

Structured Process Informed by Data, Evidence and Research (SPIDER) framework

Eight legs of success for running projects in primary care practices

Michelle Greiver MSc MD CCFP FCFP Simone Dahrouge MSc PhD Donna P. Manca MD MClSc CCFP FCFP
Alexander G. Singer MB BAO BCH FCFP Celine Jean-Xavier PhD Leanne Kosowan Himasara Pathiraja MScPH
Mathew Grandy MD CCFP Marie-Thérèse Lussier MD MSc CCMF FCMF Kris Aubrey-Bassler MD MSc CCFP(EM) FCFP
Trish O'Brien RN MScCH Marie Authier PhD Rubee Dev MPH PhD Stephanie Garies PhD

Effective teamwork and management are crucial for the success of projects in primary care practices. Research projects benefit from guidance and evidence relevant to good management practices.^{1,2} These evidence-based recommendations can be applied to primary care projects ranging from small-scale quality improvement (QI) initiatives to large collaborative international research studies.

The framework presented in this article is an approach to effectively managing clinical studies in primary care practices. It was applied using lessons learned as part of the Structured Process Informed by Data, Evidence and Research (SPIDER)³ randomized controlled trial (RCT), which aimed to improve care for elderly patients living with polypharmacy. SPIDER was a large practice-based pragmatic RCT conducted in primary care practices across Canada.³

We outline 8 recommendations for successful implementation of projects in primary care practices. These lessons can be adapted to smaller initiatives with fewer resources. For smaller projects, it may be necessary to streamline processes, prioritize recommendations, and leverage existing resources efficiently.

Administrative excellence

The cornerstones of any successful clinical study are robust administrative and management processes. Ensuring the project team has members with the skills, support, and time to implement these processes is crucial.

Excellence includes effective centralized maintenance and versioning of protocols, following data management plans, implementing communication strategies to inform relevant people of decisions, and following up appropriately.^{4,5}

Central coordination

A central research coordinator or project manager plays a pivotal role in the success of a clinical study. Ideally, the coordinator should also belong to a group such as an academic department; being a member enables sharing of expertise and experience between coordinators in different projects and can provide professional development opportunities.⁴ The central coordinator may support local coordinators if a project is distributed across multiple settings, as was the case for SPIDER.

This individual should possess specific competencies encompassing data collection and management; data quality monitoring and reporting; managing budgets; and organizing and documenting meetings relevant to the project, or being able to delegate and monitor these tasks. The coordinator should have sufficient knowledge and experience to make certain decisions independently and recognize when to involve the project leaders or other team members.

Teaming

The concept of “teaming,” as described by Dr Amy C. Edmondson,⁶ emphasizes the importance of communication, flexibility, and collaboration in fast-moving environments. Psychological safety, trust, and mutual accountability are key to this: team members working in traditionally hierarchical roles must feel able to freely communicate when there is a benefit for the project. For example, a medical office assistant could have a quick conversation with a physician when an office policy does not work well for patients of the practice.

Continuity and documentation

Maintaining continuity in coordination and management is essential, especially in the face of personnel turnover. This can be achieved through detailed documentation and clear processes. Providing written guidance for administration to personnel in other teams or regions collaborating with the central team, such as to-do lists with timelines and coordinator guides, ensures everyone is on the same page and can continue the work seamlessly.

Engaged leadership

Engaging leadership through a clear governance structure and process is vital for guiding the project.⁷ The project's leads can enable the culture of psychological safety and high expectations of each other that are critical to teaming. The leaders are also responsible for establishing and managing a team with diverse perspectives, including patient partners, clinic managers, researchers, study personnel, and clinicians. Diversity enriches the study and ensures all relevant viewpoints are considered. The leaders will also be responsible for establishing risk management strategies, including regular risk assessments and conflict resolution mechanisms.

Protocol fidelity

Each project should have a protocol outlining key elements of the project that is drafted early in the project conceptualization period and then revised as necessary. Protocols outline areas where rigid adherence is needed, and areas where flexibility to fit the clinic's context is allowed. Ensuring fidelity to mandatory elements during the study conduct is critical. This involves practising consistent and reliable data management, collection, and quality assurance. Regular auditing, site visits (which can be virtual), and collecting and reporting information on study activities helps maintain protocol fidelity. We recommend using reliable, proven, and user-friendly software for data management, such as REDCap, Qualtrics, or Microsoft SharePoint.

