CHARTing a Path to Pragmatic Tobacco Treatment Research

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Introduction: It is important to consider the degree to which studies are explanatory versus pragmatic to understand the implications of their findings for patients, healthcare professionals, and policymakers. Pragmatic trials test the effectiveness of interventions in real-world conditions; explanatory trials test for efficacy under ideal conditions. The Consortium of Hospitals Advancing Research on Tobacco (CHART) is a network of seven NIH-funded trials designed to identify effective programs that can be widely implemented in routine clinical practice.

Methods: A cross-sectional analysis of CHART trial study designs was conducted to place each study on the pragmatic–explanatory continuum. After reliability training, six raters independently scored each CHART study according to ten PRagmatic Explanatory Continuum Indicator Summary (PRECIS) dimensions, which covered participant eligibility criteria, intervention flexibility, practitioner expertise, follow-up procedures, participant compliance, practitioner adherence, and outcome analyses. Means and SDs were calculated for each dimension of each study, with lower scores representing more pragmatic elements. Results were plotted on "spoke and wheel" diagrams. The rating process and analyses were performed in October 2014 to September 2015.

Results: All seven CHART trials tended toward the pragmatic end of the spectrum, although there was a range from 0.76 (SD=0.23) to 1.85 (SD=0.58). Most studies included some explanatory design elements.

Conclusions: CHART findings should be relatively applicable to clinical practice. Funders and reviewers could integrate PRECIS criteria into their guidelines to better facilitate pragmatic research. CHART study protocols, coupled with scores reported here, may help readers improve the design of their own pragmatic trials.

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Introduction

Few hospitals treat tobacco dependence, possibly owing to a lack of practical strategies for integrating treatment into clinical practice.[1] The Consortium of Hospitals Advancing Research on Tobacco (CHART) consisted of seven studies focused on implementing tobacco treatment into hospital care across a geographically diverse group of nearly 20 private,

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public, academic, and community hospitals in the U.S.[1] Pragmatic trials deliver interventions under real-world conditions to all typical patients, to inform decision makers whether an intervention can and should be adopted into clinical practice. An explanatory trial is a highly controlled study in a selective population that gives a new intervention its best chance at demonstrating a beneficial effect.[2–5] Pragmatic trials are increasingly important to funders, providers, and healthcare systems in general to provide information about how to improve the quality of clinical practice. The present study describes the pragmatic—versus explanatory—nature of the CHART trials.

Methods

Study Design and Participants

The study was conducted from October 2014 to September 2015. Five of the projects were two-arm RCTs comparing active interventions to usual care[6–10]; one used a factorial design to test the effects of two different interventions alone and in combination[11]; and the last used group randomization procedures to assign hospitals to intervention and control conditions.[12] Some interventions were initiated during hospitalization,[6,12] but most were delivered post-discharge.[10,11] Table 1 provides study details.[12]

Measures

Assessment employed the following ten PRagmatic Explanatory Continuum Indicator Summary (PRECIS) dimensions[13]:

1. eligibility criteria;
2. flexibility of the experimental intervention;
3. practitioner expertise in experimental intervention;
4. flexibility of the comparison condition;
5. practitioner expertise in comparison intervention;
6. follow-up intensity;
7. measured outcomes;
8. participant compliance;
9. practitioner adherence; and
10. primary analysis.

Unlike the original PRECIS tool, which had no discrete rating scores,[13] raters could score each dimension from 0 (*completely pragmatic*) to 4 (*completely explanatory*). Scores were displayed as a "wheel" charted on spokes that represent each design dimension[13]—also known as a "pragmascope." Trials that took a more explanatory approach produced small wheels close to the "hub"; more-pragmatic trials produced larger wheels.

Data Collection and Management

Eleven researchers involved with the CHART studies served as raters. Ratings were based on published CHART protocol papers.[1,3–9] Raters were trained following procedures used by Glasgow et al.[14] Raters read an article on PRECIS concepts and criteria[13]; reviewed an updated slide presentation on how to apply criteria (outlined in Appendix, available online); and as a group discussed how to complete the PRECIS rating form. To enhance reliability, all 11 raters independently scored three study protocols, discussed the results, and altered the scoring form to improve usability. Then, raters used the final PRECIS form (Appendix, available online) to independently score all protocols, including the three protocols used for reliability training. Six raters scored each protocol. The final form included an "insufficient information" ("II") code for instances in which there was too little information to assign a score.

Statistical Analysis

Mean scores were calculated for each dimension of each study. Means were plotted on spoke-and-wheel diagrams. Only five of 420 dimension ratings were coded "II." In these cases, missing data were replaced with the mean of the other five scores on that dimension. The overall PRECIS score for each study was calculated by summing the means of the ten dimensions and dividing by 10; SDs were also calculated to describe the variability in scores.

Results

Table 2 displays PRECIS mean scores and SDs by site. All CHART trials tended to the pragmatic end of the spectrum with means closer to 0 than 4. Michigan had the lowest mean (0.76 [SD=0.23]), and New York the highest (1.85 [SD=0.58]). Other studies' means ranged between 1 and 2. Raters closely agreed on scores, with four trials displaying a range of <1 point (Kansas, Michigan, California, and Alabama).

Table 2 also displays the mean scores of each PRECIS dimension by site. Most studies had a mix of explanatory and pragmatic design elements. Common explanatory elements (with a mean ≥ 2) included specially trained practitioners for the experimental intervention, close adherence to study protocols, and intensive follow-up attempts to contact participants. These same protocols, however, employed a number of pragmatic features (with a mean <2) such as flexible comparison interventions and highly pragmatic primary outcome analyses. Two studies (Michigan and California) used hospital employees rather than research staff to deliver the comparison condition and used no external procedures to verify participant compliance, which rendered these sites highly pragmatic on these dimensions.

Figure 1 depicts a color-coded PRECIS spoke-and-wheel diagram for all seven studies. Congruent with their low mean scores, Michigan and California displayed the most pragmatic diagrams and New York the most explanatory diagram. There was strong concurrence across all of the trials on the Primary Analysis dimension (individual site diagrams in Appendix, available online). Interestingly, principal investigators tended to score their