Advancing Transfusion and Cellular Therapies Worldwide

AABB Validation Study of the CDC National Healthcare Safety Network's Hemovigilance Module Adverse Events Definitions Protocol

March 2014

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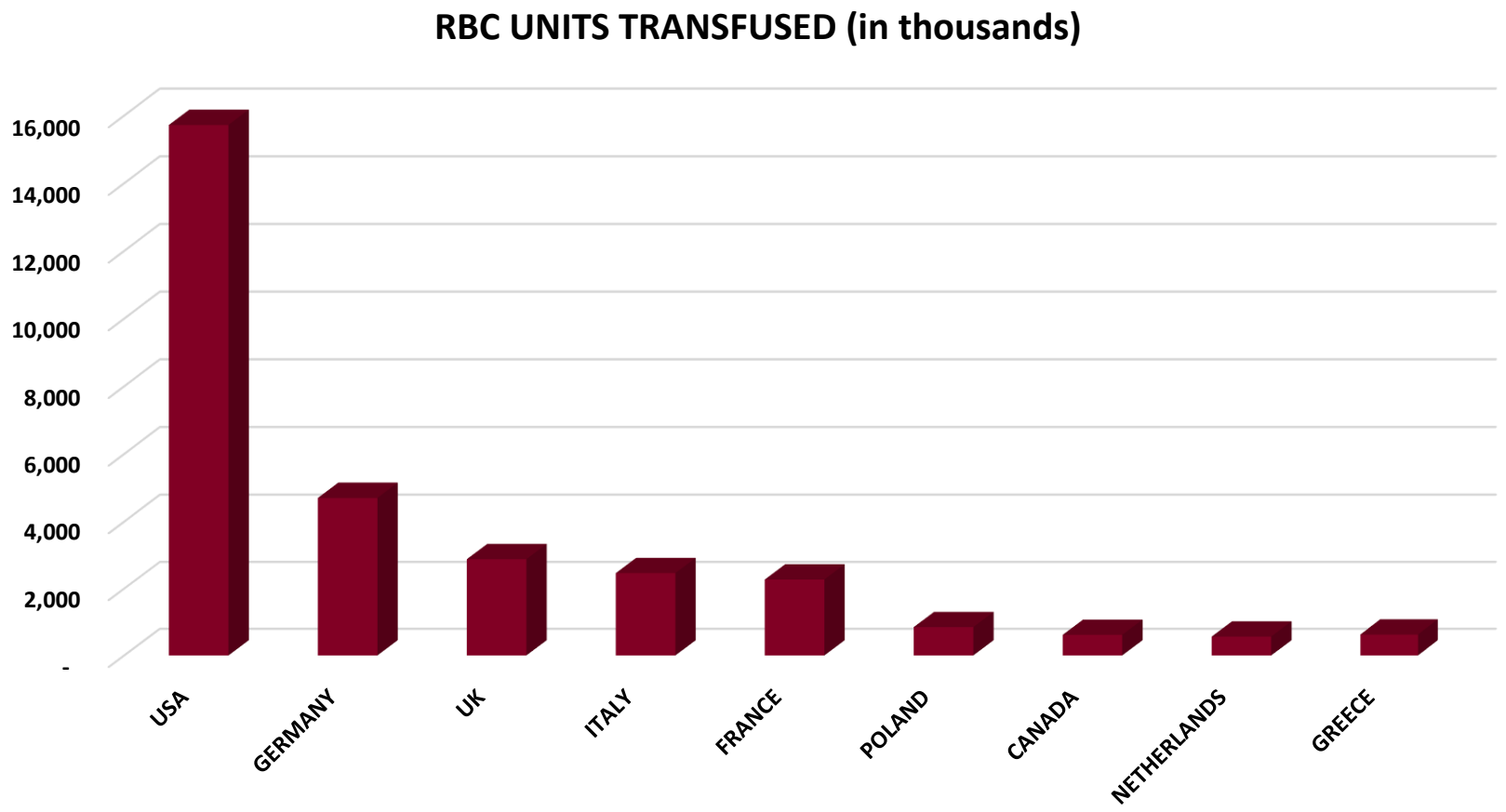
Background

- United States Health System
  - 5,000 Hospitals
  - 800,000 Beds
  - 20,900,000 components transfused
- United States Hemovigilance
  - Mandatory fatality reporting
  - Voluntary hemovigilance reporting
    - CDC National Healthcare Safety Network (NHSN)
    - AABB Center for Patient Safety

Comparative Size* of Transfusion System



*USA: 2011 National Blood Collection and Utilization Report.
UK: Annual SHOT Report 2012.
EU: EDQM Collection , testing and use of blood and blood components in Europe 2008.
CANADA: TTISS Report 2004-2005.

