERS – HOSPITALS SHOULD HAVE ULTIMATE AUTHORITY/USE IRB MODEL FOR REVIEW OF DECISIONS

III. GUIDELINES: GOALS

- CONTROL PANDEMIC
- MAXIMIZE PATIENT OUTCOMES
- ESTABLISH PRINCIPLES AND GUIDELINES FOR PROVIDING CARE IN ETHICAL MANNER
- ESTABLISH PROCESS FOR DETERMINING PRIORITIES AND PROTOCOLS
- HAVE GUIDELINES IN PLACE PROACTIVELY
- USE GUIDELINES TO RESPOND TO CHANGING CIRCUMSTANCES DURING A PANDEMIC

GUIDELINES: PRINCIPLES

A. PRIORITIES AND PROTOCOLS BASED UPON ALLOCATION OF SCARCE RESOURCES TO MAXIMIZE NUMBER OF LIVES SAVED

- DETERMINED BASED ON BEST AVAILABLE MEDICAL INFORMATION, CLINICAL KNOWLEDGE AND JUDGMENT

- EQUITABLE TREATMENT OF INDIVIDUALS/GROUPS BASED ON BEST AVAILABLE MEDICAL INFORMATION, CLINICAL KNOWLEDGE AND JUDGMENT

GUIDELINES: PRINCIPLES

A. PRIORITIES AND PROTOCOLS BASED UPON ALLOCATION OF SCARCE RESOURCES TO MAXIMIZE NUMBER OF LIVES SAVED (CON'T)

-IMPLEMENTED WITHOUT DISCRIMINATION OR REGARD TO SEX, SEXUAL ORIENTATION, RACE, RELIGION, ETHNICITY, DISABILITY, AGE, INCOME OR INSURANCE STATUS

– AGE/DISABILITY – A RISK FACTOR, BUT IMPORTANCE OF SAVING ELDERLY OR DISABLED SAME AS FOR OTHERS

GUIDELINE: PRINCIPLES

B. PERMIT FLEXIBILITY FOR PHYSICIAN DISCRETION TO VARY/MAKE EXCEPTIONS PRIORITIES AND PROTOCOLS

- GOOD FAITH JUDGMENT
- CIRCUMSTANCES WARRANT EXCEPTION
- PRIOR, EXPEDITED REVIEW (IRB/PEERS)

GUIDELINES: PRINCIPLES

C. HEALTH CARE INSTITUTIONS AND PROVIDERS HAVE RESPONSIBILITY TO DEVELOP MUTUAL AID PLANS ON REGIONAL BASIS

ENSURE COMMUNICATION AND COORDINATION

MUTUAL ASSISTANCE FOSTERS BETTER USE OF RESOURCES

GUIDELINES: PRINCIPLES

D. ASC PROTOCOLS WILL RECOGNIZE:

- CHANGES IN PRACTICES NECESSARY TO PROVIDE CARE UNDER CONDITIONS OF SCARCE RESOURCES OR OVERWHELMING DEMAND FOR CARE
- HEALTH CARE PROVIDERS DELIVERING CARE OUTSIDE THEIR STANDARD SCOPE OF PRACTICE
- USE OF ALTERNATE CARE SITES (INFLUENZA SPECIALTY CARE UNITS)
- REASONABLE, PRACTICAL STANDARDS FOR DOCUMENTATION OF DELIVERY OF CARE

GUIDELINES: PRINCIPLES

E. THE RESPONSIBILITY OF HEALTH CARE PROVIDERS IS:

- TO PROTECT THE PUBLIC'S HEALTH
- BY ADHERING TO PRINCIPLES/ASC PROTOCOLS/PRIORITIES DEVELOPED FOR A PANDEMIC SITUATION

GUIDELINES: PRINCIPLES

F. PATIENT CARE MUST BE PROVIDED WITHIN THE CONTEXT AND LIMITATIONS OF ASC NECESSITATED BY THE PUBLIC HEALTH EMERGENCY

- RECOGNIZE INHERENT TENSION BETWEEN HEALTH CARE PROVIDERS' USUAL DUTY TO PATIENTS AND DUTY TO MAXIMIZE NUMBER OF LIVES SAVED
- PROVIDERS/INSTITUTIONS ESTABLISH CAPACITY TO ASSIST PROVIDERS IN MAKING DECISIONS (IRB; ETHICS CONSULTANT/PEER CONSULTANT)

COMMUNICATION/PATIENTS' RIGHTS

- TRANSPARENCY OF DECISION-MAKING
- OUTREACH TO HEALTH CARE PROVIDERS AND PUBLIC ON DECISION PROCESS AND ASC
- STRESS COLLABORATION OF GOVERNMENT/DPH WITH HEALTHCARE PROVIDERS
- PUBLIC HEALTH OFFICIALS SHOULD DISCLOSE ONLY AS MUCH CONFIDENTIAL INFORMATION AS NECESSARY TO PROTECT PUBLIC HEALTH
- CIVIL LIBERTIES/PATIENTS' RIGHTS PROTECTED TO GREATEST EXTENT POSSIBLE – PROTECTION OF PUBLIC HEALTH MAY REQUIRE LIMITATIONS

PROVIDER LIABILITY

- GUIDELINES ADDRESS THIS SPECIFICALLY -ATTEMPT TO INFLUENCE JUDICIALLY RECOGNIZED "ALTERED STANDARD OF CARE" FOR COMMUNITY STANDARD
- IF DELIVER CARE IN ACCORDANCE WITH ASC, CONSIDERED TO BE CARE THAT WOULD BE DELIVERED BY "AVERAGE, PRUDENT PROVIDER IN COMMUNITY"
- NO BASIS FOR MALPRACTICE CLAIM IN THIS CASE

IV. FRAMEWORK: NEXT STEPS

I. DRAFT SPECIFIC ASC: PRIORITIES AND PROTOCOLS FOR DELIVERY OF CARE, INCLUDING:

- ALLOCATION OF MEDICATIONS, INCLUDING ANTIVIRALS; VACCINE IF AVAILABLE
- ALLOCATION OF RESOURCES – HOSPITAL BEDS; STAFF; VENTILATORS

II. REVIEW BY ASC ADVISORY COMMITTEE SUBGROUPS:

- MEDICAL/SCIENTIFIC
- ETHICS/PUBLIC/CONSUMER

** CONSISTENT WITH GUIDELINE PRINCIPLES?

** REVISION OF PRINCIPLES?

GUIDELINES: HOW ASC WOULD BE IMPLEMENTED

- GOVERNOR DECLARES PUBLIC HEALTH EMERGENCY
- COMMISSIONER OF PUBLIC HEALTH ORDERS ADHERENCE TO SOME OR ALL OF ASC
- USE OF ASC IMPLEMENTED ONLY WHEN NECESSARY/PROPORTIONAL TO EXISTING CONDITIONS
- CONSISTENT ACROSS COMMONWEALTH WITH HEALTH CARE PROVIDER DISCRETION
- CONTINUOUS REVIEW