## Science of Nursing and Health Practices Science infirmière et pratiques en santé

# Giving a Voice to Nurse Managers and Staff Nurses: A Two-Centres Multi-Method Research Protocol to Optimize Nurses' Actual Scope of Practice

La parole aux infirmières soignantes et gestionnaires : un protocole de recherche multi-méthode dans deux centres hospitaliers pour optimiser l'étendue de la pratique infirmière

Johanne Déry, Maxime Paquet, Louise Boyer, Nathalie Folch, Mélanie Lavoie-Tremblay et Geneviève Lavigne



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#### Résumé de l'article

Introduction : De nombreuses études ont révélé qu'un temps limité est consacré aux activités de soins à valeur ajoutée faisant partie du rôle professionnel des infirmières (Déry et al., 2022). Or, cela a un impact sur la performance des systèmes de santé en termes de coûts globaux. La pandémie de COVID-19 a exercé une pression supplémentaire sur les organisations de soins de santé, et sur les infirmières gestionnaires et soignantes.

Objectif : Mobiliser les acteurs clés d'unités de soins afin de proposer des stratégies efficaces et réalistes pour faciliter le déploiement optimal de la pratique infirmière.

Méthodes : Ce programme de recherche international comprend 3 études transversales consécutives impliquant 2 centres de santé : 1 au Canada et 1 en Suisse. Le devis qualitatif de l'étude 1 comprendra des groupes de discussion avec des infirmières gestionnaires. Le devis corrélationnel quantitatif de l'étude 2 questionnera les infirmières soignantes. L'étude 3 comprendra de multiples rencontres avec des infirmières gestionnaires, soignantes, infirmières cliniciennes spécialisées et éducateurs (acteurs clés) pour élaborer un modèle logique d'intervention.

Discussion et retombées anticipées : L'étude 1 aidera à identifier les pratiques novatrices de gestion mises en œuvre par les infirmières gestionnaires depuis la COVID-19 ainsi qu'à identifier leurs besoins de soutien et de développement professionnel. L'étude 2 permettra de brosser un portrait précis du déploiement actuel de l'étendue de la pratique infirmière, ses tenants et aboutissants. L'étude 3 mobilisera les acteurs clés de chaque unité dans l'identification de stratégies efficaces et réalistes d'amélioration adaptées à leur réalité.

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# Science of Nursing and Health Practices



Article de protocole de recherche | Research protocol article

# Giving a Voice to Nurse Managers and Staff Nurses: A Two-Centres Multi-Method Research Protocol to Optimize Nurses' Actual Scope of Practice

La parole aux infirmières soignantes et gestionnaires : un protocole de recherche multi-méthode dans deux centres hospitaliers pour optimiser l'étendue de la pratique infirmière

**Johanne Déry** https://orcid.org/0000-0001-8353-9738 Faculty of Nursing, Université de Montréal, Quebec, Canada

Maxime Paquet https://orcid.org/0000-0001-6883-5467 Department of Psychology, Université de Montréal, Quebec, Canada

Louise Boyer Faculty of Nursing, Université de Montréal, Quebec, Canada

Nathalie Folch https://orcid.org/0000-0002-2307-3849 Centre hospitalier de l'Université de Montréal, Quebec, Canada

**Mélanie Lavoie-Tremblay** https://orcid.org/0000-0001-8707-9855 Faculty of Nursing, Université de Montréal, Quebec, Canada

**Geneviève Lavigne** https://orcid.org/0009-0003-7143-7584 Department of Psychology, Université du Québec à Trois-Rivières, Quebec, Canada

## **Correspondance | Correspondence:**

Johanne Déry

johanne.dery@umontreal.ca



#### **Keywords**

#### **Abstract**

nurses' scope of practice; nurse managers; protocol; logic model; international; multi-method