Introduction

- Successful hemovigilance systems require:
  - Consistency of the information captured
  - Assurance that categorizations of observations are valid
  - Respondent ability to apply definitions appropriately and consistently
- Study: To validate the applicability of the definitions developed for the CDC NHSN Hemovigilance Module (HVM)
  - Apply standard definitions to fictional cases
  - Role of prior didactic education (i.e. training on standard definitions) impacted correct categorization

Methods

- 36 fictional cases were developed containing elements of 37 case definitions from 12 different diagnostic groups.
- Hospital demographics
  - Trained: 11 hospitals submitting data to HVM (64% academic medical centers) -
  - Not trained: 11 hospitals not submitting data to HVM (73% academic medical centers)
- Respondents categorized type of adverse event, if any, and assign a diagnostic probability, severity, and imputability.
- Concordance with expert analysis was compared for the two groups of respondents.
- Respondents were those who regularly performed this task, or who regularly signed out transfusion reaction reports.
- Only one response was submitted from each institution.

Analysis

- “Expert Assessments” were provided by the author of the cases (JPA) and another author with extensive knowledge of the HVM and the system’s definitions (MF).
- The coding was compared between hospital and experts and frequencies of matching tallied.
- To qualify for a comparison of assessment for probability, severity or imputability, responses must have a diagnosis matching the expert assessment.
- Hospitals having had hemovigilance reporting and categorization training were compared with hospitals without formal training.

