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STUDY PROTOCOL

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A study protocol to evaluate the implementation and effectiveness of the Clinical Nurse Leader Care Model in improving quality and safety outcomes

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Abstract

Aims: Patients are harmed or die every year because of unsafe, inappropriate or inadequate healthcare delivery. Registered Nurses are a recognized patient safety strategy. However, variability in research findings indicate the relationship is not as simple as "more nurses=better outcomes." Hence, currently there exists no evidence-based frontline nursing care model. One emerging model is the Clinical Nurse Leader care model.

Design: This Hybrid Type II Implementation-Effectiveness study will evaluate the effect of the care model on standardized quality and safety outcomes and identify implementation characteristics that are sufficient and necessary to achieve outcomes.

Methods: This study leverages a natural experiment in 66 clinical care units in nine hospitals across five states in the United States that have implemented the Clinical Nurse Leader care model.

Results: Findings will elucidate Registered Nurse's mechanisms of action as organized into frontline models of care and link actions to improved care quality and safety.

KEYWORDS

clinical nurse leader, evidence-based care delivery, implementation, nursing care delivery

1 | INTRODUCTION

A significant number of patients are harmed or die every year because of unsafe, inappropriate or inadequate healthcare delivery (Institute of Medicine, 2000; James, 2013; Makary & Daniel, 2016). In the United States, the Agency for HealthCare Research and Quality (AHRQ) has identified Registered Nurses (RNs) as a patient safety strategy for reducing patient mortality and morbidity (AHRQ, 2013). However, variability in research findings indicate the relationship is not as simple as "more nurses = better outcomes" (Brennan et al., 2013; Shekelle, 2013). Despite the fact that RNs are the largest health workforce component in many countries (Budden et al., 2013) with identified potential to improve patient safety (AHRQ, 2013) currently no evidence-based frontline RN care model exists (Brennan et al., 2013; Butler et al., 2011; Kitson et al., 2014). Because of this, the relationship between RN actions and outcomes in the context of value-based health care remains ambiguous (Welton & Harper, 2015). Knowledge elucidating RN's direct and indirect mechanisms of action as organized within frontline models of care is needed, including evidence linking these actions to improved care quality and safety (Kitson et al., 2014).

One emerging model highlighted by policy makers (AHRQ, 2010; Institute of Medicine, 2011; Joynt & Kimball, 2008) and increasingly taken up by health systems in the United States and abroad (e.g., Japan,

Katsumata et al., 2015) is the Clinical Nurse Leader (CNL) care model (Bender et al., 2016). The CNL is an RN with masters-level competencies in clinical leadership, care environment management and clinical outcomes management (American Association of Colleges of Nursing [AACN], 2007). The CNL utilizes these competencies as a member of the frontline clinical care staff to take the lead developing clinical structures and processes that improve care coordination, quality and safety (Bender, 2016a; 2016b). These efforts are encouraged in RN care models such as primary nursing but are not adopted because ever increasing patient acuity means staff nurses are primarily directing all their efforts towards emergent patient needs (Institute of Medicine, 2005).

Previous studies have determined the feasibility of the CNL care model to improve frontline quality and safety outcomes (Bender, 2014). However, those studies were of variable quality and lacked a consistent framework linking CNL care model structures, processes and outcomes. Furthermore, early studies identified variability in CNL structures (e.g., who CNLs report to) that influenced the consistency of CNL practice and outcomes (Bender et al., 2016). This known CNL implementation variation across units/hospitals can result in mis-estimation of CNL model effect yet has not been explicitly addressed in research to establish the conditional links between CNL care model structures, processes and outcomes (Williams & Bender, 2015). Accordingly, this study is based on extensive preliminary research to ensure conceptual clarity and methodological rigour.

1.1 | Preliminary data

In a systematic literature review conducted to determine the current CNL evidence base and identify gaps in knowledge (Bender, 2014) the overall evidence was found to be Very Low to Moderate-Low quality based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) guidelines (Guyatt et al., 2011). However, 14 of 15 studies reported quantified improvements in quality, safety and staff satisfaction outcomes, and showed consistency in the variables used, highlighting the feasibility and capacity of the model to improve outcomes. This provided the foundation for a series of studies that generated the preliminary data to support the proposed CNL implementation-effectiveness study described in this article.