Introduction: Numerous studies have revealed that a limited time is devoted to value-added care activities that are part of nurses' professional role (Déry et al., 2022). This has an impact on the performance of healthcare systems in terms of overall costs. The COVID-19 pandemic has put more pressure on healthcare organizations, on its nurse managers (NMs) and staff nurses. Objective: To mobilize key players in care units to propose effective and realistic strategies to facilitate the optimal deployment of nursing practice. Methods: This international research program encompasses 3 consecutive cross-sectional studies involving 2 healthcare centres: 1 in Canada and 1 in Switzerland. Study 1's qualitative design will include focus groups with NMs. Study 2's quantitative correlational design will survey staff nurses. Study 3 will include multiple meetings with NMs, staff nurses, clinical nurse specialists and educators (key players) to develop a logic model of intervention to propose effective and realistic strategies to facilitate the full deployment of nurses' scope of practice. Discussion and Research Spin-offs: Study 1 will help describe the innovative management practices of NMs since the onset of the COVID-19 pandemic and identify their support and educational needs. Study 2 will explore the perceptions of staff nurses regarding the work psychological climate and work recognition, their actual scope of practice, their professional satisfaction at work and their perception of the quality of care. Study 3 will take advantage of this new data and mobilize key players in the identification of improvement strategies adapted to their own reality.

#### Résumé

#### Mots-clés

Introduction: De nombreuses études ont révélé qu'un temps limité est consacré aux activités de soins à valeur ajoutée faisant partie du rôle professionnel des infirmières (Déry et al., 2022). Or, cela a un impact sur la performance des systèmes de santé en termes de coûts globaux. La pandémie de COVID-19 a exercé une pression supplémentaire sur les organisations de soins de santé, et sur les infirmières gestionnaires et soignantes. Objectif: Mobiliser les acteurs clés d'unités de soins afin de proposer des stratégies efficaces et réalistes pour faciliter le déploiement optimal de la pratique infirmière. Méthodes : Ce programme de recherche international comprend 3 études transversales consécutives impliquant 2 centres de santé : 1 au Canada et 1 en Suisse. Le devis qualitatif de l'étude 1 comprendra des groupes de discussion avec des infirmières gestionnaires. Le devis corrélationnel quantitatif de l'étude 2 questionnera les infirmières soignantes. L'étude 3 comprendra de multiples rencontres avec des infirmières gestionnaires, soignantes, infirmières cliniciennes spécialisées et éducateurs (acteurs clés) pour élaborer un modèle logique d'intervention. Discussion et retombées anticipées : L'étude 1 aidera à identifier les pratiques novatrices de gestion mises en œuvre par les infirmières gestionnaires depuis la COVID-19 ainsi qu'à identifier leurs besoins de soutien et de développement professionnel. L'étude 2 permettra de brosser un portrait précis du déploiement actuel de l'étendue de la pratique infirmière, ses tenants et aboutissants. L'étude 3 mobilisera les acteurs clés de chaque unité dans l'identification de stratégies efficaces et réalistes d'amélioration adaptées à leur réalité.

étendue de la pratique infirmière; infirmières gestionnaires; protocole; modèle logique; international; multi-méthode

Given the imperative of reaching organizational goals such as quality of care, patient safety, staff retention, and reduction in length of stay, as well as the limited available means to reach them, it is essential to better understand what drives performance in healthcare organizations. These factors have been and continue to be the target of sustained development in management of public sector organizations, especially since the onset of the COVID-19 pandemic (Denis et al., 2021). Nurses are part of the solution when it comes to reaching these organizational goals. However, they need to be able to exercise their full scope of practice. To enable this, nurse managers (NMs) must provide nurses with a favourable work environment (Déry et al., 2022). The impact of the pandemic on the psychological health, work climate performance of nurses (Cardoso et al., 2021; Kosydar-Bochenek et al., 2022; Lavoie-Tremblay et al., 2022; Marvaldi et al., 2021) risk exacerbating the retention problem of nursing resources, which was already a significant issue before the pandemic (Berlin et al., 2021). Considering the many anticipated challenges, it is expected that several healthcare teams will have to rebuild and redefine themselves following the pandemic (Berlin et al.; Chen et al., 2021). In this sense, it is essential to involve healthcare organizations' key players to establish, based on previous research as well as practical experiences, effective, and realistic strategies to mobilize healthcare personnel and ensure an optimal utilization of existing nursing resources.

