

Activities of the AABB

Interorganizational Task Force on Pandemic Influenza & the Blood Supply

Advisory Committee on Blood Safety
and Availability

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FOR THE TASK FORCE

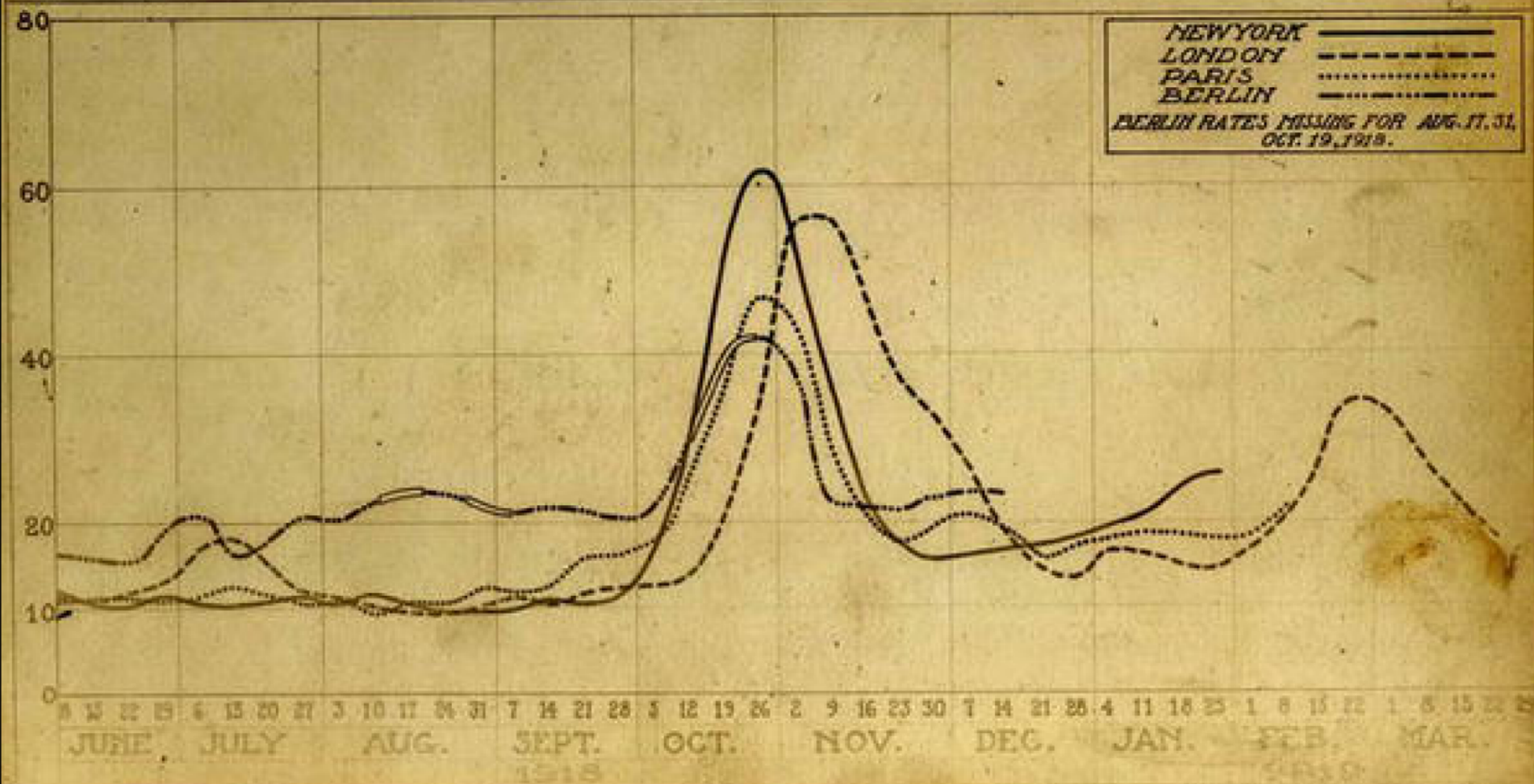
Task force deliverables

- Background with the planning assumptions and unknowns
- Checklist modeled on HHS format
- Issues outline that will list some alternatives
- A living document
- Continued liaison with HHS (CDC, FDA) and AdvaMed blood group

INFLUENZA PANDEMIC

MORTALITY IN AMERICA AND EUROPE DURING 1918 AND 1919

DEATHS FROM ALL CAUSES EACH WEEK
EXPRESSED AS AN ANNUAL RATE PER 1000



“This is a disease that spreads rapidly across the country and the idea that you can take resources from one area that’s not affected and transfer to another just doesn’t work in a pandemic.”

