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Research Article

Applying Mindfulness Techniques to the Management of Depressive Tendencies in Women in Taiwan in the Perinatal Period: A Qualitative Study



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SUMMARY

Purpose: Perinatal distress, especially depression, commonly occurs during pregnancy and the first year postpartum, but this medical condition are often undiagnosed and untreated. The present study explored how women with depressive symptoms during the perinatal period who had participated in a mind-fulness course applied the training and perceived its effects.

Methods: This descriptive qualitative study included 16 women with probable perinatal depression who had participated in an 8-week mindfulness-based childbirth and parenting program during their pregnancy and agreed to be interviewed. One-to-one in-depth interviews were conducted and recorded following the completion of the mindfulness course, approximately 1 month after childbirth. Verbatim transcripts were analyzed using content analysis.

Results: We proposed three themes and six subthemes relating to first-time mothers' experiences during and after the group mindfulness-based intervention: learning to be aware of the body and mind (confronting awareness of physical change, managing negative feelings differently), building positive family relationships (strengthening the mother—baby bond, developing a satisfactory marital partnership), and overcoming ongoing challenges (conquering childbirth pain with confidence, accepting unexpected situations). Three main themes were generated to demonstrate how women experience the effects of mindfulness training.

Conclusions: Mindfulness-based interventions helped the participants develop insight into their mood and physical changes and accept their childbirth process. Therefore, mindfulness education programs can be incorporated into prenatal care to enhance the management of the depressive symptoms of perinatal women.

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Introduction

Women are particularly susceptible to psychological distress, especially depression, during pregnancy and the postpartum period [1,2]. Depression is a leading cause of disability worldwide

and is a major contributor to the overall global burden of disease [3]. Roomruangwong and Epperson [4] revealed that the overall prevalence rate of depression in Asian women was significantly higher than that of women in Western countries. Studies have estimated that 13.2%–20.0% of Taiwanese women experience depression during the prenatal period [5–7].

The need to address perinatal depression is clear; however, few women with mental health disorders are diagnosed in the perinatal period, and they rarely receive treatment [8]. Even when pharmacological interventions are suggested, women are reluctant to accept such treatment because of concerns for their infant's safety [9]. If perinatal depression is not adequately managed, women with strong depressive symptoms experience disturbed sleep, changes in appetite, and general unhappiness [10]. Increased marital conflict, impaired infant attachment, and infanticide have been reported

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[11–14]. Moreover, for Chinese women, cultural factors can increase the risk of depression; examples include conflicts with their motherin-law [4] and a lack of support from the husband [15].

Because perinatal women prefer to undergo psychosocial therapy, the US Preventive Services Task Force recommended that all women at risk of depressive disorders during this period be referred to behavioral or psychotherapeutic interventions [16]. Mindfulness is defined as the process of focusing on the present in a nonjudgmental manner [17,18]. In recent years, research has demonstrated that mindfulness practice can improve a wide range of mental and physical health conditions because participants learn how to disengage from negative thinking [19–21]. The mindfulness-based childbirth and parenting (MBCP) approach is informed by mindfulness theory. This approach is specifically tailored to the needs of expectant parents and is producing promising results regarding perinatal mental health [22-24]. Because pregnancy triggers psychological distress in women with a depressive tendencies, identifying the extent to which MBCP programs can help such women is essential.

Peng et al [25] reported that 33.5% of Chinese women lived with their parents-in-law, and such women were more likely to experience postpartum depression. Recent evidence has demonstrated that women with postpartum depression symptoms may differ compared with women without such symptoms in help-seeking and preferences for treatment [26]. Although studies have indicated that mindfulness is effective for healthy Chinese perinatal women with mental health [27], few studies have focused on the effects of mindfulness on perinatal women with depressive symptoms. Additionally, in Chinese societies, a woman's life as an expectant mother is deeply influenced by traditional Chinese culture; therefore, we must understand how these women use mindfulness to adjust to postpartum life and clarify the underlying mechanisms of mindfulness in related scenarios. This study investigated how women with depressive tendencies during the perinatal period who participated in our mindfulness program applied mindfulness training and perceived its effects on their perinatal life.

Methods

Study design

A descriptive qualitative method [28] was used in this study. This method enables researchers to obtain information directly from participants, conduct inquiries with the minimum disruption to the natural context of the phenomenon being studied, and engage deeply with data in the analysis and presentation process.

Qualitative researchers in the health sciences have diverse backgrounds; thus, their approach to various phenomena is based on their preexisting knowledge and an rich, straightforward descriptions of an experience or event [29,30]. This method focuses on various phenomena instead of the theory and thus produces novel results that can provide a rich and direct description of an experience or event. The final product is a description of the experience in language that is similar to the participant's own language [31].

Setting and participants

This study is part of a large prenatal mindfulness intervention study. The 8-week MBCP program took place in Taiwan and was targeted at pregnant women who were nulliparous, were aged >20 years, were at 13–28 weeks' gestation with a singleton pregnancy, were able to understand and write Chinese, had no medical or obstetric complications, had Edinburgh Postnatal Depression Scale

scores >9 (score range from 0 to 30, and >9 is possible depression) [32,33], planned to give birth vaginally, and agreed to attend the MBCP program. Women were excluded if they had a diagnosed psychosis or if they or their fetuses had any medical complications.

The intervention consisted of eight 3-hour weekly sessions and was based on Bardacke's [24] original MBCP program adopted by Pan et al. [34]. This program is tailored for expectant couples, and the teaching of mindfulness is fully integrated with current knowledge on the psychological processes of pregnancy, childbirth, breastfeeding, postnatal adjustment, and the psychological needs of newborns. This knowledge is combined with the mindful attitudes of nonstriving, kindness and compassion, beginner's mind, patience, trust, nonjudging, acknowledging or accepting, and letting go. In addition, partner support, a self-regulation tool for coping with labor pain, and awareness skills to reduce or prevent stress, anxiety, and depression symptoms in perinatal life are included [23,35].

This mindfulness program was taught by the first author, and it included learning about mindfulness meditation techniques for the perinatal period. The learning content included formal and informal training. The course was run with 8–12 participants and their partners in a group. The participants were required to listen to audio recordings of formal and informal mindfulness practices that they could perform at home for 30 minutes six times a week and to additionally complete a homework assignment after the practice. We allowed the participants the necessary time to practice mindfulness outside the class with the goal and expectation that they would undertake this additional practice.

In this study, 16 participants from three groups within the MBCP program who agreed to attend the interviews and who gave birth in 2020 and 2021 were included. The interviews were held approximately 1 month after childbirth.

Ethical considerations

This study was approved by the Taiwan Adventist Hospital Institutional Review Board (Reference No. 108-E–14). Before starting each interview, the researcher informed the participant about the purpose of the study, the interview process, and plans for using the collected data. They were provided with information relating to this study in written and verbal form. All the participants were informed of the voluntary nature of their participation. Their interview records were kept confidential. Furthermore, the participants were informed that they could withdraw from this study at any time without affecting their rights to health care. All identifying information was removed from the interview records and the participants' personal data; only codes were used in the final analysis.

Data collection

The interviews were held either in a postpartum nursing center or at the participant's home. An interview guide was used, and questions such as "Please describe your experience of participating in the mindfulness program," "Please share how you have applied the mindfulness program to perinatal life," and "Tell me how you have adapted to your current life" were included. To elicit the most comprehensive descriptions, the participants were asked to answer these questions and were then prompted to clarify or expand on their answers with follow-up prompts, such as "What do you mean ...?" Upon completion of the interviews, the participants completed a short demographic survey questionnaire.

Data analysis

Braun and Clarke's method was used to conduct a thematic analysis of the data. This is a qualitative method that allows for the identification, analysis, organization, and report of patterns or themes revealed within the data [36]. Two female researchers read the transcripts and onsite notes of each participant's interview several times to immerse themselves in the data and fully understand the participant's responses and experience. Subsequently, they discussed and compared the coding of each transcript until a consensus on the codes and coding definitions was reached. The themes were discussed and finalized with the consensus of all the authors to ensure that the units of code identified were related to the themes and that the finalized themes truly represented the entire dataset [37].

Trustworthiness of the study

Several principles guided the strategies that were used to maintain the reliability of this study, namely credibility, transferability, dependability, and confirmability. This was achieved through (1) an intensive interview that lasted 50–90 min, (2) continuous observation and data analysis, and (3) data generated through recordings and verbatim records of the interviews. Credibility was supported through meetings between research teams and with colleagues and participants to discuss research findings. To facilitate transferability, diversity with regard to age, educational level, and the method of childbirth used was valuable. The interview guide was developed from a review of the literature and input from mindfulness experts. In addition, multiple collaborative sessions were held by the research team to ensure the accuracy of the data collection and analytical procedures and increase the dependability of the data. Furthermore, two interviewees were invited back to conduct further checks and describe their experiences as accurately as possible; hence, in this manner, we could establish research confirmability [38].

Results

The ages of the 16 women ranged from 23 to 38 years. Most held a bachelor's degree or above (87.5%) and were married (93.8%); 87.5% were employed during their pregnancy. Fifteen participants experienced a normal vaginal birth, and one underwent a cesarean section because the baby was in a breech position (Table 1).

At the time of their interview, all participants reported that they still practiced formal and/or informal mindfulness in their daily lives. The data were organized into three major themes to demonstrate how women experience the effects of mindfulness training: (1) learning to be aware of the body and mind, (2) building positive family relationships, and (3) overcoming ongoing challenges. Each theme contained two subthemes.

Theme 1: Learning to be aware of the body and mind

All the women described being aware of their physical and mental changes during the mindfulness practice after their participation in the mindfulness program.

Confronting awareness of physical change

Participants reported that the practice of mindful breathing and the body scan technique helped them focus on their body more and relax their muscles, resulting in fewer backaches and headaches:

"I got sore shoulders easily and suffered from headaches for many years ... Since learning these techniques, I am able to focus on the moment and on my breathing. I noticed that I didn't have any headaches before or after childbirth." (participant 13)

Participants also described feeling uncomfortable and tired in their pregnancy, but mindfulness practices improved the quality of their sleep, improved their circulation, and increased their energy levels. One participant said,

"I found the body scan pretty useful. At the very beginning of my pregnancy, I often found it difficult to fall asleep. I would listen to the 'body scan' [tape] before bedtime. I started to sleep better and felt energetic the next day." (participant 5)

Managing negative feelings differently

Overall, participants reported that they felt calmer, less anxious, and less as though they were on "autopilot," meaning that their brains wandered less after practice. One participant explained how the class and the practice helped her become aware of sensations of inner peace, making her feel calmer and allowing her to think more clearly:

"I think mindfulness calms my emotions and changes my thinking. I used to worry about a lot of things, such as the fear of a difficult birth and having a cesarean. But the mindfulness practice and childbirth knowledge in this course helped me stop worrying because what I see, think, or feel may not be the actual situation, so I don't need to worry about it, and I have slowly begun to believe that I am capable of giving birth." (participant 8)

Table 1 Demographic Characteristics of Participants (n = 16).

No	Age (years)	Education	Employment status	Mode of birth	Course attendance (no. of times)	Mindfulness training status	EPDS (Pretest)	EPDS (posttest)
1	36	University	Yes	Vaginal birth	8/8	Informal training	12	3
2	29	University	Yes	Vaginal birth	7/8	Informal training	10	6
3	23	University	No	Vaginal birth	6/8	Both, formal training (60 minutes)	19	19
4	32	Graduate school	Yes	Vaginal birth	8/8	Both, formal training (30 minutes)	15	16
5	36	Graduate school	Yes	Vaginal birth	6/8	Informal training	11	11
6	32	University	Yes	Vaginal birth	8/8	Informal training	10	7
7	28	Junior college	Yes	Vaginal birth	6/8	Informal training	15	12
8	34	University	Yes	Vaginal birth	7/8	Informal training	14	6
9	27	University	No	Cesarean section	8/8	Both, formal training (15 minutes)	12	6
10	33	Graduate school	Yes	Vaginal birth	8/8	Informal training	18	3
11	33	University	Yes	Vaginal birth	8/8	Informal training	11	7
12	32	University	Yes	Vaginal birth	8/8	Informal training	15	15
13	33	University	Yes	Vaginal birth	8/8	Informal training	12	9
14	38	Junior college	Yes	Vaginal birth	6/8	Informal training	11	8
15	32	Graduate school	Yes	Vaginal birth	7/8	Both, formal training (20 minutes)	16	11
16	37	Junior college	No	Vaginal birth	8/8	Both, formal training (30 minutes)	13	9

Note. EPDS = Edinburgh Postnatal Depression Scale.

Disappointment often occurs in life. Participants discovered that mindfulness techniques taught them to recognize their feelings and stop for a moment. They tried to consider life events from a different perspective, which helped them to avoid feeling that they were letting themselves down:

"I was told by the doctor that I had to have a cesarean because my baby was in a breech position. This was different from my original plan, but it happened ... I was very worried at the time. Then I took a deep breath and stayed focused on the present moment. I was able to think that this was just my baby's choice. I told myself that it was no big deal. And that's been really helpful for me." (participant 9)

Theme 2: Building positive family relationships

The women incorporated mindful techniques into relationships with their baby and husband. They exercised nonjudgment and ever-unfolding compassion for each and every moment, which enhanced their relationship.

Strengthening the mother-baby bond

This program helped the participants feel and interact with their baby during pregnancy. Participants reported that they used fetal movements as a reminder of mindfulness and that these movements elicited positive feelings. This maternal—fetal interaction continued until birth. Most participants experienced joy during the prenatal period:

"I felt my baby and wondered what my baby was doing. This also reminded me to be mindful with my baby. It was really fun. Sometimes she (my fetus) was very calm; sometimes she was making trouble and moving a lot. I could always feel her, and it was interesting."(participant 7)

Several months after participating in the class, several women mentioned that practicing mindfulness became easier when they let the babies be their teachers. They learned to focus completely on the baby to view their present-moment parenting experience with their baby. One participant used this technique to bond with her baby despite the baby's gender not meeting the expectations of her mother-in-law:

"I could feel my mother-in-law's disappointment, but I was engrossed in being with her. I really felt that she was my angel ... I think she understands me [looking at her baby]. She probably knows what I want to do. She keeps looking at me. People say you shouldn't praise this behavior in front of the baby, but my baby doesn't cry when she's hungry. She just gently pats me. Really! My husband also notices it. She pats me on my face like this [demonstrates the movement with her hands]." (participant 11)

Developing a satisfactory marital partnership

All the participants mentioned that when they deliberately practiced maintaining awareness of their attitudes, they began to accept their own limitations and those of their partners. They also realized their husbands had changed. These husbands understood more about their wives' changes during pregnancy and birth and their attentiveness toward their wives increased after participating in the program. One participant said,

"I found that it was good to participate in this program with my husband. In the past, he couldn't easily sense when I was experiencing discomfort. However, I think he has become more considerate after attending this program ... he has started carrying things, minding my walking pace, and helping me focus on the road. He even joins me in practicing mindful breathing in the evenings." (participant 1)

Participants believed that techniques such as loving kindness and acceptance were helpful to their marital relationship. It made them more tolerant of each other and therefore reduced friction at home. One participant, who was shy but anxious to express herself, opined,

"Speaking in class put pressure on me, but I had the motivation to continue because he [my husband] accompanied me to every class. I learned to look at myself with acceptance and found that speaking in class was not very hard [smile] ... I think it was very important to have him here, he is my greatest support." (participant 12)

Theme 3: Overcoming ongoing challenges

The majority of the participating women thought that the program helped them to cope with life's challenges. In addition to facing the pain of childbirth, they faced other major changes in life, such as caring for the baby, their husband's sudden unemployment, and returning to work. This theme reflected the women's perception of the training as effective because it enabled them to develop their strategies for dealing with threatening situations.

Conquering childbirth pain with confidence

Many participants reported a change in attitude with every session they attended. They gradually felt more confident about their pregnancy and birth. When they went into labor, mindful breathing allowed them to experience the physical sensations as pain arose, peaked, and disappeared. Using meditation to stay focused during childbirth enabled them to achieve successful labor outcomes:

"Before giving birth, I was really afraid of birth pain. I heard that it was really scary. After taking the mindfulness class, I learned not to worry about things that had not happened yet. I was able to face the birth and used breathing when each new contraction came ... I felt very happy that I could get through the labor on my own." (participant 2)

Three of the participants did not plan to use epidural analgesia for pain relief in labor but later chose to do so. They felt well informed of their choices, and thus, they were able to make the decision with confidence:

"I found that the childbirth pain was more painful than when we were holding the ice with our hands in mindful class. I really can't describe it. Later, I chose pain relief to help me manage the pain. Although this was different from what I had thought at the beginning, I don't judge myself. That's what my body needed at the time."(participant 12)

Accepting unexpected situations

Having a child results in a number of unexpected life changes, such as less sleep, no alone time, and being constantly busy. Participants noted that mindfulness helped them take a step back from the situation and take a more objective view without making emotional judgments about the situation:

"Because we are both new parents, we sometimes forget to prepare extra clothes for our baby when we go out. One time he had a bowel movement, and we had to go home immediately. Mindfulness helps us to accept what's happening right now, so we don't blame each other for not remembering." (participant 2).

Two participants mentioned their husbands losing their jobs because of the COVID-19 pandemic. Instead of reacting immediately and feeling depressed, they observed and actively noticed what was happening around them and then looked at the event from a different perspective. One participant commented,

"My husband was unemployed. Although I was mentally prepared before, I was worried at the time. I try to focus my attention on what is happening in the present moment, and I find that he has more time to be with us ... It reminds me that we shouldn't focus on the negative things in life. So, I'm not as anxious as before. I will face the future with courage." (participant 10)

Discussion

This qualitative study adds to the literature supporting the effectiveness of mindfulness learned in MBCP and specifically highlights the benefits of mindfulness techniques to these women to manage their stress.

The first theme of our study "learning to be aware of the body and mind" was similar to previous case—control studies, indicating that mindfulness interventions can reduce perinatal depression, anxiety, and stress [23,39]. Women face many changes after childbirth and must adjust to new difficulties and unexpected situations. This program can help women apply mindfulness techniques to increase their situational awareness and promote calmness and relaxation. The findings are congruent with those of quantitative studies, suggesting that higher levels of mindfulness are aid psychological adjustments and help individuals accept challenges [40]. By contrast, if they are unable to cope with disappointment and the homeostasis is disrupted, physical and mental functions may be reduced [41,42].

The women in our study considered that their positive family relationships were associated with our mindfulness interventions. The mothers became aware of the value of their attachment to their babies and felt happy that they and their babies could respond to each other. This is consistent with research revealing that mind-fulness interventions are essential for improving parents' ability to be responsive, warm, and calm, helping them to develop a more attuned mother—infant interaction [43]. These programs also give women the opportunity to strengthen their relationships with their partners, with mindfulness techniques being used to manage difficult emotions and create greater flexibility in dealing with stressful situations [44,45].

Mindfulness childbirth classes for pregnant women help them prepare for the labor and birth and increase the levels of maternal attachment and competence in motherhood [46]. The results from this study reveal that the MBCP curriculum helps women strengthen their inner processes of attention, awareness, nonreaction, and nonjudgment toward their children through their daily parenting interactions. In addition to improving the mother's mental health, mindfulness also helps the mother to be competent in her parenting role.

Notably, through qualitative content analysis, we revealed that some participants used mindfulness practices to address the challenge of conflict with their elders during the perinatal period. Traditionally, after a Chinese woman marries, she becomes part of the husband's family and lives with them. Therefore, she cannot express herself as freely as when living with her own family, which may result in her suppressing her emotional expression [47]. Furthermore, discrimination against baby girls and a lack of support from husbands are problems that still exist in Chinese society and can aggravate the symptoms of maternal depression, particularly when new mothers live with their parents-in-law [48]. Therefore, future mindfulness interventions should incorporate cultural factors, share the perinatal experiences of other women in the course, and make adjustments that cater specifically to the needs of Taiwanese women.

Three themes from this study can help women manage depression clinically. First, awareness of the body and mind allows women to be open to all experiences and live in the moment, even in unexpected or unwelcome situations [44]. Second, MBCP can improve the parent—child relationship if the parent adopts a mindful parenting attitude, including listening attentively, accepting oneself and the child nonjudgmentally, being emotionally aware of oneself and the child, adopting self-regulation, and having compassion for oneself and the child [44]. Third, the women perceived the core mindfulness practices, such as mindful breathing, the body scan, and mindful walking, as helpful. These techniques empower women both physically and emotionally during childbirth and in the postpartum period [49].

Despite the adequate sample size and data saturation, the present study has several limitations. All participants were volunteers and members of three MBCP program groups; furthermore, they were homogenous in terms of sociodemographic characteristics and geographic location. Another limitation is that the participants of this study were women with depressive tendencies; as such, the results cannot be generalized to all individuals with depression. Furthermore, most of the participants were accompanied by a male partner, although the perspectives of the partners were not explored. Future qualitative research may explore the experience of the male partners participating in the program. In addition, women with positive experiences might be more willing to share their experiences than those with negative experiences, which could affect the results.

Conclusion

This study was conducted using in-depth interviews to investigate the experience of women with perinatal depression tendencies during and after a mindfulness program. The study revealed that MBCP could be a novel means to help women raise awareness of issues that affect them, strengthen relationships with others, and overcome challenges, thus enhancing depressive symptom management. This mindfulness program also provides another option for childbirth educators to help perinatal women improve their mental health.

Conflict of interest

The authors have no conflicts of interest to disclose.

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"Life is Bitter and Sweet": The Lived Experience of Ethnic Minority Elders with Type 2 Diabetes Mellitus in Rural, Thailand



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SUMMARY

Purpose: The purpose of this study was to describe the lived experience of ethnic minority elders (EME) with type 2 diabetes mellitus (T2DM) to understand an individual's experience, perception, and behaviors connected to T2DM in rural areas where support is limited.

Method: The hermeneutic phenomenological methodology was used to explore the lived experience of EME with T2DM by using conversational interviews. Twenty EME were interviewed. The data analysis and interpretation followed the thematic analysis by van Manen.

Results: Analysis highlighted an overarching theme of "Life is Bitter and Sweet" and three main themes: (1) the struggle of living with diabetes, (2) living with inequalities, and (3) dealing with diabetes that reflects the experiences of EME with T2DM living in underserved areas based on the cultures, beliefs, and spirits.

Conclusions: The finding led to recommendations to strengthen interventions by family members, improve supportive systems and services to improve knowledge, self-management, and maintain physical well-being in order to increase the quality of life for the EME with T2DM.