#### **OBJECTIVE**

The general objective of this research program is to mobilize key players in care units to propose effective and realistic strategies to facilitate the optimal deployment of nurses' actual scope of practice (ASOP). More specifically, this research program has the following specific objectives:

1- To describe the innovative management practices (MPs) of NMs since the onset of the COVID-19 pandemic and to identify their

- support and educational needs to better cope with the challenges of the upcoming years.
- 2- To study the potential associations between the work context (characteristics related to the psychological work climate) and the outcomes (for patients, nurses, and the organizations) of the deployment of nurses' ASOP.
- 3- To develop a logic model of intervention to propose effective and realistic strategies to facilitate the full deployment of nurses' scope of practice.

To meet the three specific objectives, this program was divided into three interconnected studies, the methodology of which is described separately.

Study 1: NMs (head nurse and charge nurse). NMs can facilitate the achievement of healthcare organizations' objectives and influence several aspects of health services such as ensuring the quality and accessibility of care (Bérubé et al., 2018; Brousseau, 2019). Although the role of NMs is poorly documented, several tasks, activities, and functions are known to be associated with the exercise of this complex role and are sometimes difficult to fully implement. Among their many responsibilities are ensuring the quality and accessibility of care (Bérubé et al.; Brousseau), offering support to members of care teams in the performance of care activities (direct and indirect) (Baker et al., 2012), as well as overseeing the overall functioning of the unit (Shuman et al., 2018). In addition, they must ensure the retention of nurses (Pilat & Merriam, 2019) as well as the mobilization of healthcare teams. In this sense, it is also their responsibility to put in place the work conditions and work climate that will allow nurses to be satisfied and to realize their full potential (Shuman et al.).

Finally, the various administrative processes as well as the management of the budget are responsibilities which have been found to be difficult and time consuming for NMs (Brousseau; Warshawsky & Cramer, 2019). Since the onset of the COVID-19 pandemic, NMs have been called upon more than ever trying to maintain the fragile balance between the use of human, financial, and material resources in addition to ensuring the quality of care and the safety of patients; all without being really prepared for such an

exacerbation of previous issues (Aquilia et al., 2020). Despite the scale of the task at hand, and the significant impacts that the pandemic has and will continue to have on the psychological health of nurses (Lavoie-Tremblay et al., 2022; Marvaldi et al., 2021), NMs have all in all succeeded in keeping their teams functional and mobilized.

Study 2: Nursing staff (registered nurses). The nursing staff are also key for the achievement of healthcare organization's goals. A better use of nursing resources is essential for effective and efficient healthcare systems (Cohen et al., 2021; Fealy et al., 2015), both in terms of accessibility and continuity of care and in achieving financial balance (Davis et al., 2021; Dubois et al., 2017). These imperative stayed true during the COVID-19 pandemic, which also exacerbated the ongoing challenge of maintaining a positive work climate an optimal care and performance (Cardoso et al., 2021; Kosydar-Bochenek et al., 2022). Regardless, several million dollars is spent unnecessarily each year in a "waste" of nurses' time (Bagheri Lankarani et al., 2019; Harvey et al., 2018). This "waste" mainly refers to the time spent performing tasks (clerical, cleaning, and others) which are not part of nurses' scope of practice. These repetitive tasks may partly explain why nurses do not have the opportunity to carry out all the professional activities for which they have the training, skills, and expertise (Déry et al., 2018, 2022). The nonoptimal deployment of the nurses' ASOP is potentially influenced by the work context (Birks et al., 2019; Gagné et al., 2019; Harvey et al.). Lack of autonomy and role ambiguity, two components related to the psychological work climate (Gagnon et al., 2009; Parker et al., 2003), appear highly significantly associated with the non-optimal deployment of the nurses' ASOP (Déry et al., 2016, 2018). These results are worrying since they imply that several care activities required by the patient/family's condition (e.g., adequate discharge planning, communication, coordination of care) are not carried out. This represents a major issue for the administration of nursing services since they have negative repercussions for patients, nurses, and healthcare organizations (Ball et al., 2018; Déry et al., 2022; Feringa et al., 2018).