Study 1 (Bender et al., 2016) provided evidence that CNL implementation can succeed in a wide range of organizational settings. It also confirmed the variability of CNL implementation within these settings and identified specific implementation variations that were associated with higher levels of CNL success.

Study 2 developed and validated a CNL Practice Model (Bender et al., 2017) and CNL Practice Survey (Bender et al., 2018) that conceptualize and measure model constructs, including CNL structure and practice attributes.

Study 3 (Bender et al., 2018) provided empirical evidence supporting the validity of the CNL Practice Model's conceptual domains and components, including the hypothesized mechanism of action.

Study 4 (Bender et al., 2019) confirmed the convergent validity of the CNL Practice survey against criterion of participant's rich descriptions of CNL practice operationalization at one study site's CNL units and provides preliminary evidence that survey scores can be used to test whether levels of CNL practice predict levels of outcome improvement, answering important questions about levels of intervention adherence needed for implementation success.

Study 5 (Bender et al., 2019) confirmed the ability of the Robust-ITS modelling approach to detect the empirical change point in measured outcomes after implementing the CNL care model, as well as changes in outcome score variability pre and post-CNL care model implementation, validating the methodological rigour of Aim 1.

Study 6 (Bender et al., 2017) utilized input from key informants to validate the methods and measures that will be used in Aims 1 and 2.

These studies combined highlight robust, ongoing collaboration with practice settings in preparation for the proposed study. The PI has built a solid infrastructure connecting healthcare innovators with care delivery researchers to leverage their combined knowledge and experience to develop a feasible and scalable CNL program of research and includes leaders in the health systems participating in this study. The resulting CNL Research Collaborative (CNLRC), is an AHRQ-Affiliate Practice Based Research Network (https://pbrn.ahrq.gov/pbrn-registry/clinical-nurse-leader-research-collaborative) with a stated mission to generate evidence highlighting the ways CNL-integrated care delivery can be implemented to consistently and positively influence health and healthcare outcomes.

1.2 | Description of the CNL care model

In the hospital, what most people think of when they think of an RN is a "staff nurse." This is the RN who is assigned to a patient and is responsible for their care during their "shift," which is typically either 8 or 12 hr. This is the standard "nursing care delivery model" in hospitals, is called "primary care nursing," and is operationalized as nurse-to-patient ratios based on patient acuity (i.e., how sick the patient is). The model emphasizes the count of RNs that are required for a specific number of patients on a hospital unit per shift. For hospitals using 12-hr shifts, RNs typically work three shifts per week. Hence, a patient is cared for by many staff RNs during the course of their hospitalization.

The CNL Care Model is a different way of organizing nursing care. Instead of focusing on RN ratios, the CNL Care Model uses CNLs at the unit level to lead the organization of patient care, leveraging RN and other clinician's particular competencies and strengths, with the goal of providing consistently safe and high-quality care to patients. The validated CNL Practice Model conceptualizes these CNL structures and processes, incorporating 13 components organized into 5 conceptual domains of the care model: "Readiness for CNL integrated care delivery"; "Structuring CNL integrated care delivery"; "CNL Practice: Continuous Clinical Leadership"; "Outcomes of CNL integrated care delivery"; and "Value" (Figure 1).

Structural equation modelling confirmed directionality and significance of all hypothesized model pathways that establish the mechanisms of action explaining how the CNL care model, appropriately structured, produces expected outcomes (Bender et al., 2016). CNLs have a unique workflow that keeps them clinically oriented with no administrative management accountabilities. While CNLs are a part of the frontline clinical staff care model, and care for individual patients when needed, the CNL has additional masters-level competency in clinical systems leadership, which is used to assess frontline patient care structures and processes to identify where the coordination of the patient's plan of care can be strengthened implementing targeted improvement processes. For example, one of the biggest gaps in effective coordination is communication, exchange of information that is necessary to create a comprehensive patient care plan from admission to discharge. Traditional communication structures include health record documentation and brief handoffs between clinicians as care needs emerge, or at the beginning or end of a shift. The CNL is consistently present creating relationships with multidisciplinary clinicians that routinely deliver care services and collaboratively develop communication structures and processes to better exchange and act on relevant information. This includes developing rounding structures that fit into multidisciplinary clinician workflows; creating electronic communication tools that synthesize information across disciplines; being a consistent, real-time source of information and data exchange for frontline clinicians and patients; and having accountability for information follow-through from patient admission to discharge. Other foci include coaching and mentoring new staff, ensuring quality mandates (i.e., fall prevention and documentation) are being met, and engaging clinicians in quality improvement projects. These practices require CNL competence in data management, informatics, interprofessional collaboration, evidence-based practice and quality improvement. It also requires a focus on frontline patient care processes from a multidisciplinary perspective, which is an important difference from a staff RN, who is focused on individual patient emergent care needs over the course of their 12-hr shift.

