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Assessing the Proportion of Clinical Trial Eligibility Criteria Expressible with Standard EHR Data Elements

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Abstract. Patient recruitment for clinical trials often requires substantial human effort and experiences delays, leading to increased drug development costs. Leveraging electronic health records (EHRs) may improve the accuracy of estimates of potentially recruitable patients. We evaluated the feasibility of using EHRs by analyzing the proportion of computable eligibility criteria.

1. Introduction

Clinical trials are essential for developing new drugs and establishing evidence for new treatment guidelines. However, patient recruitment often requires substantial human effort, and patient enrollment may not proceed as anticipated, potentially causing delays in clinical trial schedules leading to increased drug development costs [1-2].

One key factor contributing to enrollment delays is the difficulty in accurately estimating the number of potentially recruitable patients [3]. With the widespread adoption of electronic health records (EHRs), leveraging EHR data is expected to improve the accuracy of those estimates, potentially reducing delays and human effort.

Our study aims to evaluate the feasibility of extracting eligible patients through clinical data searches by determining what proportion of trial eligibility criteria can be utilized in such searches.

2. Methods

We selected 12 diseases expected to have a high frequency of clinical trials in the future. For each disease, 5 clinical trials were identified, and eligibility criteria were extracted from these trials.

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Each criterion was evaluated whether it was sufficient to determine eligibility using EHR data. Instead of using actual EHR data, we assessed computability by checking whether each criterion matched standard EHR data elements (HL7 Version 2.5). Criteria with corresponding standard data elements that could determine eligibility were classified as "computable." Those without corresponding data elements, or where the data alone could not determine eligibility, were classified as "non-computable." We then calculated the proportion of computable criteria for each trial and disease.

To compare computability rates, we categorized the eligibility criteria. For this study, we developed a new set of categories based on previous research classifications.

3. Results & Discussion

From 60 clinical trials, 975 eligibility criteria were extracted. Of these, 462 (47.4%) were classified as "computable." The eligibility criteria were grouped into 23 categories.

Differences in computability rates were more pronounced across categories than across diseases. Criteria related to medications, laboratory data, and diagnoses had high computability rates, whereas descriptive criteria, such as those related to disease pathology or treatment history, had lower rates. These findings suggest that the feasibility of identifying eligible patients from clinical data depends heavily on the type of eligibility criteria and their relevance for determining eligibility.

In this study, we used standard data elements from HL7 Version 2.5 for EHR data, as this format is used in our hospital. Using other standardized data formats, including the OMOP Common Data Model and HL7 FHIR, could lead to similar results. However, converting EHR data into certain formats is additional processing, which would be challenging for many healthcare institutions to perform in routine practice.

4. Conclusion

The overall average computability rate of eligibility criteria was approximately 50%, with substantial variation depending on the disease and criterion category. Clinical trials that rely heavily on computable criteria—such as medications, laboratory data, or diagnoses—are more likely to benefit from using EHR data to identify eligible patients. Future research will focus on validating the feasibility of identifying and narrowing down eligible patients using actual clinical data.

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