

Assessing Causality: *Clinical Immunization Safety Assessment (CISA) Perspective*

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Disclosures

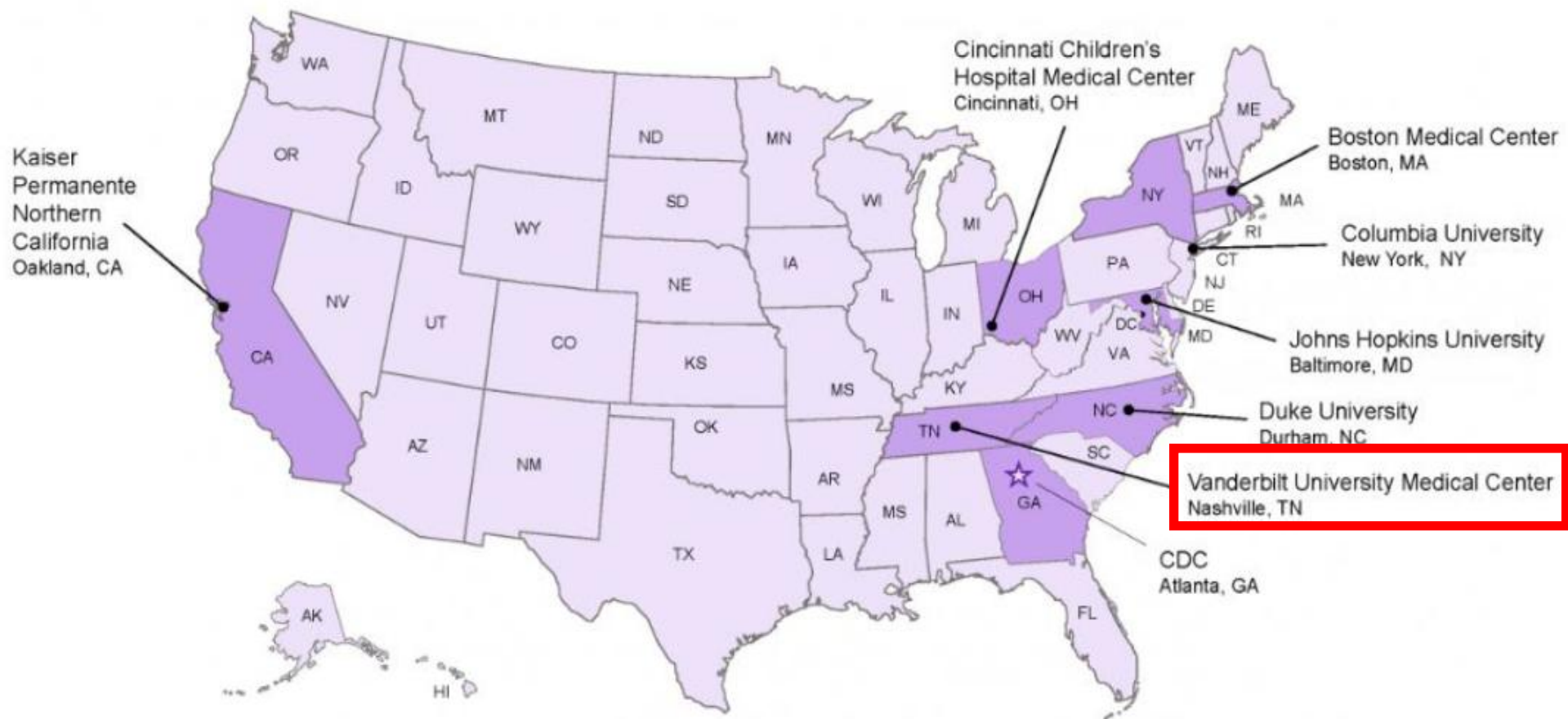
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Grant Recipient	CDC (Vaccine Safety)
Grant Recipient	NIH (Mentoring young investigators in vaccine sciences)
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Data Safety and Monitoring Board	Sanofi, X-4 Pharma, Seqirus, Moderna, Pfizer, Merck, Roche, Novavax, CEPI, Bavarian Nordic



CISA

Clinical Immunization Safety Assessment (CISA) Project

7 participating medical
research centers with
vaccine safety experts



- clinical consult services[†]
- clinical research

[†]More information about clinical consults available at
<http://www.cdc.gov/vaccinesafety/Activities/CISA.html>



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Algorithm to assess causality after individual adverse events following immunizations[☆]