2 | METHODS

2.1 | Aims

The proposed study innovatively and rigorously leverages a natural experiment in 66 clinical care units in nine hospitals across five states in the USA (GA, TX, NC, MI, IL) that have integrated CNLs into their nursing care models. The study will accomplish the following aims:

Aim 1. Evaluate the effect of CNL-integrated care delivery on changes in nationally endorsed and standardized quality and safety outcomes including patient satisfaction, infection rates, falls, LOS and readmissions. The hypothesis is that the CNL care model significantly improves patient care quality and safety outcomes.

Aim 2. Identify CNL implementation characteristics that are sufficient and necessary to achieve outcomes. The hypothesis is that specific patterns of CNL care model structures and processes will be consistently present in units with improved outcomes.

2.2 | Design/Methodology

The study will use a hybrid type II implementation-effectiveness design. This design allows for the simultaneous examination of implementation strategies during what is otherwise a traditional effectiveness trial (Curran et al., 2012). We will use the hybrid implementation-effectiveness design to study the effect of CNL implementation on outcomes, as well as how and to what extent CNLs were implemented in order to identify necessary and sufficient CNL implementation configurations that achieve effectiveness.

2.3 | Sample

The study sample is a purposive set of clinical units in USA hospitals that have adopted the CNL care model. The rationale for the unit-as-sample is that CNL practice is focused on the clinical unit to improve patient care processes and does not provide individual-level patient care, so CNL-driven outcomes will be seen at the unit, not individual, level. The sample consists of 66 clinical units across nine hospitals within five health systems. Clinicians and administrators that interact with CNLs and were involved in the adoption of CNLs into their setting's clinical units, and CNLs themselves, comprise the survey and interview sample.

The study settings were purposefully selected by the CNLRC and affiliate members for geographic region and setting ownership status diversity. The study only includes hospitals that have redesigned the unit-level RN staffing model to integrate CNLs with workflows corresponding to the CNL Practice Model, The study excludes hospitals that only integrated CNLs into the minority of their care

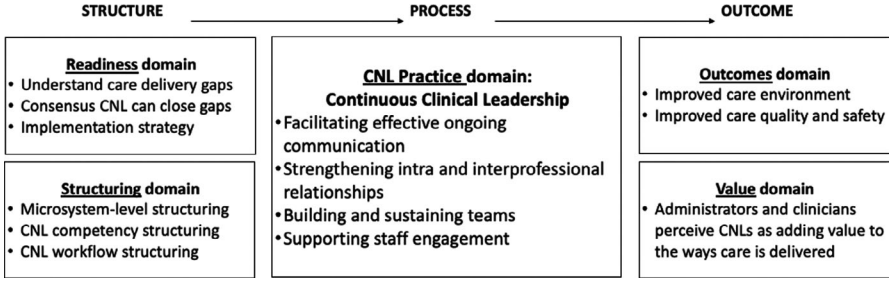

FIGURE 1 The Clinical Nurse Leader Conceptual Model

delivery units, or that hired CNLs to work in traditional nursing roles (such as manager or educator).

These inclusion and exclusion criteria are based on preliminary findings showing variability in perceived CNL success depending on stage and type of CNL adoption. The study also excludes certain speciality clinical units that have a more unique set of quality/safety measures, such as Obstetrics, and do not typically include several common measures identified for this study.

