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CHART-ing a Path to Pragmatic Tobacco Treatment Research

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Abstract

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.

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EC oversaw all aspects of the study, completed the first draft of the manuscript, collected feedback and approval from all authors, and submitted the final version of the manuscript. All other authors (KPR, CS, SD, JF, KFH, NR, SS, HAT, TIS, SD, SW, SEC) assisted with study design, served as raters, assisted with drafts of the manuscript, and approved the final manuscript.

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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.

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, 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 combination¹¹; 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) dimensions¹³:

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 dimension¹³—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), 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) 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). Interestingly, principal investigators tended to score their own trials as more explanatory, compared with the mean scores of other raters (data not shown).

Discussion

The CHART studies, similar to the smoking-cessation trial evaluated by Selby and colleagues,¹⁵ tended toward the pragmatic end of the spectrum, suggesting high applicability to clinical practice. Principal investigators tended to score their own studies as more explanatory, which differed from an earlier study, which found that principal investigators tended to rate their studies as more pragmatic compared with other raters.¹⁴ Three design features—what staff were used to deliver the interventions, strict following of study protocols, and aggressive follow-up of participants—tended toward ideal conditions rather than usual care conditions. These design domains represent good targets for research translation in the field of tobacco treatment studies. For example, instead of trained study counselors or even specialized hospital-based tobacco treatment staff, investigators could use existing clinical staff to apply interventions.

In addition, funding agencies and grant reviewers that seek to support more-pragmatic research will have to critically review their assumptions. Some of the more explanatory design features of CHART (such as training practitioners and assessing the fidelity of intervention delivery) were actually required by the request for applications. Funders who are crafting calls for proposals should consider using PRECIS criteria to evaluate their grant requirements and review criteria. When funding pragmatic trials is the goal, review panels

should be trained in pragmatic trial design and reminded of those design features throughout the review process.

Limitations

Raters included investigators involved with the CHART studies—independent raters may have provided a more objective evaluation of the study designs. A next-generation measure—PRECIS-2—was published in May 2015,¹⁶ midway through study analyses. It was not possible to switch rating tools. Although great deal of overlap exists between the original and newer PRECIS measures, future studies should use PRECIS-2.

Conclusions

The CHART trials included a number of pragmatic features but fell short of completely pragmatic designs on several key domains. In the future, highly pragmatic trials may routinely be conducted as a part of ongoing clinical care, facilitated by “learning healthcare systems” that can use clinical data to evaluate care innovations in real time.¹⁷ Until then, free-standing trials designed according to PRECIS-2 principles, as illustrated by Johnson et al.,¹⁸ can provide important models for how investigators who are aiming for highly applicable studies should design and conduct their own investigations.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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References

1. Riley WT, Stevens VJ, Zhu SH, Morgan G, Grossman D. Overview of the Consortium of Hospitals Advancing Research on Tobacco (CHART). *Trials*. 2012; 13:122. <http://dx.doi.org/10.1186/1745-6215-13-122>. [PubMed: 22852768]
2. Maclure M. Explaining pragmatic trials to pragmatic policy-makers. *CMAJ: Canadian Medical Association Journal*. 2009; 10(180):1001–1003. <http://dx.doi.org/10.1503/cmaj.090076>.
3. Karanickolas PJ, Montori VM, Devereaux PJ, Schunemann H, Guyatt GH. The practicalists' response. *J Clin Epidemiol*. 2009; 62(5):489–494. <http://dx.doi.org/10.1016/j.jclinepi.2008.08.013>. [PubMed: 19348974]
4. Oxman AD, Lombard C, Treweek S, Gagnier JJ, Maclure M, Zwarenstein M. Why we will remain pragmatists: four problems with the impractical mechanistic framework and a better solution. *J Clin Epidemiol*. 2009; 62(5):485–488. <http://dx.doi.org/10.1016/j.jclinepi.2008.08.015>. [PubMed: 19348973]
5. Rothwell PM. External validity of randomised controlled trials: “To whom do the results of this trial apply?”. *Lancet*. 2005; 365(9453):82–93. [http://dx.doi.org/10.1016/S0140-6736\(04\)17670-8](http://dx.doi.org/10.1016/S0140-6736(04)17670-8). [PubMed: 15639683]

