EVALUATION OF A FIRST-TIER SCREENING PROGRAM FOR DUAL-USE RESEARCH OF CONCERN

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Two Important Questions

What is "dual-use" research?

Politics & Diplomacy:	peaceful + military aims
Biomedical Research:	directly misapplied to pose threat to public health…

Why should I care about it?

The problem isn't going away

- The "Fink Report" (2004)
- NSABB Proposed Framework (2007)
- Congressional Hearing on Synthetic Genomics (2010)

“Perceived” Challenges

- Using the criteria in the Fink Report would force all life sciences research to be considered dual-use
- Instituting a mitigation plan will require more time, money, and personnel
- Screening for dual-use will create a barrier to publication

Establish a Screening Process

- Requirements:
  - Easy to implement
  - Require no additional resources
  - Provide review at each step in research process
- Challenge:
  - Ensure potentially harmful research/results not overlooked
  - Ensure research is not impeded
- Goal:
  - Use existing infrastructure to evaluate research programs for dual-use concerns

NIH Dual-Use Screening Program

- Instituted in 2008
- Procedure:
  - Principal Investigator (PI) completes Dual-Use Screening Survey as part of rDNA/human pathogen registration process
  - Institutional Biosafety Committee (IBC) reviews
- Provides a first-tier review
  - Initiation of research
  - Periodic review

Dual-Use Screening Survey

1. …make vaccine less effective?
2. …confer resistance to antibiotics/antivirals?
3. …enhance virulence of pathogen?
4. …increase the transmissibility?
5. …alter host range?
6. …prevent/interfere with diagnosis?
7. …enable weaponization?
8. …synthetic biology used to construct harmful product?
9. …can product be used to cause public harm?

http://dohs.ors.od.nih.gov/documents/NIH%20Dual-Use%20Screening%20Survey%20for%20RDHPRD.doc

Dual-Use Screening Survey

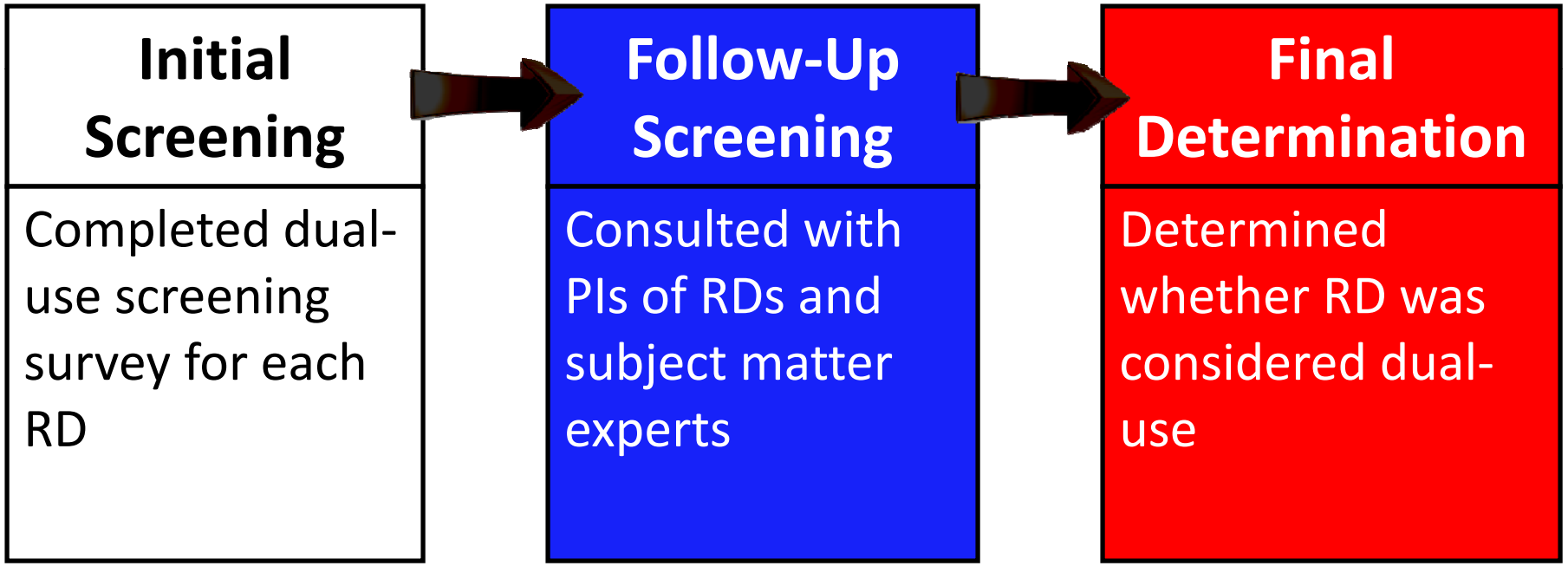
10. **After considering the above answers, do you believe there is the potential for your research data/product to be <u>readily</u> utilized to cause public harm?**