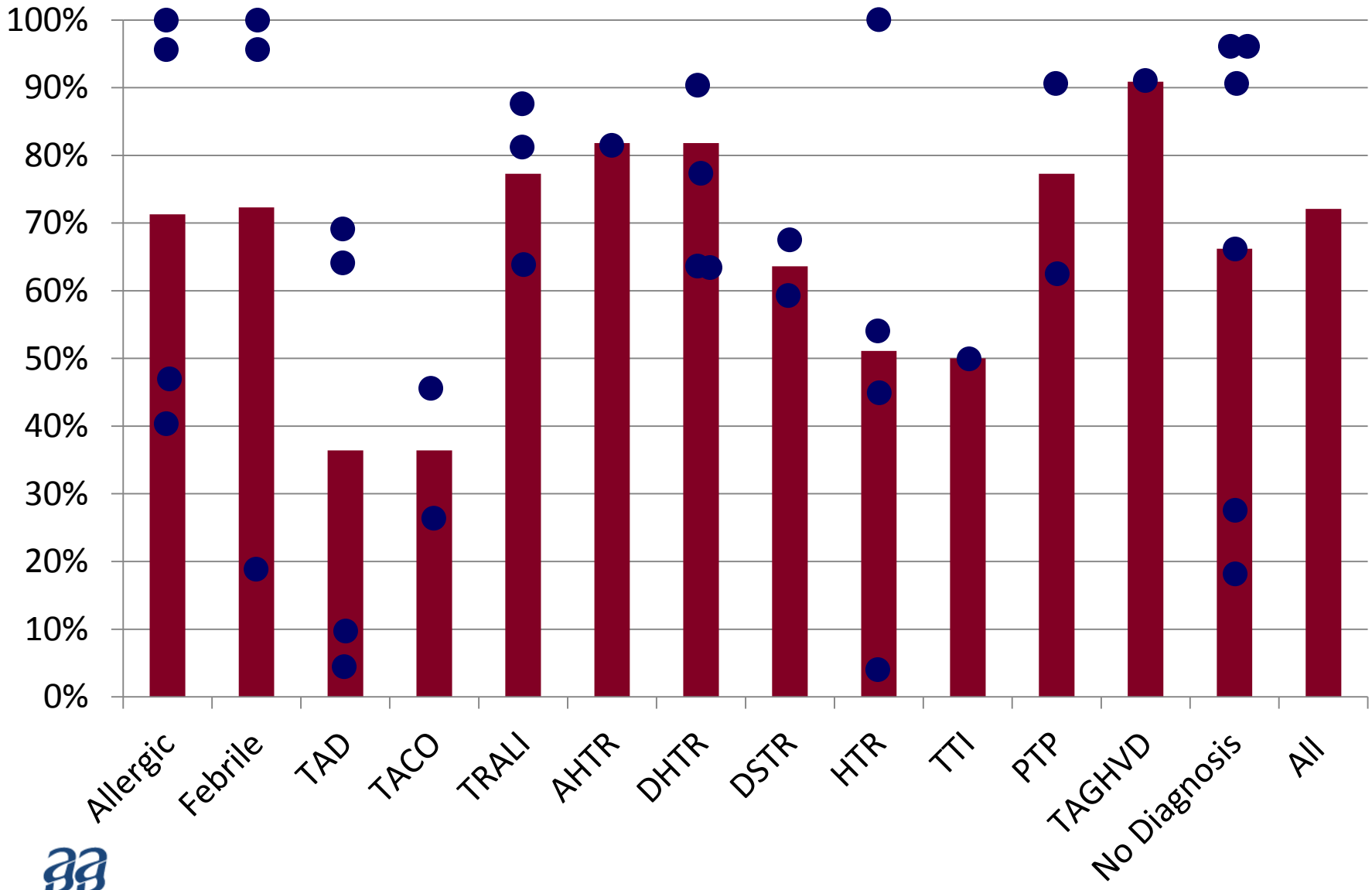
Results: Diagnosis

- 72.1% of the individual responses for transfusion reaction diagnoses matched the intended expert assessments.
- Matching for individual case diagnosis ranged from 4.5% (2 cases) to 100% (3 cases).
- Certain reactions: allergic, febrile, TAGVHD, TRALI, AHTR, DHTR, and PTP reaction cases had matching frequencies above 70%.
- The lowest aggregate matching responses were with the intended diagnoses of TAD and TACO at 36% each.
- There was no difference between the two groups (65.3% vs. 70.0% for institutions participating in the HVM vs. those that did not, respectively; $p = 0.06$).

