The Canadian Journal for the Scholarship of Teaching and Learning

Volume 13 | Issue 1 Article 8

Winter 02-15-2022

Development and Evaluation of a Research Methods Course in Protocol Writing for Learners in a Master of Public Health Program

Laura Anderson
McMaster University, ln.anderson@mcmaster.ca
Sarah E. Neil-Sztramko
McMaster University, neilszts@mcmaster.ca
Elizabeth Alvarez
McMaster University, alvare@mcmaster.ca
Susan M. Jack
McMaster University, jacksm@mcmaster.ca
Lehana Thabane
McMaster University, thabanl@mcmaster.ca
Fran Scott
McMaster University, fscott@mcmaster.ca
Emma Apatu
McMaster University, apatue@mcmaster.ca

https://doi.org/10.5206/cjsotlrcacea.2022.1.10670

Recommended Citation
Anderson, L., Neil-Sztramko, S. E., Alvarez, E., Jack, S. M., Thabane, L., Scott, F., & Apatu, E. (2022). Development and evaluation of a research methods course in protocol writing for learners in a Master of Public Health program. *The Canadian Journal for the Scholarship of Teaching and Learning, 13*(1). https://doi.org/10.5206/cjsotlrcacea.2022.1.10670

Development and Evaluation of a Research Methods Course in Protocol Writing for Learners in a Master of Public Health Program

Abstract

Training in research methods is important for improvement of healthcare delivery and population outcomes. Graduate programs of public health play a critical role in offering such education to current and future healthcare professionals as well as entry level learners with no experience in the field. A key skill across all fields of research methods and public health practice is protocol writing. It is unknown if teaching students research methods through protocol writing is a successful strategy and whether students find it to be helpful as they pursue health professions. The objective of this study was to describe the design and evaluation of a research methods course focused on protocol writing among students enrolled a Masters of Public Health Program. A case report design including description of course content, method of evaluation, and course delivery are provided. The setting was the Population and Public Health Research Methods course at a publicly funded institution in Canada. The first three cohorts of students (2016-2018) enrolled in the course were evaluated during the course period and six months after completing the course. A total of 51 students completed the survey, and the majority were students were very or extremely satisfied with the course. Overall students expressed that the course well-prepared them for their practicum or thesis work and post-graduation plans. Findings suggest that using protocol writing as a tool for teaching research methods was well-received by students and prepared them for both their potential career paths and for future research.

La formation en méthodes de recherche est importante pour l'amélioration de la prestation des soins de santé et les résultats des populations. Les programmes d'études supérieures en santé publique jouent un rôle essentiel dans la prestation de cette éducation aux professionnels et professionnelles des soins de santé actuels et futurs ainsi qu'aux apprenants et aux apprenantes qui commencent leurs études et qui n'ont aucune expérience dans ce domaine. Une compétence essentielle dans tous les domaines des méthodes de recherche et dans la pratique des soins de santé publique est la rédaction de protocoles. On ne sait pas si le fait d'enseigner aux étudiants et aux étudiantes les méthodes de recherche par le biais de rédaction de protocoles est une stratégie réussie, on ne sait pas non plus si les étudiants et les étudiantes trouvent cela utile alors qu'ils poursuivent leurs études dans les professions de la santé. L'objectif de cette recherche était de décrire la conception et l'évaluation d'un cours sur les méthodes de recherche axé sur la rédaction de protocoles parmi des étudiants et des étudiantes inscrits dans un programme de maîtrise en santé publique. L'article présente un modèle de rapport de cas comprenant la description du contenu du cours, la méthode d'évaluation et la prestation du cours. Il s'agissait du cours intitulé Population and Public Health Research Methods offert dans un établissement canadien subventionné publiquement. Les trois premières cohortes d'étudiants et d'étudiantes (2016-2018) inscrits dans ce cours ont été évalués durant la période où le cours était donné et ensuite, six mois après avoir terminé le cours. Un total de 51 étudiants et étudiantes ont répondu au sondage et la majorité d'entre eux ont indiqué qu'ils étaient très satisfaits ou extrêmement satisfaits du cours. Dans l'ensemble, les étudiants et les étudiantes ont déclaré que le cours les avaient bien préparés pour leur stage pratique ou pour leur thèse ainsi que pour leurs projets d'après l'obtention de leur diplôme. Les résultats suggèrent que l'utilisation de la rédaction de protocoles comme outil pour enseigner les méthodes de recherche avait été bien acceptée par les étudiants et les étudiantes et les avait préparés à la fois pour leur carrière potentielle et pour leurs recherches futures.