Auditing is part of a comprehensive evaluation strategy involving regular performance reviews, feedback loops, and outcome assessments.


Ethical and privacy compliance

Research projects require research ethics board (REB) approval before initiation, while QI initiatives generally do not. Rules are available to distinguish the 2; for example, the University of Alberta's Research Ethics Office has published guidelines on differentiating research, program evaluation, and QI.⁸ Understanding and adhering to different REB rules and provincial privacy legislation is crucial to avoid risks. For multisite research projects, starting with REB approval at the main site and then applying to required REBs at participating jurisdictions ensures compliance. Initiatives facilitating multisite REB review, such as Clinical Trials Ontario (<https://ctontario.ca>), should be explored if relevant to the project. Awareness of provincial privacy laws and potential risks to data custodians is essential to protect the project and its participants.

Engaging practices and providers

Engaging practices and providers is key to the success of clinical research and QI projects. Grants can include funds to compensate participating health care providers and practices; project personnel can provide study-related work for the practice (eg, mailing letters to patients) to reduce the burden on clinics.

Conclusion

The SPIDER framework provides guidance for managing clinical studies effectively. Tools can be found at <https://www.spiderdeprescribing.com/deprescribing-tools-1>. These lessons are applicable to large national studies and can be adapted to smaller-scale projects, ensuring that projects in primary care practices are well managed and impactful. 

Dr Michelle Greiver is a family physician, Professor in the Department of Family and Community Medicine at the University of Toronto in Ontario, and Principal Investigator for Structured Process Informed by Data, Evidence and Research (SPIDER). **Dr Simone Dahrouge** is Associate Professor and Scientist in the Department of Family Medicine and in the School of Epidemiology and Public Health at the University of Ottawa in Ontario. **Dr Donna P. Manca** is Professor Emeritus, Director of Quality Improvement, and Director of the Northern Alberta Primary Care Research Network in the Department of Family Medicine at the University of Alberta in Edmonton. **Dr Alexander G. Singer** is Associate Professor, Director of the Office of Research and Quality Improvement, and Director of the Manitoba Primary Care Research Network in the Department of Family Medicine at the University of Manitoba in Winnipeg. **Dr Céline Jean-Xavier** is Research Officer of the Practice- and Community-Based Learning and Research Network in the Department of Family and Community Medicine at the University of Toronto. **Leanne Kosowan** is Research Manager of the Canadian Primary Care Research Network and Manager of the Manitoba Primary Care Research Network. **Himasara Pathiraja** is Research Associate in the Department of Family Medicine in the Cumming School of Medicine at the University of Calgary in Alberta and in the Southern Alberta Primary Care Research Network (SAPCRen). **Dr Mathew Grandy** is Network Director of the Maritime Family Practice Research Network in the Department of Family Medicine at Dalhousie University in Halifax, NS. **Dr Marie-Thérèse Lussier** is Full Professor in the Department of Family Medicine and Emergency Medicine at the University of Montréal in Québec, and Scientific Director of the University of Montréal Primary Care Research Network. **Dr Kris Aubrey-Bassler** is Associate Professor and Director of the Primary Healthcare Research Unit and Acting Chair of Family Medicine at Memorial University of Newfoundland in St John's. **Trish O'Brien** is an adjunct faculty member in the Department of Family and Community Medicine at the University of Toronto and Quality Improvement Lead for SPIDER. **Dr Marie Authier** is Associate Clinical Professor in the Department of Family Medicine at the University of Montréal. **Dr Rubee Dev** is Assistant Professor in the Faculty of Applied Sciences in the School of Nursing at the University of British Columbia in Vancouver, and Co-Director of the BC Primary Health Care Research Network at the UBC Centre for Health Services and Policy Research. **Dr Stephanie Garies** is Adjunct Assistant Professor and Primary Care Scientist in the Department of Family Medicine at the University of Calgary and Co-Director of SAPCRen.

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Competing interests

None declared

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