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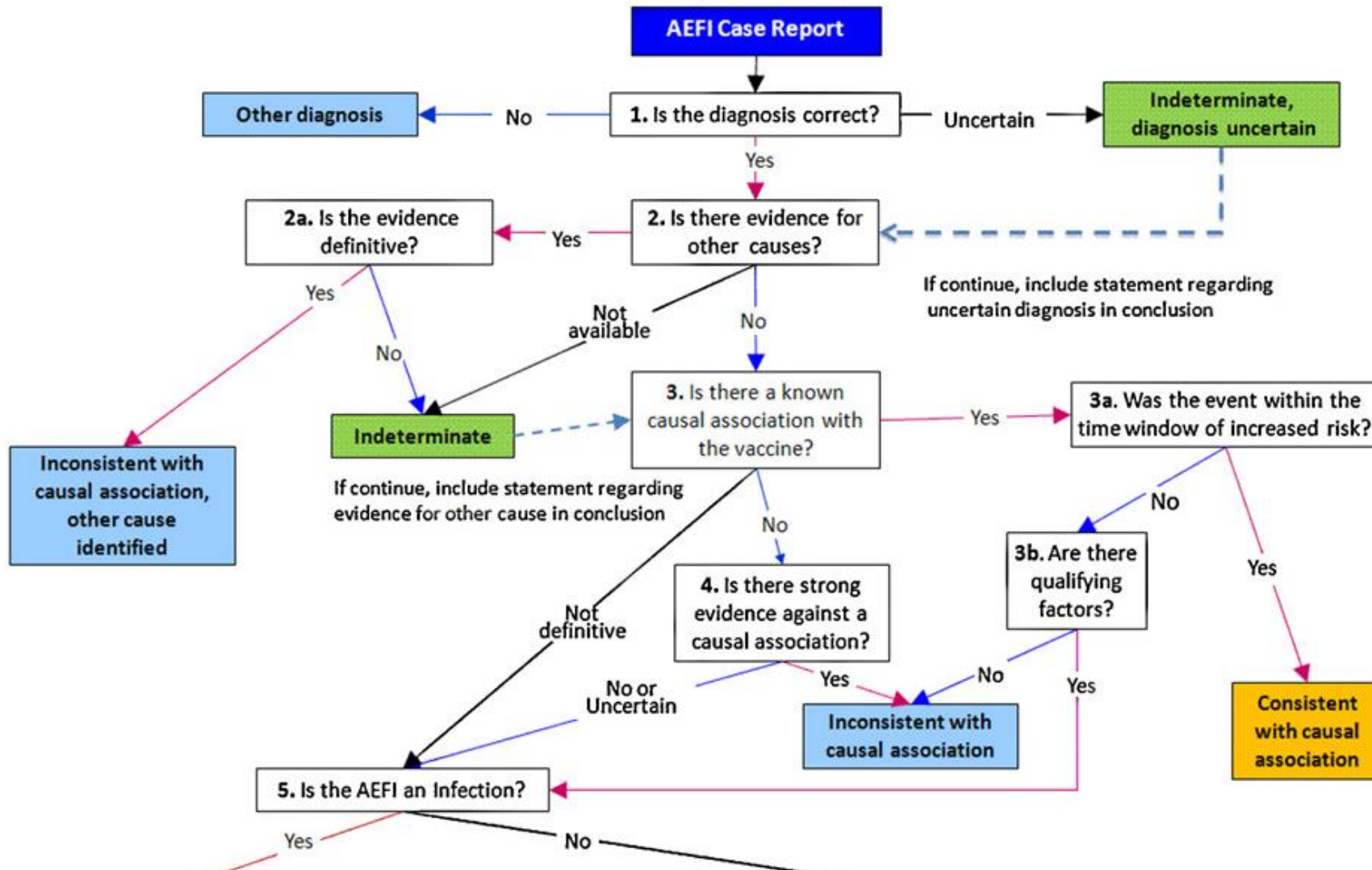
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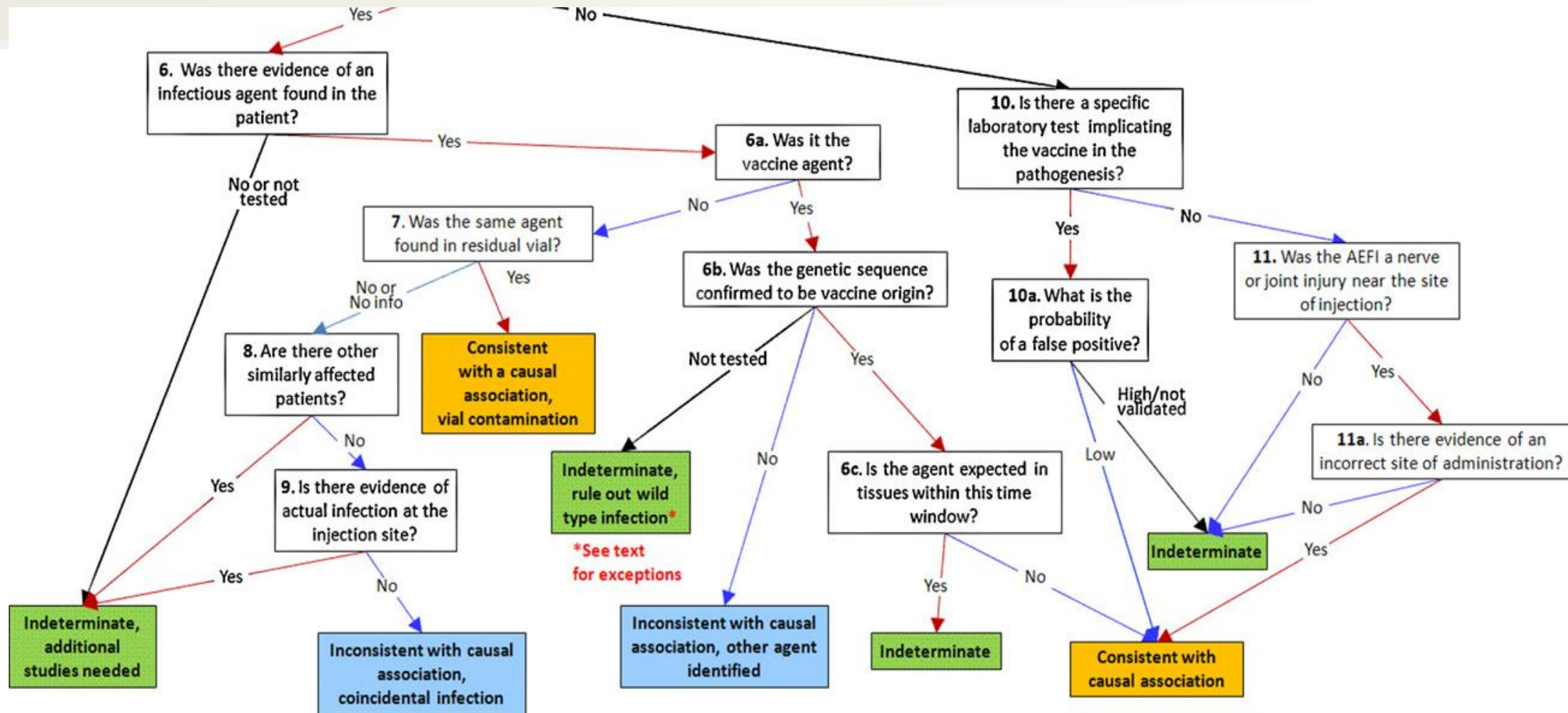
Causality Work Group of CISA