At the patient level, care activities not performed by nurses can directly threaten the quality of care and patient safety (Harvey et al., 2018; Kalisch et al., 2014). For example, teaching activities are essential for adequate discharge preparation as well as for reducing readmissions (Harvey et al.), failure to perform them would therefore constitute a direct threat to patients' safe return home. Similarly, a deficit in communication and coordination of care, another essential nursing activity, can generate errors or major breaks in the continuity of care (Fowler et al., 2021; Khan & Tidman, 2022).

At the nurse level, the non-optimal deployment of ASOP can contribute to a decrease in their work satisfaction (Déry et al., 2015, 2018; Halcomb & Ashley, 2017) as well as to a perception of not being able to provide quality care (Harvey et al., 2018; Papastavrou et al., 2014). At the healthcare organization level, the non-optimal deployment of nurses' ASOP can have significant negative financial consequences. The difficulties in retaining nurses, staff turnover, overtime, sick leave as well as patient readmissions lead to significant economic consequences.

Study 3: Intervention logic model. A promising method to propose effective and realistic strategies facilitating the optimal deployment of nurses' ASOP, collaboratively between various key players of a healthcare organization, is the development of a logic model of intervention (W. K. Kellogg Foundation [WKKF], 2004). The development of a logic model is a sequential and iterative process that leads to a graphical representation of the problems and needs, the facilitating and limiting factors, as well as the best strategies to achieve the desired outcomes (WKKF). Key players, such as NMs, staff nurses or clinical nurse specialists and educators are called upon:

- To examine problems from the perspective of studies 1 and 2 and practical experience;
- To identify the strategies most likely to lead to the desired outcomes.

This approach is in line with the need to increase the voice and enhance the political power of nurses in order to give them a proper role in the definition and reconstruction of healthcare (Salette, 2020).

#### STUDY 1

**Design.** Study 1 will be an exploratory descriptive study, using a transversal qualitative design (Creswell & Plano Clark, 2018).

Participants and eligibility criteria. A convenience sample of voluntary NMs from each hospital centres under study will be recruited. NMs who have not been working since the start of the COVID-19 pandemic (March 2020) will not be eligible.

Data collection. NMs will be invited by their director to take part in a focus group of approximately 75 minutes (Jayasekara, 2012) that will be held and recorded via the Zoom/Webex videoconferencing software. This will allow for subsequent validation and confirmation of different statements. The feasibility of using videoconferencing technology for qualitative research, and especially for focus groups, has recently been demonstrated (Halliday et al., 2021). Interested participants that will contact the research team by email will receive a web link leading them to a consent and confidentiality form to be completed online. This link will also allow NMs to complete a brief socio-demographic questionnaire and to indicate their preferred time slots for the focus groups. Each focus group, led by the research team coordinator, will include between two and five NMs. Based on mobilization and work climate models (Gagnon et al., 2009; Tremblay & Wils, 2005), the discussion guide will consist of 11 open-ended questions developed specifically to allow the research team to deepen the understanding of NMs' experience in recent months as to the MPs they have implemented and of their need for support, and professional development.

**Data analysis.** Qualitative data will be analyzed using thematic analysis, which is "a method for identifying, analyzing, and reporting patterns (themes) within data" (Braun & Clarke, 2006, p. 6). Descriptive statistics will be used to portray participants' socio-demographic data.

#### STUDY 2

**Design.** For this study, a two-centres descriptive quantitative correlational design was chosen, because it allows for the exploration and description of the relationships that exist simultaneously between the variables of interest (See "Methods" section) (Tabachnick & Fidell, 2019). To collect data from a significant number of nurses, a self-administered questionnaire will be used. In addition, organizational data relating to human resources management and nursing outcomes will also be collected in collaboration with the managers of each participating units of the two healthcare centres.