6. Richter KP, Faseru B, Mussulman LM, et al. Using “warm handoffs” to link hospitalized smokers with tobacco treatment after discharge: study protocol of a randomized controlled trial. *Trials*. 2012; 13:127. <http://dx.doi.org/10.1186/1745-6215-13-127>. [PubMed: 22853047]
7. Japuntich SJ, Regan S, Viana J, et al. Comparative effectiveness of post-discharge interventions for hospitalized smokers: study protocol for a randomized controlled trial. *Trials*. 2012; 13:124. <http://dx.doi.org/10.1186/1745-6215-13-124>. [PubMed: 22852832]
8. Grossman E, Shelley D, Braithwaite RS, et al. Effectiveness of smoking-cessation interventions for urban hospital patients: study protocol for a randomized controlled trial. *Trials*. 2012; 13:126. <http://dx.doi.org/10.1186/1745-6215-13-126>. [PubMed: 22852878]
9. Fellows JL, Mularski R, Waiwaiole L, et al. Health and economic effects from linking bedside and outpatient tobacco cessation services for hospitalized smokers in two large hospitals: study protocol for a randomized controlled trial. *Trials*. 2012; 13:129. <http://dx.doi.org/10.1186/1745-6215-13-129>. [PubMed: 22853325]
10. Harrington KF, McDougal JA, Pisu M, et al. Web-based smoking cessation intervention that transitions from inpatient to outpatient: study protocol for a randomized controlled trial. *Trials*. 2012; 13:123. <http://dx.doi.org/10.1186/1745-6215-13-123>. [PubMed: 22852802]
11. Cummins S, Zhu SH, Gamst A, et al. Nicotine patches and quitline counseling to help hospitalized smokers stay quit: study protocol for a randomized controlled trial. *Trials*. 2012; 13:128. <http://dx.doi.org/10.1186/1745-6215-13-128>. [PubMed: 22853197]
12. Duffy SA, Ronis DL, Titler MG, et al. Dissemination of the nurse-administered Tobacco Tactics intervention versus usual care in six Trinity community hospitals: study protocol for a comparative effectiveness trial. *Trials*. 2012; 13:125. <http://dx.doi.org/10.1186/1745-6215-13-125>. [PubMed: 22852834]
13. Thorpe KE, Zwarenstein M, Oxman AD, et al. A pragmatic-explanatory continuum indicator summary (PRECIS): a tool to help trial designers. *J Clin Epidemiol*. 2009; 62(5):464–475. <http://dx.doi.org/10.1016/j.jclinepi.2008.12.011>. [PubMed: 19348971]
14. Glasgow RE, Gaglio B, Bennett G, et al. Applying the PRECIS criteria to describe three effectiveness trials of weight loss in obese patients with comorbid conditions. *Health Serv Res*. 2012; 47(3 Pt 1):1051–1067. <http://dx.doi.org/10.1111/j.1475-6773.2011.01347.x>. [PubMed: 22092292]
15. Selby P, Brosky G, Oh PI, Raymond V, Ranger S. How pragmatic or explanatory is the randomized, controlled trial? The application and enhancement of the PRECIS tool to the evaluation of a smoking cessation trial. *BMC Med Res Methodol*. 2012; 12:101. <http://dx.doi.org/10.1186/1471-2288-12-101>. [PubMed: 22824225]
16. Loudon K, Treweek S, Sullivan F, Donnan P, Thorpe KE, Zwarenstein M. The PRECIS-2 tool: designing trials that are fit for purpose. *BMJ*. 2015; 350:h2147. <http://dx.doi.org/10.1136/bmj.h2147>. [PubMed: 25956159]
17. Smith, M.Saunders, R.Stuckhardt, L., McGinnis, JM., editors. Best care at lower cost: The path to continuously learning health care in America. Washington, DC: The National Academies Press; 2013. Introduction and overview.
18. Johnson KE, Neta G, Dember LM, et al. Use of PRECIS ratings in the National Institutes of Health (NIH) Health Care Systems Research Collaboratory. *Trials*. 2016; 17(1):32. <http://dx.doi.org/10.1186/s13063-016-1158-y>. [PubMed: 26772801]