AEFI Case Report

Causality Algorithm (1-5)



Causality Algorithm (6-11)



Years 1-8 AEFI Causality (N=119 cases*)

Assessment	Year 1 (N=29)	Year 2 (N=19)	Year 3 (N=24)	Year 4 (N=11)	Year 5 (N=11)	Year 6 (N=11)	Year 7 (N=7)	Year 8** (N=7)	Total (N=119)
Inconsistent with	2 (7%)	3 (16%)	4 (17%)	2 (18%)	3 (27%)	2 (18%)	2 (29%)	0 (0%)	18 (15%)
Consistent with	7 (24%)	5 (26%)	6 (25%)	2 (18%)	1 (9%)	3 (27%)	1 (14%)	3 (43%)	28 (23%)
Indeterminate	20 (69%)	11 (58%)	14 (58%)	7 (64%)	5 (45%)	4 (37%)	3 (43%)	4 (57%)	68 (57%)
Non-unanimous determinations	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (18%)	2 (18%)	1 (14%)	0 (0%)	5 (5%)

*3 Men B (Investigational New Drug) emergency response cases are not included in total

** Year 8: October 2019 – May 2020

AEFI=Adverse events following immunization

Conclusions From CISA Causality Assessment Algorithm

- Key questions asked:
 - Is the diagnosis of the AEFI correct?
 - Does clinical or laboratory evidence exist that supports other causes?
 - Is there a known causal association between the AEFI and the vaccine?
 - Is there a specific laboratory test implicating the vaccine?
- Causation grouped into three categories:
 - Consistent with causal association with vaccine
 - Indeterminate
 - Inconsistent with causal association with vaccine.
- Using this algorithm, **119 cases of AEFI were assessed in CISA; 23% were determined to be consistent with causation, 57% indeterminant, 15% inconsistent with causation, and 5% non-unanimous determination.**