2.4 | Instruments and measures

2.4.1 | Quality and safety measurement (Aim 1)

The investigators and the CNLRC have identified nationally endorsed quality and safety outcome metrics that are nursing-sensitive and legislatively mandated to be publicly reported in standardized format across the nation (Table 1). All data are pre-existing and calculated as monthly counts/rates/ratios aggregated to the hospital/unit level by the hospital's quality reporting department. Covariate measures include staffing level, bed size and patient population.

2.4.2 | CNL Implementation and Practice Measurement (Aim 2)

The CNL Practice Survey and interviews/focus group data will be used to measure CNL implementation and practice. The survey measures the latent constructs of the CNL Practice Model (Figure 1), including Readiness for the CNL Care Model (Readiness), Structuring the CNL Care Model (Structuring), CNL Practice (Practice), Unit outcomes associated with CNL Care Model (Outcomes) and Value of the CNL care Model (Value). The survey has 69 items and takes 20–30 min to complete. Readiness is measured with 13 items, for example "Nurse leaders/managers commit adequate resources to CNL implementation." Structuring is measured with 19 items, for example "CNLs assess the clinical environment to identify areas for outcomes improvement." CNL Practice is measured with 19 items, for example "The CNL facilitates communication between nurses, patients and other professions at the point of care." Self-reported Outcomes are measured with 14 items, for example "Multi-professional clinicians regularly work together to solve clinical problems." Value is measured with 4 items, for example "CNL practice is valued by point of care staff." Participants respond with the extent each item is present from 0%–100%. The survey also contains 16 demographic items about participant-level characteristics, participant work setting characteristics and participant work setting CNL role characteristics.

Interviews supplement and validate the accuracy of survey measurement data by providing explicit details about if and how the presence or absence of constructs were manifested. A semi-structured interview tool was successfully used in Study 3 to collect data about how CNLs were structured and what types of activities CNLs routinely engage in. The interview tool includes semi-structured interview questions: What is your professional role]; What unit do you primarily work on; When considering the roll out of the CNL initiative at your setting, (a) what do you think went right, and (b) what could have been done better; (c) tell me what CNLs do from your perspective and how do you interact with them?

2.5 | Data collection procedures

2.5.1 | Quality and Safety Data (Aim 1)

Pre-existing outcome measures in each system's data warehouse will be extracted by a health system champion (or delegate) and organized into.csv datasets.

2.5.2 | Implementation and Practice Data (Aim 2)

Survey and interview data have been collected. We obtained 1,186 valid survey responses from clinicians and administrators who answered "yes" to being involved with their organization's CNL implementation at the time of adoption. The survey was formatted for electronic administration via the Qualtrics platform. The survey remained open for 2 months at each site: the PI and champion reviewed survey participation reports weekly to gauge when recruitment efforts reached a plateau.

We conducted 399 interviews, ranging from brief 10-min chats answering a single question to extensive 2-hr focus group interviews with respondents from multiple disciplines, all who were working at the time of their organization's respective CNL implementation period. The PI travelled to all health systems to conduct the interviews and focus groups in person. We achieved 100% response rate from clinicians and administrators recruited for individual interviews across nine hospital settings. Respondents included staff nurses, advanced practice nurses, social workers,

TABLE 1 Quality and safety variables for each unit

Metric type	Variable
Quality	Patient Experience,[a,c] Length of Stay, [b]Readmission rate[b,c]
Safety	Catheter-Associated Urinary Tract Infection Rate[b,a] Central Line-Associated Blood Stream Infection Rate,[b,a] Fall/Injury Fall Rates, [a,b,c]Hospital/Unit Acquired Pressure Ulcer Rates[a,b,c]
Covariate	Bed size, Nursing Skill Mix, Specific patient population.

Note: Endorsed by [a]CALNOC; [b]National Quality Forum; [c]American Nurses Association/NDNQI.

case managers, physicians, pharmacists and administrators (e.g., chief nursing and medical officers, quality and safety directors), all of whom were able to be scheduled for interviews. The PI also identified potential participants at the clinical setting after arrival by asking staff RNs and ancillary staff on CNL units if they would like to participate in the study. This resulted in numerous 10-min "chats" with clinicians that were present at their respective CNL launch date that provided a robust amount of information about perceived success of CNL structuring and practice. Chats and interviews were conducted in a closed room and lasted 10–60 min. Interviews were recorded for participants agreeing to being recorded, otherwise, case notes were taken by the PI. Individual interviews were conducted to retain anonymity. Focus groups were conducted to elicit group understanding of CNL structure and activities. There was one focus group per hospital consisting of all CNLs working in the hospital. These focus groups were scheduled at the convenience of the CNL participants, lasted 2 hr, and were audio recorded.