Figure 1. Pragmatic-explanatory continuum indicator summary (PRECIS) "spoke and wheel" diagram of CHART studies, color-coded by site.

Description of Consortium of Hospitals Advancing Research on Tobacco (CHART) Studies.

Table 1

Site	Target patient population ^a	Intervention	Intervention delivered by	Comparison	Comparison delivered by	Evaluation intensity
Michigan	English speakers; willing to complete questionnaires. Exclusion: patients with hospital stay of less than 24 hours; involved in a concurrent smoking cessation trial; are unavailable to participate; are not cognitively or physically able to participate	Manual-driven "Tobacco Tactics" with post-discharge phone support	Hospital nurses; volunteers for phone support	Smoking cessation bedside advice/counseling (usual care)	Hospital staff	Moderate—multiple calls
California	English/Spanish speakers; provide sufficient contact information for intervention; physician approval. Exclusions: not planning/trying to stay quit at discharge; patients smoking <6 cigarettes per day; anticipated hospital stay of less than 24 hours; pregnant; unable to communicate	3 intervention arms: 1 NRT 2 2 Quitline 3 NRT + Quitline	Respiratory therapists and nurses; quitline staff	Brief bedside intervention + nicotine patches	Hospital staff; Respiratory therapists or nurses	Moderate—up to 30 calls
Alabama	English speakers/readers. Exclusions: no email or Internet; pregnant or breastfeeding; in palliative care, psychiatric or some intensive care units; another household member in study; significant co-morbidity (acute illness, communication barriers)	Post-discharge interactive web-based program with tailored information, group support, text messages, and phone calls	Hospital tobacco treatment staff; automated web system	Inpatient tobacco cessation consult and booklet (usual care)	Hospital tobacco treatment staff or Lung Health Center staff	Intensive—Multiple calls to main + alternate phones, mailed reminders
Oregon	English speakers; willing to attend in person follow-up visit. Exclusions: not planning/trying to stay quit at discharge; no phone; lives > 50 miles of hospital; pregnant/breastfeeding; psychiatric patients; admitted to a critical care or labor unit; significant co-morbidity (acute illness, communication barriers)	Post-discharge interactive voice response (IVR) system integrated with hospital systems	Hospital tobacco treatment staff; IVR system	Inpatient tobacco cessation consult and a printed information (usual care)	Hospital tobacco treatment staff	Intensive—Multiple calls to main + alternate phones, mailed reminders
Kansas	English/Spanish speakers. Exclusions: not planning/trying to stay quit at discharge; no phone; planning to move within 6 months; another family member in study; pregnant or breastfeeding; significant co-morbidity (acute illness, communication barriers)	In-hospital warm handoff to state quitline	Hospital tobacco treatment staff; quitline staff	Fax referral to quitline post-discharge	Hospital tobacco treatment staff; quitline staff	Moderate—multiple calls, including alternate phones