– Benjamin Schwartz, MD
National Vaccine Program Office
ACBSA May 16, 2005

This is a different disaster paradigm

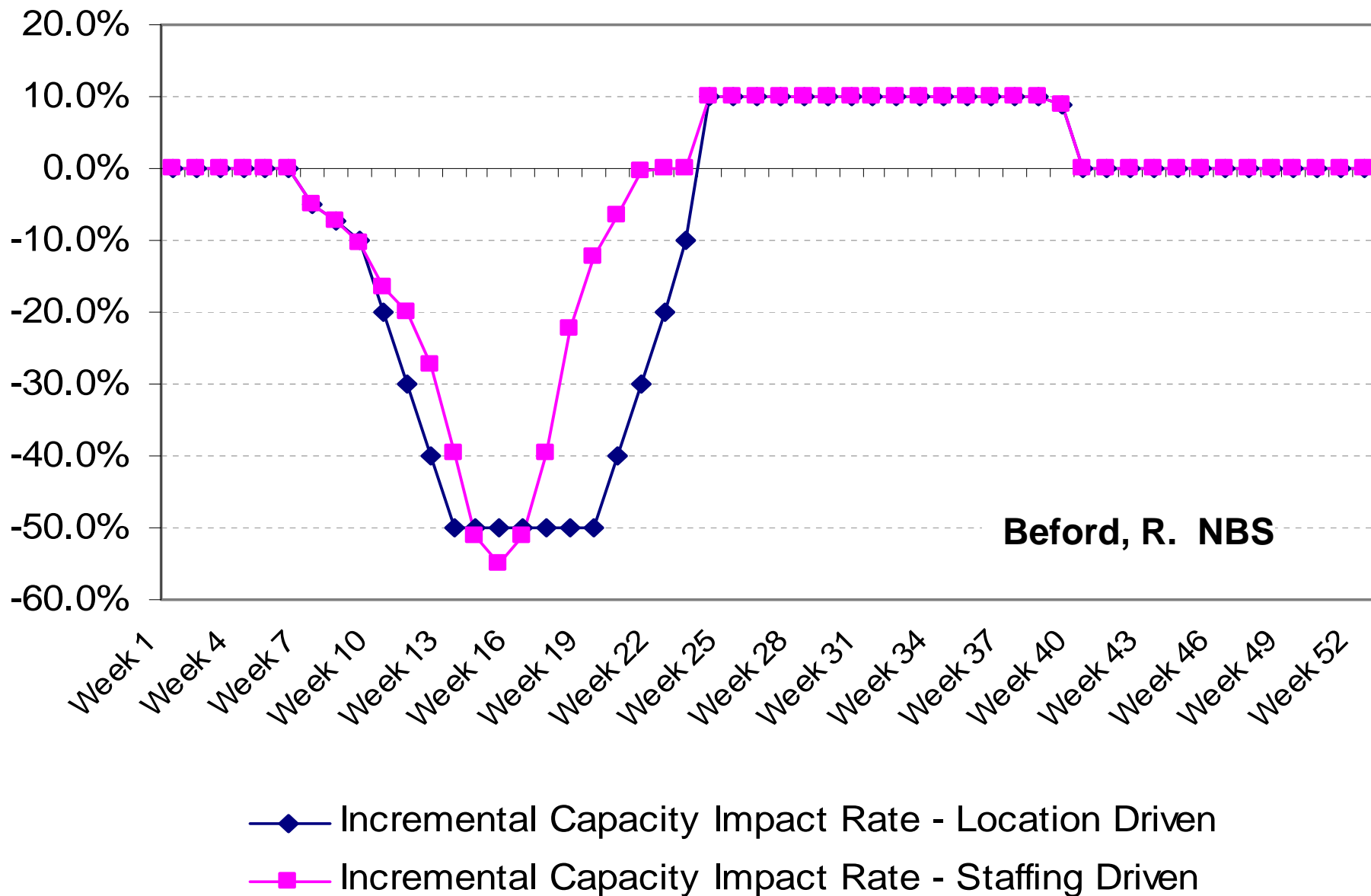
“My conclusions are that in influenza pandemic, there will be a decrease in blood supply, a decrease in demand and blood drawing capacity, but no major impact on the safety of blood itself.”