2.6 | Data analysis

2.6.1 | Quality and Safety data analyses (Aim 1)

The Robust- ITS (Cruz et al., 2017) and generalized Robust-ITS models, as well as the supremum Wald Test (SWT) will be used to perform inference on time series data: (a) change point (i.e., if and when change occurred postintervention); (b) pre- and postchange point correlation structure; (c) pre- and postvariance of the outcome measure; and (d) pre- and postchange point trajectory. The Robust-ITS and generalized Robust-ITS modelling approaches will isolate the effect of the CNL care model, controlling for pre-intervention trends and autocorrelation, for continuous and discrete (count, rates and binary) outcomes, respectively. Robust-ITS modelling additionally controls for random fluctuation around the mean, while the generalized Robust-ITS modelling accounts for the mean-variance relationship present in discrete responses, leading to more robust results for both continuous and discrete outcomes. The SWT will be used to test for the existence of a change in the outcomes around the CNL care model implementation, rather than assuming a change exists. For this study, we will analyse each outcome separately and report the effectiveness for each, which is considered an appropriate approach to analysis of time series data (AHRQ, 2014).

We will then conduct meta-analyses to determine the impact of the CNL care model on each outcome. The analysis will determine units with similar CNL care model implementation, thus ensuring comparison of "like with like," a prime rationale to combine n-of-1 trials. (AHRQ, 2014) Capitalizing on this similarity via a meta-analysis leads to an increase in statistical precision in determining the CNL care model effect sizes. To carry out the meta-analyses, we will implement multilevel random effects ITS techniques that will determine unit-specific effect sizes as well as one aggregate effect size for each outcome. Due to presumed unit-level covariate heterogeneity, we will conduct sensitivity analyses that will examine the variability in unit-specific effect sizes under various sub-unit (e.g., ED units in a specific health system vs. all ED units vs. all units, etc.) analyses. We will include unit-level demographics as covariates in all analyses (bed-count, skill mix, nursing hours per patient day) to estimate the adjusted effect on the outcomes. To account for the multiple hypotheses testing we will use the Benjamini-Hochberg procedure (Benjamini & Hochberg, 1995) that controls for false positive error among the tests that yield significant results (e.g., the false discovery rate).

2.6.2 | CNL Implementation and Practice Data Analysis (Aim 2)

Survey data will be exported from Qualtrics into SPSS format, and all analyses will be conducted in SPSS 22 and Mplus 7. The survey includes two parts: demographic survey and practice survey. For demographic survey items with multiple-choice questions, frequencies and percentages will be calculated. For the CNL Practice Model domains, we will first test the measurement invariance of the practice domains across clinical units and then quantify the level of CNL practice for each unit. The measurement invariance test will examine whether the structure and interpretation of the practice domains hold consistent across units (Schmitt & Kuljanin, 2008; Vandenberg & Lance, 2000). To quantify CNL practice, scores for each domain item will be aggregated and averaged to the clinical unit level to determine the level of each domain presence for each unit, from 0%–100%. Accuracy of score will be validated with the interview data using the process described in the cross-validation section below.

Interview data will be analysed using deductive and inductive qualitative content analyses (Elo & Kyngas, 2008; Hsieh, 2005). All transcribed texts and notes will be tagged to hospital, unit, and role to enable descriptive analysis of coding variation by profession and unit. Qualitative data will first undergo deductive coding, linking data to an existing CNL Practice Model domain and component coding framework. The coded excerpts will then be exported to an excel spreadsheet, where inductive coding will begin. Data coded onto model components will be sorted by unit, and then analysed to derive a description corresponding to each unit's empirical operationalization of model domains/components.