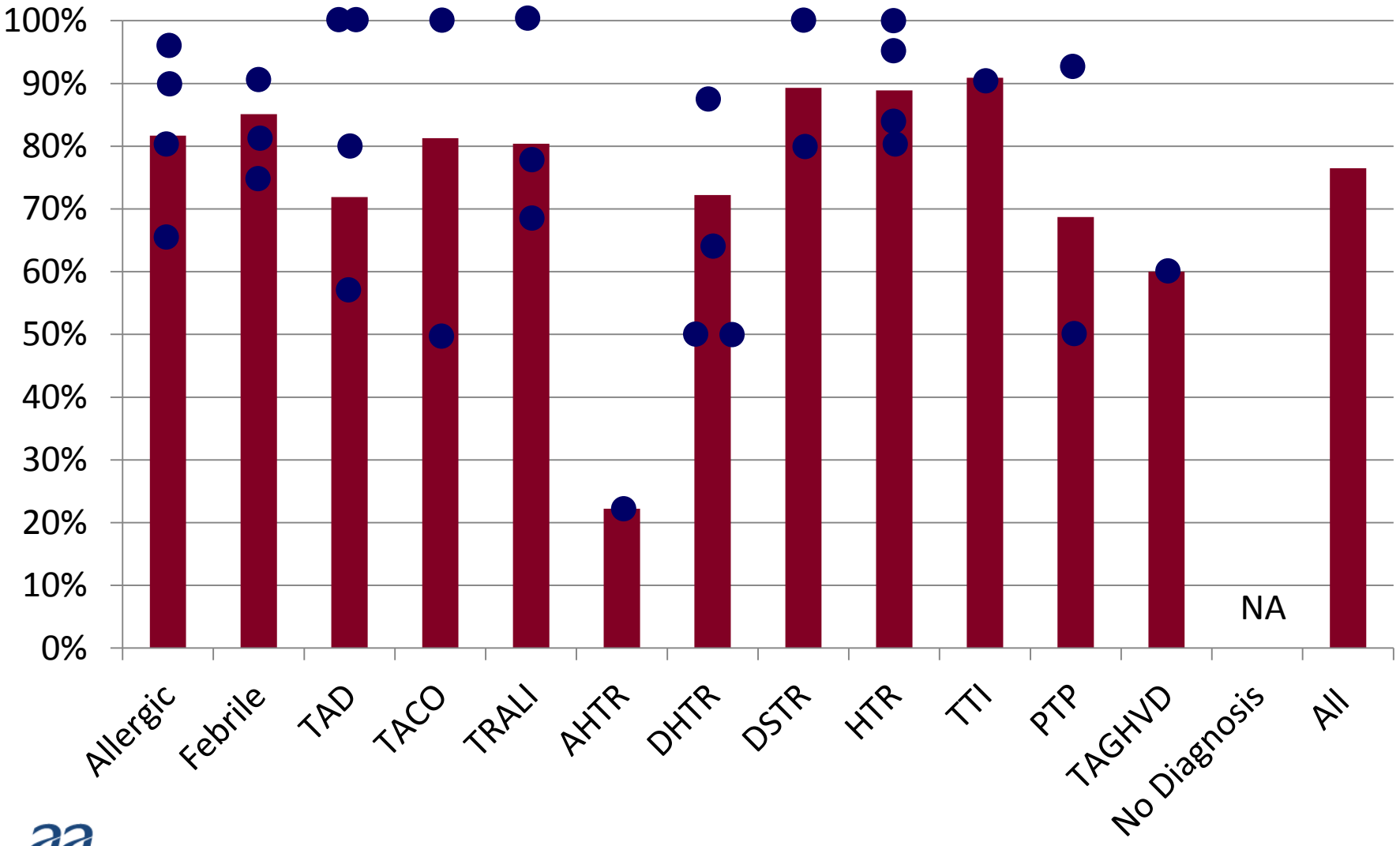
Results: Other Coding

- Matching of case definition criteria, severity, and imputability:
  - 76.5% of responses matched for case definition
  - 69.6% of responses matched for severity
  - 64.4% of responses matched for imputability
- Aggregate scores for severity and imputability were not different by training vs no-training grouping when analyzed in each case separately.