Participants and eligibility criteria. The target population is all the nurses working in four preselected units in the Canadian centre, for a total of 196 nurses, and all the nurses working in the 15 preselected units in the Swiss centre, totalizing 308 nurses. A response rate of at least 70% is expected (n > 353). To select the participating units, NMs from both centres will be informed of the study and of its potential implications. The interested NMs will be asked to provide the email addresses of the nurses working in their unit. Finally, the research team will send the link to the web questionnaire, which will include the consent form, to all eligible nurses. To be eligible, nurses from the selected units must meet two criteria: 1-be employed by the hospital centre as a nurse (college diploma, baccalaureate); and 2-hold a part-time or full-time position. Nurses working all shifts will be invited to take part in the study.

**Data collection.** In both centres, all nurses working in the preselected units who meet the eligibility criteria will be invited to complete a webbased questionnaire (approximately 30 minutes to complete, in one or more session). Data collection will take place over a three to 12-week period or more, depending on the evolution of the health context (COVID-19 pandemic).

Variables and measures. The individual characteristics are nurses' age, experience and level of education. Socio-demographic data will also be collected to describe the sample of participants.

The Psychological Climate Questionnaire measures the perception of the work climate with 60 items grouped under 15 subscales (four items subscale). This instrument has psychometrically validated with two Canadian populations, French-speaking and English-speaking (Gagnon et al., 2009) and its reliability was found satisfactory (Cronbach's alphas between 0.64 to 0.91 in the English sample and between 0.57 to 0.92 in the French sample). The Workplace Recognition Questionnaire (Paquet et al., 2011) is composed of 15 items grouped into three dimensions: recognition from the organization, from superiors, and from peers. An additional item assesses recognition from patients. Each of the specific subscales measures recognition behaviours (between four and seven per subscale). Past research has reported satisfactory reliability indices for this questionnaire with Cronbach's alphas ranging between 0.75 and 0.89. Both questionnaires are answered on a five-point Likert scale, ranging from "Strongly disagree" to "Strongly agree".

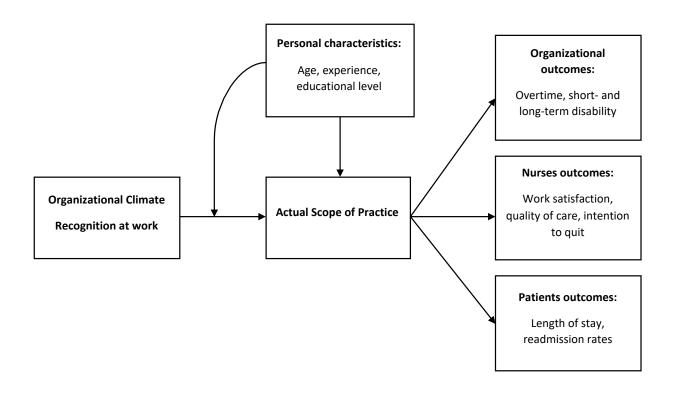
The ASOP questionnaire developed by D'Amour et al. (2012) will be used to measure this variable. It will allow staff nurses from both participating healthcare centres to report the frequency with which they perform the 26-care activities that are part of their scope of practice. The 26 items are grouped into six dimensions: 1- assessment and care planning; 2- teaching of patients and families; 3- communication and care coordination; 4- integration and supervision of staff; 5- quality of care and patient safety; 6- knowledge updating and utilization. In each of these dimensions, activities are divided into three levels of complexity: (1) low, (2) moderate, and (3) high. Level 1 corresponds to the basic practice expected of any nurse, including novice nurses. Level 2 refers to more complex procedures that can be performed by any nurse with experience, regardless of training. Level 3 interventions that can mainly be implemented by nurses who have good experience undergraduate university training. Satisfactory reliability indices have been reported for this measure including an overall Cronbach's alpha of 0.89 and Cronbach's alpha ranging from 0.61 to 0.70 for the six dimensions (D'Amour et al.).

