Implementation Science: Applying CONSORT Standards when Reporting Research Results within the Context of a PBRN

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BACKGROUND

- Health IMPACTS for Florida is a PBRN collaboratively developed by the University of Florida and Florida State University College of Medicine.
- One of the two initial pilot projects was an intervention study designed to improve the frequency and quality of health risk assessments (HRAs) with adolescent patients in primary care settings.
- This intervention was designed to (1) reduce the time the provider spent administering the HRA and (2) improve the quality of the discussion by presenting a summary of the HRA.
- Framing this research using recommended CONSORT standards traditionally used for reporting randomized clinical trials may help PRN researchers organize and present their findings in a way that highlights both the advantages and limitations of the intervention.
- Limitations: an intervention in real-world clinical settings often has to forego the strict controls on recruitment and adherence to study protocols that are typically found in randomized clinical trials. Reporting of response rates may appear too low for journal publications.
- Advantages: ecological validity. Demonstrating that an intervention can be successful in a typical clinical setting has the ability to improve quality of care and patient outcomes.

METHODS

- Basic Study Design:
  - Primary care practices in four geographic areas of North and Central Florida were approached about participating in the Health IMPACTS for Florida PBRN and the HRA study.
  - Eligible adolescents were 14-18 years old.
- The intervention was the use of novel software to administer the HRA via IPad and to summarize the results for the primary care providers and participants. Summaries included risk information related to self-reported risk-taking behaviors that were found in the adolescent’s home zip code.
- Adolescents at the two comparison clinics were recruited into the study using the IPads, but these adolescents reported only demographic items and received usual care, which could have included an HRA.
- Intervention Evaluation:
  - Although the primary outcome of this study was the feasibility of developing a PBRN, the study intervention was evaluated using the Young Adult Health Care Survey (YAHCS) to assess adolescents' perceptions of quality of care.
  - Participants from both study groups completed the YAHCS via telephone within 6-8 weeks.
- A mixed-model accounting for within-clinic correlation and unequal numbers of participants per clinic was fitted separately for each of the eight YAHCS quality domains.
- The final set of predictors, chosen prior to inclusion, were gender, age, and intervention.
- Adolescents receiving the intervention reported higher levels of confidential and private care and higher levels of screening on emotional health and relationship issues compared to adolescents receiving the comparison clinics who received self-adjusted scores 0.42 vs. 0.08 out of 1.0, p<0.01; 0.85 vs. 0.57, p<0.01, respectively.

RESULTS

- Challenges Encountered When Completing the CONSORT Flow Diagram:
  - Practices were recruited differently in the four geographic regions (Tallahasee, Jacksonville, Gainesville, and Orlando, FL).
  - Start data for implementation of the HRA study were staggered.
  - The vendor for the telephone follow-up survey was only contracted to conduct the YAHCS for three months.
  - Some practices conducted shortened versions of the HRA and YAHCS.
  - For the final YAHCS analysis, there were exclusions at each level of the CONSORT flow diagram.
- Exclusions were due to small numbers of respondents in the following categories: (1) two of the four geographic regions; (2) respondents to the short form, and (3) respondents reporting ‘other’ for race/ethnicity.
- Individual practices and individual practices were allowed to opt out.
- Initially, the flow diagram included all practices and participants and identified and quantified all exclusions. For simplicity:
  - The flow diagram was amended to include only those geographic areas and practices that contributed to the final dataset.
  - Discussion of the overall study design was simplified and restricted to the methods section.

CONCLUSIONS

- Applying CONSORT standards when communicating research findings in real-world PBRN studies can be challenging but they should still be used as a gold standard to produce the most quality scientific discovery. The challenge lies in addressing each CONSORT item in a meaningful way that is both honest and straightforward.
- The CONSORT standards were developed for randomized clinical trials requiring strict adherence to all elements of a study protocol. Implementing interventions in real-world settings requires many minor, situational modifications which can make writing methodology sections for academic publications difficult. Using CONSORT standards guide the development of the methodology section to include sufficient information to provide an honest accounting of the research activities while avoiding becoming overly detailed and confusing.
- Researchers should review CONSORT recommendations during the study design phase to ensure that a sufficient plan is in place prior to beginning data collection to gather all the required information.

PRACTICAL IMPLICATIONS

- Study teams should include a team member with a high level of experience working with data and intimate knowledge of the research design.
- Complete the CONSORT Flow Diagram to ensure that the flow diagram requires a high level of attention to detail that ultimately results in a high level of confidence in the data analysis and study conclusions.
- Adherence to implementation science protocols within the setting of a diverse PBRN can be demanding. Reporting research results, investigators need to be honest about study limitations and stress the importance of the validity of their findings. Finding statistically significant differences between study groups can often limit the interpretation of the data.
- Researchers working in community-based PBRNs that encounter issues with protocol adherence and response rate may need to explain their work carefully when submitting their work for publication. Manuscript reviewers need to understand that the level of adherence may be lower than what is expected with randomized clinical trials. Further, some journals will systematically reject manuscripts when a response rate is deemed too low. Researchers should address these issues when preparing a manuscript for submission to an academic journal.

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