Resilient Drug Supply Project: Examining Current Lists

Presented to:

The National Academies of
SCIENCES • ENGINEERING • MEDICINE

December 1, 2020

PRIME Institute
University of Minnesota

CIDRAP
Center for Infectious Disease Research and Policy

Formation of Resilient Drug Supply Project Critical Acute Drug List

- Developed during an expert workshop in December 2018
  - Experts from government, academia, & private sector
  - Disciplines represented were Pharmacy, Medicine, Nursing, Public Health
  - Stakeholders participating: Federal Agencies, Manufacturers, Wholesalers, Other Supply Chain & Drug Distribution, Health Systems & Hospitals, Emergency Medical Services, and Emergency Preparedness & Response

- Definition of critical, life-saving
  - Very high likelihood people will die without timely use of this drug
  - Excess mortality is expected without this drug or alternates
  - Cannot provide humane care without this drug or alternates
  - Drugs with no reasonable alternatives

Defining Critical Acute Drugs

Critical Acute Drugs:

"Drugs that when medically needed in acute care must be available and used within hours or days of the need or the patient will suffer serious outcomes which may include disability or death."

Absence of a **Critical Acute Drug**, or lack of availability of an effective substitute, may cause serious health outcomes or limited ability to provide humane care."

- **156** drug molecules
- **25.6%** (40/156) in shortage according to FDA
- **41.7%** (65/156) in shortage according to ASHP

Defining Critical COVID-19 Drugs

Critical COVID-19 Drugs:

"Drugs that are medically needed to treat COVID-19 positive patients and related symptoms."

Absence of a **Critical COVID-19 Drug**, or lack of availability of an effective substitute, may cause serious health outcomes or limited ability to provide humane care."

- **40** drug molecules
- **45.0%** (18/40) in shortage according to FDA
- **75.0%** (30/40) in shortage according to ASHP

Defining Critical Chronic Drugs

Critical Chronic Drugs:

"Drugs that when medically needed in chronic care must be available and used within a few days or weeks of the need, and on a regular basis, or the patient will suffer serious outcomes which may include debilitating disease progression and worsening health status resulting in emergency care, hospitalization or death."

Absence of a **Critical Chronic Drug**, or lack of availability of an effective substitute, may cause serious health outcomes or shortened life span due to death.

The vast majority of medical conditions are chronic diseases such as diabetes, high blood pressure, asthma, epilepsy, thyroid problems, or cancer. For example, insulin is a Critical Chronic Drug for most Type I diabetic patients.

- **~500** drug molecules expected in list under development
- **? %** (?/500) in shortage according to FDA
- **? %** (?/500) in shortage according to ASHP

RDSP Team & Funding

Michael Osterholm, Co-Principal Investigator mto@umn.edu

Stephen Schondelmeyer, Co-Principal Investigator schon001@umn.edu

James Seifert, Project Manager seife202@umn.edu

David Markgraf, Pharmaceutical Scientist margr005@umn.edu

Funded by a generous grant from the Walton Family Foundation