The dependent variables are the "patient indicators (length of stay, readmission rate)", the "nursing indicators (professional satisfaction, perception of the quality of care)", and the "organizational indicators (overtime rate, short illness and long term)". The "patient indicators" as well as the "organizational indicators" are data that already exist in the organizations' databases (do not require any request from nurses or new data collection). These indicators will be provided by the human resources department and managers of the units under study. All data obtained will be anonymous. With respect to "nursing indicators", nurses' job satisfaction refers to nurses' opinion of the quality of care they provide, the time they have to accomplish the various care activities, as well as the feeling of pleasure they derive from them (Hinshaw et al., 1987). To measure this dependent variable, the Nurse Job Satisfaction Scale (Hinshaw et al., 1985) will be used. This questionnaire was translated into French by Roch (2008), and is composed of 22 items ( $\alpha$  = 0.91) divided into three dimensions: "Quality of care" (three items,  $\alpha =$ 0.74); "Pleasure at work" (11 items,  $\alpha = 0.91$ ); "Time to do optimal work" (eight items,  $\alpha = 0.84$ ). Nurses' perception of the quality of care given to patients will be measured by four items proposed by Aiken et al. (2002) on three different 4-point Likert scales (for example, from "Excellent" to "Bad"). This measuring tool obtained an alpha of 0.61 in a recent study (Déry et al., 2022). Finally, nurses' intention to leave will be measured with two items proposed by O'Driscoll & Beehr (1994): Both items are answered on a 7-point Likert scale ranging from "Not at all agree" to "Very strongly agree".

**Data analysis.** Descriptive analyses will be carried out for all the variables under study. Then, correlational and multiple regression analyses will be performed to determine the relationships between the study variables. A structural equation model will also be tested in line with the hypothesis proposed by Déry and colleagues (2015; see Figure 1). All analyses will be conducted using IBM SPSS 28 and AMOS version 19.

Figure 1

Research model for Study 2



#### STUDY 3

**Design.** For this study, a two-centres qualitative action-research design was chosen, to benefit from the complementary expertise of the researchers and participants (Guillemette & Savoie-Zajc, 2012). More precisely, Study 3 will use the intervention logic model (WKKF, 2004) with key players in two healthcare centres, specifically staff nurses, NMs, clinical nurse specialists and clinical nurse educators, to propose effective and realistic strategies that could facilitate the optimal deployment of the nurses' ASOP.

Participants and eligibility criteria. The target populations are NMs, staff nurses, clinical nurse specialists and clinical nurse educators working in the units that were included in the Study 2. A sample of four to five units per centre is targeted. Each unit will be represented by up to two NMs, as well as between two and three staff nurses and up to two clinical nurse specialists and clinical nurse educators.

Data collection. NMs from identified units will receive an email invitation from the research team presenting the research program. Following the reception of this invitation, they will be invited to contact the research team for more information and to invite the staff nurses, clinical nurse specialists and clinical nurse educators working in their unit. NMs will communicate to the research team the names of the people who will have agreed to participate in the development of the intervention logic model. The research team will then email them the informed consent form, a brief socio-demographic questionnaire, as well as the commitment and confidentiality form. Individuals interested in participating will be invited to contact the research team to obtain more information and return the completed documents.

Three meetings per work team (unit) will be organized, during regular work hours, for a time duration of around three hours each. Between three and six weeks will elapse between the

meetings. Each meeting will begin with an introduction during which the meeting plan and objectives will be presented. Each meeting will be moderated by the principal investigator following a focus group technique (Jayasekara, 2012). The ultimate goals of the three meetings will be to describe and understand, by mutual agreement by the participating members, the problems and needs of each unit, recognize the facilitating and limiting factors as well as to identify various strategies to achieve the desired outcomes.