Retrospective Review

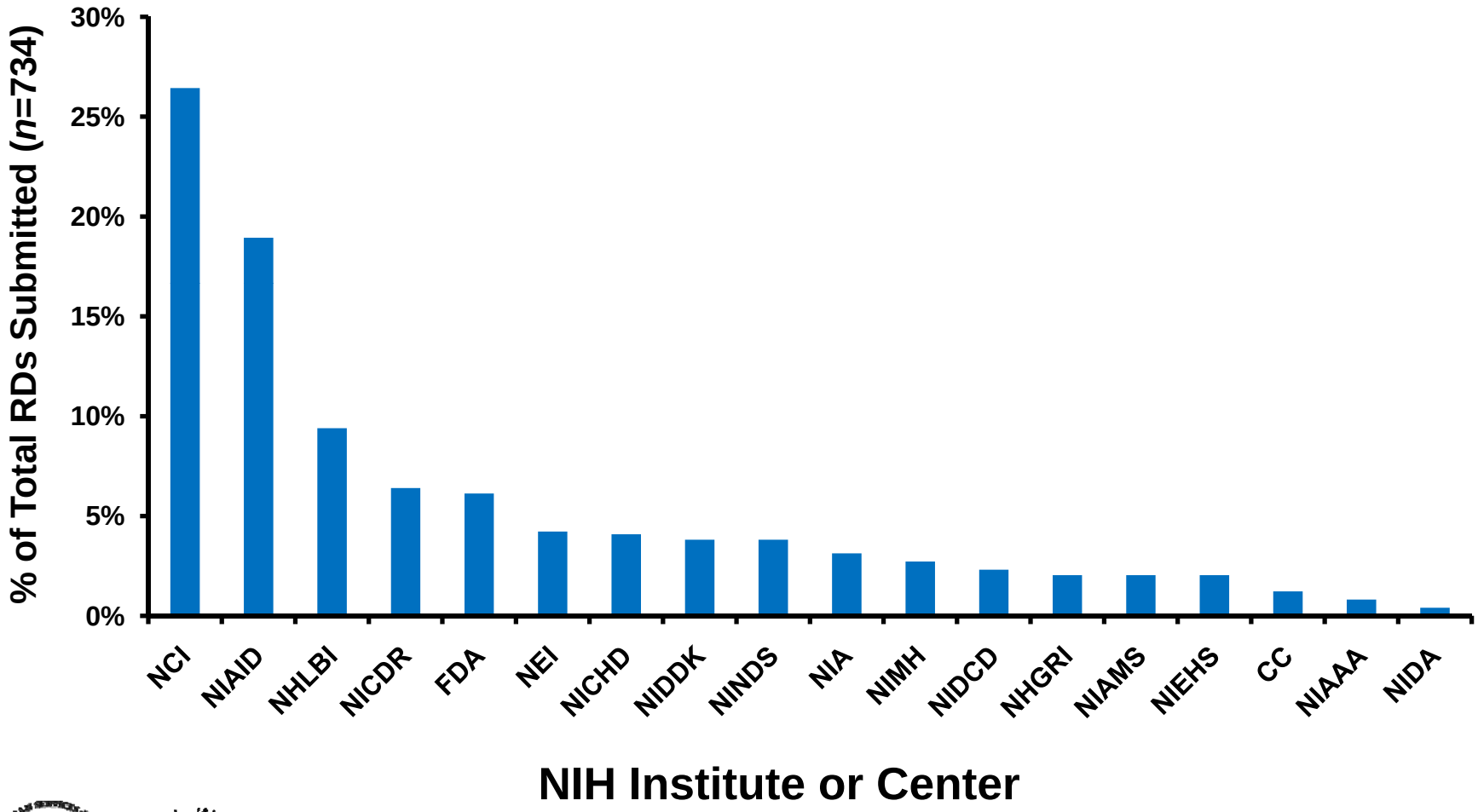
- Objectives
  - Determine if any previously approved research could be considered dual-use
  - Address perceived challenges
- Review previous registration documents (RDs)
- Screening performed by 4 fellows in Division of Occupational Health and Safety
  - Subset reviewed by entire group for consistency

Retrospective Review: Method

Reviewed all RDs submitted to NIH IBC 2004-2008 (*n*=734)



Sample Distribution



How Often Were Questions Answered "Yes"?

Individual Screening Questions	Affirmative Answers
1. Will an intermediate or final product of your research make a vaccine less effective?	**0**
2. Will the intermediate or final product of your research confer resistance to antibiotics or antivirals? • Rephrased to include, *"…other than those typically used for selection?"*	**590**
Questions 3 – 9	**≤21**

Retrospective Review: Results

Initial Dual-Use Research of Concern Determination		
"After considering the above answers... potential for your research data/product to be readily utilized to cause public harm?"	**12**	**1.6%**

Follow-Up Dual-Use Research of Concern Determination		
"After considering the above answers... potential for your research data/product to be readily utilized to cause public harm?"	**0**	**N/A**

Follow-up with experts is crucial!