Site	Target patient population ^a	Intervention	Intervention delivered by	Comparison	Comparison delivered by	Evaluation intensity
Massachusetts	English speakers. Exclusions: not planning/trying to stay quit at discharge; no phone; pregnant; substance abuse; unwilling to accept medication; already received hospital cessation intervention; significant comorbidity (acute illness, communication barriers)	Post-discharge IVR assisted phone counseling; cessation medication	Hospital tobacco treatment staff; physicians prescribed medications; IVR; research counselors	Inform about counseling resources, recommend discharge medication (usual care)	Hospital tobacco treatment staff	Intensive-Multiple calls to main + alternate phones, mailed reminders
New York	English/Spanish/Mandarin speakers. Exclusions: no phone; pregnant or breastfeeding; discharged to an institution (jail, prison, nursing home, psychiatric facility)	Post-discharge multi-session telephone counseling; cessation medications	Highly trained study staff for counseling; physicians and nurses prescribed medications	Referral to state quitline	Quitline staff; physicians and nurses prescribed medications	Intensive-Multiple efforts to mail; three calls attempted + alternate phones, emailed reminders

^a All studies required participants to be 18 years of age; smoked cigarettes in past 30 days.

NRT, nicotine replacement therapy.

Pragmatic-Explanatory Continuum Indicator Summary (PRECIS) Scores for Studies, by Site and PRECIS Dimension

Table 2

Dimension	Site						
	Michigan, M (SD)	California, M (SD)	Alabama, M (SD)	Oregon, M (SD)	Kansas, M (SD)	Massachusetts, M (SD)	New York, M (SD)
Participant eligibility	1.2 (1.0)	1.7 (0.8)	1.3 (0.5)	2.2 (0.7) ^a	1.8 (0.7)	2.2 (0.4) ^a	0.8 (0.4)
Flexibility of experimental intervention	1.3 (0.8)	1.0 (0.6)	1.8 (0.7)	1.3 (0.8)	2.0 (0.0) ^a	1.8 (0.9)	2.2 (0.7) ^a
Practitioner expertise (experimental intervention)	0.8 (0.7)	0.7 (0.8)	2.0 (0.6) ^a	2.3 (0.8) ^a	1.7 (1.0)	2.2 (0.9) ^a	3.0 (0.9) ^a
Flexibility of comparison intervention	0.0 (0.0)	0.4 (0.8)	0.5 (0.5)	1.0 (0.9)	2.0 (0.6) ^a	1.0 (0.9)	1.7 (1.0)
Practitioner expertise (comparison intervention)	0.2 (0.4)	0.2 (0.4)	1.0 (0.9)	1.8 (0.9)	1.5 (0.8)	1.8 (1.5)	1.8 (1.3)
Follow-up intensity	1.0 (0.6)	1.3 (0.5)	2.5 (1.0) ^a	2.2 (0.4) ^a	1.8 (0.7)	2.2 (1.2) ^a	2.3 (1.0) ^a
Primary outcome	1.0 (0.6)	0.8 (0.7)	1.8 (0.4)	1.7 (0.8)	1.2 (0.7)	2.0 (0.9) ^a	1.2 (0.7)
Participant compliance	0.3 (0.5)	1.0 (0.0)	1.5 (1.4)	1.7 (0.8)	1.7 (0.8)	1.3 (0.5)	2.1 (0.9)
Practitioner adherence to protocol	1.3 (0.5)	1.3 (0.8)	2.0 (0.9) ^a	2.0 (0.6) ^a	2.5 (0.8) ^a	1.8 (0.7)	2.3 (0.8) ^a
Outcome measures	0.5 (0.5)	0.3 (0.5)	1.2 (0.9)	0.4 (0.8)	0.7 (0.5)	1.2 (0.7)	1.0 (0.6)
Site, μ (SD)	0.7 (0.23)	0.8 (0.3)	1.5 (0.3)	1.6 (0.4)	1.6 (0.3)	1.7 (0.6)	1.8 (0.5)
Site minimum/maximum	0.4 (1.0)	0.5 (1.3)	1.0 (2.0)	1.0 (2.1)	1.2 (2.1)	0.9 (2.7)	1.0 (2.5)

Note: 0=completely pragmatic; 4=completely explanatory.

^aScores 2–tend toward the exploratory end of the spectrum.