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Introduction

Diabetes mellitus (DM) is a common chronic disease and a major public health problem worldwide. The proportion of people with type 2 diabetes is increasing in most countries and it is expected that the number will rise to 700 million by 2045 [1]. Approximately 90% of people with diabetes have type 2 diabetes mellitus (T2DM) [2]. The increasing prevalence of T2DM is usually attributable to factors such as aging populations and an increasing level of sedentary lifestyles that seem to accompany economic development. According to a current study in the United States, 22% to 33% of people over 65 years of age diagnosed with T2DM experience a higher risk of

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lower extremity amputation, myocardial infarction, visual impairment, and end-stage renal disease than the rest of the population [3,4]. In Thailand, the prevalence of T2DM in people over 65 was 10.1% in 2014 and is already at 19.6% in 2020. Over half (52.4%) of the elderly with T2DM failed to control their blood sugar level (HbA1c >7%), and approximately 200 people die of the consequences of T2DM every day [5,6]. Moreover, this situation may be worsening due to poor access to healthcare, low levels of disease management, and poverty, especially among vulnerable people who live in poorer communities and rural or mountainous areas [7–10].

In Thailand, an estimated 6.1 million ethnic minorities comprise 9% of the total population and live mostly in Chiang Rai Province [9]. The identities of ethnic minorities are displayed in multiple ways, such as lifestyle, language, beliefs, culture, attitudes, values, and economic status. Ethnic minorities have long been stigmatized as alien, uncivilized, and dangerous [11,12]. Ethnic minority elders (EMEs) are a clear example of a vulnerable group who suffer inequalities in the healthcare systems of all countries due to language barriers, health literacy, or self-care management [13]. Apidechkul et al. (2018) reported that over 30.0% of EMEs were not granted a

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Thai identification (ID) card, which is used to access public services, including free medical services [14,15].

Most of the previous studies focused on the prevalence or incidence of T2DM, factors related to hospitalization, and other comorbidities in the elderly. These studies were used to amplify treatment regimens but did not provide a deep understanding of their experiences [11,14—18]. To date, there is little available information with respect to the EME with T2DM. There is a need to gain a deeper understanding of their perspectives and about their understanding and management of their disease in rural and underserved areas [19]. The purpose of this study is to describe the lived experience of EME with T2DM and to understand individual experiences, perceptions, and behaviors related to T2DM in rural areas.

Methods

Study design

For this study, Max van Manen's hermeneutic approach was chosen as a methodology that offers researchers a way to explore and understand the complexity of a phenomenon or interest by empathetically capturing and transmitting the sense and feeling of living through different experiences. Van Manen's approach, which is explicitly hermeneutic, recognizes the role of the researcher as an interpreter and even as an inventor of meaning and provides researchers with space to identify and understand various perspectives on human experiences. The use of hermeneutics phenomenology enables the exploration of participants' voices, feelings, emotions, attitudes, and nuances of EME when living with T2DM in rural areas [20].

Van Manen's approach goal is to attempt to describe a lived experience in a way that retains and communicates the essential meaning of that experience [20]. Van Manen's approach offers a strong philosophical concept grounded and built upon the works of early phenomenological philosophers. This approach is appropriate for this study as little is known about the investigated phenomena, and relevant information in the current literature is scarce [21,22]. Van Manen portrays the methodical composition of phenomenology as a dynamic interplay among six research activities: (1) identifying the phenomenon of interest; (2) exploring evidence as it is lived and not as it is preconceived; (3) reflecting on themes; (4) writing and rewriting; (5) maintaining a strong and oriented relationship with the phenomenon; (6) considering the parts as a whole of the phenomenon in question [20]. Following this methodology, the transcripts and textual data of the participants' stories were examined, and the spoken accounts of their experiences were interpreted to discover what was telling, meaningful, and thematic. From the participants' life stories, a rich textual description was produced and interpreted for meaning. The aim of phenomenology is to transform lived experience into a written format in a way that challenges normative assumptions, making the text a reflective appropriation of something meaningful and offering a crucial paradigm, solutions, and relevance to nursing as a research methodology [23].

Setting and sample

Twenty EMEs with T2DM who met the inclusion criteria were invited to participate in the study by a nurse at a subdistrict health promotion hospital (SDHPH) during their monthly medical appointment. Participants were recruited from two disadvantaged villages in the Mae Chan district and were approximately 60 km, or about 2 hours away, from the provincial capital. The following criteria were used to recruit participants into the study: 60 years of age or older, able to speak the Thai language, and diagnosed with T2DM over a 5-year period with no cognitive disorders, as indicated by a Mini-Mental Status Examination (MMSE) below 24.

Data collection

Descriptions of EME with T2DM were obtained through indepth interviews and open-ended questions. Interviews took place from September 2019 to January 2020 and were conducted in Thai. They were held in locations preferred by each EME, including their home, an SDHPH meeting room, and community centers. These meetings were conducted face-to-face, and the questions asked were based on the study objectives.

The researchers on this project worked at a university and came from various backgrounds. Two held doctorates in nursing and were qualitative experts, two were advanced nurse practitioners in chronic care elderly, and one was a community nurse professional with extensive experience with the ethnic minority population in these areas and qualitative method expertize. The primary investigator set up a three-day research workshop for team members to mentor and train junior qualitative researchers in critical and reflexive engagement with the data and other team members, such as trained research assistants, in overcoming language problems during interviews.

During the first meeting, the researchers established a rapport with the participants by introducing the research members, asking the participants questions, and giving them information about the study objectives. This step was important as it allowed the participants to feel comfortable, thereby encouraging them to provide more detailed information. The interviews were carried out by KP and KM, who were qualitative experts with 10 years of experience, and initiated with a broad, open-ended question that prompted the participants to talk freely about their experiences of living with T2DM in rural areas. Typical questions were: (1) "What do you know about T2DM? What was it like when you were diagnosed with T2DM?" (2) "Can you describe a typical daily activity in your life?" and (3) "What kind of support do you have when experiencing T2DM?"

Narrative data collection can provide access to ethnic elders' experiences of facing inequity in healthcare services by listening to their voices and understanding their circumstances [20]. It may also add to a continuing care model, instead of focusing on pathology and disease. As participants narrated their stories, the researchers prompted them to explain their particular situations with probing questions, such as, "Could you please tell me a bit more about that?" or "What did you think or feel about it?" For two participants who could not speak Thai fluently, trained research assistants who were fluent in Thai and could speak the same languages as the participants helped explain and clarify particular questions. All interviews lasted between 55 and 90 minutes, were audiorecorded, and were subsequently transcribed with the participants' permission. In addition, the participants' diabetes personal health booklets were reviewed after the interviews to gather treatment history and blood sugar level.

Most participants were interviewed once at the appropriate places, and the interviewing continued until we deemed data saturation to have been reached. For three participants, more than one interview was carried out to help the researcher probe exactly what was most important by returning to ask participants to validate their responses to certain questions. No more participants were recruited after 20 interviews as, at this point, no new data, themes, or ideas emerged from the interviews, and a good phenomenological gestalt was reached. All taped interviews were transcribed and checked for errors by a bilingual research assistant as well as the primary investigator before being returned to the participants for confirmation and/or corrections. Coding trees of the main findings were developed, key findings were extracted, and data saturation was discussed among the researchers.

Data analysis

In this study, the data analysis and interpretation followed the thematic analysis by van Manen. Initially, the interview texts were transcribed and then reviewed by the research team several times to gather a general understanding. Next, the main concept of the texts was written up in two to three paragraphs (a holistic approach), which helped the researcher immerse in the data, and think more deeply about the phenomenon. In this approach, we used the NVivo software package to organize the data. Each interview text was read, re-read, reflected transcription, and moved back and forth between the elements of the text and the whole text to reveal the essence and meaning of the phenomenon.

Van Manen suggests that using a team approach can strengthen the identification of themes by enabling the research to see beyond the text and interpret meaning [20]. Next, the research team members exchanged views and discussed the preliminary themes. The agreement was reached between researchers by moving ideas around and re-visiting the original interpretation until the resulting contents and themes were aggregated in the best possible way. Each theme was supported by direct quotations from the participants and captured the lived experience of EME with T2DM in rural areas.

Trustworthiness

The trustworthiness of the study was enhanced by several strategies establishing credibility, prolonged engagement with participants, non-participant observation, member checking, and establishing an audit trail. Prolonged engagements ensured constant interaction with put on hold the prior knowledge about the phenomenon of interest and abandoning ideas that were not supported by the data. We read the transcripts multiple times and compared the coding systems results, which led to the emergence of themes and subthemes as a measure of ensuring the trustworthiness of the data. In the course of writing the manuscript, the emergent themes were compared with the transcripts individually and as a whole. Sharing research findings with five participants, three were Thai speakers and two were not fluent in Thai, to conduct a member check in order to confirm its accuracy and enhance the trustworthiness of the research. These include reflecting on what participants narrated, discussed as well as issues they did not narrate or discuss in the interviews. Finding from the observation notes were used to validate the in-depth interview along with a discussion of each other's interpretations which helped to identify implicit biases toward the data. Finally, contextual information about the research findings was described in as much detail as possible so that readers could assess whether or not the findings were transferable. [24].

Ethics approval and consent to participate

All research protocols were performed in accordance with relevant guidelines and regulations. All instruments and methods were approved by the Committee (CRPPH No. 6/2562). The participants who met the inclusion criteria were informed about the purposes, risks, confidentiality, and benefits before they voluntarily decided to participate. Informed consent was obtained on a voluntary basis. Those who could not write were asked to provide a fingerprint representing informed consent on a voluntary basis.

Results

Twenty EMEs with T2DM participated in the study (17 females and three males) consisting of nine Lahu, six Lisu, three Mien, and two Akha living with T2DM for an average of 10.40 years. The ages of the participants varied (ranging from 63 to 92 years old), and none of the participants had attended school. The participants' characteristics are provided in Table 1.

"Life is Bitter and Sweet"

The analysis of participant narratives revealed the overarching theme, *life is bitter and sweet*, and captured the meaning of the lived experience of the EME living with T2DM in rural areas. There were three main subthemes. The first, *the struggle of living with diabetes*, reveals the mixed emotions of illiterate ethnic elders diagnosed with T2DM. The second, *living with inequalities*, illustrates the suffering of participants who tried to access healthcare services and faced discrimination regardless of ethnicity. The third subtheme, *dealing with diabetes*, highlighted the importance of disease management by using traditional medicine and facilitating support from family members and the community. These three subthemes were not disparate but intertwined; the researchers interpreted them as weaving together a phenomenological interpretation of the experience of living as an EME with T2DM in rural areas.

The struggle of living with diabetes

According to the participants' narratives, their understanding of T2DM depended on their level of literacy. When participants diagnosed with T2DM were considered illiterate, most considered themselves a burden on the family because they could not care for themselves. Most felt overwhelmed trying to do the right thing without a proper understanding of what they were supposed to do.

Illiterate elders

All the participants in this study had no formal education, which affected their ability to understand the nature of the disease, seek information, and manage their disease. Some participants

Table 1 Detail of Participants' Characteristics (N = 20).

Characteristics	N (= 20)	%
Gender		
Men (mean age = 74.33 years, S.D. = $+15.50$)	3	15.0
Women (mean age = 68.05 years, S.D. = $+4.93$)	17	85.0
Marital status		
Married	16	80.0
Separated	2	10.0
Widowed	2	10.0
Education		
No formal education	20	100
Ethnicity		
Lahu	9	45.0
Lisu	6	30.0
Mien	3	15.0
Akha	2	10.0
Number of living with T2DM		
5-10 years	9	45.0
>10 years	11	55.0
(mean = 10.40 years, S.D. + 4.28)		
Blood sugar level within 3 months (mg%)		
<110 (mean = 100.67 mg%, S.D. = +3.32)	6	30.0
111-125 (mean = 120.67 mg%, S.D. = +4.17)	6	30.0
>125 (mean = 146.75 mg%, S.D. = +20.47)	8	40.0
*data from a diabetes personal health booklet		
Body mass index (Kg/m ²)		
<18.50	-	0
18.50-22.99 (mean = 22.22 kg/m2, S.D. = +0.11)	2	10.0
23.00-24.99 (mean = 23.94 kg/m2, S.D. = +0.49)	6	30.0
>25.00 (mean = 27.18 kg/m2, S.D. = +1.93)	12	60.0

perceived that diabetes was not a serious disease because there was a high number of diabetes patients in the community. They did not realize that risk factors such as hypertension, obesity, and low physical activity were linked to diabetes.

It was too bad ... that we could not understand what was in the diabetes handbook I never attended school ... so the people my age could not read or write, and some people cannot even speak Thai. I knew I had diabetes when a nurse told me that I had very high blood sugar and that it could lead to brain coma or damage to my feet. Then she gave me a handbook, which was useless. (PF10)

I can speak Thai, but sometimes I could not continue the conversation because I cannot understand, especially the medical terms in Thai, and no one could speak my language ... most of the time, so I just said yes, no, and, okay. (PF3)

Emotional difficulties

The experience of illiteracy created other problems for the EME when experiencing a disease as profound as T2DM. The problems began when the participants were unable to gain a clear understanding of the trajectory of their disease, the treatment plan, and self-management. This caused them to feel as if they had lost their previously normal lives. Many participants also described feeling frustrated, confused, overwhelmed in response to recommendations, and cognitively paralyzed, all of which caused chaos in the lives of EME with T2DM who live in rural areas.

I cannot follow the guidelines. I cook what I have, and I decided just live with DM Everything is hard ... visiting the hospital back and forth ... not my life. (PF11)

The nurse said I have to exercise regularly, but I hardly do... because I work in the fields—it is better than exercise But my sugar level remains high It means exercise did not help me, and I don't think it is a problem since I can work every day (PF2).

Living with Inequalities

It was evident from participants' narratives that their complex living situations compounded the difficulties they experienced with T2DM in rural areas. Inequalities associated with health insecurity, geographic distances, lack of healthcare providers and disease expertize, and poor housing conditions created barriers to accessing better healthcare services. Another difficulty was that the participants sensed that healthcare providers were condescending or unwilling to listen, which created mistrust, active social avoidance, and degradation in the quality of their lives.

Living in isolated areas

The participants discussed a series of inequities that they experienced as minority people. Living with T2DM in a rural area means accepting that death is possible and that the risk of complications remains present, regardless of disease management. Some participants mentioned that there were no diabetes specialists to care for EME with T2DM in rural areas. Their narratives revealed a sense of despair in having T2DM while living on top of a mountain. Some participants related their stories as follows:

There are only nurses and health officers ... no more doctor If you have serious symptoms, you have to visit the doctor in the hospital in the city ... too far and I do not have money. (PF9)

I spent 300 baht (\$10) to travel to the hospital when I was receiving a subsistence allowance of 600 baht (\$20) monthly This is half of my income And when I reached the hospital, I waited for 3–4 hours but talked with the doctor for only 10 minutes, and then I went back to my place. It was very hard for my children, who said that they were waiting for me for a long time. (PF3)

Experiencing discrimination toward ethnic minority populations

Participants perceived alienation and differences in how they were regarded in comparison to majority populations when visiting the hospital. These differences led them to feel left out, which affected their conversations, the transfer of information, and adherence to the treatment plan. Some participants indicated feeling frightened and intimidated when outside their community, which affected their communication. They stated that the healthcare providers were also not proactive in providing assistance and had not adapted to ethnic minority populations.

The problem I had with the healthcare professionals was that they did not pay much attention to me. I could feel it Perhaps they don't understand what I am saying, or maybe I am too rural, or maybe both I am different from them. (PF4)

Because we are a minority, we are very intimidated in the urban community, so I don't want to visit it It's so painful when I speak to them in my language I will be seen as an alien and recognized as a minority. (PF18)

Dealing with diabetes

Regardless of the EMEs' age, family caregivers are important for helping them manage their disease by, for example, preparing food and medication, observing the signs and symptoms of complications, and encouraging them to use herbs based on the cultures, beliefs, and spirits. Many participants stated emphatically that support from the community, especially village health volunteers (VHVs)—that is, lay workers who took a basic health training course developed by healthcare providers—benefitted the ethnic minority population.

Using tribal medicines and home remedies

The EME with T2DM claimed that following professional healthcare guidance was difficult. Instead of depending on modern medicine, many participants preferred to use their cultural practices and manage disease by themselves without adverse complications, giving them a sense of freedom. Moreover, most participants said that they believed in ancestral spirits that live alongside them in their homes. For them, the home serves as the most powerful place for expelling bad spirits and diseases.

Like other people, no matter what race we are. I know modern medicine is the best ... drugs are important for diabetes patients. But for me, I used herbs, such as lady's finger tea or chrysanthemum tea, to reduce my sugar level. My parents suggested it and I was okay with that (PF15).

My wife said diabetes is a chronic illness and cannot be cured. I tried to use other methods, such as ingesting bitter leaf or getting a gua sa massage, eating black chicken soup or offering sacrifices to the ancestors. It really helps me to control my sugar no need to see a doctor and no more medicines (PF9).

Support from family members and the community

The EME with T2DM recognized that family caregivers are the mainstay of their physical and emotional support when enduring difficulties and trying to manage diabetes. They also believed that they would have a better life when living with their family, described as "sweet blood family." The EME with T2DM were also generally satisfied with the support they received from VHVs, who were willing to help elders living in remote areas.

The VHVs visit me every month to check my blood sugar, follow-up on my health conditions, and we speak in the same language. It really helps to prevent complications. By the way, I say thank you to VHVs for the services provided (PF6).

Even though my son, my daughters, and I live in different places, when I need help, they come to see me immediately. It is not only a tribal cultural mandate to care for their parents, but I know that they are willing to do everything for me, such as bringing me to the hospital and giving me money. I am always happy to have my entire family together again. Even the VHVs called us sweet blood family (PF19).

My daughter-in-law prepared food for me. She is a VHV, and she knows about diabetes, so she cooks food for me separately from the others, and sometimes she has brought me to the hospital too. She said she was taught to care for her husband's family like her family or better. I feel it really warms my heart (PF18).

Discussion

This study aimed to understand the lived experiences of EME with T2DM. The results reflect van Manen's four lifeworld existentials—lived space, lived body, lived time, and lived other—and offer an understanding of EME living with T2DM in rural Thailand. In this study, the participants indicated that home was a fundamental space for managing their disease and providing a sense of security and spirituality, which relates to van Manen's concept of lived space [20]. The EME with T2DM expressed that home was not only a familiar environment but also a safe place to use complementary herbal medicines as home remedies, such as a bitter leaf, lady's finger, and chrysanthemum, to reduce sugar levels. Similar to this study, other research conducted in low-resource countries, such as Sri Lanka and Nepal, has demonstrated that patients with diabetes in rural communities were willing to take herbal medicine at home, mainly due to availability and easy accessibility [25]. Therefore, nurse practitioners or clinicians should not underestimate the role of complementary medicines or herbs in diabetes care as evidence suggests that they are commonly used in many low-to-middle-income countries. However, when discussing the location in other ethnic minority contexts, 12 participants in this study mentioned that they did not receive appropriate care because they lived in rural areas that lacked resources, as has been shown in other studies [26,27].

Another significant finding from this study concerns participants' low resources and limited understanding of T2DM, which were related to disease complications. In this study, participants also expressed feelings about their disease trajectory as well as selfcare abilities. This relates to van Manen's concept of the lived body [20]. Understanding the lived body existential provided the participants with insight into their disease when living with T2DM in rural areas. In this study, most participants considered themselves illiterate, underserved, and different from the general Thai population. This vulnerable condition increases the risk of diabetes complications and mortality rates while decreasing quality of life and emotional well-being. These findings support the arguments of Adhikari et al. (2021) and Omodara et al. (2021) on barriers to and factors limiting healthcare services for diabetes management among elderly ethnic populations in the United Kingdom and Nepal [28,29]. The findings also clearly illustrate the need to develop inclusive knowledge and culturally appropriate information to improve how self-care behaviors are communicated by healthcare providers and the participants' families.

In the current study, the participants reported that having T2DM affected them throughout their lifespan, beginning with their diagnosis and continuing through the trajectory of their disease [30,31]. This relates to van Manen's concept of lived time [20]. Routine activities for managing and controlling T2DM are required, and some participants reported that when they experienced high blood sugar levels, their children had to leave their jobs to take care of them and watch over them for complications at home or in hospital. As the literature shows, diabetes is a chronic disease, and patients may experience difficulty managing their disease as a lifelong journey and require long-term services appropriate for ethnic minority cultures and practices from healthcare providers [32,33].

In the interviews, the participants spoke about the strong support they received from their family members, which relates to van Manen's concept of lived other [20]. Family members can generate a positive environment for EME with T2DM by providing information as well as physical and emotional support. Losing abilities or being ill led participants to initially react with anxiety, fear, and frustration. However, previous studies have reported that support from spouses, children, and other family members is critical in allowing them to develop a sense of security, empathetic understanding, and compassion [34-36]. Although the participants mentioned language barriers, healthcare shortages, and experiences with discrimination, they also valued and were satisfied with help from VHVs in bridging communication gaps and sharing information directly with the participants and families using a specific language. This strategy is related to the lifeworld existential that van Manen terms the lived relationship [20].

The findings from this study have multiple implications for healthcare professionals who provide direct physical care and psychological support for EME with T2DM in remote areas. A regular home visit program by culturally competent and linguistically appropriate visitors should be provided to care for EME with T2DM at the village level [32]. This could help control their blood sugar levels, reduce the risk of complications, and reduce the cost of transportation. A future study on the level of support, as well as the development of family-based intervention programs, for EME with T2DM in rural areas would also be beneficial [37].

Limitations

The study findings must be considered within the context of ethnic elder minority interpretation when having T2DM. There is the potential for bias in the study findings since most of the participants were women and had no education, which may affect their experiences living with diabetes. Two participants could not speak Thai fluently, important details may not have been captured which might affect the amount and accuracy of the information obtained. Few questions were also translated from local languages into Thai, opening the possibility of translation discrepancies and loss of language-specific nuances. Another limitation was that many of the participants were interviewed for approximately an hour, and it could be argued that this limited amount of time may be an inadequate reflection of a whole lifetime of living with T2DM in rural areas.

Conclusion

This study is a comprehensive examination of the experiences of EME with T2DM in rural and underserved areas of Thailand. A phenomenological inquiry developed by van Manen [20] was used to explore the essence of the phenomenon and gain an understanding of the lifeworld of the elderly with T2DM in an ethnic minority context. "Life is Bitter and Sweet" emerged, which

highlights how EME with T2DM experience their lives. "Bitter" refers to the difficulties they faced, such as geographical problems, language barriers, and discrimination from healthcare. On the other hand, "Sweet" refers to the feelings they experience when having high blood sugar levels while receiving care from the family members and the community. This study also demonstrates how EME with T2DM seeks support from the healthcare system, which provides recommendations for living with T2DM. It also shows the strategies they use to maintain their everyday lives. Finally, when reading and analyzing the narrative texts, the researchers were somewhat surprised when EME with T2DM explained the strategies they employed when dealing with their complicated situations, such as using herbal medicine and receiving visits by VHVs when living in isolated areas.

Available of data and materials

All relevant data are within the manuscript and its Supporting Information file. However, these data will be available upon request, by contacting katemanee.moot@mfu.ac.th.

Consent for publication

Not applicable.

