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Background and Aims:

Historically, there is considerable heterogeneity in the recognition and classification of HEp-2 IFA patterns worldwide. Aiming to expand the efforts for international standardization in the HEp-2 IFA test, ICAP launched the HEp-2 CIC project: Clinical and Immunological Characterization of HEp-2 Patterns, which aims to collect information on methodology and result reporting in laboratories across the world.

Methods:

Participating laboratories were selected obeying a criterion of global geographical representation and were required to provide information on the characteristics of the laboratory and the HEp-2 IFA methodological operation. Invited participating laboratories should have expertise in autoantibody testing, consistent scientific productivity in the field, and/or recommendation by members of the ICAP executive board.

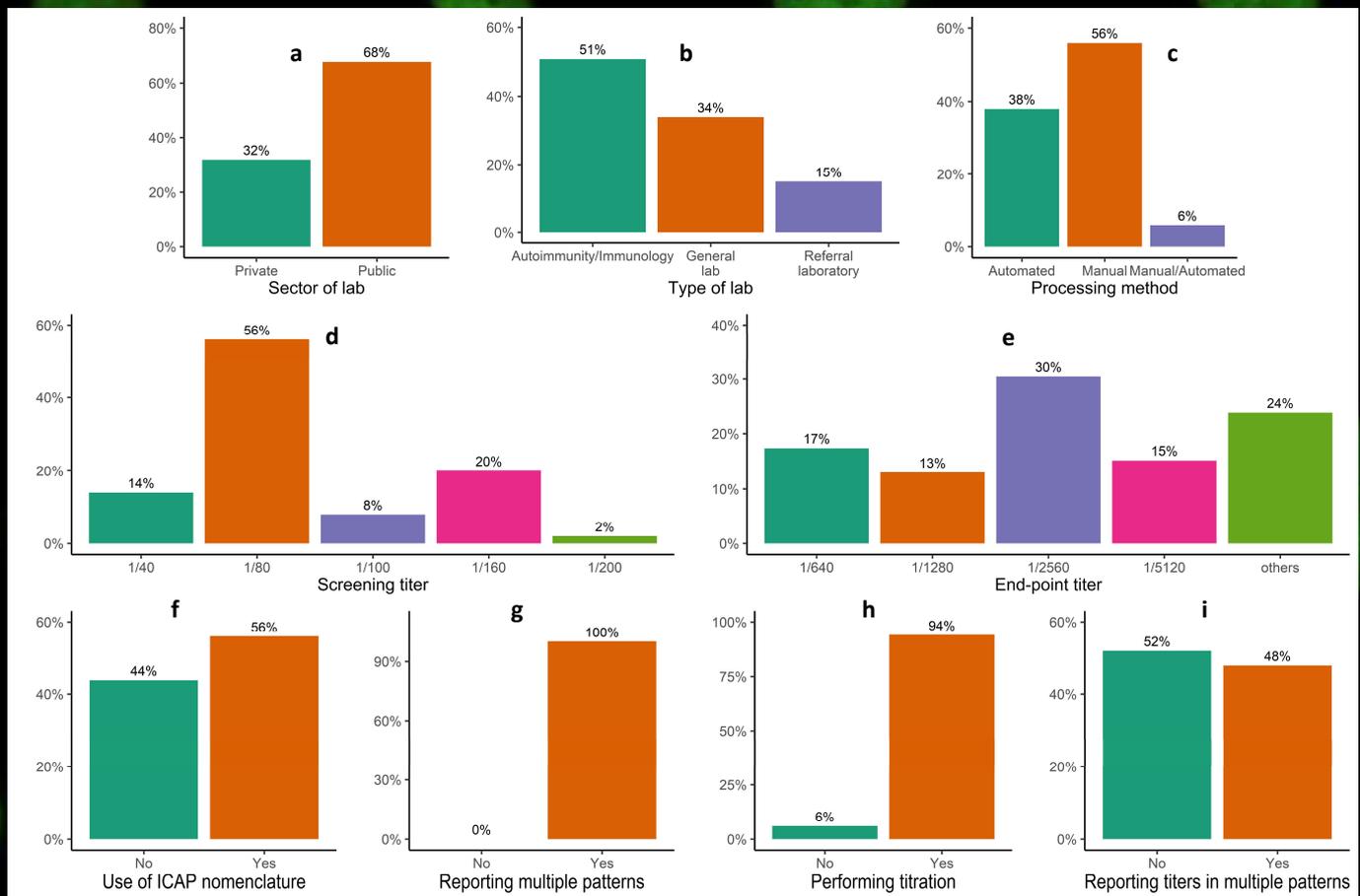


Figure 1. Distribution of laboratories according to several institutional and operational characteristics

- (a) Public or private laboratory: Most participating laboratories belong to the public sector.
- (b) Specialty versus general laboratory: Half were Autoimmunity/Immunology laboratories.
- (c) Processing method: Half are processing the slides manually. Only a few assumed to use both methods: automated and manual.
- (d) Screening titer: Most frequent report is 1/80, followed by 1/160. Other dilutions were reported by a few laboratories.
- (e) End-point titer: Diversity of reported end-point titers, being the 1/2560 the most frequent used as end-point titer.
- (f) Use of ICAP nomenclature: Approximately half of the participating laboratories are using ICAP nomenclature in their reports.
- (g) Reporting multiple patterns: All the laboratories assumed to report multiple patterns (sometimes just like an observation/note).
- (h) Performing titrations: Almost all of the laboratories do perform dilutions on positive samples.
- (i) Reporting titers in multiple patterns: In case of more than one pattern only half of the laboratories reported both titers.

Preliminary conclusions

The HEp-2 IFA test is a worldwide used method for screening for autoantibodies against a host of cellular antigens. However, there is considerable variability on how results are obtained and reported in different laboratories. Part of the heterogeneity derives from the diversity of HEp-2 slide brands with inherent differences in the methods of cell culture, fixation, permeabilization, as well as particularities in fluorescent conjugate and buffers. The present results add operational aspects that contribute to the heterogeneity in results, including heterogeneity in the screening and end-titer dilutions, manual versus automated processing, and nomenclature of patterns.

These results emphasize the need for improvement in standardization and harmonization in the operational processing and reporting strategy of the HEp-2 IFA test.