The HIV experience

Advisory Committee on Blood Safety and Availability
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MMWR.

Dec. 10, 1982 / 31(48);652-4

"If the platelet transfusion contained an etiologic agent for AIDS, one must assume that *the agent can be present in the blood of a donor before onset of symptomatic illness & that the incubation period for such illness can be relatively long*…"

Interventions considered for TA-AIDS in Jan. 1983

- Explicit donor inquiries about sexual behavior
- Surrogate testing (anti-HB core & T4/T8 ratios
- Voluntary self-deferral by at-risk donors

Background to recommendation for voluntary self-deferral in 1983

- Scientific uncertainty
- Distrust of CDC
  - Swine flu experience (“fiasco”)
  - Imminent budget cuts proposed for CDC
- Civil rights/ethical considerations
- Perception that direct questions would have a harmful risk (& cost)-benefit ratio

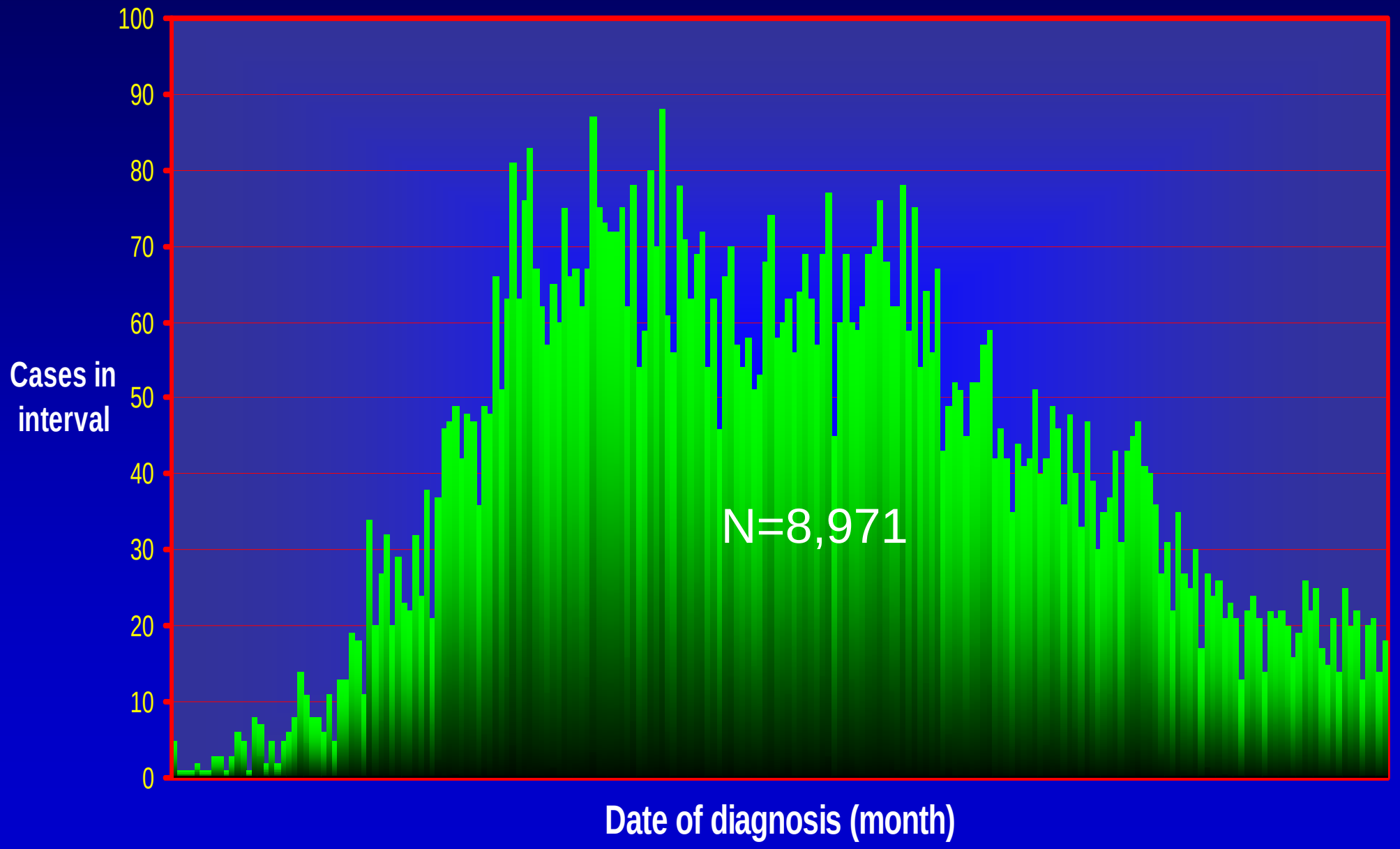
Risk-benefit & decision making?

"How many deaths do you need? Give us the threshold of death you need in order to believe that this is happening, & we'll meet at that time & we can start doing something."