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Conflict of interest

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Research Article

Factors Influencing Military Nurses' Reporting of Patient Safety Events in South Korea: A Structural Equation Modeling Approach

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SUMMARY

Purpose: This study explored how just culture, authentic leadership, safety climate, patient safety knowledge, and safety motivation all affect military nurses' reporting of patient safety events. *Methods:* This study adopted a cross-sectional and descriptive correlational design. Data were collected from 303 nurses working across eight military hospitals under the jurisdiction of the Armed Forces Medical Command in South Korea, from June 17 to July 25, 2020. The hypothesized model was then validated using structural equation modeling.

Results: The participating military nurses did not show any proactive attitudes toward reporting near misses when compared with their responses to adverse or no-harm events. The final model exhibited goodness of fit. Herein, both safety climate ($\beta = 0.35$, p = .009) and patient safety knowledge ($\beta = 0.17$, p = .025) directly influence patient safety event reporting. Moreover, just culture indirectly influences patient safety event reporting ($\beta = 0.31$, p = .002). The discovered influencing factors account for 22.9% of the variance in explaining patient safety event reporting.

Conclusions: Our findings indicate that just culture, safety climate, and patient safety knowledge either directly or indirectly affected patient safety event reporting among military nurses. These findings then serve to provide a theoretical basis for developing more effective strategies that would then improve military nurses' patient safety behaviors.

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Introduction

Internationally, patient safety is one of the most important goals in healthcare institutions. The occurrence of any adverse events caused by unsafe care is one of the top ten causes of death and disability worldwide [1]. In South Korea (hereafter, Korea), the number of adverse events voluntarily reported by medical institutions has more than doubled from 2586 in 2017 to 6932 in 2020 [2]. Patient safety event reporting plays an important role in preventing the recurrence of any adverse events through the initiation of investigations and analyses, which then result in improvements in patient safety, awareness, and the institution's internal and external systems [3]. It has been found that sentinel and

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adverse events are often eventually disclosed, but that near misses may go underreported if the organizational culture favors concealing or downplaying said events [4].

Nurses comprise the largest proportion of the workforce in medical institutions and are at the frontline of patient care, which then facilitates their ability to identify medical errors [5]. The study by Lee indicated that Korean nurses feel more comfortable reporting events directly rather than filing event reports, as well as the fact that their rate of medication error reporting was 6.3%-29.9% regardless of hospital type [6]. In Taiwan, Chiang et al. found that nearly 60% of nurses demonstrate a non-proactive attitude toward reporting errors or near-miss events [7]. Underreporting then reduces opportunities for shared learning and hinders stakeholders' ability to generate effective changes within the healthcare system that are aimed at preventing the recurrence of errors and improving patient safety [8]. Research has shown that patient safety event reporting is associated with both organizational (e.g., culture, safety climate, and leadership) and individual factors (e.g., safety knowledge and motivation) [9-13].

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A just culture refers to an organizational climate in which individuals feel that they are treated fairly when issues like patient safety events occur, which then creates a balance between the organizational system and individual accountability [14]. Woo and Avery outlined the fact that nurses often have insufficient experience with voluntary error reporting, with them also pointing out the limitations of organizations in advocating a just and open safety culture to help support error reporting [11]. Furthermore, Lee et al., in a qualitative study of tertiary hospital doctors and nurses, reported themes like fear of blame, inappropriate responses, and the possibility of potential blame as factors that hinder safety event reporting in Korea [4]. Other studies have noted that an open and just culture increases nurses' patient safety activity and has a positive influence on their error reporting experiences [11,15]. Furthermore, others have reported that, within a just culture, authentic leadership has a positive impact on nurses' trust in their managers, which then provides them with a supportive practice environment, encourages them to speak up, and is able to accurately predict patient safety and quality of care [13]. Walumbwa et al. posited that authentic leadership implies a positive leadership style that focuses on ethics, an understanding of oneself and others, the prioritizing of individual growth, the embracing of a transparent relationship between leaders and followers, and the promoting of a positive ethical climate [16]. Further, Dirik and Intepeler found that managers' authentic leadership is an important predictor of safety climate among nurses [17].

Specifically, safety climate refers to a shared perception of the importance and value of safety-related procedures and practices within an organization [18]. Safety climate influences individual factors, such as safety knowledge and safety motivation [19]. Previous research has reported a significant correlation between safety climate and error reporting, with it being established that a positive safety climate fosters better safety event reporting [20].

The knowledge underlying patient safety practices, as outlined in the extant literature, is reported to be a facilitating factor for patient safety event reporting [10,11]. Brasaite et al. found that one of the main requirements in ensuring patient safety is the development and maintenance of medical professional safety knowledge. Moreover, undesirable patient outcomes can be avoided by ensuring knowledge sharing and facilitating error reporting among staff [21]. Safety motivation refers to an individual's willingness to enact safety behaviors according to their own interests and beliefs [22]. Prior research has shown that nurses' lack of motivation acts as a barrier in their reporting of patient safety events [12]. Moreover, it has been demonstrated that safety motivation and knowledge influence corresponding safety behaviors [19].

Nursing staff at military hospitals, specifically, have a clear understanding of the hierarchical relationships therein because of the uniform command system that exists within the classoriented climate, which is a distinguishing characteristic of military culture [23]. The characteristics of military hospitals (wherein healthcare providers regularly rotate every one or two years through various network hospitals or departments) require nurses to function consistently in new work environments, with them then being exposed to an increased risk of patient safety issues [24,25]. Therefore, identifying the factors that affect military nurses' reporting of patient safety events is critical for improving patient safety in military hospitals. Except for studies that focus on the relationships between patient safety culture, safety management activities and competency, and communication with other healthcare professionals [24–26], few have comprehensively investigated the factors that influence military nurses' safety behaviors at both the organizational and individual levels. Thus, this study examined the organizational (including just culture, authentic leadership, and safety climate) and individual (including patient safety knowledge and safety motivation) factors that influence military nurses' patient safety event reporting, while also verifying factors that have a mediating effect on this relationship. This study's findings then provide evidence to facilitate the development of effective intervention strategies to ensure patient safety in military hospitals.

Hypothesized model

The hypothesized model for this study was derived from both a literature review [9-13,15,17,19,20] and the safety model developed by Neal et al. [18]. Their model assumes that organizational climate (which encompasses leadership, work roles, and communication) significantly impacts the overall safety climate, while this climate then influences safety behaviors through its impact on staff members' relevant safety knowledge and motithe hypothesized model of this study vation. Thus. (Supplementary Figure S1) is as follows: (1) just culture and authentic leadership have a direct effect on safety climate and patient safety event reporting; (2) just culture and authentic leadership indirectly affect patient safety event reporting through the impact of safety climate, patient safety knowledge, and safety motivation; (3) safety climate has a direct effect on patient safety event reporting; (4) safety climate indirectly affects patient safety event reporting through patient safety knowledge and safety motivation; and (5) patient safety knowledge and safety motivation are individual factors that directly influence patient safety event reporting.

Methods

Study design

This was a cross-sectional, descriptive-correlational study conducted in eight military hospitals under the jurisdiction of the Armed Forces Medical Command in Korea.

Setting and sample

The sample included 396 nurses working at eight military hospitals across Korea who gave their informed consent to participate in this study. The inclusion criteria were as follows: (1) nurses who had been working for at least six months in the same department and (2) nurses who delivered care directly to patients. Nursing managers that worked as head nurses or had an equivalent position were excluded. This study's sample size was found to be adequate because the minimum sample required for the maximum likelihood method (which is commonly used in structural equation modeling) was found to be 200 [27]. Of the 396 candidates, 378 responded (95.4% response rate). Of these 378 responses, 75 were excluded due to incomplete or incorrect responses. Thus, 303 responses were included in our final analysis.

Measurements

Participants were provided with a self-administered questionnaire (specifically developed for this study) that collected data about their general characteristics, patient safety event reporting, the overall just culture, authentic leadership, safety climate, patient safety knowledge, and safety motivation. The general characteristics included their age, sex, educational level, clinical experience in their current department, clinical career, and patient safety education experience. Patient safety event reporting

Patient safety event reporting was assessed using nurses' perceived levels of their own reporting rates on adverse, no-harm, and near-miss events. These factors were measured using three questions from the translated [28] and modified versions [29] of the Hospital Survey on Patient Safety Culture (HSOPSC) [30], including: (1) "If a patient safety event that causes harm to a patient occurs, how frequently is it reported?" (adverse event report); (2) "If a patient safety event cecurs but the patient is unharmed, how often is this reported?" (no-harm event report); and (3) "If a patient safety event is detected and corrected before it affects the patient, how often is this reported?" (near-miss report). The participating nurses responded to the HSOPSC's items on a 5-point Likert scale ranging from 1 ("never") to 5 ("always"). In this study, the Cronbach's α of this scale was found to be 0.71.

Just culture

Just culture was measured using the translated Korean version [31] of the Just Culture Assessment Tool (JCAT) [32]. The JCAT comprises 27 items across six subdomains, including: trust, continuous improvement, quality of the event reporting process, balance, openness of communication, feedback, and communication. The participating nurses responded to the JCAT's items on a 5-point Likert scale ranging from 1 ("strongly disagree") to 5 ("strongly agree"). At the time of development, the Cronbach's α for all of its sections was higher than 0.7, except for the quality of the event-reporting process (≥ 0.63). In this study, the Cronbach's α of this scale ranged from 0.83 to 0.86.

Authentic leadership

Authentic leadership was measured using the translated Korean and modified versions [33,34] of the Authentic Leadership Questionnaire (ALQ) [16]. The ALQ has 16 items across four subdomains: self-awareness, rational transparency, internalized moral perspective, and balanced processing sections. Nurses responded to the ALQ's items on a 5-point Likert scale ranging from 1 ("strongly disagree") to 5 ("strongly agree"). The instrument's original Cronbach's α was 0.79 [16], whereas it was found to be 0.95 in this study.

Safety climate

Safety climate was measured using the translated Korean version [35] of the Safety Attitudes Questionnaire Short Form [36]. This tool includes 31 items measuring teamwork climate, safety climate, job satisfaction, stress recognition, perception of management, and working conditions. Again, nurses responded to this instrument's items on a 5-point Likert scale ranging from 1 ("strongly disagree") to 5 ("strongly agree"). The stress recognition domain was eliminated due to it having a factor loading lower than 0.1 in this study (p > 0.05). The instrument's original Cronbach's α was 0.90 [36] and was 0.90 in this study.

Patient safety knowledge

Patient safety knowledge was measured using the patient safety knowledge domain from the Patient Safety Competency Tool [37]. This tool has six items, with the nurses then rating these on a 5-point Likert scale ranging from 1 ("strongly disagree") to 5 ("strongly agree"). Cronbach's α was 0.89 in the study by Jang [37] and was found to be 0.87 in this study.

Safety motivation

Safety motivation was measured using the translated Korean version [38] of the Safety Motivation Tool [39]. This tool includes five items that were each rated on a 5-point Likert scale ranging from 1 ("strongly disagree") to 5 ("strongly agree"). The

instrument's original Cronbach's α was 0.93 [39]. In this study, specifically, its Cronbach's α was 0.93.

Data collection

Eight military hospitals in Korea were visited by the researchers to brief potential candidates on the objectives of this study and to obtain their consent for data collection. Nurses who wished to participate were provided with survey packets that included information on the study, the questionnaire, an informed consent form, and a return envelope. Participants were then asked to complete the questionnaire and return it to a sealed box placed in each ward. In addition, they were also informed that they could withdraw from the study at any time. Each participant was provided with a gift certificate of \$5 (USD). Research data were collected from June 17 to July 25, 2020.

Statistical analyses

All collected data were analyzed using SPSS 26.0 and AMOS 26.0 software. A descriptive statistical analysis method and Pearson's correlation coefficient were used to analyze participants' characteristics, the mean and standard deviations of the data, the skewness, the kurtosis, and any correlations between variables. Structural equation modeling was then used to test the hypothesized model. First, a confirmatory factor analysis (CFA) was performed to identify the validity of the latent variables [40]. Then, a model estimation and an examination into the effects between variables were performed using the maximum likelihood estimation method. The bootstrapping method was then used to determine the significance of the indirect effects among the study variables. The model's goodness of fit was evaluated using the following indices: the X^2/df ratio index < 3 [27], the comparative fit index (CFI) > .90 [41], the standardized root mean square residual (SRMR) < .08 [41], and the root mean square error of approximation $(RMSEA) \le .08 [27].$

Table 1 Participants' Characteristics (N = 303).

Characteristic	п	%	Mean (SD)
Gender			
Men	71	23.4	
Women	232	76.6	
Age			29.46 (± 5.91)
≤ 25	85	28.1	
26-< 30	111	36.6	
≥ 30	107	35.3	
Education level			
College degree	29	9.6	
Bachelor's degree	254	83.8	
\geq Master's degree	20	6.6	
Clinical experience in the			1.79 (± 1.69)
current department (years)			
< 1	80	26.4	
1-< 3	189	62.4	
3-< 5	21	6.9	
≥ 5	13	4.3	
Clinical career (years)			6.08 (± 5.22)
< 1	13	4.3	
1-<3	85	28.1	
3-< 5	65	21.5	
≥ 5	140	46.2	
Patient safety education			
experience (in the previous year)			
0	44	14.5	
1	156	51.5	
2	77	25.4	
\geq 3	26	8.6	

Note. SD = standard deviation.

The RMSEA was reported using the AMOS software with a 90.0% confidence interval. If the RMSEA is 0, the confidence interval becomes one-sided, wherein the upper bound estimate is greater than the RMSEA. Hence, the 90% confidence level was used in this study instead of the more common 95%, which is more conventional for use within two-sided confidence intervals [42].

Ethical considerations

This study received ethical approval from the institutional review board of the Armed Forces Medical Command (approval no: AFMC-20102-IRB-20-102).

Results

Participants' characteristics

As shown in Table 1, the mean age of the participants was 29.46 years (SD = 5.91). Women constituted 76.6% of the total number of participants and 83.8% held a bachelor's degree in nursing. Only 11.2% of the nurses had worked in their current department for more than three years. Additionally, the participating nurses had worked for an average of 6.08 years (SD = 5.22). Finally, 85.5% of the nurses had participated in patient safety training at least once in the past year.

Descriptive statistics and factor loading of the confirmatory factor analysis

As shown in Table 2, the reporting level of near misses (mean = 3.84 ± 0.84 , range 1–5) was lower than that of adverse (mean = 4.50 ± 0.80 , range 1–5) and no-harm events (mean = 4.11 ± 0.87 , range 1–5). Furthermore, participants reported moderate levels of just culture (mean = 3.70 ± 0.50 , range 2–5). Additionally, the quality of the event reporting process domain scored the highest, whereas that of trust scored the lowest. Nurses perceived their managers' authentic leadership (mean = 3.64 ± 0.50 ; range 1–5) and safety climate (mean = 3.61 ± 0.47 ; range 2–5) as being moderate. Among the

individual factors, although nurses did not exhibit high levels of patient safety knowledge (mean = 3.71 ± 0.68 ; range 1–5), they did report high levels of safety motivation (mean = 4.59 ± 0.51 ; range, 3–5). The absolute values of all measures of skewness were less than 2 and the absolute value of the measure of kurtosis was less than 7. Thus, the measured variables were normally distributed. Based on the CFA, the criteria for convergent validity (factor loading ≥ 0.5 , AVE ≥ 0.5 , and CR ≥ 0.7) were satisfied; however, an AVE value was not greater than the square of the correlation coefficient, therefore, the discriminant validity was only partially satisfied (see the diagonal line in Supplementary Table S1) [27].

Correlations of study variables

Table 3 shows the relationships between the study variables. Patient safety event reporting was found to be significantly and positively associated with just culture (r = .32, p < .001), authentic leadership (r = .18, p = .002), safety climate (r = .40, p < .001), patient safety knowledge (r = .33, p < .001), and safety motivation (r = .19, p = .001).

Testing the hypothesized model

The hypothesized model fit the data well $(X^2/df = 2.468, CFI = .908, RMSEA = .070 [90\% CI: .064-.075], and SRMR = .068).$ The model was tested by including all the participants' general characteristics as control variables. The results were consistent with those of the model without control variables (Figure 1).

As shown in Table 4, just culture indirectly but significantly influences patient safety event reporting ($\beta = 0.31$, p = .002). Regarding the specific indirect effect, just culture indirectly influences patient safety event reporting via the safety climate ($\beta = 0.25$, 95.0% CI: .080–.153) as well as via both safety climate and patient safety knowledge, serially ($\beta = 0.06$, 95.0% CI: .003–.513) (Supplementary Table S2). Furthermore, safety climate directly influences patient safety event reporting ($\beta = 0.35$, p = .009), with patient safety knowledge affecting safety event reporting ($\beta = 0.35$, p = .009), with patient safety knowledge affecting safety event reporting ($\beta = 0.17$, p = .025). Additionally, authentic leadership and safety motivation had no significant direct or indirect effects on patient safety event

Table 2 Descriptive Statistics and Factor Loadings of Confirmatory Factor Analysis (N = 303).

Variables	Mean ± SD	Range	Skewness	Kurtosis	Factor loading (p)	CR	AVE
Just culture	3.70 ± .50	2-5	25	.06		.87	.52
Trust	3.44 ± .63	1-5	09	.35	.72 (< .001)		
Continuous improvement	3.83 ± .65	1-5	52	.99	.78 (< .001)		
Quality of event reporting process	3.92 ± .52	2-5	08	0.00	.73 (< .001)		
Balance	3.53 ± .65	1-5	22	.18	.68 (< .001)		
Openness of communication	$3.67 \pm .70$	1-5	75	1.19	.79 (< .001)		
Feedback and communication	3.89 ± .68	1-5	60	.57	.62 (< .001)		
Authentic leadership	$3.64 \pm .50$	1-5	36	.54		.93	.76
Self-awareness	3.55 ± .82	1-5	30	09	.91 (< .001)		
Transparency	3.73 ± .67	1-5	27	.60	.88 (< .001)		
Balanced processing	$3.56 \pm .86$	1-5	55	.18	.90 (< .001)		
Moral/Ethical	$3.67 \pm .67$	1-5	58	1.39	.78 (< .001)		
Safety climate	3.61 ± .47	2-5	.04	.10		.89	.62
Teamwork climate	3.59 ± .57	2-5	22	.27	.79 (< .001)		
Safety climate	3.80 ± .57	2-5	08	03	.89 (< .001)		
Job satisfaction	3.68 ± .73	1-5	38	.05	.80 (< .001)		
Perception of management	$3.44 \pm .68$	1-5	.01	19	.70 (< .001)		
Working condition	$3.48 \pm .66$	1-5	12	.50	.76 (< .001)		
Patient safety knowledge	3.71 ± .68	1-5	18	.16		.87	.53
Safety motivation	4.59 ± .51	3-5	-1.02	.22		.94	.75
Patient safety event reporting						.75	.51
Near miss	$3.84 \pm .84$	1-5	63	.33	.55 (< .001)		
No-harm event	4.11 ± .87	1-5	-1.06	1.29	.92 (< .001)		
Adverse event	$4.50 \pm .80$	1-5	-1.86	3.60	.62 (< .001)		

Note. AVE = average variance extracted; CR = construct reliability.

Variables	1	2	3	4	5	6
	r (p)	r (p)	r (p)	r (p)	r (<i>p</i>)	r (p)
1. Just culture	1					
2. Authentic leadership	.60 (< .001)	1				
3. Safety climate	.69 (< .001)	.57 (< .001)	1			
4. Patient safety knowledge	.36 (< .001)	.27 (< .001)	.48 (< .001)	1		
5. Safety motivation	.34 (< .001)	.17 (.003)	.35 (< .001)	.31 (< .001)	1	
6. Patient safety event reporting	.32 (< .001)	.18 (.002)	.40 (< .001)	.33 (< .001)	.19 (.001)	1





X²/df = 2.468; CFI = .908; RMSEA = .070 (90% CI: .064-.075); SRMR = .068

Figure 1. Path diagram of the final model.

Note. CFI = comparative fit index; RMSEA = root mean square error of approximation; SRMR = standardized root mean-square residual. The dashed lines with arrows represent non-significant relationships.

reporting. These influencing factors accounted for 22.9% of the variance in explaining patient safety event reporting.

Discussion

The findings of this study partially support our hypothesized model. The patient safety event reporting of military nurses was found to be both directly and indirectly affected by organizational factors, such as safety climate and just culture, as well as by more individual factors, such as patient safety knowledge. Our finding that organizational factors are greater contributors to nurses' patient safety event reporting than are individual ones confirms the importance of enhancing patient safety in hospital settings through the use of more holistic organizational efforts. Although these results possess an explanatory power similar to those in a previous study [43], it would have been higher if authentic leadership and safety motivation had a significant relationship with patient safety event reporting. Further research is thus needed to examine other factors related to patient safety event reporting given the non-significant effects of the examined variables in our study.

Our study also reveals that military nurses perceive the need to report adverse events and no-harm events more often than near misses, which is consistent with the results of Kim et al. [29]. Chen et al. stated that a high proportion of nurses in Taiwan had limited experience with medical incident reporting [5]. Patient safety event reporting is an important tool for the timely detection and correction of adverse events in order to create a safe medical environment [4]. However, mistakes considered as having a lower severity are not reported as often as more serious errors. Employees often do not feel the need to report errors they perceive as acceptable, being likely that this behavior results in the underreporting of patient safety events [3,7]. Furthermore, military nurses did not show a proactive attitude toward reporting near misses, as compared to adverse events or no-harm events.

Among all the variables, safety climate had the most significant effect on patient safety event reporting. This study found that, specifically, safety climate positively correlates with nurses' safety behavior [44]. Lee et al. reported that a positive safety climate reduces barriers for nurses to report errors [45]. This is important to note as military nurses must constantly adapt to new working environments due to their profession's rotational policy [23,24]. Thus, to improve their safety climate, nursing managers should promote unit-based patient safety programs that contain resources that would help staff nurses understand the patient safety mechanisms while improving their patient safety communication and teamwork [46]. It is also necessary to conduct periodic leadership walks to ensure that staff nurses trust their managers and are able to communicate with them proactively about patient safety [44,46].

In this study, patient safety knowledge was found to directly affect patient safety event reporting; this finding is supported by those of previous studies [9,47]. For example, Agustian et al. reported that, between organizational and individual factors, patient safety knowledge is the variable with the most significant effect on Indonesian nurses' patient safety event reporting [9]. Additionally, Kim and Eun reported that patient safety knowledge is a predictor of nurses' safety activity. They emphasized the importance of

Endogenous variables	Exogenous variables	Direct effect (p)	Indirect effect (p)	Total effect (p)	SMC
Safety climate	Just culture Authentic leadership	.71 (< .001) .12 (.061)		.71 (< .001) .12 (.061)	.633
Patient safety knowledge	Safety climate	.53 (< .001)		.53 (< .001)	.283
Safety motivation	Safety climate	.41 (< .001)		.41 (< .001)	.166
Patient safety event reporting	Just culture	.10 (.494)	.31 (.002)	.41 (.001)	.229
	Authentic leadership	11 (.201)	.05 (.147)	06 (.472)	
	Safety climate	.35 (.009)	.08 (.089)	.43 (.002)	
	Patient safety knowledge	.17 (.025)		.17 (.025)	
	Safety motivation	01 (.844)		01 (.844)	

Note. SMC = squared multiple correlation.

training and education on nurses' patient safety knowledge in increasing their safety-based behaviors [47]. The development of a standardized patient safety education program for nurses in military hospitals is thus necessary to reduce the relevant knowledge gaps among them. In addition, the implementation of objective measurements and differential patient safety training programs according to individual knowledge levels are both required [20].