Benjamin Schwartz, MD
National Vaccine Program Office
ACBSA May 16, 2005

Are there valid impact models?

- Of the range of impacts of pandemic flu scenarios on our ability to collect, process and distribute blood?
- Of blood use in a pandemic given 2005 ff. levels of medical care?

RBCs (severe): 35% attack rate.10 wk *1st wave*



(Some) planning assumptions

- Donors/staff will be impacted like the general population and donations will fall
- Elective surgical needs will decline
- Platelet needs, e.g. to support hematologic malignancy and hematopoietic progenitor cell transplants, will be maintained
- Some assume flu victims will need few products, but this may be incorrect esp. in ICU setting

Challenges

- Operational continuity with up to 40% absenteeism over a pandemic wave
- Effectiveness and capacity to implement/enforce infection control procedures
- “Buy in” for blood donation as a priority
 - National, state, and local public health and EMAs
 - Vaccine and antiviral priorities
 - Regulatory flexibility in the “worst case”
- Effective internal and external communication before and during the pandemic

Operational continuity and maintenance of blood supply adequacy

- Prevention of introduction and transmission at collection sites and communication of those efforts
- Maintenance of collections despite social distancing
- Work rules and respite to preserve capacity
- “Amended” procedures in the face of critical blood or supply shortages
- Triage of blood and component use
- Supply chain integrity

Prevention of introduction and transmission

- Education about transmission
- Entry check points for staff and donors
- Hand hygiene and cough etiquette
- PPE
- Environmental disinfection policies
- Donor room layout
- Vaccine and antiviral priority and use
- Public confidence is key

Maintenance of collections despite social distancing

- Prospective education of and planning with individual donors, corporate, community blood drive supporters
- Recruitment of recovered donors
- Explicit messaging from all levels of public health that blood donation has an “exemption” from stringent distancing initiatives

Work rules to preserve capacity

- Survey employees about attitudes and availability for extended hours
- Exclusion and return-to-work rules
- Extra staffing from retired employees, volunteers, cross-training
- Telecommuting and related interventions
- Labor union input
- Post-pandemic surge planning
- Respite considerations

Influenza as a TTD??

- Never observed, but would we have recognized it?
- Viremia occurs, mainly in the ill who will not be eligible donors. Poorly characterized for the strains studied and not at all for future pandemic strains
- Animal models may or may not be relevant
- Deferral for contact may impact a very large proportion of donors during a severe pandemic wave
- We believe FDA should remain silent on issues of contact and deferral until there are direct data

“Amended” procedures in the face of critical blood or supply shortages

- Hemoglobin
- Travel deferrals
- Weight limits, vital signs
- Interdonation intervals
- WNV NAT, HIV/HCV NAT
- QC testing, audit timing, reporting requirements for BPDRs etc.
- Hepatitis after 11 years
- Cross-training is not an on-the-fly strategy

<http://www.fda.gov/CBER/infosheets/dstrbld.htm>

Triage of blood and component use

- Prospective planning in hospital transfusion services with medical staff et al
- Prospective planning in collection facilities for “rationing” of limited supplies
- Role of professional organizations in providing guidelines for use of blood and components in the face of limited supplies
- This is about altering physician behavior

Supply chain integrity

- Continued provision of just-in-time delivery of critical supplies
- “Their” planning
- Transportation issues
- Border controls

Supply chain mixed-messages

- 6-8 week stockpile of med-surg supplies
 - HHS, Nov. 2005:
- 2-3 week stockpile of med-surg supplies
 - Homeland Security, May 2006:
- Do not stockpile
 - Assoc. for Healthcare Resource and Materials Management (AHA), May 2006:
- 59% of hospitals maintain ≤ 7 days of supplies
 - VHA survey
- Where is the space for 6-8 weeks of supplies?

The reality of the just-in-time supply chain economy

Preparedness
(public health) = Excess
capacity = Waste

So let me get this straight, Dr. Katz. For an event that has occurred once in recorded history (the 1918 pandemic), you are asking us to revamp our entire business model.

Blood community checklist

- Operational risk planning
- Donor issues
- Staff issues
- Blood safety and availability
- Supply chain
- Local and state public health liaison
- Communications planning