Don Francis, CDC. Quoted in Shilts, R. And the Band Played On: Politics, People, & the AIDS Epidemic. 1987. p. 220

AIDS associated with receipt of blood:

adults & adolescents by month of ***diagnosis:*** before 1982-2001



An analysis of crisis decisionmaking

"The events of the early 1980s, however, revealed an important weakness in the system– in its ability to deal with *a new threat that was characterized by substantial uncertainty."*

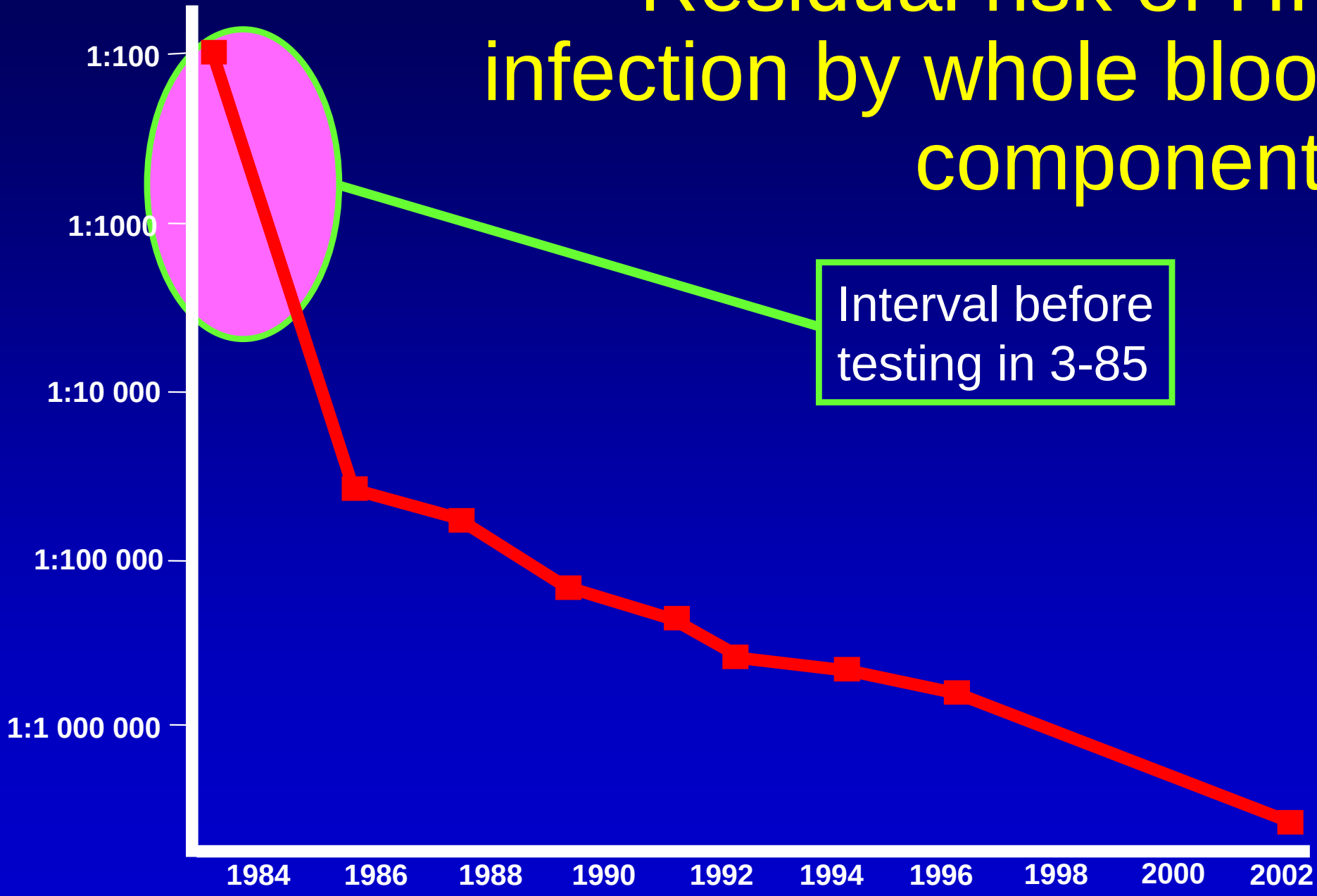
HIV and the Blood Supply: an Analysis of Crisis Decisionmaking.
www.nap.edu/catalog/4989

Chronology of interventions*

- 1st Q 1983: *gay men with multiple partners asked not to donate*
- Mar 1983: all risk groups asked to refrain
- Dec 84: MSM defined as "more than one"
- Mar 85: *serological testing*
- Sept 85: MSM redefined as "even once"
- Oct 86: "CUE" recommended by FDA
- Spring 87: HIV-2 African exclusions
- Feb 91: *explicit donor queries required*
- Spring 92: HIV-2 EIA
- Mar 96: HIV-1 p24 antigen
- 1996: HIV O donor exclusions
- Spring-fall 99: minipool NAT (*under IND*)
- Jan 2005 variance for +NAT as confirmation