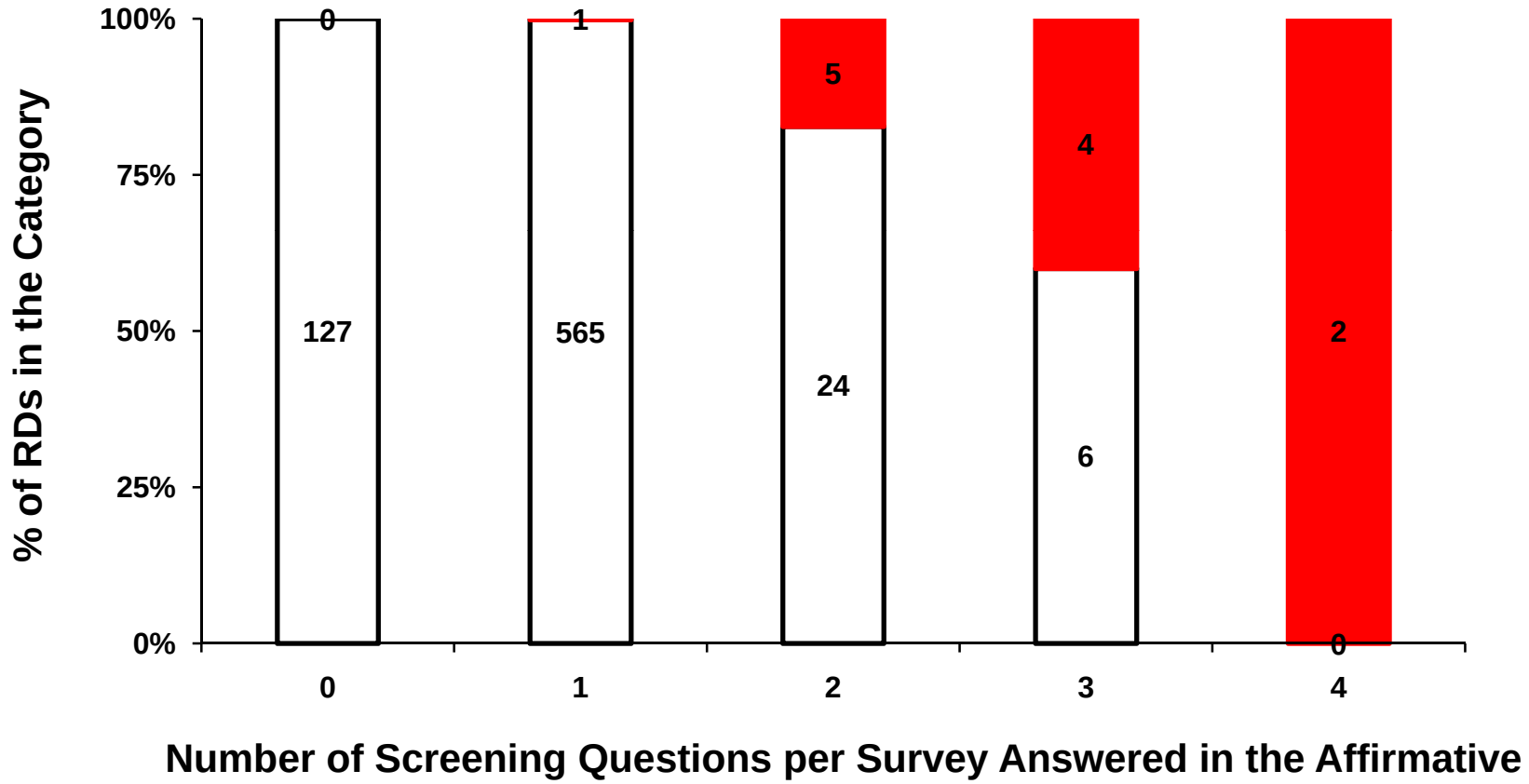
Commonalities in Dual-Use Concerns?

- Evaluated qualitative characteristics of 12 RDs with initial concerns

Institute/Center	Select Agent Status	Research Technique
Principal Investigator	Biosafety Level	Clinical Trials
Biological Agent	Animal Model	Vaccine Development

- No obvious relationships were found
- Review of research as a whole is key

Relationship Between Number of Affirmative Screening Questions



Conclusions

- Dual-use review easily incorporated into the IBC process
- First-tier is able to identify potential concerns
  - 6 of 9 questions significantly associated with dual-use in initial screening
- Does not stop there
  - Review at other levels and with other mechanisms needed

Conclusions

- NO previously approved research considered dual-use
  - Dual-use research is NOT common
  - Follow-up discussions are crucial
- Impact can be minimal
  - Initiation, progression, and publication of research
  - Research support system
  - **ZERO cost**

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