This research also found that just culture indirectly influences patient safety event reporting via safety climate. This finding is supported by the results of previous studies, which found that organizational factors, such as incident-reporting cultures, just cultures, and safety climates, have a significant effect on safety event reporting [7,15,45]. Our study also found that just culture has a direct effect on safety climate. Thus, it is important to create a just culture in military hospitals to improve patient safety behaviors among nurses. Military hospitals are characterized by a one-sided command system culture and discourage open communication [23,24]. Considering these organizational characteristics and this system's rotational position policy, military nurses are influenced more by the climate of their specific unit rather than by any widescale organizational culture. Therefore, continuous education should be conducted to disseminate the conception and awareness of a widescale just culture among nursing managers and frontline nurses in military hospitals in order to create a positive safety climate for each unit [8]. In addition, just culture was found to have a indirect effect on patient safety event reporting through both safety climate and patient safety knowledge serially. This finding is supported by those of previous studies that outline the fact that organizational factors and safety knowledge are both significant factors within the process of safety event reporting [10,45,47]. This research also found that a positive safety climate enhances safety knowledge through the resulting generation of an environment of training or discussion in which safety information is communicated, either formally or informally [19]. Therefore, in order to improve patient safety reporting by military hospital nurses, efforts to improve the overall system, create a safety culture, and to form a positive working environment should be conducted. Contrary to our expectations, as well as in contradiction to previous studies, just culture did not directly affect patient safety event reporting [7,15]. This study found that military nurses did not positively perceive the organization's just culture, which is consistent with previous studies on clinical nurses [15,48]. Levine, Carmody, and Silk mentioned that current hospital organization cultures do not facilitate the reporting of medical errors because nurses do not associate organizational culture with patient safety [49]. Patient safety education should thus be provided to frontline nurses so that they can recognize the overall just culture and patient safety in connection with clinical practice [14].

Interestingly, nursing managers' authentic leadership did not influence the safety climate or directly influence patient safety event reporting, which is a significant difference from the findings of previous studies [17,50]. Labrague et al. stated that nursing managers' authentic leadership significantly affects nurses' safety actions and their quality of care [50]. Nursing managers in military hospitals are mainly active-duty officers, with military nurses being trained to obey the instructions of their superiors. These organizational characteristics encourage frontline nurses to familiarize themselves with managers who have a clear vision, charisma, and the capability to motivate them [23]. Ma et al. reported that military nurse managers need to develop a team leadership ability, set a clear vision, motivate their team personnel, manage conflict and stress, be adaptable, and be able to manage change [51]. Although authentic leadership did not have a significant effect on military nurses' safety event reporting level, to promote their safety behavior, studies need to explore the leadership type most appropriate for nursing managers in military hospitals.

Moreover, safety motivation had no direct effect on patient safety event reporting, which again represents a significant difference from previous studies that posited the influence of safety motivation on safety behavior [19,39]. For example, Toren et al. stated that most nurses (80.0%) demonstrated an intention to report medical errors and near misses, although 53.0% of them had not reported near misses in the past year [52]. Thus, there was a difference found between participants' reported intentions and their actual near-miss reporting. Another prior study showed that 58.0% of nurses did not report adverse events in the preceding 12month period [20]. For military nurses within a distinct hierarchical relationship, organizational factors and patient safety knowledge (rather than safety motivation that is comprised of a more voluntary nature) have a significant impact on patient safety event reporting [9,10,20,22]. However, few studies have explored the relationship between safety motivation and patient safety event reporting. Further studies on the individual factors of this relationship are thus required.

Strengths and limitations

Our study is the first to identify the organizational and individual factors that affect military nurses' patient safety event reporting, based on Neal et al.'s safety model [18]. This study verified that safety climate and patient safety knowledge directly affect patient safety event reporting. Another notable finding is our confirmation that just culture indirectly influences patient safety event reporting.

Our study contributes to nursing research by comprehensively exploring factors affecting the safety activities of military nurses in ensuring patient safety in military medical institutions. Further, it elucidates a rationale for developing effective strategies and programs to create a just culture and safety climate, as well as for improving military nurses' safety knowledge, in a way that takes into account the unique characteristics of military nursing personnel. This study does possess several limitations. First, patient safety event reporting was measured through nurses' subjective responses, rather than through their actual reporting rate, meaning that our results should be interpreted with care. Second, because closed questions and direct surveys have inherent limitations in revealing participants' honest answers, other data collection methods (e.g., online surveys and in-depth interviews) should be used in future studies in consideration of the vertical hierarchical structure of the military nursing organization.

Conclusions

This study confirms that safety climate (an organizational factor) and patient safety knowledge (an individual factor) significantly influence military nurses' reporting of patient safety events. Further, this study found that just culture has an indirect effect on patient safety event reporting. However, authentic leadership and safety motivation are not statistically significant factors for patient safety event reporting. This study emphasizes the fact that leaders and nursing managers in military hospitals should create a just culture and a safety climate that fosters nurses' safety activities, keeping in mind the unique characteristics of this organization. Further, nurses should be provided with adequate training that then improves their knowledge of patient safety and the importance of reporting errors so as to enhance the quality of care in military medical organizations.

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Data availability

The data generated and analyzed during the current study is confidential; however, they can be made available from the corresponding author upon reasonable request.

Conflict of interest

All authors declare that there are no conflicts of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2022.05.006.

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Research Article

A Comparison of Self-evaluated Survey and Work Sampling Approach for Estimating Patient-care Unit Cost Multiplier in Genetic Nursing **Activities**

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SUMMARY

Purpose: To compare patient care multipliers estimated from subjective evaluation against work sampling (WS) techniques in genetic nursing activities.

Methods: An observational WS technique was conducted from November to December 2019 with nine genetic nurses in a tertiary referral center in Malaysia. The WS activity instrument was devised, validated, and pilot tested. All care- and non-care-related activities were sampled at 10-minute intervals within 8 hours of working over 14 days, followed by a subjective evaluation of activities survey over the same period. Bonferroni correction was undertaken for multiple testing with a p value of 0.0025.

Results: The two techniques produced significant differences in genetic nurses' activities categorization. The WS showed that compared with subjective evaluation, direct care (19.3% vs. 45.0%; p < .001) was estimated to be significantly lower, and indirect care (40.4% vs. 25.6%; p < .001) and unit-related activity (28.5% vs. 16.9%; p < .001) were higher. Both techniques produced a similar proportion of time spent in other non-care activities (12.0%) but differed in genetic meetings and information-gathering activities. While the multipliers for patient face-to-face contact were significantly larger between WS (4.57) and the survey (1.94), the multipliers for patient care time were smaller between WS (1.47) and the survey (1.24), indicating that caution should be taken when multiplying for patient contact time compared to patient care activity to determine the cost of care provision.

Conclusion: A considerable proportion of time spent away from the patient needs to be allocated to patient-related care time. Thus, estimating the paid cost solely based on direct time with patients considerably underestimates the cost per hour of nurses' care. It is recommended to employ 'patientrelated activity' instead of the 'face-to-face contact' multiplier because the former did not significantly differ from the one estimated using WS.

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Introduction

Rare disease (RD) is a debilitating hereditary disease that affects only a small fraction of the population and is extremely difficult to treat. There are between 7000 and 8000 RDs worldwide. Approximately 80% of them are genetic disorders affecting young children, and the remainders are rare cancers, autoimmune diseases, congenital malformations, and the rare manifestation of common diseases. Unfortunately, due to a lack of attention from health care providers (HCPs), health system leaders, and health policy-makers. these patients are at a risk of missing life-saving treatment. The issue stems from gaps in disease knowledge among HCPs, diagnostic difficulties, and high treatment costs [1]. In Malaysia,

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Abbreviations: CE, Cost-effectiveness; HCP, Healthcare professional; TMS, Timeand-motion study; RD, Rare disease; WS, Work sampling.

patients with RD are managed by a tertiary referral genetic unit. Geneticists, paediatricians, genetic counsellors, and nurses are the front-line providers of medical genetics services in the country [2].

Nurses remain the largest group of personnel resources employed by the Ministry of Health in the labor force [3]. In today's economic climate, HCPs, including nurses, must constantly perform at the highest level by re-evaluating their quality of care. As a result, there is considerable interest in measuring nurses' activities and/or workload via a professional judgement or subjective evaluation [4], clinical work indicators (or productivity data) [5], and time and motion study (TMS) [6,7], for instance, in intensive care units (ICUs) [8–10], emergency departments (Eds) [11], medical wards and surgical wards [12], ambulatory care [13], general wards [14], and community nurses [15]. In recent years, outpatient genetic care has played a significant role in medical genetic management [1]. However, there have been no works published thus far to the best of the author's knowledge about the work activity of genetic nurses in comparison to geneticists [16] and genetic counsellors [17,18]. Thus, there is an obvious need to comprehend and disseminate information regarding their progressive role as the patient's primary point of contact in this largely unexplored area of RD.

Patient care is a time-consuming [18,19] and complex activity [10,16] because of the lengthy process and skill mix [20] that nurses engage in while performing clinical activities, patient-related tasks, administrative work, communication, and personal tasks. Generally, these multitasking activities are categorized as either direct or indirect patient care activities, depending on whether they are performed in front of or away from the patient [8,21,22]. There are significant disparities in the proportion of time spent by nurses on direct and indirect care activities that have been reported in other areas of practice [11]. In addition, previous studies over the last decade have demonstrated that the workload and the interplay between direct and indirect patient-related activity significantly impact the quality-of-care delivery [10,16,23]. Thus, estimating direct contact time alone will underestimate the time required to provide care.

Cost and cost-effectiveness (CE) intervention is designed to achieve the maximum possible health care delivery through the optimum use of limited resources. However, despite the wealth of literature available in this field [24,25], there is a dearth of discussion of how 'hidden' or indirect patient-related activities should be handled and how they ultimately affect costs. The cost of care accounts for a sizeable amount of HCPs' time. Previously, the problem was addressed with the hidden-to-observed cost ratio [26] or 'overhead' associated with patient care delivery [23]. While a recent study [27] focuses more on cost-effective care, less attention is placed on how to account for this overhead that was needed for the provision of care-related activity [10]. In addition, the CE guidelines indicate that all costs that are likely to be impacted by intervention should be included in the analysis [28]. Thus, this study extends and generalizes the concept of an adjustment factor or multiplier (e.g., the ratio of direct to indirect time spent on care activity) as a metric to allow for the higher costs associated with providing patient-related care activity than the direct care cost [23.26].

The multiplier is typically approximated via time diaries, sheet surveys, focus groups, and verbal reports [23,29,30], or by explicitly requesting the percentage (or minutes) of time spent in the actual practice from the HCP [31]. The given estimate is then converted to a ratio of direct to indirect time spent with patients or performing patient-related activities. When calculating the total time required to deliver patient care, the ratio's components are added together and multiplied by the total direct contact time and unit cost component. This time allocation more accurately reflects actual care activities, resulting in a more equitable valuation of the resources required to hire an HCP. These approaches have become the incumbent method for obtaining information on the proportion of direct and indirect time spent on different locations (e.g., patient, clinic) or activities due to practical and cost reasons. This is the approach employed by the Personal Social Services Research Unit (PSSRU) [32] to reflect current care practices in their health and social care services unit cost estimates.

In contrast, other work pattern estimation methods exist, such as the gold-standard TMS [14], activity log [33], video recording [15], and work sampling (WS) [34], which have been used in health care service research. For instance, WS is widely used as an experimental and practical technique for measuring work in nursing and non-nursing research [33,35]. However, it was not used to estimate the multiplier because it required more time and effort than the previous methods. Compared to TMS, WS measures activity frequencies that can easily be proportioned to determine the percentage of total time spent and the ratio of direct to indirect time [36]. Moreover, WS is less prone to personal and recall bias than the typical methods, e.g., focus groups, surveys, and verbal reports, which rely heavily on subjective judgement. The WS method not only provides an estimate of the amount of time spent in each activity but also accounts for actual work patterns in circumscribed working areas [15,20]. Nonetheless, the direct observational technique may introduce other instances of bias, known as the Hawthorne effect [34,36]. To our knowledge, no prior studies have explicitly compared the generation of multipliers for nurses' paid care hours unit cost between WS and the survey.

Therefore, it is imperative to investigate nursing care time allocation, as the provision of medical genetics management has shifted dramatically over the past two decades. Clearly, additional evidence is required for the conference, continuous medical education, and general administrative tasks that we assumed to be overheads on patient activity to accurately reflect the actual cost of care provision [37].

The purpose of this study was to compare the proportions of time spent on each activity in the total activity using two methods: WS and the survey. The following goals are of interest: (1) estimate the percentage of time required for patient-related care activities; (2) calculate the multipliers for human resource cost estimations in future economic evaluation of RDs.

Methods

Study design

The study was conducted in two stages. First, an observational WS technique was used to describe the work activities of genetic nurses for two weeks within an eight-hour working period, immediately followed by a subjective evaluation of activities over two weeks. Nurses were unaware that the subjective evaluation technique would subsequently be employed.

Setting and participants

The observations were taken at a tertiary referral genetic centre at a government hospital in Malaysia between November and December 2019. The centre is overseen by a head nurse and 11 registered nurses who work during office hours (from 8.00 am to 5.00 pm). The centre provides care to approximately 8000 patients with RD and receives approximately 600 new referrals per year. A total of nine registered nurses were recruited. The nurses were purposively sampled with job scopes focusing on patient care rather than managerial roles.

Sample size and power

The study was designed to capture the least often occurring activity for indirect care activity (ICA) in obtaining a representative number of observations needed to allow for acceptable statistical inferences to be made in line with earlier studies [19,34]. The following formulas are used to determine the minimum: (1) sample size, e.g., N = $z^2 P(1 - P)/d^2$ [38]; (2) sampling period, e.g., T = $\tau/2$ 480.p.nf [39]. First, the preliminary sample estimates are obtained from the trial runs. Then, the minimum number of observations for each activity category is determined (Table 1). For instance, ICA was expected to occur 43.0% of the time, and the minimum number of observations needed was 600, so we have 95% confidence that the activity is within the $\pm 5\%$ level of accuracy (i.e., the minimum acceptable error, d, was set to 0.04 as presented in Table 1). To determine the sample period, we have $\tau =$ time interval between observations (10 minutes), p = minimum probability of occurrence for an activity (0.001), ηf = number of nurses per shift, and $480 = 8 \text{ h} \times 60 \text{ minutes}$; hence, the minimum sample period corresponded to 11 days. With observations every 10 minutes, the maximum working time is 8 hours per day, and the number of nurses who can be observed simultaneously is 2; the daily data points required are 28 (e.g., 600 observations ÷ 11 days ÷ 2 nurses).

Instruments and validation

A literature review identifies the list of potential nurses' activities attributable to care delivery. Then, interviews with practising nurses and leaders were conducted to elicit the normal work activities. These lists were contrasted and grouped. Then, a single list of activities was discussed for inclusion or exclusion from the final WS instrument. We adopted a categorization of work activity from the established sources [19,21,22,33,39]: (1) direct care activity, DCA (e.g., care activity requires patient's interaction or is performed directly with patient and family); (2) indirect care activity, ICA (e.g., care activity that is performed from a distance of patient and family but benefitting them); (3) unit-related activity, URA (non-care activity pertaining to the normal maintenance of the unit and its organization); (4) personal activity, PA (including rest periods and personal requirements unrelated to the professional task). Alternatively, we classified PA, idle time, and breaks as 'other' activities (OA).

Additionally, the activity descriptions are developed and refined during the testing period by the author. Next, the author and nurse manager validated the instrument's content by standardizing the terminology and comparing the listed activities to local clinical practices [33]. This process informed the refinement of techniques and methods for the trial runs. The runs help the author become familiar with the criteria and activity descriptions that will be used to identify the dominant activity occurring concurrently during the observations [33]. The emphasis was to document what had taken place and not to define which activity had the greater priority. Following this procedure, the final data collection form organized 26 nurse activities (Figure 1) that were mutually exclusive, defined,

Table 1	l Activity	Categories	' Frequency	and	Sampling	required
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	%	% Category (no of observations)					
	DCA	ICA	URA	OA			
Preliminary trial 1 Preliminary trial 2 Estimated proportion Minimum observations needed n	14.5 (17) 17.5 (32) 16.0 (25) 350	47.0 (55) 38.8 (71) 42.9 (63) 600	28.2 (33) 21.3 (39) 24.8 (36) 400	10.3 (12) 22.4 (41) 16.3 (27) 350			
Limit of error	0.04	0.04	0.04	0.04			

Note. n = number of data points; DCA = direct care activity; ICA = indirect care activity; URA = unit-related activity; OA = 'others' activity.

and precoded into four categories of work: DCA, ICA, URA, and OA. The list of work activity descriptions with inclusion and exclusion criteria is available for each of the tasks in the online appendix.

Procedure

A pilot WS study was initially undertaken with seven nurses for three working days at random. The trial runs and study observations were made from 8.00 am to 4.30 pm and from 8.00 am to 5.00 pm, respectively, at 10-min fixed intervals by the first author. The interval set time was considered less demanding than the randomly distributed time sampling and a standard method in health services research [34]. In addition, it allows the sample to be randomized adequately since the nature of the health care activity follows some to no patterns [40]. The pilot study provided an opportunity to test the data collection tool and gain insight into the following observation techniques. The observer moved to an exact spot from eight observation locations at random and positioned within earshot of the nurses prior to observing the activity while remaining as unobtrusive as possible. Then, two observations were made at each time interval instantaneously. The observed activities were logged on a tabular data collection form using a unique numbering assigned to each task adopted from a previous study [33]. The observer documented all unforeseeable events that occurred during the period.

Following that, the same author provided the nurses with similar activity descriptions and forms to evaluate and reflect on over the same period. Then, they were required to give estimates on the amount of time they spent on the specific activities and rated their confidence for those estimates via a survey form.

Data analysis

First, data from WS were aggregated by individual activity and grouped into categories. Then, the descriptive statistics were used to compute the average proportion of time for each activity and category. All values are reported as the mean and standard error of the mean. Second, the summarized data are contrasted with the estimates we obtained from the survey. The survey data are presented as the mean and standard deviation (SD) of the mean. The Bonferroni correction was undertaken for multiple testing and adopted a *p value* of 0.0028 for the significance test [41]. Finally, the multiplier for the respective unit cost is calculated following the published method [23,32]. All data were entered into Microsoft Excel 2013 (Microsoft Corporation, Redmond, Wa) and then transferred electronically to R version 4.0.2 (R Foundation for Statistical Computing, Vienna, Austria) for data wrangling and statistical analyses.

Ethical considerations

Ethical approval was granted by the Medical and Research Ethics Committee of the Ministry of Health, Malaysia (NMRR-19-610-46077). This study poses no risk to patients and nurses, and the observations did not disrupt the patient's visit or nurse's routine care. The participants volunteered to participate in the study.

Results

Demographic characteristics

The participants' age ranged from 28 to 35 years, with a median age of approximately 30 years [IQR = 3.51]. The majority were female (77.8%, n = 7), and most had obtained a 3-year diploma in nursing and were staff nurses (75.5%, n = 6). In addition, the vast



Mean proportions of nurses' time by individual activity

Mean Proportion(%)

Figure 1. Genetic Nurse Activities and Their Categorization identified from the Study. The normal activities of genetic nurses obtained from the work sampling. The insert shows the mean proportions for the category. The error bar represents the standard error. Note. CME = continuous medical education.

majority (75.5%, n = 6) had between 5 and 10 years of clinical experience. The nurses qualified as nurses as early as 2001 (the latest in 2016).

Work sampling

A total of 2,333 observations were recorded (including 300 trial run observations). The minimum daily observations required were not achieved at three periods for category OA due to one nurse being on emergency leave and meeting the week after. No significant changes to the WS instrument were made except for one activity, i.e., 'hygiene/cleaning' was excluded from the finalized instrument because it was not observed during trials. There are 26 types of activity descriptions that have been identified; of these, the 7, 9, 6, and 4 activities are categorized into DCA, ICA, URA, and OA, respectively (see Table 2 for list of activities).

Nurses in our study spent 19.3% of their clinical operational time on direct patient contact performing DCA. Most of the activities were spent away from the patient (80.7%); 40.4% were on ICA, 28.5% on URA, and 11.8% on OA. Together, DCA (19.3%) and ICA (40.4%) equate to 59.7% of patient-related care activities. On the other hand, time spent on non-patient care activities accounted for 40.3% of the activities, with 28.5% and 11.8% on URA and OA, respectively. The complete time distribution of the activities is presented in Table 2 below.