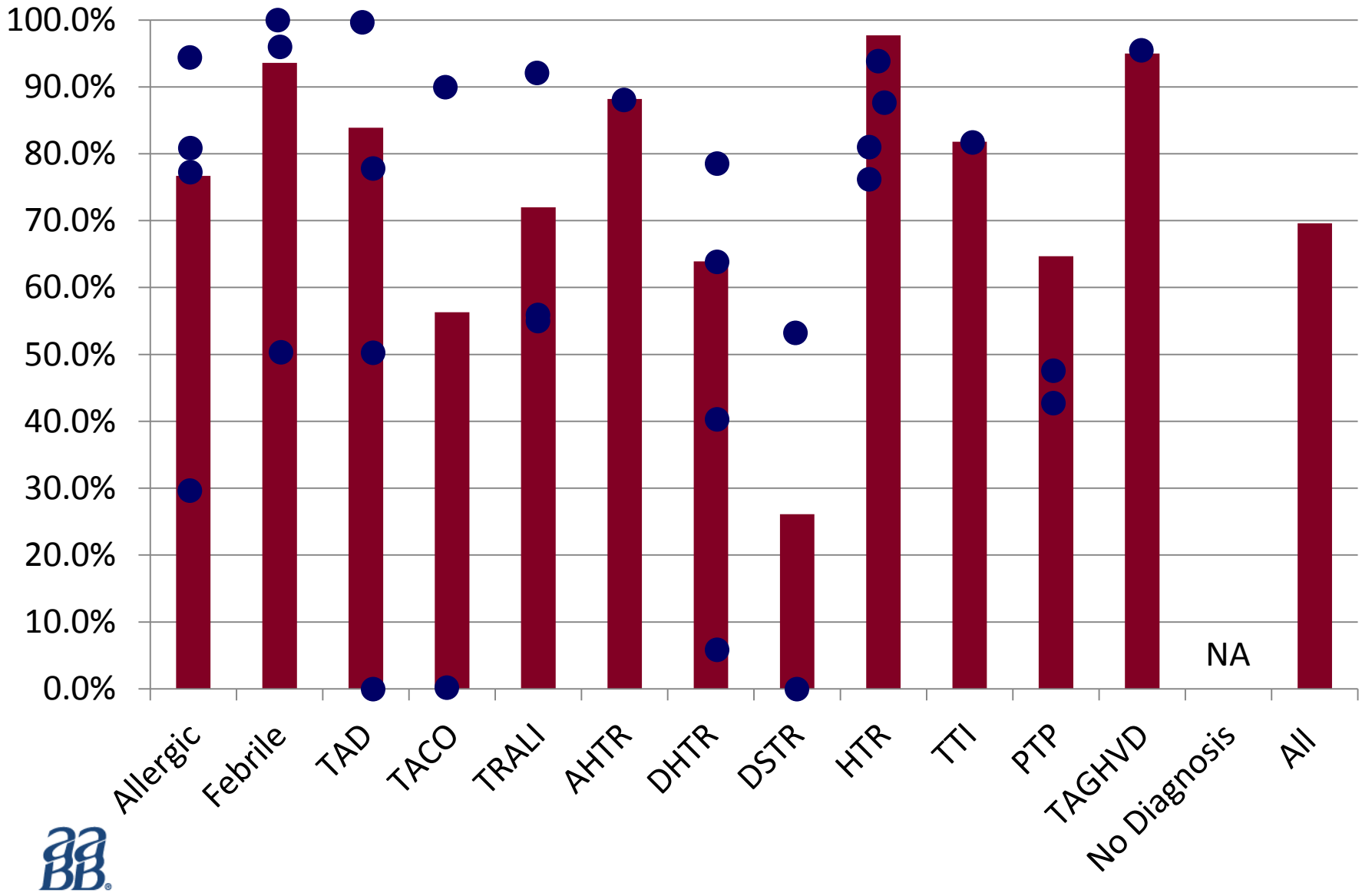
Agreement with Expert Assessment: Diagnosis