Keywords
public health, research methods, study protocols; santé publique, méthodes de recherche, protocoles d'étude

Cover Page Footnote
Corresponding author: Laura N. Anderson, Department of Health Research Methods, Evidence, and Impact, McMaster University, CRL-221, 1280 Main Street West, Hamilton, ON Canada L8S 4K1
phone: 905-525-9140 x 21725; email: LN.Anderson@mcmaster.ca

This research paper/Rapport de recherche is available in The Canadian Journal for the Scholarship of Teaching and Learning: https://doi.org/10.5206/cjsotlrcacea.2022.1.10670

Understanding research methodology is important for the advancement of healthcare delivery and population and public health outcomes. Graduate public health programs play a vital role in the provision of continuing education in research methods. Furthermore, previous research has noted that educational experiences that use a public health perspective can lead to positive learning outcomes (Hudmon et al., 2011). Students completing graduate programs in public health often pursue the degree after or concurrently with other study and pursue a wide range of health-related careers. Irrespective of the student's background, a solid understanding of the research process is important whether they work as knowledge users in applied health care/public health settings or take part in generating new knowledge through involvement in conducting research. Competency-based training guidelines across North America recognize the importance of research skill acquisition. For example, in Canada there are 36 core competencies expected of public health professionals broadly organized under seven categories (Government of Canada, 2017). Several of these competencies are related to an understanding of research methods, including critical thinking of public health sciences, assessment and analysis of data and resources for evidence-based decision making, evaluation of programs and policies, and communication and interpretation of information. In addition, the Council of Education for Public Health (United States) requires Master of Public Health (MPH) students to also demonstrate proficiency in research methods across several foundational core competencies (Council on Education for Public Health, 2016).

Development of study protocols are central to job duties in both research and practice careers. They are useful when seeking funding, obtaining ethics approvals and requesting data access. In many fields, it is now an expectation that protocols will be published and or registered prior to starting any research to improve transparency in research reporting (e.g., PROSPERO for systematic reviews; see Booth et al., 2011; Kirkham et al., 2010). Further, dissemination of protocols may be of benefit to others to learn about the methods or ongoing research in the field, generate new opportunities for collaboration and to inform stakeholders. Engaging in protocol writing establishes a process for planning and designing a rigorous study and identifying the resources (time, staffing, funds, expertise, technology needs) that will be required to successfully conduct a study. However, given practical considerations there are few students, particularly among those enrolled in a course-based Master's program, who will have the opportunity to be involved in the early stages of conducting primary research and contribute to writing a research protocol. The process of designing a research protocol may encourage students to more actively consider the practical considerations necessary when designing a study, beyond traditional didactic learning activities.

Many articles have been written about how to write protocols, in particular with respect to improving successful grant protocols for funding, most often specific to clinical research (e.g., Thabane & Lancaster, 2019). Guidelines exist for protocol writing, for example SPIRIT (Chan et al., 2013) for Randomized Controlled Trials and PRISMA-P (Moher et al., 2015) for systematic reviews. Published protocols contribute to increased transparency and accountability, reduce selective reporting of results and improve methodology (Al-Jundi & Sakka, 2016; Chan, 2008; Eysenbach, 2004; Li, Abbade, et al., 2018). Within the public health training context, previous work has explored whether there is benefit in partnering students with community-based organizations in a grant writing course (Bentley & Swan, 2018), but to the best of our knowledge there is no research on whether writing a research protocol improves the understanding of research methods. We hypothesized that teaching students to write research protocols will contribute to a deeper understanding of the research process and feasibility, expanding research methods skills

through application to a specific problem, and contribute to the development of scientific writing skills.

Given the importance of both understanding research methods and developing experience writing research protocols, we sought to merge the two by using protocol writing as a primary mechanism to learn research methods for graduate students in the Masters of Public Health Program at a research intensive institution in Canada. The objectives of this paper are to describe the design and evaluation of a research methods course focused on protocol writing for graduate students in public health.