Overall category analysis indicates that nurses spend the most time on ICA (40.4%), followed by URA (28.5%), DCA (19.3%), and OA (11.8%) (see insert in Figure 1). The three activities for ICA with the most significant frequency were 'daily patient progress documentation' (19.2%), 'professional communication' (18.0%), and 'attending genetic meetings' (16.6%). These three combined equal 53.8% of ICA (508 observations). In the URA category, 'clerical work' dominated with 36.1%, followed by 'patient transit' and 'education' at 16.1% and 16.0%, respectively. These three combined equal 68.2% of URA (448 observations). In the DCA category, the three activities with the highest frequency of observed activities were 'assisting the doctor

		(O) - h(T- + -1.0())			% ^a (SE) ^b		
Category, by activity	ODS, n	"O" ODS, n(10tal %)	Total	By Activity By Category		IVIAX /o	
Direct care	453	(14.3)	19.3 (3.8)	_	_	_	
Assisting Dr	141	1	_	5.9 (1.3)	31.1 (0.5)	14.3	
Pt. interaction	120	0	—	5.1 (0.8)	26.5 (0.3)	10.8	
Pt. assessment	58	1	—	2.6 (0.5)	12.8 (0.2)	7.4	
Clinical procedures	54	1	—	2.3 (0.3)	12.0 (0.2)	4.3	
Registration	38	2	—	1.6 (0.3)	8.4 (0.1)	4.0	
Meds. admin	25	3	—	1.2 (0.3)	5.5 (0.1)	3.2	
Pt. mobility	17	6	—	0.8 (0.2)	3.8 (0.1)	3.2	
Indirect care	944	(15.1)	40.4 (8.3)	_	_	_	
Pt. progress	181	0	—	8.1 (1.1)	19.2 (0.2)	15.1	
Communication	170	0	—	7.3 (0.9)	18.0 (0.2)	11.6	
Genetic meetings	157	8	—	5.8 (2.6)	16.6 (0.6)	31.3	
Data entry	123	0	—	5.6 (0.9)	13.0 (0.2)	13.5	
Meds. order	88	3	—	3.8 (0.8)	9.3 (0.1)	8.4	
Treat. preparation	86	1	—	3.4 (0.7)	9.1 (0.2)	7.3	
Phone follow-up	70	2	—	3.1 (0.4)	7.4 (0.1)	6.0	
Care coordination	49	2	—	2.4 (0.6)	5.2 (0.1)	6.4	
Gather information	20	3	—	0.9 (0.2)	2.1 (0.0)	2.6	
Unit-related	656	(22.6)	28.5 (5.9)	_	_	_	
Clerical	237	0	—	10.2 (0.9)	36.1 (0.3)	16.8	
Meeting	98	6	—	5.0 (1.6)	14.9 (0.4)	19.1	
Transit	106	0	—	4.6 (0.5)	16.1 (0.1)	7.7	
Education	105	10	—	3.8 (2.1)	16.0 (0.7)	26.2	
Errands units	67	0	—	3.0 (0.4)	10.2 (0.1)	7.1	
Stocking	43	3	—	2.0 (0.4)	6.6 (0.1)	4.4	
Others	280	(10.7)	11.8 (2.8)	—	—	_	
Idle time	159	0	—	6.7 (1.6)	56.8 (1.1)	18.5	
Personal	51	2	—	2.2 (0.5)	18.2 (0.3)	5.7	
Pantry	40	3	—	1.6 (0.5)	14.3 (0.3)	5.4	
Restroom	30	1	—	1.3 (0.2)	10.7 (0.1)	2.6	

Note. '0' = zero; Admin. = administration; Dr = doctor; Max = maximum; Meds. = medication; n = number of data points; Obs. = observations; Pt. = patient; Treat. = treatment.

^a Percentage of weighted proportion.

^b Standard error of percentage

during review' (31.1%), 'patient/family interaction' (26.5%), and 'patient assessment' (12.8%). These combined activities equal 70.4% of DCA (319 activities). Conversely, in OA, nurses spend more than half of the time in 'idling' (56.8%) activity alone, more than in 'personal' (18.2%) and 'pantry' (14.3%) combined. These three combined equal almost 90.0% of OA (251 observations) (see Table 2).

Overall activity analysis shows that nurses spend most of their time on 'clerical work' (10.2%), 'patient progress documentation' (8.1%), 'professional communication' (7.3%), 'idle time' (6.7%), 'assisting doctor during review' (5.9%), and 'genetic meetings' (5.8%). In contrast, the lowest proportion of time was spent on 'mobilizing patient' (0.8%), 'gathering information' (0.9%), 'medication administration' (1.2%), and 'using the restroom' (1.3%). From Table 2, we can see that, although 'education,' 'administrative meetings,' 'genetic meetings,' and 'mobilization of patient' activities were not observable (higher number of zero observations) daily, the activities had a significant impact on the overall proportion of the time spent. Collectively, URA (22.6%) had the highest percentage of zero observations, followed by ICA (15.1%), DCA (14.3%), and OA (10.7%).

Subjective evaluation

The nurses had estimated that they spent 45.0% of their time on DCA [SD = 14.4], 25.6% (SD = 8.21) on ICA, 16.8% (SD = 5.94) on URA, and 12.5% (SD = 7.07) on OA. The nurses were 67% (SD = 13.35) confident with their estimates (on a 0–100 scale). Regarding specific care activities, the nurses approximated a minimum of 30–60 minutes and a maximum of 60–90 minutes weekly for 'gathering information.' In contrast, 'genetic meetings' had twice that weekly time spent, ranging from 60 to 120 minutes to a

maximum of 120 to 210 minutes. We divided these activity estimates (minutes per week) by the total minutes per week (2,400 minutes) to obtain the expected proportion of time for the survey method (see Table 3). The chi-square tests showed that the given estimates differed significantly from the WS data for DCA, ICA, and URA, with p < .001 except for OA, for which p = .578 indicated no significance. Additionally, the two techniques showed no significant difference in the proportion of time spent on 'genetic meetings' (5.8% vs. 7.3%, p = .578), whereas 'gathering information' was significant (0.9% vs. 3.4%, p < .001).

Multiplier

We have identified that the 'others' activity can be removed from the proportion of time used for patient care. Therefore, this overhead should not be included in the ratio and multiplier. Our results can be interpreted likewise (Table 4). Since we have a complete breakdown of time use, time spent on OA is classified outside of these care and non-care activities that did not generate outputs to the patient care delivery. The procedure for estimating multipliers to allocate time is illustrated using the three steps below [23].

Step 1. To calculate loading, we require a multiple of patient care-providing hours that reflect the relationship between care (C) and non-care (NC) activities and the total number of hours worked (T). The basic equation for this multiple (q) is represented as follows:

$$T = qC$$

T = C + NC

Table 3 Comparison Frequency of Activities Derived from Work Sampling and Subjective Evaluation.

Category/activity	Observed (%) WS	Expected (%) SEV	d.f.	χ^2	р	Modified Bonferroni adjusted alpha	Adjusted significance
Direct	453 (19.3)	1,049 (45.0)	1	616.94	<.001***	<.001 ***	No
Indirect	944 (40.4)	596 (25.6)	1	594.55	<.001***	<.001 ***	No
Genetic meetings	157 (5.8)	170 (7.3)	1	1.12	.289	.578	No
Gather information	20 (0.9)	79 (3.4)	1	45.92	<.001***	<.001 ***	No
Unit	656 (28.5)	394 (16.9)	1	209.06	<.001***	<.001 ***	No
Others	280 (11.8)	291 (12.5)	1	0.53	.467	.578	No

Note. SEV = subjective evaluation; WS = work sampling; d.f. = degree of freedom; ***p < .001.

Table 4 shows the breakdown of time spent delivering patient care at 59.7%. Thus the proportion of NC time is:

C = 0.597

T = 1.0

NC = 0.403

Step 2. The multiplier, *q*, is then calculated as follows:

1 = 0.597 + 0.403

1 = q0.597

 $q = \frac{1}{0.597}$

Step 3. However, we identified the need to include the information above to ensure that OA is not allocated to patient care delivery. To calculate the time spent on patient care, we must subtract the time spent on 'others':

qC = T - OA

$$q = \frac{T - OA}{C} = \frac{0.882}{0.597}$$

= 1.47

Therefore, when estimating the cost per hour of a nurse in the genetic clinic, $\cot = 1.47 \times '\cot$ per hour.' In comparison, the multiplier calculated from the survey data was 1.24. Similarly, other multipliers, e.g., patient face-to-face contact, can be approximated as 4.57 and 1.94 for WS and the survey, respectively (calculation not shown).

Discussion

This study explicitly compares two techniques for estimating unit cost multipliers of nurses in medical genetics. The WS and the survey indicated that nurses spend more than half of their time working away from patients, at 80.7% and 55.0%, respectively. The

 Table 4 Care and Contact Types of Activity with their Associated Time Use.

Category (notation in equation)	Care type	Contact type	% of time
Care activity (C)	All patient care	_	59.7
Direct care activity (DCA)	Direct care	Face-to-face	19.3
Indirect care activity (ICA)	Indirect care	Away	40.4
Noncare activity (NC)	All noncare	_	40.3
Unit-related activity (URA)	Unit-related	Away	28.5
'Others' activity (OA)	Others	Away	11.8
Total time (T)	Total	Total	100

nurses spent half (40.4%) and less than half (25.6%) of that away time on patient care activities in WS and the survey, respectively. In addition, the nurses reported that they spent more time on DCA (45.0%) than on ICA (25.6%) in the survey. However, we discovered from WS that the nurses spent significantly less time on DCA (19.3%) than on ICA (40.4%). This finding is consistent with nurses who work in the ICU [8], ED [11], surgical ward [12], and as research nurses [29,42], all of which indicate that HCPs tend to overestimate the time spent on the direct patient-related activity. While surveys are beneficial in providing insights into work patterns, their accuracy might be impacted by recall error and desirability bias [43].

We demonstrated that OA was excluded from the multiplier, with idle (6.7%) and personal (2.2%) activity accounting for the majority (75.0%) of the category. Studies have shown that PA varied widely among nurses in surgical wards (2.5%), home nursing (5.1%), medical-surgical clinics (12-18.0%), neurorehabilitation units (19.0%), ICUs (24.0%), critical care units, and EDs (42.0%) [11,12,39,44-46]. Our nurses' personal time was lower due to further subdividing OA into smaller activities to help us identify the activity unrelated to services, patient care, and professional development. Additionally, some authors classified education and training as personal tasks [19], contrary to our approach, which categorized them as an overhead of patient care. Furthermore, variations also existed in the major categorization of the activities. In an Australian study [8], medication preparation was defined as DCA for ICU nurses, whereas we categorized it as ICA. These variations in definitions and categorization are well accepted to accommodate the particular objective of a study [33,47]. Thus, the specific definition and categorization of the activities should be further inspected whenever a multiplier is to be estimated from the published study.

There are significant disparities in the proportions of time spent by nurses on direct and indirect care activities that have been reported in other areas of practice [11]. In comparison, research indicates that geneticists spend more time directly contacting patients [17], and genetic counsellors spend less time directly contacting patients than they do indirectly [18]. Moreover, the considerable time spent on indirect patient-related activity distinguishes genetic management from many other disciplines. These include gathering disease information, case conferencing, and continuing education of HCPs [16,17]. Thus, estimating direct contact time alone will underestimate the time required to provide care.

The study highlighted 'genetic meetings' as the activity that significantly contributed to the provision of patient care. Specialists led the meeting, and nurses took turns attending to discuss patient treatment. This is crucial because most patient cases are complicated and require collective input from team members to make pragmatic treatment and care management decisions. These are the most prominent features of genetic nurses compared to nurses in other fields. It is important to note that documentation activities classified as 'clerical' and 'patient progress documentation' are the most time-consuming tasks for nurses. The timely documentation was congruent with medical-surgical units, acute care, and nursing home nurses [7,44,47]. The required documentation is not only necessary for compliance with local healthrelated policies and regulations but also the maintenance of care quality.

Many studies consistently report that nurses can perform multiple activities simultaneously [8,27], with communication being the most common multitasking activity among DCAs in high-care nursing homes (40.0%) and medical-surgical units (25.0%) [27,44]. Overall, 'professional communications' ranks third according to our study and recent findings of neurorehabilitation and medicalsurgical unit nurses [19,27]. Moreover, communication with patients represents the second largest proportion of the nurses' direct care time, contrary to a previous study that indicated nurses devoted little time to interact with their patients [10]. The finding demonstrates that two modes of communication are essential for maintaining the organization's effectiveness and ensuring the delivery of quality genetic care.

Limitations

Our study has some limitations. First, it was conducted in a single genetic clinic. Then, the observation period happened to be two weeks full of unit briefings, audits, and renovation activities to meet the end of the current year. This may partly explain why activities such as 'education' were recorded at a slightly higher percentage (4.0%) than for nurses in the rehabilitation unit (<1.0%) [19,33]. A previous report suggested that HCPs [16] also use a significant amount of preclinic and postclinic time to research, read, and prepare cases for patients. We have limited evidence of how this might impact nurses' total care activities. This may limit the generalizability of the findings.

Second, the differences arising from the two techniques could also be attributed to the observer not practicing in nursing and potentially having a different interpretation of the activity definitions. However, we believe the impact was minimal because we rectified any discrepancies with the nurse leaders during the trial runs. In addition, we conducted a short communication with the nurses at gaps between time intervals to resolve any discrepancies immediately. Moreover, we have tested both techniques to differ significantly, prompting the methods themselves to influence the results.

The observer was not permitted to enter observation rooms during patient assessment in certain circumstances. In this instance (unobserved activity), we made a reasonable assumption based on the information provided to the observer about the tasks the nurses were performing. Additionally, we left the observation unrecorded when participants failed to disclose their planned destination (e.g., outside the clinic) to the observer. Occasionally, participants engage in an activity that lasts longer than the activity being recorded. Nonetheless, the pattern identified in this study was obtained from a primary referral centre in Malaysia, and these limitations were found to be minimal.

Advantages

There were activities that we recorded at a distance from the participant to reduce the Hawthorne effect. Previous reports suggested that the effect was likely to affect time engaged in personal time, meal breaks, and idle time [41]. However, we did not find any significant difference in the OA category between the two techniques. Moreover, while the previous study showed that the HCP tends to give estimations in favour of PRA [29], we found that the estimated proportion of PRA was lower for WS than that of the survey, suggesting that there was no significant Hawthorne effect in this study.

Whilst surveys are relatively less expensive and take less time to administer, they lack the degree of detail required in assessing the overhead. In this instance, surveys may further reduce the representativeness of the multipliers. It is worth mentioning that WS is incomparable to the 'gold standard' TMS study [48] in terms of the sequence of activities and actual duration of time [33,49]. However, the level of information obtained in this study was sufficient for the purpose of describing the working pattern. Despite its inferiority to TMS, WS enables a more objective description of time distribution while potentially avoiding the recall error and personal bias associated with surveys or self-reports. This suggests that WS appears to be a straightforward and cost-effective technique for estimating the multiplier.

Implications and recommendations

The two techniques produced high variability in the overall categorization of nurses' activities except for OA. While the multipliers for patient face-to-face contact were significantly larger between WS (4.57) and the survey (1.94), the multipliers for patient care time were smaller between WS (1.47) and the survey (1.24). Consequently, when comparing the true cost of patient care delivery between WS (1.47 × 20/h = 224.0) and the survey (1.24 × 20/h = 24.80), the gap in the true cost of patient face-to-face contact was 2.5 times greater between WS (4.57 × 20/h = 91.40) and the survey (1.94 × 20 = 38.80). Thus, estimating the paid cost solely based on direct time with patients considerably underestimates the cost per hour of nurses' care delivery. Additionally, caution should be taken when multiplying the patient contact time by the patient-related activity to determine the cost of care provision, as demonstrated in this study.

The study demonstrates the importance of adequately allocating overhead to ensure that the activities unrelated to patient care (e.g., PA) are not included as overhead on patient care costs, particularly when evaluating human resource expenses. However, numerous CE studies have ignored this critical component entirely from the analyses [25]. One possible explanation for this is the complexity and difficulty of quantifying overhead. Cost estimation is a fundamental component of economic analysis. Despite the wealth of literature available in this field [24,25], there is a dearth of discussion of how 'hidden' or indirect patient-related activities should be handled and how they ultimately affect costs. This study sheds light on quantifying the actual cost of nursing care intervention for resource prioritization, as highlighted by previous CE studies in nursing [29,50]. The differences in cost and unit cost estimates can alter the final CE conclusion of whether a new intervention is effective. While the sensitivity analysis [50] can be used to account for the uncertainty around the estimates, it is crucial to have a realistic range of parameter values (e.g., a multiplier) rather than being utterly arbitrary during the model simulation [29].

A critical first step is to raise awareness to bridge gaps in knowledge and attitudes regarding the role of economic analysis in minimizing harm to the patient by recognizing the 'value' of nursing interventions for a cost-effective care strategy. This emphasizes the theoretical basis for characterizing genetic nursing care workloads and work patterns in estimating the actual cost of care delivery [50]. However, a conservative approach can be used by assuming that all time is spent on patient care [23] when there is no detailed breakdown of time; for instance, limited information is available from standard workload measurements (e.g., patient turnover) for non-care-related activity [10]. This necessitates the use of alternative (e.g., WS) or combined-with-standard methods to reconcile the actual pattern of care provision, provided that the findings and sensitivity of the results are explicitly stated as demonstrated by this study.

The overarching process proves that the multiplier is beneficial in converting other forms of unit cost into terms that are also important compared to the cost per hour, e.g., cost per bed. Alternatively, the term 'patient-related activity' found in previous studies can be used in reference to patient care delivery, as in our study, for instance, when estimating geneticist [16] and genetic counsellor [17,18] multipliers from published sources. We recommend employing 'patient-related activity' instead of the 'face-to-face contact' multiplier because the former did not significantly differ from the one estimated using WS in this study. The actual cost will include care overheads in the cost per hour of care delivery.

Conclusion

The observational data reflect current genetic nurses' work practices. The ratio of time on patient care activities to time spent on non-care activities is 1:0.47. This means that for every hour nurses spend on care activity, e.g., assisting doctors, an additional 28 minutes are spent on non-care activity, e.g., clerical time, to deliver appropriate patient care. Hence, every hour spent with a patient requires 1.47 paid hours. We will utilize the adjusted total paid hours per nurse attributable to patient care delivery in a future CE model. This ensures that the total cost approximately reflects our current local practices.

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Conflict of interest

The authors declared no conflict of interest.

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Appendix

Additional file: The definitions of normal work activitites performed by the nurses with inclusion and exclusion examples. Activitites are categorized into four categories of work: direct and indirect care, unit-related and 'others' activity. Codes listed were those used during data collection.

Code	Activity	Activity definition	Inclusions and exclusions
Direct Care: Perf	ormed in the presence of the patient and/or family		
1.	Registration and new admission	This involves taking registration at the counter.	Includes: Telephone registration, clearing patient appointment routine. New and returning patients at the main counter. Excludes: Rewriting/re-entering electronic medical record (EMR) in computer
2.	Patient assessment	This involves nursing assessing patient overall health status. Additionally, readings taken from medical devices	Includes: Vital signs, objective and subjective findings, measurement, weighing. Obtaining temperature. Excludes: Other clinical procedures specified at Activity 4 .
3.	Medication administration	Administration of medication during clinic hours	Includes: ERT and non-ERT injections such as premedications. Excludes: Activity 2 and 4
4.	Clinical procedures	This involves all medical procedures conducted in the treatment room.	Includes: Branula insertion, poking, equipment attaches to patient, blood and urine samples, emergency procedures <u>Excludes</u> : Procedure conducted in the doctor's room will be classified under Activity 6 . Performing patient assessments prespecified under Activity 2 .
5.	Patient mobility	This involves moving and directing patient to another location within the clinic.	Includes: Infusion area. Treatment area. Excludes: Activity 7
6.	Assisting doctor during a review	This involves any clinical and administrative procedures done in the presence of the doctor.	Includes: Conducted in the assessment and treatment room. Filling out other forms. <u>Excludes</u> : Filing conducted outside prespecified rooms
7.	Patient interactions	Spend time communicating and addressing the needs of the patient and family physically.	Includes: Child's handling, instruction or counselling, and conversation with patient or family. <u>Excludes:</u> Over the phone patient contact is classified under Activity 15 . Moving and directing patients is under Activity 5 .

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Code	Activity	Activity definition	Inclusions and exclusions
Indirect Care: Pe	rformed away from the patient, but specifically on t	he patient's behalf	
8.	Professional communications	This involves asking, reporting patient results and other required information for patient care.	Includes: Reporting results of patient to other colleagues within the clinics. Seeking consultations, specialist, other hospital staff. Excludes: Activity 14
9.	Room and equipment setup, cleaning	This involves preparatory time before and after seeing the patient.	Includes: Treatment and assessment room. Gathering supplies. Preparing equipment. Excludes: Medication-related is
10.	Medication tasks	Indent, send Rx, and collect medication at the pharmacy. Prepare IV administration and dilute.	Includes: Present the prescription to the pharmacy and wait for the medication to be dispensed. Prepare and check medication.
11.	Progress and discharge notes documentation	This involves working on making discharge summaries and progress notes on the observation day.	Includes: Yellow files only <u>Excludes</u> : Long overdue files management. This will be classified under Activity 20 .
12.	Data entry and retrieval	This is specific to the activity conducted using the computer.	Includes: White computer. Entry into the SMS system Excludes: Black computer
13.	Gathering information from phones, computers	This includes information searches conducted during patient assessment.	Includes: Reviewing images, diseases information, journals Excludes:
14.	Telephone contact for follow-up	This includes getting information of the lab results and other relevant units ready prior to the assessment and arranging the collection of samples.	Includes: Pediatrics, MRI via phones. Excludes: Activity 15
15.	Coordination of care	This involves the planning of care over the phone and the clinic's mobile phone. Referring to support groups	Includes: Call and text messages via clinic's mobile phone (iPhone4 unit's phone) Excludes: Personal mobile phone, Activity 14
16.	Genetic meetings	This includes general metabolic meetings specific to patients.	Includes: Thursday and Friday <u>Excludes</u> : Other administrative meetings are classified under Activity 21
17.	Education and in-service	This involves participation in teaching and learning activities such as CME to meet learning needs.	Includes: Departmental audits, continuous medical education Excludes:
18.	Supplies check (stocking)	This involves checking medical equipment stocks and ordering supplies.	Includes: Storage area Excludes:
Unit-related task 19.	x: Non-care activity related to general maintenance Errands of unit	of the genetic unit This involves getting necessary tasks completed as soon as possible.	<u>Includes</u> : Lab results, obtain urgent stock. Excludes:
20.	Clerical work	This involves unit-related work and records. Nurse will spend time in counselling room after noon.	Includes: Brown files Excludes: Yellow files classified under Activity 11
21.	Administrative meetings	This involves meetings and administrative work purposes.	Includes: Ad hoc and planned meetings Excludes: Genetic and metabolic meetings
22.	Transit	This involves time spent between tasks for work-related activities	Includes: Getting equipment from one patient to another. Movement from patient to equipment Excludes: Activity 5
Others: Not patie	ent- and unit-specific		<u>Excludes</u> , retivity 5
23.	Personal	This involves using a personal phone during working hours.	Includes: Web surfing, praying, talking, sleeping <u>Excludes</u> : Use of phones for gathering information is classified under Activity 13 .
24.	Idle time	Waiting for the end of some activities. This involves no prespecified activity being conducted when the observation is made	Includes: Inactive time Excludes: Personal, pantry, and praying
25.	Pantry	Time spent in pantry during the observation time	<u>Includes</u> : Middle pantry. Extra room in the unit. Excludes:
26.	Restroom	Toilet use	Includes: Built-in toilet

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Research Article

SEVIER

Development and Psychometric Validation of the Perinatal Bereavement Care Competence Scale for Midwives



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SUMMARY

Purpose: The aim of this paper is to develop a scale for measuring the perinatal bereavement care competence of midwives and assess its psychometric properties. *Methods:* The Perinatal Bereavement Care Competence Scale was developed in four phases. (1) Item generation: 75 items were formulated based on a literature review and interviews with midwives. (2) Delphi expert consultation: 15 experts evaluated whether the items were clear/appropriate/relevant to the questionnaire dimensions, and the items were optimized. (3) Pilot test: The comprehensibility, acceptability, and time required to complete the questionnaire by midwives were assessed. (4) Evaluation of reliability and validity: The scale was validated by initial item analysis, exploratory and confirmatory factor analyses, and internal consistency reliability and test—retest reliability. *Results:* The final scale consisted of six dimensions and 25 items: maintaining belief (three items),

Results: The final scale consisted of six dimensions and 25 items: maintaining belief (three items), knowing (four items), being with (six items), preserving dignity (four items), enabling (five items), and self-adjustment (three items). Exploratory factor analysis yielded a six-factor structure that was consistent with the theoretical framework and explained 70.8% of the total variance. Confirmatory factor analysis indicated a good fit for the six-factor model. Cronbach's α for the scale was 0.931, and the test –retest reliability coefficient was 0.968.