2.6.3 | Cross validation of survey and interview data

For the interview data, a valence score will be used to document intensity of domain/component operationalization for each unit, with −1 corresponding to data showing an emphatic absence of the domain component (e.g., "the CNL was never on the unit"), 0 corresponding to concrete lack of evidence of component presence (e.g., nobody said anything about CNLs), 0.5 corresponding to evidence for the presence of the component (e.g., "I interacted with the CNL once per week"), and 1 corresponding to the emphatic

presence of the component ("the CNLs made sure communication was seamless"). Next, data from the surveys and interviews will be levelled. Unit-level survey domain scores will be transformed to quartiles using bootstrapping for 95% quartile confidence intervals. The data sets will then be merged and correlations will be calculated between the quartile and valence scoring. Strong correlations (=>0.5) show convergence of survey and interview data, validating the survey scores and providing a link between the domain presence score and the domain operationalization and intensity (i.e., valence) that can be compared across units. Weak correlations will prompt post hoc covariate analysis to determine if factors such as low sample size, specific unit type, etc. explain the variation. This information will be used to select clinical units for the QCA and ITS analyses, ensuring only units with robust data are analysed.

2.6.4 | Linking CNL implementation and practice with outcomes analysis (Aim 2)

Qualitative Comparative Analysis (QCA) will be used to identify the necessary and sufficient CNL configurations that achieve outcome effectiveness. QCA offers an analytic approach for detecting patterns that may be invisible to conventional statistical techniques such as linear regression (Ragin, 2008, 2013; Schneider & Wagemann, 2012). QCA's value for the present study is that it can be used to analyse complex configurational relationships across a sample of heterogeneous cases, such as clinical units nested within hospitals. QCA is based on Boolean, rather than linear algebra and operates by identifying and measuring the strength of subset relationships. These subset relationships may be interpreted in terms of necessity and sufficiency (Ragin, 2008, 2013; Schneider & Wagemann, 2012).

For this study, the hypothesized primary relationship is that clinical units with improved quality and safety are a perfect subset of clinical units with adequate CNL practice (i.e., continuous clinical leadership, see Figure 1). This means, CNL practice is a necessary condition for outcomes improvement. The other main hypothesized relationship is that clinical units with certain configurations of CNL implementation will produce adequate CNL practice, while others will not. This is critical knowledge: if we determine that on average there are not adequate levels of CNL practice on clinical units, the QCA analysis will allow us to determine if the lack of outcomes is due to the ineffectiveness of CNL practice or is related to inconsistencies in or sub-thresholds of CNL practice, or perhaps contextual barriers prohibiting the implementation of CNL practice. We will conduct two different analyses to test these two related hypotheses. First, we will consider CNL practices as the conditions (i.e., the four core CNL activities of communication, relationship building, team building, staff engagement; see Figure 1), and a composite metric of all analysed outcomes as the outcome for each clinical unit, stratified into high, moderate and low outcome improvement. The second analysis will consider CNL Readiness and Structuring as the conditions, and the presence of adequate CNL practice as the outcome, stratified into high, moderate and low CNL Practice.

There are three stages to the analysis: data calibration, necessity analysis and sufficiency analysis. The calibration process involves recoding each measure as a fuzzy set. This is a data preparation step that takes place after conventional data cleaning and prior to analysis. The conditions will be calibrated three ways –high, moderate and low presence- which will permit assessment of the specific condition thresholds required for the outcome's occurrence. The second stage involves identifying necessary conditions; conditions that must be present for the outcome to occur. Two measures assess goodness of fit: consistency reports the strength of the necessity relationship while coverage reports its empirical importance. The third stage involves identifying sufficient conditions; conditions whose presence ensures that the outcome will occur. There are two steps to the sufficiency analysis: (a) transforming the calibrated data set into a truth table and (b) reducing the truth table to a set of explanatory Boolean equations. The truth table construction process involves identifying the types of clinical units present in the calibrated data set and then measuring the degree to which each of these clinical units belongs to each identified type. This information is presented as a truth table that reports the degree to which each identified type exhibits the outcome of interest. This truth table is then reduced to a set of Boolean equations that report the various combinations of conditions that are and are not sufficient to achieve the outcome. Measures of consistency and coverage are again used to assess, respectively, the strength and empirical importance of the identified sufficient conditions. The software package Kirq will be used to conduct the analysis.

2.7 | Ethical considerations

All aspects of this study were reviewed and approved by the University of California Irvine Institutional Review Board as exempt research (#2015-2323) and at each healthcare setting's respective Institutional Review Board.