Method

In Fall 2015, the first class of 25 students enrolled in the new MPH program in the Department of Health Research Methodology, Evidence, and Impact at McMaster University, which is a research intensive university in Canada. The Department and University are known internationally as leaders in evidence-based medicine and problem-based learning (Smith & Rennie, 2014). The MPH program at the institution is relatively unique in Canada in that students pursue a generalist public health degree with the choice of completing either a practicum (a 4 month experiential placement) or a traditional masters' research thesis, as one of the degree requirements, and make the decision once they have started the program.

Standard course evaluations were administered during the term that the course was taught, but for the purpose of this evaluation, we sought to follow students prospectively after completion of the course to understand satisfaction with the course after students had some experience and whether the course helped to prepare students for their next steps in the public health field. A repeated cross-sectional survey was delivered to the first three cohorts (2016-2018) of students. Students were asked to complete the survey approximately six months after their completion of the research methods course (in November of the subsequent year). Data were collected using a paper survey delivered for the first two cohorts and using an online survey delivered via email for the third cohort.

Students were asked to respond to three close-ended statements about the research methods course (in addition to other questions about their studies not described here in this manuscript) and were provided the option of any open answer responses. The first statement was: "On a scale of 1 (extremely unsatisfied) to 7 (extremely satisfied), please rate your satisfaction with the Population and Public Health Research Methods course." Response options were 1=Extremely unsatisfied, 2=Very unsatisfied, 3=Unsatisfied, 4=Neutral, 5=Satisfied, 6=Very satisfied, 7=Extremely satisfied. The next two statements were: "On a scale of 1 (extremely poorly) to 7 (extremely well), please indicate how well each course prepared you for your Practicum or Thesis" and "On a scale of 1 (extremely poorly) to 7 (extremely well), please indicate how well each course prepared you for your next steps after graduation from the MPH program (i.e., a career in public health or further education)." The response options for these two statements were: 1=Extremely poorly prepared, 2=Very poorly prepared, 3=Poorly prepared, 4=Neutral, 5=Well Prepared, 6=Very Well Prepared, 7=Extremely Well Prepared.

Human Participant Compliance Statement

Research ethics approval was not required for this project as it was considered part of program evaluation. Completion of the follow-up survey was completely voluntary, and all data

collected were anonymous with no personal identifiers. We were exempt from research ethics board approval because the data were collected as part of routine course evaluation and were also anonymous.

Results

Course Description and Objectives

The Population and Public Health Research Methods course described in this paper is a mandatory course for all MPH students in their second term (winter). The first term includes required courses in epidemiology, biostatistics, foundations of practice, and a seminar series. Following completion of the first two terms in the MPH program, students conduct their practicum or begin their thesis work in the third term (spring/summer) and then return to class in the fall for a 4th term (fall of year 2). Most practicum students graduate at the end of their 4th term (after 16 months in the program) and thesis students generally complete the program in 20-24 months. Students from other health related graduate programs have been included with permission of the course instructor.

Course Objectives

The Population and Public Health Research Methods course runs for 13 weeks. In the course, students are introduced to the methodological principles of quantitative, qualitative, and mixed methods research; knowledge that will be useful for future work in both research and applied settings. Student skill development in the course focuses on: literature searching, critical appraisal, the design and conduct of primary studies and systematic reviews, and the development and evaluation of interventions or programs. Additionally, students learn about ethical considerations in conducting public health research and how to locate research funding. Students who are considering the thesis stream are encouraged to choose a topic that is different than their proposed thesis.

Course Content

The course content is broadly divided into four sections: (a) introduction to research in public health, (b) study designs, (c) data collection, and (d) research communication. Table 1 summarizes the course content. Each class includes a lecture and small group discussion component facilitated by senior graduate students or other large group interactive session.

Table 1

Course Content Population and Public Health Research Methods

Week	Area of Focus	Large Group (Lecture) Topic	Small Group Activity
1	Introduction	Introduction - developing a research question and review of study designs	Small group discussion of published protocols
2	Study designs	Systematic reviews and meta-analysis	Small group discussion of published protocols
3		Observational study designs, trials and population health interventions	Research in action – presentation from a local study manager
4		Secondary data analysis and using existing databases	Presentation from local data managers of national survey data and administrative data institute
5		Qualitative methods	Small group discussion of published protocols
6		Mixed methods	Small group discussion of published protocols
7	Data collection	Sampling	Protocol presentations
8		Measurement	Protocol presentations
9		Survey design	Small group survey exercise
10		Sample size	Protocol presentations
11	Research communication	Research in action (attend departmental research day)	N/A
12		Knowledge translation	Protocol presentations
13		Scientific writing	Protocol presentations
14		Funding sources, budgets and timelines	Peer problem solving (protocol Q&A session)

