

# Thoughts About Population Health Nursing Research Methods: Questions About Participants and Informed Consent

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## Abstract

The purpose of this essay is to discuss who participants should be in population health nursing research within the context of the Conceptual Model of Nursing and Population Health. The emphasis is on recruitment of research participants who constitute populations rather than samples drawn from populations and the challenges of obtaining informed consent from populations.

## Keywords

population health, nursing research, methods, informed consent, conceptual model of nursing and population health

The contemporary global focus on populations and population health continues nursing's heritage—at least since the 19th-century time of Florence Nightingale—on aggregates. At the same time, however, nursing has an intense and continuing tradition of nursing practice and research targeted to individuals. The purpose of this essay is to discuss approaches to recruitment of participants for population health nursing research and the challenges of obtaining informed consent from populations. The discussion follows from thinking about how nursing research with an emphasis on population health should be conducted within the context of the Conceptual Model of Nursing and Population Health (CMNPH; Fawcett & Ellenbecker, 2015).

## Background

The CMNPH was developed as a way to think about the intersection between nursing and population health. Fawcett and Ellenbecker (2015) defined population health as “lifespans wellness and disease experiences of aggregate groups of people residing in local, state, national, or international geographic regions or those populations with common health-related characteristics” (p. 290). With this definition as the starting point, the CMNPH encompasses the five interrelated concepts and their dimensions listed in Table 1.

Fawcett and Ellenbecker (2015) explained that the literature indicates that population health is not the same as public health, community health, or epidemiology (Batchelor, 2012; Kindig & Stoddard, 2003; Radzysinski, 2007; Stoto, 2013). Therefore, the usual methods used for recruitment of participants and obtaining informed consent for public health research, community health research, or epidemiological research are not completely consistent with population health

nursing research. The major methodological issue we have encountered in dialogue with colleagues who also are interested in population health nursing research is who the participants should be. The specific issue is whether a sample of participants drawn from a population is appropriate for population health nursing research.

## Participants for Population Health Nursing Research

Zangerle, Harris, Rimmasch, and Randazzo (2016) pointed out that “the term *population health* . . . stymies clinicians, academicians, policy makers, and consumers” (p. 318). Thus, the starting point for our discussion of who should be participants for population health nursing research is an understanding of the definitions of populations, aggregates, and clusters. As can be seen in Table 2, the definitions of population, aggregate, and cluster are remarkably similar; all indicate that participants for population health nursing research should *not* be individuals. Indeed, the integrity and rigor of population health nursing research depends on recruiting entire groups—whether referred to as populations, aggregates, or clusters—rather than from “unrelated individuals [who are] grouped by a researcher on the basis of common characteristics (e.g., age and gender) for the *purposes of subgroup analysis*” (Christie, O'Halloran, & Stevenson, 2009, p. 128; italics added).

Inasmuch as population health focuses on entire populations, the usual way of conducting nursing research, with its

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**Table 1.** Conceptual Model of Nursing and Population Health Concepts and Dimensions.

Concepts	Dimensions
Upstream factors	Socioeconomic environment Physical environment
Population health factors	Population level Genetic factors Behavioral factors Physiological factors Resilience Health state
Health care system factors	Providers Organizations Institutions Payers Policies
Nursing activities	Population-based nursing practice processes Culturally appropriate wellness promotion, restoration, and maintenance Culturally appropriate disease prevention
Population health outcomes	Population level Wellness Disease burden Functional status Life expectancy Mortality Quality of life

**Table 2.** Definitions of Population, Aggregate, and Cluster.

Terms	Definitions
Population	The “collective inhabitants of a country, town, or other area; a body of inhabitants” (Oxford English Dictionary Online, 2016c)
Aggregate	A “complex whole, mass, or body formed by the union of numerous units or particles; an assemblage, a collection” (Oxford English Dictionary Online, 2016a)
Cluster	The “number of persons, animals, or things gathered or situated close together” (Oxford English Dictionary Online, 2016b)

emphasis on unrelated individuals, is not appropriate. From the perspective of the CMNPH, the participants for population health nursing research should be aggregates or clusters who reside in specific geopolitical countries, geographic regions (states or provinces or regions of a country), communities, or neighborhoods. Other sources of populations are aggregate groups or clusters that have common characteristics, such as a certain gender identity, age, or age range; and/or are of a specific race, ethnicity, or culture; or are employees of a particular company or industry; or are prisoners. Still other populations are aggregate groups or clusters who have the same or similar health-related characteristics, such as high-level wellness or a specific disease or disability. In

addition, aggregate groups or clusters of healthcare team members and patients could be considered populations.