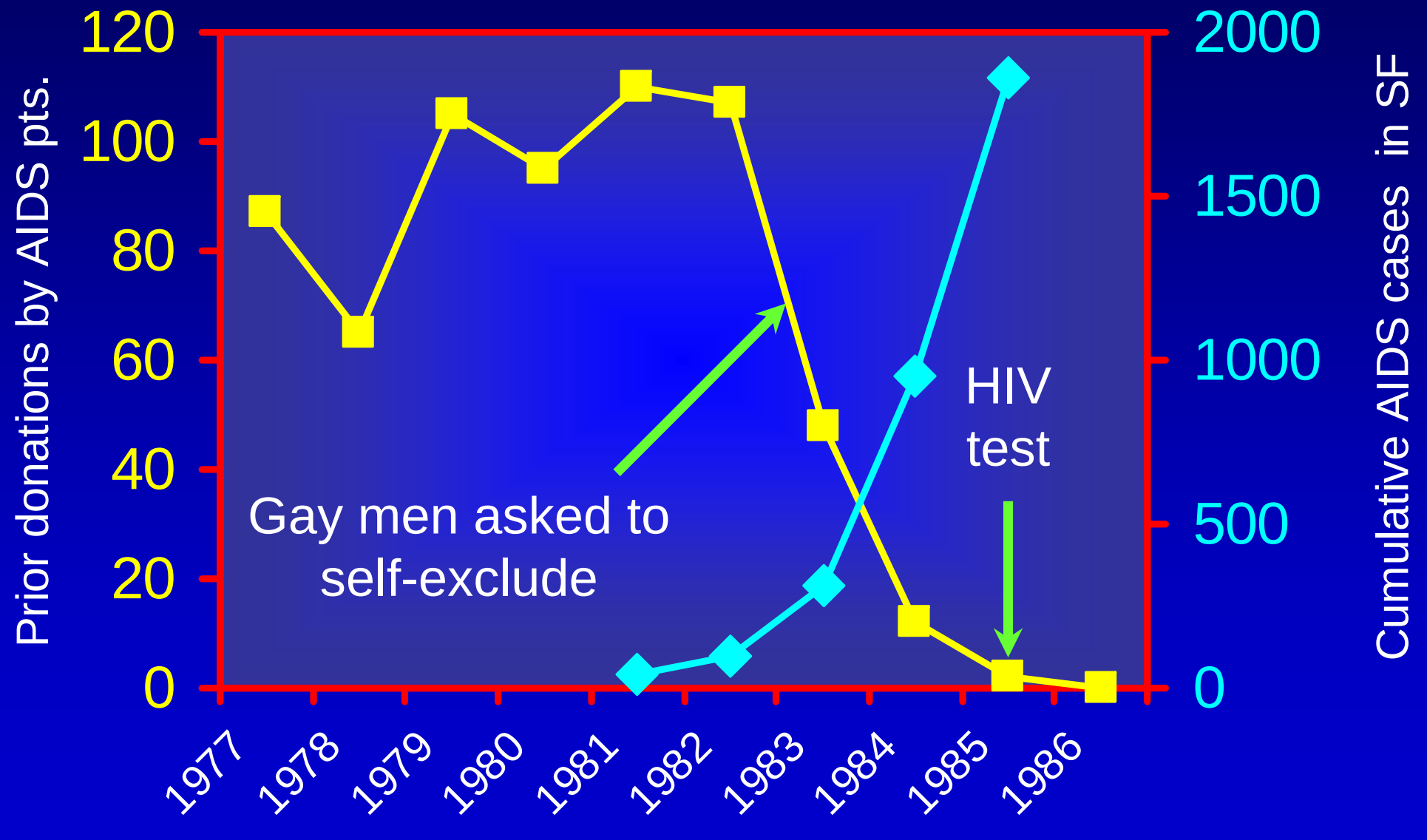
*Pers. Comm. and thanks to Jane Starkey and Kay Gregory

Residual risk of HIV infection by whole blood components



Modified from: Goodnough LT *et al. NEJM* 1999;341:126-7

Effectiveness of measures to protect the blood supply from HIV



After Perkins, H et al. *Transfusion*. 1988;28:601

What is left??

- Improved donor screening for risk
- Improved specificity of serological assays
- Improved availability of group O (*et al*) serological assays
- Improved specificity of supplemental assays for RR-EIA and negative NAT
- Single donation NAT
- Will there ever be sufficient confidence in serology + NAT to adjust deferrals for behavior??

"There's something about blood"

- Classic public health perspectives (greatest good to greatest number) is not relevant to society or regulators
- Costs are (apparently) not relevant
- Safety based interventions that have been implemented based on little or no data are difficult to rescind

Emerging bugs & safety policy

- Recipient protection paramount
- Rapid assessment & proactive decisions, often with little data, required
- Globalization of risk such that international dialogue mandatory

In a health care system that stuggles to establish priorities, we will continue to be guided by precautionism. At least we can ask that it be paid for.

“Celso, do we dwell on all the wasted years behind us or the terrifying years ahead?”