The first lecture provides an introduction to the research process and developing a research question, including the use of PICOT to frame research questions that clearly specify the target *P*opulation, *I*ntervention of interest, *C*omparator intervention, *O*utcomes, and the *T*ime frame (Thabane et al., 2009). Students are expected to learn which research questions are best addressed through qualitative versus quantitative study designs. The second area of focus includes five lectures that are focused on study designs. For our course, this consists of a review of the quantitative study designs that the students learned earlier in the core curriculum in epidemiology, including both observational study designs and interventions (randomized controlled trials and quasi-experimental designs). A brief review of threats to study validity, including bias, confounding and measurement error, is provided, building on topics that were covered in detail in previous required courses on epidemiology and biostatistics. An introduction to the methods for systematic literature reviews and meta-analyses is provided along with an interactive session by an academic health librarian on literature searches. Finally, two classes are dedicated to providing an in-depth introduction to the methods and purpose of qualitative and mixed methods studies. In the qualitative lecture, students are introduced to the EPPiC framework for developing overarching qualitative research questions. This includes attention to, and language related to the study:

*E*mphasis, *P*urposeful sample, *P*henomenon of *I*nterest being studied, and the *C*ontext in which that phenomenon exists.

For the third area of focus, methods for quantitative data collection are discussed. This includes lectures on sampling, both probability and non-probability based methods, and sample size calculations. Students are taught the importance of adequately planning for sample size to ensure sufficient power and not waste resources planning a study that will not have adequate sample size to detect a statistically significant difference if one exists. Further, calculation of sample size contributes to the feasibility and understanding of the scope of the study. Considerations for studies conducted using secondary analysis are discussed in detail, including the use of both administrative data sources, population surveys (e.g., the Canadian Health Measures Survey (Tremblay & Connor Gorber, 2007) and provincial and national cohort studies (e.g., Canadian Longitudinal Study on Aging [Raina et al., 2009], Ontario Child Health Survey [Boyle et al., 2019]). Measurement and survey design are included as one lecture, as is research ethics for public health, where students also complete the Canadian Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2) online course (Government of Canada, 2019). The fourth section of the course focuses on research communication, including knowledge translation, scientific writing, funding sources, and preparation of budget and timelines.

Methods of Student Evaluation

The course objectives could have been met using a variety of course assignments including tests and/or short assignments. However, it was decided that the objectives should be met through the following distribution of six assignments: protocol proposal (20%), protocol presentation (10%), mid-course protocol (20%), peer-review of another student's protocol (10%), final protocol (35%), and class participation (5%). The student evaluation was designed so students had the opportunity to expand on both their oral presentation and written communication skills through iterative drafts. In many courses, student evaluations test concepts at only one point in time and then move on, but this course was designed with an iterative learning process where students learned to consider, respond to, and incorporate feedback from multiple sources (peers, instructor, and teaching assistant). This iterative evaluative process was chosen to be more reflective of the real-world process in both academic careers and applied public health settings. This evaluation process also taught students to receive and give constructive peer-review feedback both in writing and orally following presentations. For the three iterations of this course, all students have successfully passed the course.

Assigned Readings and Text Book

The textbook used for the course was *Health Research Methods: A Canadian Perspective* (Bassil & Zabkiewicz, 2014). This book was selected based on the wide range of methods that it covered, including both qualitative and quantitative study designs, and the Canadian-specific content with applied and practical examples of public health research in Canada, including some consideration of Indigenous research in Canada. Although the textbook was not specific to writing a research protocol, it covered many of the topics discussed in class and included a chapter on writing and reporting health research (Cole et al., 2014). The material from the textbook was supplemented for the graduate level with additional readings assigned each week from peer-reviewed journals, including published protocol papers and methods papers as examples.

Course Evaluation

A total of 51 students out of 78 eligible students (65%) completed the 6-month follow-up survey over the three years (2016-2018) that it was administered. The response rate was highest in the first two years with 24 (100%) respondents in 2016 and 16 (67%) in 2017 when the survey was delivered using pen and paper in the classroom setting, and fewer students completed the survey in the third year when it was delivered online via email n=11 (37%) in 2018.