2.8 | Validity and reliability

The complexity of care delivery and the cost associated with changing care models for research purposes means a fully experimental design is not possible for this study. While we have overcome this issue by taking advantage of a natural experiment (health systems that have already implemented the CNL care model) and using a quasi-experimental design to estimate effect of care model change, outcomes may be influenced by demographic and/or implementation variation across so many units/hospitals, resulting in mis-estimation of CNL care model effect. To overcome this issue, we use a hybrid implementation-effectiveness design that allows us to explicitly incorporate variation into the analyses, which not only strengthens study internal validity, but also results in increased external validity,

identifying recipes of successful CNL implementation that stakeholders can compare and align with their settings to improve implementation success. We also use ITS analyses, which accounts for pre-intervention trends, temporal trends and random fluctuation. The data is pre-existing and can be analysed with precision using the Robust-ITS method for before-and-after changes for each unit: Each unit has a specific CNL "start' date and the data will be collected 24 months before and after that specific start date to determine effectiveness for each unit. We will conduct a covariate analysis as part of the meta-analysis, to control for potential bias from unit heterogeneity. We do not expect missing outcome because the outcomes are routinely data collected and mandated to be reported to system-level or national-level boards. However, if missing data occurs, it will undergo criteria testing for invalidity, and if valid, be handled by full information maximum likelihood (FIML) estimation.

3 | DISCUSSION

The study is innovative in its orientation, organization and methods. This study is innovative in how it approaches nursing care delivery. The evidence is clear that RNs influence patient quality and safety outcomes. What remains unclear is how to organize and implement nursing knowledge and practice into care delivery models that consistently achieve national quality mandates. Nursing care delivery models are complex, dynamic and inherently context-sensitive. There is growing consensus in the health services research field that inquiry into and evaluation of complex healthcare delivery systems must move past traditional binary questions of efficacy and towards a more sophisticated exploration of "generalizable determinants of beneficial outcomes," which include implementation strategies that facilitate adoption and success (Glasgow et al., 2003; Hawe, 2015; Raine et al., 2016). This orientation drove innovation in the design, organization and methods, resulting in a conceptually clear understanding of the CNL care model that delineates a complex conditional pathway of effectiveness that can be rigorously tested in this study.

In terms of organization, it is a multisite study that builds on strong partnerships between the PI and the healthcare nursing community, meaning the study has been co-developed collaboratively with health system leaders (whose health systems are sites for this study) to answer questions that are pertinent to both them and policy makers (Bender et al. 2019). In terms of methods, we have explicitly chosen a research design and methods with the capacity to reflect and capture the dynamic interdependency of contextual factors in nursing practice. Hybrid effectiveness and implementation study design is an important and innovative methodological advance because it provides necessary information about intervention implementation; that is, in what ways and to what extent an intervention is adopted in diverse clinical settings, as well as determining the interventions' overall effectiveness (Curran et al., 2012). This study is the first large scale implementation-effectiveness study of ANY nursing care delivery model, and through meticulous preliminary research, has the tools to specifically measure CNL practice, as well as systematically delineate how CNLs have been implemented into redesigned care delivery systems and determine how implementation influences CNL practice and health outcomes.

Finally, the novel Robust-ITS (interrupted time series) statistical modelling approach we developed and tested for this study has enabled the creation and analysis of an until-now untested outcome variable; change in variability around an outcome of interest before (up to 24 month) and after (up to 24 months) implementation of a nursing care delivery intervention. Standard approaches to ITS segmented regression assume a pre-specified interruption time point or censor data for which the effects of the intervention are hypothesized not to be fully realized and assumes no changes in variance pre- and postintervention. Models incorporating these assumptions can bias effect estimates. Our approach is an advance over standard ITS segmented regression approaches because it explicitly models the lag between an intervention's introduction and its effect in practice, as well as changes in variation and correlation pre and postintervention.

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CONFLICT OF INTEREST

All authors declare no conflict of interests.

AUTHOR CONTRIBUTION

All authors were involved in the development and writing of the study protocol.

DATA AVAILABILITY STATEMENT

Raw data generated to support the findings of this study will be available from the corresponding author [MB] on request.

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