Conclusion: The Perinatal Bereavement Care Competence Scale is a valid and reliable instrument for measuring the competence of midwives in caring for bereaved parents who have experienced perinatal loss.

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Introduction

Perinatal loss is a highly painful event for parents and families [1]. Most bereaved parents suffer from devastating psychological and emotional symptoms including grief, depression, anxiety, selfblame, and post-traumatic stress, which even cause adverse effects for subsequent pregnancies [2,3]. Appropriate bereavement care provided by hospital staffs is essential for helping parents cope

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with perinatal loss and reducing its negative impact [4,5]. Specifically, healthcare professionals should use simple and appropriate language, provide adequate and personalized information, acknowledge grief and parenthood, offer the important choice to parents of seeing and holding their baby, and provide commemorative items such as photographs, footprints, or baby clothes to help parents create meaningful memories and support the grieving process [6].

In China, fetal death that occurs during the second or third trimester of pregnancy is attended by midwives who provide compassionate care and support to the women and are likely to be involved in the bereavement process to help parents make decisions that minimize regret (e.g., over the missed opportunity of seeing their baby) [7]. However, unlike routine nursing tasks, perinatal bereavement care is challenging for many midwives because of the lack of a standardized approach. Midwives often report that supporting bereaved parents is emotionally demanding

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and stressful, and in some situations, they may experience a sense of personal failure accompanied by guilt and helplessness if they feel that they are unable to provide adequate assistance [8]. This can have serious consequences such as emotional burnout, selfdoubt, and even professional resignation [9,10]. Moreover, the emotional pain of grieving parents can be exacerbated when midwives cannot meet their needs for bereavement services [11]. Therefore, improving midwives' ability to provide perinatal bereavement care is important not only for the psychological wellbeing of the parents but also for midwives' career development.

Swanson's Caring Theory can serve as a guide for healthcare professionals offering care to parents who have experienced pregnancy loss [12]. The theory encompasses five processes: (1) "maintaining belief," which refers to conveying confidence and faith that the bereaved parents can get through perinatal loss and face a meaningful future; (2) "knowing," which is trying to understand the meaning of perinatal death for the women and assessing their partners' perspective and family support; (3) "being with," which includes simply being there, sharing grief feelings, and conveying ongoing availability without burdening the bereaved parents; (4) "doing for," which is anticipating and meeting bereaved parents' needs, with a focus on protecting them from harm and protecting their dignity; and (5) "enabling," which is facilitating the bereaved parents' capacity to grow using professional knowledge and information and helping them focus on important issues and generating alternatives [13,14].

Up to now, there have been few studies examining Asian midwives' performance when caring for parents suffering pregnancy loss. A qualitative study in China has shown that most midwives experienced negative feelings when supporting bereaved parents, some were able to provide support through empathetic nursing, while others adopted negative coping strategies such as avoiding in-depth communication with the parents [15]. As we know, a cross-sectional survey can effectively identify midwives' shortcomings in perinatal bereavement care and may be useful for developing strategies to increase their competence, which is not addressed by existing instruments. For example, a self-report questionnaire on nurses' attitudes toward perinatal bereavement care was developed [16], but there was no confirmatory factor analysis (CFA) in different samples to validate the factor structure. Recently, an instrument that includes four independent subscales, i.e., bereavement support knowledge, skills, self-awareness, and organizational support, was developed [17]; however, the subscales are difficult to be synthesized to measure midwives' comprehensive competence of perinatal bereavement care due to duplication of some items.

In the present study, we developed Perinatal Bereavement Care Competence Scale (PBCCS) based on Swanson's Caring Theory and evaluated the validity and reliability of this scale in a cohort of midwives from different hospitals in China.

Methods

This study had four phases: (1) item generation and scale construction; (2) expert panel review; (3) small-scale pilot study; and (4) large-scale reliability and validity testing.

Phase 1: Item generation

Using Swanson's Caring Theory as a guide, the basic framework of the PBCCS was established through semi-structured interviews with midwives and a literature review. To explore the feelings and perceived competency status of midwives in China providing bereavement care for parents who have experienced perinatal loss, we interviewed 18 midwives from 11 grade 3A hospitals in Guangdong, China. We found that some midwives had maladaptive negative emotions that caused them to feel overwhelmed, so they distanced themselves from grieving parents [15]. Accordingly, we included "self-adjustment" as a dimension of the PBCCS. At the same time, we extracted specific items from five evidence-based guidelines for perinatal bereavement care through systematic quality appraisal [18]. We generated an initial pool of 75 items. Based on discussions among the authors, some items were removed because they were unclear, repetitive, or did not align with Chinese culture. The remaining 64 items were grouped into six dimensions including "maintaining belief" (four items), "knowing" (eight items), "being with" (13 items), "doing for" (18 items), "enabling" (15 items), and "self-adjustment" (six items).

Phase 2: Delphi expert consultation

A group of experts including nine midwifery experts, five clinical psychologists, and one hospice care expert was convened by email invitation; all had the title of senior deputy and over 10 years of professional experience. The experts were asked to rate the importance of each item on a 5-point scale ranging from 1 (extremely unimportant) to 5 (extremely important) after discussing whether the item was clear or appropriate and listing the specific reasons and suggestions for revision. After two rounds of expert consultation, items that met any of the following criteria were deleted [19]: (1) average importance score <4; (2) full score ratio <0.2; and (3) variation coefficient >0.2. We also optimized the dimensions and specific items of the scale based on the experts' opinions. For example, the items ("effectively evaluating parents' expectations of pregnancy and parenthood" and "effectively evaluating the level of family support received by bereaved mothers") were added to the "knowing" dimension; and an item ("making bereavement care plans with the parents") in the "doing for" dimension was deleted as recommended by the clinical midwifery experts because there are no specific bereavement care plans and no timeline for midwives to accomplish this work in clinical practice. Two items ("if requested, providing additional resources that are in line with the bereaved parents' religious beliefs" and "if requested, providing additional resources that are in line with the bereaved parents' customs and habits") in the "doing for" dimension were merged into a single item ("if requested, providing additional resources that meet the bereaved parents' religious and social custom needs"). The experts suggested changing the expression of some items to improve their comprehensibility. Ultimately, two items were added, 16 were deleted, and four were merged, yielding 46 items for the questionnaire.

Phase 3: Pilot study

We invited 16 midwives from grade 3A hospitals to offer their perspectives regarding the ease of completion, comprehensibility, clarity, and acceptability of the questionnaire, with the items adjusted and revised accordingly. The midwives thought five items should be modified because they lacked clarity. For example, they thought that the item "keeping appropriate silence in due course" was ambiguous because it was unclear what was meant by "due course." The item was therefore reworded as "keeping appropriate silence when communicating with bereaved parents." The revised version of the questionnaire was further tested in different midwives until no further problems were identified. In general, the questionnaire was easy to complete and took about 5–10 min.

Phase 4: Validity and reliability testing

To assess the validity and reliability of the scale, midwives were recruited from different hospitals by convenience sampling from September to November 2020. Midwives who worked in delivery rooms and consented to participate in the study were included: those who had no experience in perinatal death were excluded. We used Wenjuanxing (www.wix.cn), a reliable investigation website used in China, to design and publish our electronic questionnaire. Participants could click on relevant links to access and complete the questionnaire anonymously and could only do so once using their own electronic devices. To evaluate test-retest reliability, 15 of the participants were selected to complete the questionnaire again 2 weeks later. Some questionnaires with less than 3 minutes to complete or obvious irregularities were deleted. Based on the random splitting method, all valid questionnaires were divided into two equally sized groups: Sample 1 was used for exploratory factor analysis (EFA), and Sample 2 was used to confirm the factor structure of the scale by CFA. The internal consistency reliability and test-retest reliability were also evaluated. For factor analysis, the sample size should be least 5–10 times the number of all items [20]; because the PBCCS had 46 items, the minimum sample size for EFA and CFA was 542, considering that 15.0% of questionnaires would be invalid.

Ethics statement

This study was reviewed by the Institutional Review Board of Southern Medical University (Ethics Committee of Southern Medical University [2020] No. 17). The participants were also informed that completing the questionnaire was voluntary. The data were kept anonymous and were used only for study purposes.

Table 1	Characteristics of Participants	Who Completed	the Perinatal I	Bereavement Care
Compete	nce Scale Questionnaire ($n = 3$	507).		

Variable	n (%)
Age, years	
20–29	201 (39.6)
30–39	229 (45.2)
40-49	66 (13.0)
50-54	11 (2.2)
Gender	
Men	1 (0.2)
Women	506 (99.8)
Educational background	
Secondary specialized school	6 (1.2)
Junior college	93 (18.3)
Undergraduate	398 (78.5)
Master's	10 (2.0)
Professional title	
Nurse	86 (17.0)
Nurse practitioner	200 (39.4)
Nurse-in-charge	192 (37.9)
Associate director nurse	27 (5.3)
Director nurse	2 (0.4)
Certificate of competency in maternal and infant health care	
Yes	453 (89.3)
No	54 (10.7)
Years working in obstetrics department	
<1	12 (2.4)
1–5	141 (27.8)
6-10	149 (29.4)
11–15	78 (15.4)
16–20	75 (14.8)
>20	52 (10.3)
Experience of delivery care in perinatal death in the last 3 months	
Yes	220 (43.4)
No	287 (56.6)

Data analysis

Data were analyzed using SPSS v22.0 and AMOS v24.0 software (IBM, Armonk, NY, USA). Descriptive statistics were applied to the demographic characteristics of the participants, which are presented as mean + standard deviations and numbers and percentages. Construct validity was assessed by item analysis. EFA, and CFA. In the item analysis phase, items that met any of the following criteria were deleted [20]: (1) no statistically significant items in a critical ratio; (2) item total correlation (Pearson's correlation coefficient) <0.40; (3) factor loading value <0.40; and (4) items that reduced the overall Cronbach's α level. EFA was performed to extract common factors in the items by principal component analysis and varimax rotation. The Kaiser-Meyer-Olkin (KMO) and Bartlett's tests were used to assess sampling adequacy for EFA. Combined with the scree plot, one factor with an eigenvalue >1.00was extracted [20]. CFA with maximum likelihood estimation method was performed to verify the fit of the factor structure

Table 2 Analysis of the 46 Items of the Perinatal Bereavement Care Competence Scale.

Item t valu	e Corrected item total correlation	Cronbach's α if item deleted	Factor loading
	- coefficient		
1 –3.90	.243	\uparrow	.209
2 -5.22	79.421	Unchanged	.407
3 -4.42	.411	Unchanged	.405
4 -6.20	57 .465	\downarrow	.470
5 –10.08	.586	\downarrow	.594
6 –9.96	57 .592	\downarrow	.603
7 –10.28	.577	\downarrow	.589
8 -7.92	.521	\downarrow	.520
9 –11.16	.665	\downarrow	.686
10 –11.52	.666	\downarrow	.690
11 –11.87	.657	\downarrow	.683
12 -8.62	.645	\downarrow	.686
13 -10.03	.666	\downarrow	.688
14 -9.61	.679	\downarrow	.723
15 -10.56	.687	\downarrow	.723
16 –7.50	.618	\downarrow	.627
17 –6.36	.562	\downarrow	.575
18 -9.93	.656	\downarrow	.686
19 –7.76	.558	\downarrow	.551
20 -6.66	.446	Unchanged	.379
21 -6.33	.448	Unchanged	.392
22 -7.18	.489	Unchanged	.421
23 -6.86	.546	\downarrow	.518
24 -8.77	.576	Ļ	.557
25 -8.18	.485	\downarrow	.451
26 -8.48	.651	Ļ	.652
27 -10.46	.725	Ļ	.727
28 -10.51	.697	Ļ	.706
29 -10.68	.653	Ļ	.656
30 -10.64	42 .678	Ļ	.693
31 -10.04	41 .643	Ļ	.656
32 -8.36	.646	Ļ	.646
33 -11.31	.710	Ļ	.721
34 -8.06	.605	Ļ	.594
35 -9.70	.585	Ļ	.564
36 -7.95	53 .520	Unchanged	.488
37 -11.84	47 .731	Ţ	.738
38 -12.59	.706	i.	.708
39 -13.20	.766	Ļ	.787
40 -7.50	.571	Ļ	.565
41 -9.18	.683	, L	.701
42 -10.63	.696	Ĩ	.711
43 _9.94	59 .700	Ť	.710
44 -10.46	51 595	*	.585
45 -10.2	30 .594	*	.585
46 -10.67	.584	Ť.	.579
		*	

Note: *All values were significant at p < 0.001; \downarrow/\uparrow decrease/increase in Cronbach's α upon deletion of the item.

derived from the EFA based on the following indices: χ^2/df , goodness-of-fit index (GFI), adjusted goodness-of-fit index (AGFI), comparative fit index (CFI), Tacker–Lewis index (TLI), incremental fit index (IFI), root mean square error of approximation (RMSEA), and root mean square residual (RMR). The χ^2/df between 1 and 3, GFI, AGFI, CFI, TLI, and IFI values 0.90 or above, and RMSEA values less than 0.08 with RMR less than 0.05 suggested a good model fit [21]. After CFA, convergent validity was assessed based on the average variance extracted and composite reliability. Reliability analysis was performed by calculating the internal consistency reliability (Cronbach's α coefficient) and the test–retest reliability (intraclass correlation coefficient) for the total scale and its dimensions, respectively.

Results

Sample characteristics

A total of 585 questionnaires were distributed, and 507 valid questionnaires were recovered, for a response rate of 86.6%. The 507 participants were from 142 different hospitals across China and ranged in age from 20 to 54 years. The participants had worked in the obstetrics department for a mean (\pm SD) of 10.63 (\pm 7.61) years, and 43.4% had experience in providing care for perinatal death in the previous 3 months. The characteristics of the participants are shown in Table 1.

Construct validity

Item analysis

Data from Sample 1 were used to analyze and select the items. Three items (Items 1, 20, and 21) were deleted according to the exclusion criteria of item analysis, and a trial scale containing 43 items was created (Table 2).

Exploratory factor analysis

To identify the common factors in the items, we conducted seven rounds of EFA. Items with a lower theoretical correlation and factor loading \leq 0.4 were removed from item selection. In the final round of EFA, the KMO value was .903, and the result of Bartlett's

Table 3 Factor Loading of the Perinatal Bereavement Care Competence Scale with the Maximum Variance Rotation Method (25 Items).

Item	Factor loading					
	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5	Factor 6
Item 2: Believing that the grief response of each mother is unique	0.784	0.158	0.027	0.211	0.118	0.062
Item 3: Believing that the needs of each bereaved mother are different	0.841	-0.007	0.148	0.172	0.093	0.028
Item 4: Believing that bereaved mothers require support from midwives	0.692	0.236	0.231	-0.025	0.122	0.134
Item 5: Effectively evaluating parents' expectations of pregnancy and parenthood	0.138	0.766	0.250	0.035	0.280	0.100
Item 6: Effectively evaluating the mood changes of bereaved parents	0.180	0.777	0.276	0.039	0.240	0.090
Item 7: Identifying abnormal behavior in bereaved mothers	0.113	0.772	0.269	0.104	0.108	0.119
Item 8: Effectively evaluating the level of family support received by bereaved mothers	0.038	0.680	0.146	0.217	-0.030	0.311
Item 11: Easily empathizing with bereaved mothers	0.058	0.386	0.610	0.238	0.145	0.128
Item 12: Accepting different emotional displays by	0.143	0.172	0.797	0.156	0.092	0.221
bereaved mothers (e.g., crying and anger)						
Item 13: Patiently listening to bereaved mothers	0.143	0.228	0.835	0.141	0.151	0.075
Item 14: Effectively comforting bereaved mothers using appropriate language	0.079	0.241	0.816	0.170	0.252	0.068
Item 15: Effectively comforting bereaved mothers using appropriate body language (e.g., hugs and back pats)	0.087	0.268	0.812	0.184	0.176	0.105
Item 16: If necessary, leaving bereaved mothers alone under the precondition of guaranteed safety	0.238	-0.044	0.496	0.268	0.245	0.275
Item 23: Acknowledging parenthood	0.209	0.002	0.173	0.580	0.170	0.107
Item 27: Asking bereaved parents whether they wish to see their baby after birth	0.118	0.076	0.239	0.739	0.335	0.143
Item 24: Referring to the baby with the appropriate terms	0.007	0.414	0.076	0.651	0.055	0.167
Item 26: Treating dead babies with sufficient love and respect	0.108	0.068	0.268	0.773	0.231	0.041
Item 32: If necessary, informing parents of the possible cause of the baby's death	0.083	0.085	0.194	0.241	0.781	0.137
Item 34: If necessary, providing information about the autopsy to the parents	0.050	0.129	0.102	0.088	0.816	0.168
Item 33: If necessary, providing supportive suggestions about future pregnancies	0.166	0.207	0.234	0.282	0.722	0.140
Item 30: Providing information about maternal recovery (e.g., wound care and lactation suppression)	0.225	0.206	0.304	0.300	0.528	0.142
Item 39: Encouraging parents to be involved in communication and decision-making regarding nursing	0.212	0.207	0.348	0.390	0.461	0.212
Item 44: Acknowledging my own negative emotions in perinatal bereavement care work	0.085	0.091	0.201	0.093	0.168	0.841
Item 45: Understanding my own negative emotions in perinatal bereavement care work	0.094	0.168	0.146	0.128	0.139	0.784
Item 46: Effectively coping with my own negative emotions in perinatal bereavement care work	0.051	0.270	0.107	0.150	0.199	0.692



Figure 1. Confirmatory Factor Analysis of the Perinatal Bereavement Care Competence Scale.

 Table 4
 Reliability of the Perinatal Bereavement Care Competence Scale (25 Items).

Dimension	Number of items	Cronbach's α	Test-retest reliability
Maintaining belief	3	0.771	0.954
Knowing	4	0.851	0.922
Being with	6	0.900	0.895
Preserving dignity	4	0.701	0.909
Enabling	5	0.865	0.953
Self-adjustment	3	0.881	0.906

test of sphericity was adequate ($\chi^2 = 4021.419$, p < 0.001), indicating that the data were appropriate for EFA. Consequently, we removed 18 items (Items 9, 10, 17, 18, 19, 22, 25, 28, 29, 31, 35, 36, 37, 38, 40, 41, 42, and 43), and the principal component analysis identified six factors that accounted for 70.8% of the total variance in the 25 items; these factors were named "maintaining belief," "knowing," "being with," "preserving dignity," "enabling," and "self-adjustment." The factor loading of each item was >0.4 (Table 3).

Confirmatory factor analysis

After EFA, a CFA of Sample 2 was conducted based on the sixfactor model, and the results confirmed a structure with a good model fit ($\chi^2/df = 1.848$, RMSEA = 0.058, GFI = 0.868, AGFI = 0.835, TLI = 0.932, RMR = 0.035, IFI = 0.942, and CFI = 0.941). Each item loaded significantly on its corresponding factor, with standardized factor loadings ranging from 0.523 to 0.975; average variance extracted in the six domains ranged from 0.500 to 0.742 and composite reliability ranged from 0.799 to 0.895, indicating good convergent validity. The minimum square root of average variance extracted corresponding to the six factors (0.707) was greater than the maximum correlation coefficient between factors (0.633), indicating good discriminant validity. Figure 1 shows the CFA model of PBCCS.

Reliability

The Cronbach's α for the whole scale was 0.931, and the Cronbach's α of the subscales ranged from 0.771 to 0.881 (Table 4). The maximum value for test–retest reliability was 0.968.

Discussion

The aim of this study was to develop a new scale for assessing the perinatal bereavement care competence of midwives and confirm its validity and reliability. Based on Swanson's Caring Theory, we developed an item pool through semi-structured interviews with midwives [15] and a review of relevant guidelines [18]. Items from instruments that measure perinatal bereavement care knowledge [17], attitudes [16], and skills [17] were selected and adjusted according to specific clinical circumstances. Unexpectedly, some items could be categorized in more than one dimension of Swanson's Caring Theory in the initial phase of item generation, which was also the major problem encountered in other studies, given that the five caring processes are interrelated [22]. For example, the item "accepting different emotional displays by bereaved mothers (e.g., crying and anger)" could be classified under "being with" and "enabling." Furthermore, some items in "enabling" such as "if necessary, informing parents of the possible cause of the baby's death" were found to be appropriate in the "doing for" dimension when reworded as "help grieving parents understand the cause of their baby's death." Therefore, the definitions of the five caring processes were refined according to basic principles of perinatal bereavement care as follows: "maintaining belief," which refers to having confidence and faith that the bereaved parents can get through perinatal loss; "knowing," which is striving to understand the meaning of the perinatal loss experience for the couple and assessing the level of support provided by their family; "being with," which includes sharing feelings of grief and conveying ongoing availability without burdening the bereaved parents; "preserving dignity," which focuses on the recognition of parenthood; and "enabling," which involves explaining important information and involving bereaved parents in communication and decision-making regarding nursing [13,14]. These changes were approved by experts through two rounds of consultation. The PBCCS required just 5–10 min to complete and can thus be easily adopted in clinical settings.

Although most items were highly sensitive and differentiated, three items ("believing that the bereaved parents can get through perinatal loss," "supporting parents in creating memories through the collection of mementoes such as photographs, handprints, and footprints," and "supporting parenting activities such as holding, bathing, and dressing the baby") were deleted according to the exclusion criteria [20] during the item analysis phase. These changes may raise some professionals' worries about the comprehensiveness of the scale; however, they are more in line with the clinical reality under the Chinese cultural background and may improve the broad applicability of PBCCS. In order to identify meaningful variables, EFA was conducted with the principal component analysis method of extraction and varimax rotation [20]. On the one hand, this yielded a six-factor model were consistent with Swanson's theoretical framework and our previous findings, demonstrating that the PBCCS has good content validity [23]. On the other hand, our findings provide empirical validation of Swanson's five caring processes and further promote the development of caring theory in the field of perinatal loss [12]. The factor structure of the scale was evaluated by CFA using Sample 2 (n = 254). Most of the indices met the statistical requirements except for GFI (0.868) and AGFI (0.835) although these could be considered as acceptable (>0.80) [24]. The results of the convergent and discriminant validity tests also confirmed that the scale has good construct validity. It is worth noting that two of the dimensions, "maintaining belief" and "self-adjustment," each had just three items. However, this is a sufficient number to test the characteristics of a specific factor [25]. The Cronbach's α and test-retest reliability of the whole scale were both >0.9, indicating that the scale has excellent reliability [26].