Meeting 1. During the first meeting, components 1 (the problems) and 2 (the resources and needs) of the logic model (WKKF, 2004) will be discussed. Regarding the component 1, the research team will present the results and conclusions of studies 1 and 2. The ASOP, its antecedents (individual and work characteristics) and outcomes (for patients, nurses, organizations) will be presented to participants. Participants will then be invited to share their perceptions and experiences in connection with the deployment of the ASOP as well as to comment on the definition of the problems. Resources and needs, for the component 2, will be identified by the participants based on their knowledge, experience, and expertise. Then, they will be invited to comment, improve, and discuss on the description of their resources and needs.

Meeting 2. During the second meeting, components 3 (desired outcomes) and 4 (influencing factors) of the logic model (WKKF, 2004) will be discussed. Regarding the component 3, participants will be called upon to identify the desired outcomes from their perspectives. Regarding the component 4, the facilitating and limiting factors identified in Studies 1 and 2 of this research program as well as in the scientific literature will be presented to participants. They will then be invited to comment on these as well as identify other positive and negative factors for each of the desired outcomes.

Meeting 3. Finally, during the third and final meeting, components 5 (strategies) and 6 (hypotheses) of the logic model (WKKF, 2004) will be discussed. Participants will be asked to comment and elaborate further on the strategies that could lead to the desired outcomes. Finally, regarding the component 6, participants will be

asked to justify the assumption(s) underlying the choice of strategies proposed.

Data analysis. Each meeting will be summarized and analyzed using Braun and Clarke's (2006) thematic analysis method as described in Study 1. The logic model will be gradually built in collaboration with the work teams. Following each meeting, the summary and the identified themes will be sent to the participants so that they can modify, add, or remove some information. At the following meeting, the discussions will resume from the version of the logic model improved by the participants.

#### **ETHICAL CONSIDERATIONS**

All three study protocols have received ethical approval from the research ethics committee of the Canadian centre (*Centre hospitalier de l'Université de Montréal* 2022-9924, 21.117; 2022-9890, 21.133; 2022-9927, 21.409) and from the equivalent authority of the Swiss centre (*Centre hospitalier universitaire vaudois*). All participants will read and sign the consent forms as well as the commitment and confidentiality form (Study 3). Data will be collected from fall 2021 to summer 2023.

#### DISCUSSION AND RESEARCH SPIN-OFFS

Given the difficult context in which healthcare centres must navigate and the imperative of reaching organizational goals such as quality of care, patient safety, staff retention, and reduction in length of stay, as well as the limited available means to reach them, it is essential to better understand how we can maximize and use the limited human resources.

With a broader knowledge and understanding of the innovative MPs that have had positive impacts on nursing teams, it will be possible to support the professional development of NMs. Ultimately, this knowledge could lead to new innovative MPs and help influence the improvement of certain health policies, which is also part of the role of NMs (Brousseau, 2019). Moreover, a clearer understanding of nurses' ASOP and its association with their psychosocial work environment and work satisfaction will make it

possible to establish reliable and solid basis for discussions with key players in the search for concrete strategies adapted to their reality.

#### LIMITATIONS

A few limitations deserve to be mentioned. First, all three studies of this research program are cross-sectional. This will specifically limit our ability to formulate conclusions based on the causal relationships between the variables studied in Study 2. Also, data will be gathered at the unit level, with a discrepancy between healthcare centres regarding the number of participating units. This reality will hinder the possibilities of generalizing conclusions to the whole organizations. Future longitudinal research with the whole organizations would be beneficial, especially to study the changes resulting from the implementation of the strategies formulated in the Study 3. Second, both included healthcare centres are in large metropolitan cities, the realities of rural centres may differ. Finally, although some organizational indicators will be collected from existing databases in both centres, most variables will be self-reported by participants.

**Authors' contribution**: JD and MP lead the conceptualization of the research program, designed the three studies, and developed the research protocol. LB, NF, MLT helped conceptualize and design the research program. LB, NF and MLT also made substantial comments on the research protocols and on the first draft of this article. GL actively collaborated in the writing of the protocol and of this manuscript. All authors reviewed and edited the final manuscript.

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