## Recruitment of Populations

Recruitment of entire populations is admittedly difficult and can be both time-consuming and expensive, especially when the population is very large. It may be difficult and time-consuming to locate all members of the target population. Thus, a question is whether the accessible population—that is, the members of the population who can be identified—is acceptable. Recruiting all members of the target or accessible population may be expensive, especially if several paid researchers or research assistants are needed to recruit the participants.

## Sources of Population Health Data

Some investigators who are interested in population health nursing research are beginning to explore the possibility and feasibility of “big data” as a way to access population-level data. “Big data encompass data that exceed human comprehension, that exist at a volume unmanageable by standard computer systems, that arrive at a velocity not under the control of the investigator and possess a level of imprecision not found in traditional inquiry” (Brennan & Bakken, 2015, p. 477). Regardless of the amount of data, big datasets still are made up of data from samples of individuals drawn from populations rather than from entire populations (F. J. Fowler, personal communication, February 23, 2016).

It may be that data for population health nursing research have to come from national databases. Census data are from populations. Other sources of population-level data that may be useful are from the National Center for Health Statistics (<http://www.cdc.gov/nchs/index.htm>) and perhaps from insurance claims (Stoto, 2014). Still other potential data sources are “electronic health record systems that help access, track, and report on health behaviors for [populations] ... and that link providers to current guidelines” as well as “electronic systems that schedule and track initial and follow-up visits for health behavior change” (Spring et al., 2013, p. 2172).

However, census data “may not be useful for tracking population health improvements” (Stoto, 2014, p. 11). Furthermore, national or other large databases often do not reflect a particular conceptual or theoretical perspective. Consequently, research variables that represent CMNPH concepts may not be available in the dataset. Thus, within the context of the CMNPH, secondary analyses of large datasets are appropriate only if the data represent the CMNPH concepts of interest for a particular study.

## Obtaining Informed Consent From a Population

A major challenge is how to obtain informed consent from a population. We asked ourselves, how is informed consent

obtained from an entire population? What does it mean when an entire population is expected to provide informed consent? What happens to autonomy? Or does consent have to remain at the level of the individual participant?

Informed consent is, of course, a cornerstone of ethical nursing research. All research in which human beings participate or are in some other way involved (such as their health records) must be reviewed and approved by an Institutional Review Board (IRB) or ethics committee before the research may proceed. The typical expectation is that informed consent must be obtained from each individual who participates in the research. Therefore, it is unclear what happens when one or more members of a population do not agree to participate in the research. Can the researcher continue to claim that the research is at the level of the population, or is the research now at the level of a sample of volunteers from the population? If the latter, how does the research differ from any other research that relies on a sample of volunteers?

Sim and Dawson (2012) argued that informed consent from individuals who make up a cluster should not always be necessary. Focusing on cluster-level experimental research, they stated, “The problem is that gaining informed consent within at least some cluster-randomized trials either is impossible or would seriously undermine the ability of the cluster-randomized trial to answer the relevant research question” (p. 481). They went on to note that if an intervention is targeted to an entire community, “there is little or no scope for any individual community member to opt out” (Sim & Dawson, 2012, p. 481). They conceded, however, that “individual consent may feasibly be given or withheld for outcome assessment or access to health records” (p. 481).

Christie and colleagues (2009) and Sim and Dawson (2012) contended that obtaining approval from representative guardians or gatekeepers—which may be people or organizations assumed to be acting in the interests of the populations—is appropriate when individual consent is not feasible. It is, however, unclear whether an IRB or ethics committee would approve of this substitute for individual informed consent.

## Conclusion

This discussion has raised more questions than answers. Given the difficulty of conducting research with entire populations, are we willing to compromise by falling back on individual-level data provided by samples? If we have to use samples, how can we claim to be conducting population health nursing research?

The answers to the questions raised in this essay are currently elusive. Perhaps the next generation of nurse researchers who are committed to population health will invent new ways of thinking about and conducting research and, therefore, provide answers to the questions.

Although the emphasis in this paper is on population health *nursing* research, we recognize that the thinking of researchers from multiple disciplines is needed to answer the questions. We welcome the readers of *Nursing Science Quarterly* to contribute to the discussion.

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