The results of our analyses demonstrate that the 25-item PBCCS is reliable and valid for assessing perinatal bereavement care competence among midwives. The PBCCS can provide guidance for midwives in their care of bereaved parents and a means for midwives to assess their own level of competence in this aspect of their work. The scale can also be used as a tool to evaluate the effectiveness of perinatal bereavement care education and training. The PBCCS should be validated for other medical professionals who engage in perinatal bereavement care such as obstetricians, neonatologists, perinatal psychiatrists, nurses, and community medical workers; it would be interesting to compare the level of competence among these groups and explore the possible reasons for any differences.

There are several limitations of our study. First, although we recruited participants from 142 hospitals in China, our study sample is not sufficiently representative via convenience sampling. Second, the sample size of 15 participants for test—retest reliability is relatively small. Therefore, a larger sample is recommended to further validate the stability reliability of the PBCCS. Third, the scale is a self-reported instrument, and social desirability bias may have influenced reporting of self-capability. In order to reduce the reporting bias, the midwives were asked to fill out questionnaires anonymously. Finally, the PBCCS was developed based on the Chinese culture, and its validity and reliability study was conducted in China. Accordingly, further testing of this scale is still needed with more diverse samples from other cultures and countries.

Conclusions

The 25-item PBCCS is a valid and reliable tool for measuring midwives' competence in providing bereavement care to parents who have experienced perinatal death. The scale can also serve as a practical framework for midwives to assess their own feelings when providing support to bereaved parents. Additional studies are needed to determine whether the PBCCS can be applied to other healthcare professionals who participate in bereavement care.

Declaration of interest

None.

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Research Article

Development and Validation of Clinical Nursing Teacher Self-Efficacy Scale and Investigation of Self-Efficacy among Clinical Nursing Teachers



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SUMMARY

Purpose: The purpose of this study was to (1) add relevant contemporary items to develop an assessment instrument for the self-efficacy of clinical nursing teachers, to verify and evaluate the validity and reliability of the instrument, and (2) investigate the self-efficacy of clinical nursing teachers. *Method:* A cross-sectional study was designed. A total of 205 clinical nursing teachers were recruited in

Taiwan. Data were collected using the Clinical Nursing Teacher Self-efficacy Scale. An exploratory factor analysis was performed to examine the scale.

Results: The degree of self-efficacy of clinical nursing teachers was moderate to high. The 35-item scale showed great psychometric qualities. The Cronbach coefficient of the overall scale was 0.92; and 0.83, 0.91, 0.93, and 0.87 on the four subscales were acceptable. Four factors were extracted by exploratory factor analysis and explained 68.53% of the total variance. Four factors were (i) teachers' professional growth ability, (ii) teaching ability, (iii) clinical nursing competencies, and (iv) personality traits. The highest self-efficacy category evaluated by teachers was personality traits; the second was clinical nursing competencies; after that, teaching ability and teachers' professional growth ability. The item with the lowest self-efficacy was foreign language ability (English).

Conclusion: Clinical nursing teachers have a moderate to high degree of self-efficacy. This scale with good reliability and validity can be used for the training and evaluation of the self-efficacy of clinical nursing teachers.

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Introduction

Clinical nursing teachers (CNTs) are those who teach nursing students in a clinical setting. The term "clinical nursing teacher" is defined as someone who integrates theory into practice and creates an optimal learning environment [1]. In Taiwan, CNTs are typically experienced clinical nurses and registered nurses employed in university or college nursing schools to provide clinical instruction to nursing students in a variety of clinical settings [2] and are responsible for helping nursing students achieve learning outcomes. Taiwanese CNTs are full-time employees of nursing school; they were assigned to guide a group of six to seven students to perform clinical practice at clinical sites [3]. Since clinical practice is a compulsory and very important part of the nursing curriculum, CNTs are essential to promote students learning in clinical practice, improve students' professionalism, and improve their professional ability [4]. CNTs are considered to be able to guide differences between students and nurses; it means the difference from theory to practice; the gap between theory and practice is defined as the difference between knowledge and theory learned by student nurses in the classroom and their practical experience in clinical settings [5]. CNTs must create a supportive learning environment to achieve learning integration, especially the learning environment related to differences in theory and practice in the clinical environment [6].

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The significance and importance of self-efficacy of CNT are that when CNTs teach nursing students in clinical practice, it is necessary to help students achieve a balance between the theoretical knowledge obtained in the class and the application of the theory in the clinical setting [6,7]. Therefore, CNTs must be aware of effective self-efficacy and equipped with the necessary competencies [8]. Nursing also emphasizes the need for a hands-on experience [7,9]: it is important to identify what kinds of behavior or characteristics of CNT are effective and modify clinical teaching methods to achieve learning effectiveness [10]. Furthermore, to ensure the quality of clinical teaching, CNTs are required to apply classroom theory to concrete clinical situations; they need to demonstrate the clinical skills and abilities to create strategies that are conducive to clinical learning and help students combine theory with practice to improve clinical decision-making [10,11]. CNTs must demonstrate good self-efficacy to facilitate the best clinical teaching, evaluate students' critical thinking, provide support, and establish good relationships with students to guide students toward achieving clinical learning goals and outcomes [12].

The concept of self-efficacy was derived from Bandura's social cognitive theory of behavioral change [13,14]. Bandura describes self-efficacy as "a judgment of a person's ability to organize and execute a course of action to achieve a specified type of performance" [14]. Teacher efficacy is "a teacher's confidence in his or her ability to promote student learning" [15,16]. According to Bandura (1997), teacher efficacy refers to teachers' beliefs about their ability to influence student achievement [14]. It refers to the belief of teachers that they have the ability to cope successfully with tasks, obligations, and challenges related to their professional activities. thus playing a key role [15]. Teachers use their professional abilities, professional attitudes, and confidence to demonstrate their professional knowledge to help students learn effectively and achieve learning goals [17]. It is important for its implications for teaching effectiveness, teaching practices, and student academic results (e.g., student achievement and motivation) [16]. Self-efficacy will be used throughout this paper to refer to teacher's efficacy (confidence) in their influence on students' achievement.

Knox and Mogan (1985) [18] pointed out that the effectiveness of nursing clinical teachers is teaching ability, nursing competence, evaluation, interpersonal relationships, and personality traits. The effectiveness and competencies of clinical teaching are the key determinants of the quality of clinical learning; the most effective behavior was teaching ability/competence, which was reported to be 96% [19]. The definition of competence is the application of skills in all domains for the role of practice, focusing on specific outcomes, improving levels of competence, accountability of the learner, practice-based learning, self-assessment, and individualized learning experience [20]. The effective clinical teaching characteristics of CNT included nursing competencies, teaching ability, professional knowledge, interpersonal relationships, and positive personality traits [17]. Several studies report that teaching ability and nursing competence were the highest rated evaluations, which were more important than evaluation skills, personality factors, and relationships with students [21,22]; however, personality was the most favored teaching characteristics of students [10]. Additionally, factors that affect teaching competence include knowledge expansion; Kelly (2007) [23] found that teacher knowledge is the most important, become a knowledgeable teacher; followed by feedback and communication skills, create a positive learning environment, demonstrate professionalism and academic characteristics, and provide support [18,24]. Teacher efficacy includes showing motivation to teach and being a good role model in a clinical setting. Collaboration between CNTs and nurses transforms the patient care unit into an environment that supports the learning of nursing students [19]. Furthermore, the internationalization of nurses continues to be a common phenomenon today. With the globalization and collaboration of educational programs, increased mobility requires nurses to have a foreign language ability and good language skills to communicate with patients and nurses from other countries [25].

Overall, the characteristics of effective clinical educators and the most important competencies included teaching abilities, nursing competencies [4,11], clinical teaching skills, professional knowledge, clinical skills, interpersonal relationships [16,17], personality traits [16], among which being a role model is important for nurse educators [18,19,21,26]. The conceptual framework of self-efficacy of CNTs is shown in Figure 1.

Aims

To evaluate the self-efficacy of CNTs in complex clinical situations, this study aimed to (1) add contemporary applicable items to develop an assessment tool for the self-efficacy of CNTs (the Clinical Nursing Teachers Self-Efficacy Scale), validate psychometric properties and evaluate its validity and reliability; and (2) survey and describe the self-efficacy of CNTs.

Methods

Study design

This was a descriptive cross-sectional study conducted in the nursing department of universities and colleges.

Participants

A convenience sample was used and CNTs were recruited from 43 universities and colleges [27]. The average number of CNT members in each nursing school is five to ten; therefore, the total sample size of CNT was estimated to be 215-430 in Taiwan. The inclusion criteria were (1) currently employed full-time CNTs by the department of nursing in colleges and universities, (2) more than 3 months of clinical nursing teaching experience; exclusion criteria were (1) within 3 months of probation period, (2) part-time employed, (3) according to the voluntariness principle, teachers who refused to participate were excluded. A previous exploratory factor analysis (EFA) study has shown acceptance of a small sample size [21]. The latest review of psychological research reports that a sample of 200 subjects or less is acceptable in 40-60% of studies [28]. A total of 35 items were included on the scale in this study, and considering the attrition rate, a sample size between 175 and 350 (n = 205 in our study) was estimated.

Measurement

Demographic questionnaire

This questionnaire includes gender, age, education level, years of clinical nursing work, and years of clinical nursing teaching.

Clinical Nursing Teachers Self-Efficacy Scale

The Clinical Nursing Teacher Self-Efficacy Scale (CNT-SES) was developed to comprehensively measure the self-efficacy of CNTs in guiding students' clinical practice. The CNT-SES survey tool developed by the authors determined the CNT-SES items through a literature review [10-12,16-19,21-26,29-33], expert consultation, and a preliminary small sample survey.

Morgan and Knox (1987) [11] developed the Nursing Clinical Teacher Effectiveness Scale, which divided teacher characteristics into five categories: teaching ability, nursing competence, personality traits, interpersonal relationship, and evaluation. In addition,



Figure 1. The Conceptual Framework of Self-efficacy of Clinical Nursing Teachers.

Hou et al. (2011) [21] developed a clinical nursing faculty competence inventory (CNFCI) that indicated the competencies of clinical nursing faculty, including leadership ability, problem-solving ability, educational intelligence, general teaching ability, and clinical nursing skills. The difference between our CNT-SES and these two inventories was that we have added contemporary applicable items, focus on the future development trends of the nursing profession; apply modern education technology and innovative teaching methods [30], pay attention to the development of nursing science, proficiency and ability in nursing research, participating in interdisciplinary research projects and interdisciplinary learning [31], presentation at international conferences, international foreign language ability [25], decision-making [32] and evidence-based nursing [33]. Finally, we develop the "CNT-SES" consisting of 35 items. There are four dimensions: (1) teachers' professional growth ability (1-8; 8 items), (2) teaching ability (9–19; 11 items), (3) clinical nursing competencies (20–24; 5 items) and (4) personality traits (25-35; 11 items). The scoring range for each item was 0-4; participants were instructed to rate all items on a 5-point Likert scale (4 = strongly agree, 3 = agree, 2 = neutral, 1 = disagree, 0 = strongly disagree); and the total score range was 0-140. The range of subscale scores was 0-32, 0-44, 0-20, and 0-44, respectively; the higher the score, the stronger the self-efficacy of the CNTs.

Data collection

The investigation of CNT self-efficacy was divided into three stages: (1) item generation and content validity; (2) preliminary survey; and (3) collect data in the descriptive and cross-sectional study.

Stage 1: Item generation and content validity

The instrument development procedure was based on a theoretical and literature review [2,4,6,8,10–13,16–20,23,24,28–33] and initially constructed a list of 60 items in six categories: (1) teachers' professional growth ability, (2) teaching ability, (3) clinical nursing competency, (4) personality traits, (5) fostering student learning ability, and (6) competencies of clinical nursing educators. Three experienced nursing education experts were invited to review the initial 60 items to examine the content validity of the generated items. The experts offered comments and suggestions and also rated the suitability of each item on a 5-point scale. According to experts' suggestions, categories and some items were merged, the content validity index of these items ranged from 0.85 to 1 [34], and the scale-level CVI calculated based on the experts' score was 0.95 [35]; therefore, the questionnaire was revised to 50 items in four categories.

Stage 2: Preliminary survey

At this stage, the procedure included recruiting 20 CNTs to assess the suitability of the 50 items. Twenty participants from a university in central Taiwan conducted a questionnaire survey of 50 items, hoping to find out whether the description of the items was clear, readable, unambiguous, equivocal, and accurately reflects the self-efficacy of CNTs. They reported that it takes approximately 10–15 minutes to complete the instrument. In the preliminary study, the 50 items were carefully modified to make them more specific and explicit. A preliminary survey showed that the mean age of 20 CNTs was 43.25 (\pm 5.39) years; clinical nursing teaching experience was 9.50 (\pm 4.56) years, and clinical nursing work experience was 9.35 (\pm 4.58) years. Respondents said that these items were easy to understand; it takes an average of 10 to 15 minutes to complete the questionnaire.

Stage 3: Collect data in the descriptive and cross-sectional study

We collected descriptive and cross-sectional data from July 2019 to January 2020. Data were collected from nursing schools in northern, central, southern, and eastern Taiwan. We do our best to contact all potential participants to complete the questionnaire electronically by sending an email invitation with a link to the questionnaire to potential participants. All participants were informed of the purpose of the study, read informed consent, and the time required to complete the survey. 400 emails were sent and 205 questionnaires were returned, and the response rate was 51.25%. The questionnaire was distributed and returned at the appointed time. Since the design of the questionnaire required that all questions be answered, otherwise the questionnaire was invalid and the valid questionnaires were 100%. After collecting the data, 15 items that did not meet the statistical significance were eliminated by item discriminant analysis; the initial 35 items were retained. The flow chart of data collection and item generation is shown in Figure 2.

Data analysis

SPSS version 26.0 was used for data analysis. The statistical significance level was set at p < .05 (two-tailed). The descriptive statistics of the demographic data are the standard deviation (SD) and frequency (rate). Psychometric properties consider validity, reliability, and rigor. The content validity index was used to assess the content validity of the scale. Internal consistency was determined by the Cronbach's α coefficient (>0.70). Item analysis is the process of examining the responses to individual items to assess the quality of the items; and identify the underperforming items; including the mean and standard deviation [34-37]; the critical ratio (CR) is a test for item discrimination, and good item discrimination is statistical significance [34-37]. Pearson correlation analysis is used to test the correlation between the items and the total score, and the significance level is 0.01 [21,34,38]. EFA was used to determine the construct validity of the scale and used principal component analysis. To determine whether it is suitable for factor analysis, the Kaiser-Meyer-Olkin (KMO) value was used to measure the adequacy of the sampling. Bartlett's test of sphericity, factor loading, and measure of sampling adequacy were used to determine the suitability of items. Items with factor loading <.5 would be excluded; factors with an eigenvalue greater than 1.0 were retained as common factors. The factorization of the correlation matrix was determined by the KMO test >.70 was acceptable, and significant on the Bartlett's test of sphericity [39].

Ethical considerations

This study was approved by ethics committees; the approval came from an Institutional Review Board (No. CS2-19024). All participants gave their informed consent. Research data will be strictly protected and confidential. All participants were informed that they could withdraw from the study at any time without affecting their rights.

Results

Demographic characteristics

A total of 205 participants came from 43 nursing schools in different regions of Taiwan. CNTs (400 in total) were invited to participate; 205 questionnaires were completed for data analysis, with a response rate of 51.25%. The age of the CNTs was between 26 and 57 years, with a mean age of 41.20 (\pm 6.41) years; all were women (n = 205, 100%). Participants with a master's degree were 71.70% (n = 146) and with a bachelor's degree were 28.30% (n = 59). The mean clinical nursing work experience was 9.42 (\pm 5.11) years, and the clinical nursing teaching experience was $8.38 (\pm 5.76)$ years. Most of the clinical nursing experience was 11-15 years (n = 76, 37.07%), the clinical teaching experience was 1-5 years (n = 68, 33.17%) and 11-15 years (n = 66, 32.20%) accounted for the majority (Table 1).

Overall status of the Clinical Nursing Teacher Self-efficacy Scale

The CNTs demonstrated moderate to high self-efficacy (neutral to strongly agree); in this study, the most highly rated category was personality traits, which implies that the CNTs demonstrate confidence in their personality traits (3.04 ± 0.34) ; the second was

Table 1 Demographic Data of CNTs (N = 205).

Characteristic	n (%)	Mean (SD)
Age (years)		41.20 ± 6.41
Gender		
Women	205 (100)	
Education level		
Bachelor	59 (28.30)	
Master	146 (71.70)	
Years of clinical nursing work		9.42 ± 5.11
1-5	44 (21.46)	
6-10	68 (33.17)	
11–15	76 (37.07)	
≥16	17 (8.29)	
Years of clinical nursing teaching		8.38 ± 5.76
1-5	68 (33.17)	
6-10	55 (26.83)	
11-15	66 (32.20)	
≥ 16	16 (7.80)	

clinical nursing competencies, that is, the CNTs recognize the importance of having clinical competencies (3.02 ± 0.45) ; after that was teaching ability (2.89 ± 0.43) and the teachers' professional growth ability (2.50 ± 0.65) . Among the 35 items, the mean of each item ranges from $2.09 (\pm 0.79)$ to $3.27 (\pm 0.49)$, indicating that the respondents were neutral or strong agree on this scale. Twenty-four of these items had a mean score of $2.09 (\pm 0.79)-2.99 (\pm 0.47)$, indicating that the respondents were neutral or agree with the 24 items. There were 11 items with a mean score was higher than 3.0, which means that the CNTs in these 11 items showed agree or strong agree on self-efficacy (Table 2). However, the item with the lowest mean score of $2.09 (\pm 0.79)$ was "Foreign language ability - English" (Table 2).

Items discrimination analysis and homogeneity test

Add all items in each subscale to get the total score. In the item discriminant analysis, the high-score group was in the top 27% and the low-score group was in the bottom 27%. Item analysis focuses on item and test quality and explores difficulty index (p-values; pvalues converted to percentages) and discrimination index. The observed proportions in the two extreme groups into measures of item difficulty and item discrimination. Item discrimination helps to detect the ability of items to discriminate between low-achieving group and high-achieving score group [40,41]. Item analysis constructs a high-low-27% group method. Generally, the top 27% are regarded as the high-achieving group, and the last 27% (73%) are regarded as the low-achieving group [40,41]. In this study, item analysis was performed showing the discrimination indices, as well as the percentage of people in the upper and lower 27% who responded to each alternative. To examine the significant differences between the high-score group and the low-score group, an independent *t*-test was used; there was a significant difference between two groups (t = -10.634, p < .001) [34–37]. A total of 15 items that did not meet the significant difference were eliminated; the remaining items showed statistically significant in CR values (Table 2).

Internal consistency

The overall scale reliability of the Cronbach α coefficient (>0.7 was acceptable) was 0.92, and 0.83, 0.91, 0.93, and 0.87 for the four sub-scales were acceptable [42]. Regarding the correlation of each item with the total score, the results of Pearson's correlation analysis between the items and the total scale score ranged from 0.310 to 0.662 (p < .001) (Table 2), which means that the 35 items correlated well with the scale, showing satisfactory reliability.

No	Items	Mean (SD)	Critical ratio (CR)	p value	Correlation coefficient (r)	p value
A. Tea	chers' professional growth ability					
1	Ability to read and study extensively in one's own professional field.	2.73 (0.58)	4.425	<.01	.467	<.001
2	Ability to understand current or future development trends of the nursing profession.	2.53 (0.62)	8.035	<.01	.507	<.001
3	Ability to learn and use modern and innovative teaching methods to assist in teaching.	2.60 (0.58)	8.857	<.01	.574.	<.001
4	Ability to develop nursing science and apply evidence-based nursing (EBN).	2.61 (0.61)	8.849	<.01	.525	<.001
5	Ability to conduct independent nursing research.	2.52 (0.65)	6.972	<.01	.590	<.001
6	Have the ability to read the nursing research literature.	2.55 (0.59)	5.199	<.01	.451	<.001
7	Have self-improvement ability (such as participating in continuing education, academic	2.35 (0.77)	5.054	<.01	.516	<.001
	conferences, presentation at international seminars, participating in teamwork, or					
	interdisciplinary research projects).					
8	International foreign language ability (English etc.)	2.09 (0.79)	3.899	<.01	.311	<.001
B. Tea	ching ability					
9	Ability to assess students' knowledge and clinic skills.	2.94 (0.36)	2.768	<.01	.527	<.001
10	Answer students' questions carefully and accurately.	2.95 (0.38)	1.714	<.01	.364	<.001
11	Stimulate students' reasoning ability.	2.87 (0.44)	4.086	<.01	.603	<.001
12	Ability to assess students' knowledge and clinic skills.	2.89 (0.45)	3.703	<.01	.661	<.001
13	Stimulate students' interest in nursing.	2.71 (0.57)	6.304	<.01	.662	<.001
14	Effectively organize and arrange clinical teaching plans.	2.90 (0.44)	2.230	<.01	.431	<.001
15	Guide students to solve problems based on literature and evidence.	2.89 (0.42)	3.037	<.01	.623	<.001
16	Establish a good learning environment.	2.92 (0.43)	3.921	<.01	.540	<.001
17	Show students the clinical decision-making process.	2.86 (0.43)	3.935	<.01	.611	<.001
18	When students encounter difficulties, provide individual help.	2.97 (0.43)	4.221	<.01	.546	<.001
19	Quickly grasp the meaning of students' questions or students' words.	2.87 (0.39)	4.069	<.01	.598	<.001
C. Clin	ical nursing competency				- 10	
20	Have good clinical nursing skills.	3.06 (0.48)	4.989	<.01	.546	<.001
21	Have a good clinical problem assessment ability.	3.01 (0.43)	4.900	<.01	.621	<.001
22	Have the ability to make judgments and analyses based on clinical data assessment.	3.03 (0.43)	3.524	<.01	.508	<.001
23	Possess professional knowledge of the subject.	3.02 (0.42)	3.339	<.01	.548	<.001
24	Ability to handle emergencies properly.	2.99 (0.47)	4.420	<.01	.589	<.001
D. Per	sonal traits	2 10 (0 42)	2 2 6 0	01	422	001
25	Establish interpersonal relationships and a harmonious teamwork spirit.	3.10 (0.43)	2.269	<.01	.423	<.001
26	Empatny	3.08 (0.53)	3.744	<.01	.493	<.001
27	with rules).	3.08 (0.49)	3.558	<.01	.541	<.001
28	Understand self-limitations.	3.09 (0.46)	3.460	<.01	.524	<.001
29	Good communication skills.	2.97 (0.43)	3.979	<.01	.506	<.001
30	Open-minded and not critical.	2.96 (0.48)	2.569	<.01	.418	<.001
31	Enthusiastic and energetic.	2.92 (0.60)	3.960	<.01	.510	<.001
32	Be responsible for your behavior.	3.27 (0.49)	2.838	<.01	.310	<.001
33	Be a good role model for nursing students.	3.09 (0.44)	3.180	<.01	.429	<.001
34	Master the level of student learning ability.	2.90 (0.40)	4.770	< 0.01	.581	<.001
35	Touch people's hearts (understand students to express their thoughts and feelings, so as	3.02 (0.46)	4.358	<0.01	.656	<.001
	to perceive and evaluate their own behavior).					