Overall, the results of the evaluation suggested that the majority of students were students were "very satisfied" or "extremely satisfied" with the course (median response was 6; see Table 2). In terms of how well they felt the course prepared them for their practicum or thesis, and post-graduation plans, the results suggest that the students felt the research methods course left them "very well prepared" (median = 6), or "well prepared" (median=5), respectively.

Table 2

Results of Student Survey Completed Six Months After Completion of the Research Methods Course (n=51; from 2016-2018)

	Median [a]	IQR
Course Satisfaction	6.0	5.0, 7.0
Preparedness for practicum or thesis	6.0	5.0, 7.0
Preparedness for next steps after graduation	5.0	4.5, 7.0

[a] Responses were measured on a scale of 1-7 where 7 is extremely satisfied or extremely well-prepared.

Only 12 of the 51 students provided any additional open-text comments about the research methods course. Thematic analysis identifying the positive and negative themes was conducted (Braun & Clarke, 2006). Eight of the 12 open-text comments highlighted the usefulness of the course. Specifically, students noted that the course provided knowledge and technical skills in writing protocols and in research ethics. These were seen as useful for practicum experiences, other research projects, research assistant positions and other research-based jobs beyond graduation from the program. For example: "I was very satisfied with biostatistics and research methods as I saw a great degree of application of my learning during my practicum." Whereas, five of the comments reflected that, as an introductory course, the content was general. Students wanted more in-depth training in "practice specific methods." Specifically, students mentioned wanting more training on qualitative research methods (e.g., developing qualitative surveys and conducting qualitative reviews) and academic writing.

Discussion

Graduate public health programs fulfill a vital need by offering research methods courses to a variety of learners ranging from practicing health professionals to entry-level students with no background in healthcare or public health. In this case study, the development and implementation of a graduate level course teaching research methods through protocol writing was feasible and well received by students. It was perceived as a useful technical skill that helped to prepare students for subsequent components of their graduate training, namely thesis or practicum placements, and students felt that it helped to prepare them for their post-graduation plans, which include further education or entrance into the workforce.

The incorporation of a wide-range of methods in the course appears to appeal to students and allows them to choose to learn more about a specific topic and study design of their choice. Thesis students are encouraged to choose a topic different than their thesis one. Over the three years, a wide range of study protocols have been developed including systematic reviews, qualitative studies, randomized controlled trials, quasi-experimental studies, and other observational study designs. A very broad range of subject areas have been explored by students in their choice of protocols, which provides an introduction to a wide range of topic areas for the entire class through the peer-review and group presentation assignments.

A few students went on to conduct the studies that they wrote protocols for and have now published the results of these studies (Agarwal et al., 2018; Li, Kamel, et al., 2018) Other students reported that they found the work that they conducted in the course useful in developing their thesis protocols, either for their master's programs or future work as PhD students or research assistants.

The iterative process of evaluating protocols and receiving feedback from multiple people was well received by students. However, after reflection, we realized the submission of a mid-course and final protocol, in addition to the protocol proposal and presentation, was too repetitive. The mid-course protocol assignment was removed in the most recent year of the course offering, and the peer-review assignment was revised to be a group assignment. Future directions also include the incorporation of more small group activities throughout class, use of technologies for real-time quizzes, and using online videos to supplement the traditional lectures and reading. Early constructive feedback is essential to ensure students do not fall behind as they progress through the protocol development.

Future research could examine application of research skills to applied or independent study/course work such as practicums or thesis tracks at longer follow-up periods and seek to determine if the course meets the needs of external stakeholders, including practicum placement supervisors and potential employers. Furthermore, more detailed study of learner needs and outcomes should be assessed as public health graduate research courses appeal to various healthcare and public health professionals.

Teaching essential public health skills through protocol development fosters student learning and a deeper understanding of all aspects of the research process as well as skills in scientific writing and peer-review. The results of this manuscript are intended to benefit others who are teaching public health research methods by providing a detailed explanation of the content of a graduate level population and public health research methods course. Further, as reported in this manuscript, students perceived that a research methods course which incorporated protocol writing prepared them for subsequent components of their graduate training and for their post-graduation plans, including joining the public health workforce.

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