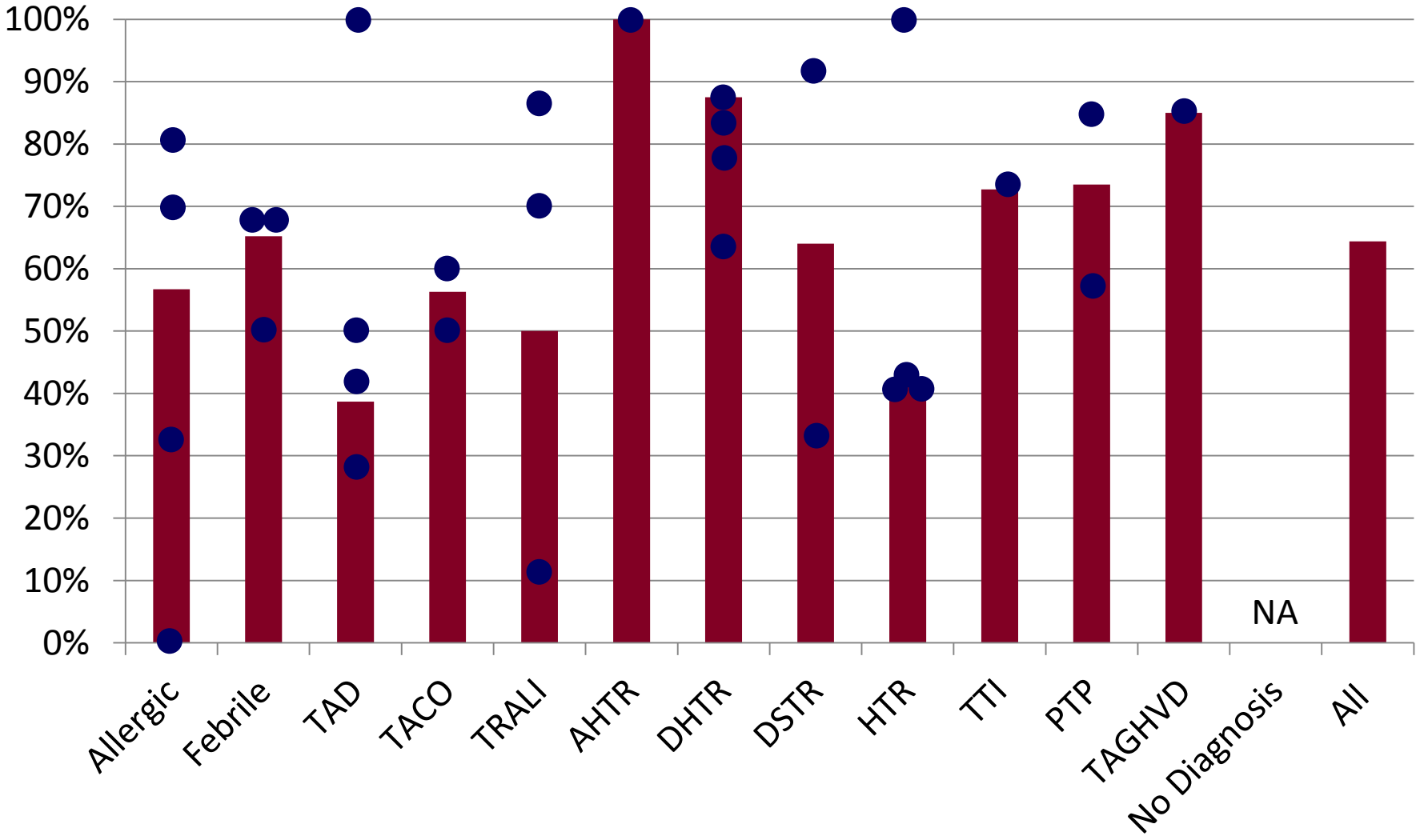
Agreement with Expert Assessment: Diagnostic Probability Match



Agreement with Expert Assessment: Severity



Agreement with Expert Assessment: Imputability



Conclusions

- Assignment of diagnoses, diagnostic probabilities, severities and imputabilities according to the criteria of the HVM system was achieved about two-thirds of the time.
- Accurate application of the definitions did not improve with prior participation in or access to training.
- The failure to precisely apply the system's definitions poses significant difficulties in the analysis of hemovigilance data.
- Additional steps are needed to address this coding dilemma
- Additional resources and continued validation are needed before categorization of adverse reactions is consistent and reliable.

Acknowledgements

- Aspirus Wausau Hospital: Sarah Sewall and Mary Kickbush
- Beth Israel Deaconess Medical Center: Michele Herman
- Children's Healthcare of Atlanta; John Roback
- Crouse Hospital: Ursula Pedersen and Rachel Elder
- Dartmouth-Hitchcock Medical Center: Ziggy Szczepiorkowski
- Emory University: Beth Polstra
- Genesis Medical Center: Sharlene Billiet
- Holy Family Memorial Hospital: Marilyn Starzewski
- Inland Northwest Blood Center Transfusion Service: Robert Ranlett
- Lifespan: Joseph Sweeney
- Massachusetts General Hospital: Sunny Dzik
- MedStar Georgetown University Hospital: S. Gerald Sandler
- Memorial Health University Medical Center: Lynne Thompson
- North Shore Long Island Jewish Hospital: Andrew Heaton
- Robert Wood Johnson University Hospital: Kashmira Patel and Grace Tenorio
- Seattle Children's Hospital-Puget Sound Blood Center: Meghan Delaney
- The Johns Hopkins Hospital: Christi Marshall, Lisa Shifflet, Monica Pagano and Paul Ness
- University of California, San Diego: Tom Lane
- University of Michigan: Robertson Davenport
- University of Minnesota: Jeff McCullough and Claudia Cohn
- University of Rochester: Scott Kirkley
- Washington University St. Louis: Brenda Grossman

Thank you