Exploratory factor analysis

EFA was conducted to examine the psychometric properties of the developed scale, in this study, EFA extracted four factors: (1) the teachers' professional growth ability; (2) teaching ability; (3) clinical nursing competencies; and (4) personality traits. Our result showed that the KMO value was 0.949, and Bartlett's test of sphericity was significant ($\chi 2 = 6457.117$, df = 595, p < .001). The results showed that 35 items were acceptable for factor analysis. Four factors explained 68.53% of the total variance (Table 3), and the variance explained for each factor (21.523, 19.633, 15.348, and 12.021) was presented in Table 3. The final version of the CNT-SES consists of four factors and 35 items.

Discussion

Demographic characteristics

In this study, the majority of teachers have a master' degree (71.70%), with clinical teaching experience 6–10 years (26.83%) and 11–15 years (32.20%) accounting for the majority, which means that more than half of the CNTs are experienced (59.03%). The result of this study showed the self-efficacy of CNT, with 33 out of the 35 items were agreed or strongly agreed (mean \geq 2.5). This study was

consistent with Cayır and Ulupınar (2021) who found that perceptions of general self-efficacy and performance levels increased with age, occupational experience, and academic experience [43]. Although the individual items on the scale range from strongly disagree to strongly agree, the participants conducted a highly consistent assessment of these 33 items.

Construct validity and reliability of the CNT-SES

The newly developed CNT-SES showed a satisfactory estimation of psychometric properties. In the original CNT-SES development process, an item analysis was performed to guarantee fitting items for EFA; the results of the item analysis showed that 15 items were excluded because they did not meet the statistically significant and these 15 items obviously showed caring for students. Additionally, previous studies emphasized problem-solving ability, general teaching ability, nursing competence, clinical nursing skills, interpersonal relationships, and personality traits [11,21]; in this study, the item analysis of these items was considered a high score. The item analysis identified the high-score group and the low-score group, and an independent sample *t*-test was required to test whether there was a significant difference in the total score between the high-score group and the low-score group. The CR was statistically significant, indicating that the total score of the high-

Table 3 Factor Loading for Clinical Nursing Teacher Self-Efficacy Scale.

Item			Comp	onents	
A. Teachers'	professional growth ability				
1	Ability to read and study extensively in one's own professional field.	.182	.163	.698	.195
2	Ability to understand current or future development trends of the nursing professio	n204	.267	.768	.128
3	Ability to learn and use modern and innovative teaching methods to assist in teachi	ng284	.216	.720	.147
4	Ability to conduct independent nursing research.	.121	.177	.692	.209
5	Ability to develop nursing science and apply evidence-based nursing (EBN).	.126	.201	.722	.311
6	Have the ability to read the nursing research literature.	.183	.117	.738	.135
7	Have self-improvement ability (such as participating in continuing education, acader	nic .002	.202	.679	.197
	conferences, presentation at international seminars, participating in teamwork, or				
	interdisciplinary research projects).				
8	International foreign language ability (English etc.)	.148	.188	.560	.235
B. Teaching	ability				
9	Ability to guide students to organize patients' problems.	.296	.675	.212	.430
10	Answer students' questions carefully and accurately.	.369	.701	.182	.231
11	Stimulate students' reasoning ability.	.291	.676	.332	.200
12	Ability to assess students' knowledge and clinic skills.	.304	.723	.308	.308
13	Stimulate students' interest in nursing.	.329	.658	.240	.104
14	Effectively organize and arrange clinical teaching plans.	.261	.700	.235	.360
15	Guide students to solve problems based on literature and evidence.	.322	.750	.286	.249
16	Establish a good learning environment.	.462	.635	.265	.177
17	Show students the clinical decision-making process.	.421	.668	.294	.223
18	When students encounter difficulties, provide individual help.	.453	.668	.260	.134
19	Quickly grasp the meaning of students' questions or students' words.	.414	.599	.284	.234
C. Clinical n	ursing competency				
20	Have good clinical nursing skills.	.314	.274	.269	.745
21	Have a good clinical problem assessment ability.	.339	.354	.288	.726
22	Have the ability to make judgments and analyses based on clinical data assessment.	.333	.325	.250	.767
23	Possess professional knowledge of the subject.	.341	.299	.263	.742
24	Ability to handle emergencies properly.	.398	.241	.244	.725
D. Personal	traits				
25	Establish interpersonal relationships and a harmonious teamwork spirit.	.744	.230	.116	.258
26	Empathy.	.731	.245	.134	.212
27	Effective self-management (such as emotional stability, punctuality, and compliance	.694	.285	.158	.174
	with rules).				
28	Understand self-limitations.	.715	.252	.141	.174
29	Good communication skills.	.759	.244	.197	.172
30	Open-minded and not critical.	.687	.315	.199	.171
31	Enthusiastic and energetic.	.695	.237	.169	.186
32	Be responsible for your behavior.	.690	.239	.118	.247
33	Be a good role model for nursing students.	.679	.307	.106	.289
34	Master the level of student learning ability.	.614	.455	.202	.195
35	Touch people's hearts (understand students to express their thoughts and feelings, so	o as .578	.464	.281	.148
	to perceive and evaluate their own behavior).				
The percent	age (%) of variance by factors (Rotation sums of squared loading)				
Factor 1	Factor 2	Factor 3		Factor 4	
21.525	19.633	15.348		12.021	
Total percen	tage of the factor model 68.53%				

score group and the low-score group had good discrimination [44]. Additionally, correlation analysis was used to test whether the scores of each item were correlated with the total scale score. The higher the correlation coefficient, the stronger the internal consistency between items. Pearson correlation coefficients were interpreted as weak (r = .10-.30), moderate (r = .40-.60), strong (r = .70-.90) or very strong (r = 1.00) [45]. The correlation coefficient is reported weakly with an r of .30; and consider removing items with correlation coefficients below .30 [34,36,43]. Fortunately, in this study, the correlation coefficient for each item was >.30. In addition, the results of the Cronbach α coefficient reliability test for the overall scale and for the four sub-dimensions were acceptable, ranging from 0.83 to 0.90, showing that the higher the value of Cronbach α , the higher the internal consistency between items. Furthermore, factor analysis is the most effective method to test construct validity; from these factors, some structural elements of psychostatistical concepts can be identified to understand the valid measurement factors [39]. The four dimensions explained 68.53% of the total variance, which met the criteria for selecting factors.

Self-efficacy of CNTs and the significance of each attribute of the scale in clinical practical implications

This study surveyed the self-efficacy of CNTs in clinical teaching settings by developing a structured questionnaire; CNT-SES was divided into 4 factors with a total of 35 items.

Teachers' professional growth ability

Items 1 to 8 were professional growth, research ability, and innovative teaching methods to facilitate teaching; according to our results, the CNT showed that the lowest self-efficacy was the professional growth ability. Hou et al. (2011) [11] found that teaching ability and clinical practice ability were the top two competence characteristics of clinical faculty; which was the same as our study included teachers' professional growth ability and proficiency in theoretical knowledge, teaching ability, clinical nursing competencies, and clinical skills proficiency. However, despite having the lowest score in the four categories, the CNTs still highly recognized by the professional growth ability. This result was consistent with the results of previous studies on teaching effectiveness and competencies among CNTs [11,21]. Professional growth can effectively improve the general professional ability and teaching ability of teachers, which is conducive to mastery of the clinical knowledge and operational practices of nursing students [8]. In addition, especially in item 8 "International foreign language ability-such as English" (2.09 \pm 0.79), indicating that CNTs lack the ability or confidence to speak a foreign language (English). This result showed that the lowest ability was the ability to speak a foreign language, which means that the confidence of CNTs in the ability to speak a foreign language was not as good as other items, which was consistent with the study [21]. Therefore, we suggest that teachers pay more attention to cultivating foreign language skills. Nursing professions face new challenges at any time, and these challenges are accompanied by the need for new technologies and skills development to ensure that clinical nursing continues to advance and educate its profession. Teachers are more confident when they have extensive experience and expertise in the field they teach, use advanced technology to aid learning, and serve as role models for their students [46]. The self-professional growth of nursing teachers enables them to achieve proficiency in clinical competencies [47,48], and implementing optimal teaching of nursing curriculum, support training programs, and provide nursing students with quality nursing education is critical. Therefore, the promotion of professional growth and development of CNTs is of great significance and administrators should consider investing in the professional growth and development of CNTs.

Teaching ability

In this study, the teaching ability score was 2.89 (\pm 0.43). Good clinical teaching leads to good clinical learning [8]. The focus of CNTs is clinical practice teaching; they must be able to instruct students while providing care to the patient, including helping students learn to care for patients, nursing technology and skills, planning assignments or evaluating students' learning outcomes, maintaining patient safety and fostering relationships with students, patients and nursing staff [3,17,21,47]. CNTs are responsible for cultivating students' abilities in decision-making, critical thinking, and developing successful interpersonal relationships in clinical practice [3,21]. They guide students to implement the correct nursing interventions to improve their skills and prepare them to be a good nurse [6,49]. In addition, CNTs' assignments include classroom lecturing, research, or participation in seminars to improve their teaching ability.

Clinical nursing competencies

Additionally, CNTs recognize the importance of having clinical competencies (3.02 ± 0.45) . The clinical nursing competencies of CNTs are the most important factor that affects the clinical learning [47,48]. However, when teachers have insufficient clinical experience and lack the relevant skills to facilitate student learning, students cannot learn effectively in the clinical field, and the level of CNT skills may affect students' perception of the teacher's ability [38,45,50]. Professional competence has been proposed as a core element of nursing [39,49]. The development of professional competence, that is, the provision of nursing services according to professional standards, is crucial. In the past, the professional competence of nurses was defined as the combination of skills, knowledge, attitudes, values, and competencies that lead to effective or high performance in occupational and professional positions [51]. Similarly, the professional competence of nursing teachers is an essential requirement, and nursing teachers must be more competent and committed to their nursing or clinical teaching.

Personality traits

Items 25–35 are related to personality traits; they demonstrate self-efficacy in their personality traits. The literature indicated that the personality traits and characteristics of CNTs have a profound impact on the clinical experiences of students [17,19]. In this category, teachers showed greater confidence in communication skills and interpersonal relationships, which was consistent with previous studies showing that the ability to develop interpersonal relationships is the most valued skill by clinical teachers [12,16,25]. Certain items such as empathy, open-mindedness and enthusiasm are also consistent with Collier (2018) who identified approachability as the most important personality trait of clinical teachers [15]. Furthermore, being responsible for behavior, emotional stability, punctuality, obedience to rules, and understanding selflimitations, which means focusing on proactive behaviors, including aspirations and efforts to start changing yourself and/or the environment, as well as self-initiated (as opposed to passive) and change-oriented (as opposed to maintaining the status quo) and focus on the future (instead of focusing on the current situation) [52].

Looking toward the future

In this study, the author suggested that the definition of selfefficacy of CNT was that the CNTs possessed four characteristics: professional growth ability, teaching ability, clinical nursing competencies, and positive personality traits. In recent years, with the rapid development of international health issues and international nursing education, several studies have appeared on teacher selfefficacy. However, the strengths of the tool we developed and compared to similar tools in the past were that this study highlights the potential and self-efficacy of CNT in the future nursing profession, modern education technology, innovative teaching methods, nursing science, international conferences, leadership, evidence-based nursing, research competence, and interdisciplinary learning; these issues have received more attention [53]. To maintain the pace and progress in nursing practice and education, we may need to pay more attention to the application of EBN and independent research ability in clinical nursing practice rather than traditional concepts of competency [54].

Study limitations

The limitation of this study was that it was not easy to collect data while having direct face-to-face contact with all CNTs in Taiwan because the participants were teachers of nursing schools and assigned to various hospitals and scattered in various regions. Therefore, the sample was not expanded, which was our main limitation. Additionally, it was not easy to collect data directly and complete the questionnaire, which may limit sample sizes. Therefore, we sent email notifications and questionnaires to collect data, and the email was sent many times to all potential participant; however, the response rate was not as expected. Furthermore, more comprehensive studies are needed to explore the self-efficacy of CNTs in different cultures and contexts.

Recommendations

We encourage researchers to use the entire scale for future research or clinical practice. In future research, we suggest that this tool can be used to explore the perceptions of nursing students about CNT in nursing education. We suggested modifying the CNT-SES from the views of nursing students to measure students' perceptions of the effectiveness and competence of CNTs. This tool can serve as the basis for creating a self-efficacy assessment tool in the field of nursing education, which can be used to train and assess the self-efficacy of CNT. CNT-SES can also serve as an assessment tool for observational and intervention studies of teacher self-efficacy in future research. The significance of using this tool depended on the evaluation results of each attribute of the scale, to formulate strategies for CNTs to improve self-efficacy. Therefore, it is important to refer to the various items of the CNT-SES in clinical practice to develop teaching strategies to promote the self-efficacy of CNTs and further facilitate the clinical learning of students. Our suggested strategies include an appropriate continuing education course should be formulated for each attribute of the item, encouraging the setting of personal goals, sharing teaching experiences and participating in Nursing Teachers Associations, building self-confidence and empowerment to help teachers improve their self-efficacy.

Conclusions

The 35-item CNT-SES provides an available assessment tool with good reliability and validity. CNTs showed moderate to high selfefficacy. The study findings offered information on the characteristics of self-efficacy of CNT, including nursing professional growth, teaching ability, nursing competence, ability to develop interpersonal relationships, and certain personality traits. These efficacy characteristics are mainly reflected in the perception of self-efficacy of CNT, and their identification can guide clinical nursing teaching strategies.

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Ethical approval

The study protocol was reviewed and approved by the Ethics Committee of Chung Shan Medical University Hospital (No. CS2-19024). Date of approval: May 15, 2019.

The author agrees to be responsible for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of interest

The authors declare that they have no competing interests.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.anr.2022.05.001.

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Epidemiological Characteristics of Carbapenemase Producing Carbapenem-Resistant *Enterobacteriaceae* Colonization*

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SUMMARY

Purpose: This study identified the epidemiological characteristics, including the size and major strains, of carbapenemase-producing carbapenem-resistant *Enterobacteriaceae* (CP-CRE) and CP-CRE-related factors by comparing the characteristics of patients in the CP-CRE and non-CP-CRE groups and the CP-CRE and non-CRE groups.

Methods: This secondary data analysis study included 24 patients in the CP-CRE group, 113 patients in the non-CP-CRE group, and 113 in the non-CRE group. The size and type of CP-CRE were analyzed in terms of frequency and percentage, and CP-CRE risk factors were identified using multiple logistic regression analysis.

Results: The rate of CP-CRE positivity among patients with CRE was 17.5%, and the most common causative organism in the CP-CRE group was *Klebsiella pneumoniae* (81.8%). There were no significant differences between patients in the CP-CRE and non-CP-CRE groups. When compared with the non-CRE group, the isolation of multidrug-resistant organisms except for CRE, particularly vancomycin-resistant *Enterococcus*, was confirmed as a major risk factor.

Conclusion: To prevent CP-CRE acquisition, patients with multidrug-resistant organisms require treatment with more thorough adherence to CRE prevention and management guidelines.

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Introduction

Carbapenem-resistant *Enterobacteriaceae* (CRE) are antibioticresistant strains and refer to *Enterobacteriaceae* that have acquired resistance to carbapenem antibiotics [1]. CRE emerged after carbapenem antibiotics were used as a treatment for extendedspectrum beta-lactamase-producing gram-negative strains [2] and have become a global public health threat due to widespread

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antibiotic resistance and high mortality rates [3–7]. In the United States, there were 13,100 cases of CRE infection in 2019, with 1100 infections resulting in death [8]. In Korea, the number of reported CRE infections rose from 5717 in 2017 to 18,113 in 2020, with the number of deaths increasing sharply from 37 to 226 over the same period [9]. According to recent studies, including systematic literature review studies, exposure to antibiotics, especially carbapenems, is the most important risk factor for CRE acquisition [10,11]. In addition, underlying diseases, invasive procedures including mechanical ventilation, use of medical devices such as central venous tubes, admission to intensive care units (ICUs) [11–13], multidrug-resistant organism (MDRO) colonization or infection [13], Acute Physiology and Chronic Health Evaluation (APACHE) II score [12,13], and transfer between hospitals [12] are related to CRE acquisition.

Carbapenemase-producing CRE (CP-CRE) is a CRE that exhibits resistance to β -lactam antibiotics through the production of carbapenemase-producing enzymes [10,14] and is distinguished from non-CP-CRE, which exhibits antibiotic resistance through mechanisms such as the production of extended-spectrum β -

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lactamases (ESBL) or AmpC cephalosporinases with decreased outer membrane permeability [15,16]. Since the carbapenemase gene of CP-CRE is located in a mobile genetic element, such as a plasmid or transposon, it can demonstrate faster patient-to-patient transmission than non-CP-CRE [5,15]. Therefore, it is necessary to develop an effective CP-CRE management strategy based on an understanding of the characteristics that distinguish CP-CRE from non-CP-CRE or non-CRE.

According to previous studies, the positivity rate for CP-CRE differs depending on the CRE-infected or colonized patients varies widely from 20% [17] to 67.9% [18]. CP-CRE-related characteristics also showed different results depending on which of the CREinfected or colonized patients were targeted. In a case-control study in which patients with CRE bacteremia were classified into CP-CRE and non-CP-CRE groups in China, old age, cancer, and use of carbapenem antibiotics were identified as risk factors for CP-CRE [19]. In a cohort study of US veterans, heart disease and gastroesophageal reflux disease [18] were identified as risk factors for CP-CRE. In contrast, in a study that divided patients with CRE into CP-CRE and non-CP-CRE groups at an Israeli tertiary hospital, prehospital antibiotic use, experience in nursing homes, and the presence or absence of pressure sores were identified as risk factors for CP-CRE; age was not a risk factor [20]. The use of mechanical ventilation was a protective factor for CP-CRE when the CP-CRE and non-CP-CRE groups were compared, whereas the use of mechanical ventilation appeared as a risk factor when compared with the non-CRE group [20]. In another study with CRE colonized group, the mechanical ventilation was identified as a risk factor for CP-CRE because the use of mechanical ventilation [21] in the CP-CRE group was higher than that of the non-CP-CRE group.

As a result of the literature review, studies on the CP-CRE positivity rate and related factors have been limited to a few countries, such as the United States, Israel, and China; therefore, information on epidemiologic characteristics is limited, and consistent results are not reported, with varying findings depending on the study population or design. In particular, the Korean government is strengthening efforts to identify the epidemiological characteristics of CP-CRE through the revision of regulations by requiring that CP-CRE clusters are identified, and an epidemiological investigation conducted to identify the source of infection [22]; nevertheless, there is very little research in this regard. Therefore, the purpose of this study was to identify the epidemiological characteristics of CP-CRE colonization in patients admitted to the ICU, a department where patients are at high risk of acquiring CRE. The specific objectives of this study were to investigate the size and major strains of CP-CRE and identify the CP-CRE-related factors by comparing the characteristics of patients in the CP-CRE and non-CP-CRE groups and the CP-CRE and non-CRE groups.

Methods

Study design

This case-control study used secondary data analysis to understand the epidemiological characteristics of CP-CRE in patients in the ICU.

Study participants

The primary data for this study came from previous studies that developed a CRE acquisition risk prediction model [13] and evaluated the external validity of the developed predictive model [23]. Each study was conducted using data between October 1, 2016 and October 31, 2017 and between November 1, 2017 and May 31, 2018, respectively. Eight hundred fifty-eight patients admitted to the ICU

of a tertiary general hospital located in Y-city, and acquired CRE from the CRE active surveillance culture test at least once within 1 week of admission and from 1 week after admission until discharge, were included in the primary data (137 in the CRE acquisition group and 721 in the nonacquired group). In the study hospital, CRE active surveillance culture test was performed for every patient admitted to the ICUs using a perirectal swab within 7 days of hospitalization (baseline screening), and weekly thereafter until 7 days after discharge [13,23]. And all patients with CRE isolated from clinical specimens were also subjected to the test. CRE acquisition was confirmed not using clinical specimens but using a rectal swab for the purpose of active surveillance testing for CRE colonization. CRE colonization was confirmed by carbapenem antimicrobial susceptibility testing (imipenem ≤ 22 mm, $\geq 2 \mu g/mL$ minimum inhibitory concentration (MIC); ertapenem ≤ 21 mm, $\geq 1 \mu g/mL$ MIC) using the disk diffusion method, which was performed in accordance with the legal communicable disease diagnostic criteria of the Korea Centers for Disease Control and Prevention (KCDC) [24]. For CRE cases, carbapenemase production was tested using the modified Hodge test (MHT) method based on the Clinical & Laboratory Standards Institute's recommendations. MHT is known to have a high level of sensitivity (>90.0%) and specificity (>90.0%) in detecting Klebsiella pneumoniae carbapenemase-type carbapenemases [25]. As a result of the test, 24 and 113 patients were allocated to the CP-CRE and non-CP-CRE groups, respectively.

The study participants were classified into three groups: CP-CRE, non-CP-CRE, and non-CRE groups. The non-CRE group was randomly selected to have the same number of participants as the non-CP-CRE group. For achieving this, 721 people in the non-CRE group were assigned a serial number; random numbers were generated using Excel, and 113 subjects with a serial number matching the generated numbers were selected as the non-CRE group. Therefore, the final numbers of the study participants were 24, 113, and 113 in the CP-CRE, non-CP-CRE, and non-CRE groups, respectively. The sample size for the case-control study design was calculated using an online program called the Open Source Epidemiologic Statistics for Public Health [26] at .05 as the significance level (α), .80 as the power, and 1:5 as the ratio of cases to controls [27]. For an exposure ratio of 20.8% and odds ratio of 4.1 for the control group, assuming that mechanical ventilation was a risk factor for CP-CRE based on a previous study [21], the minimum sample required was 19-24 in the case group and 94-119 in the control group.

Study variables

The variables examined in this study were demographic characteristics, clinical characteristics at the time of admission to the ICU, and clinical characteristics during ICU stay, which were mainly considered for CRE-related factor studies [11-13,17] or CP-CRErelated factor studies [18-21]. Sex and age variables were included as demographic characteristics, and clinical characteristics at the time of admission to the ICU included APACHE II score, Charlson comorbidity index score (CCIS), and underlying diseases (diabetes, heart disease, respiratory disease, renal disease, liver disease, and solid cancer). APACHE II score was used instead of APACHE III because the study hospital uses a computerized system that automatically calculates the APACHE II score. A recent study showed a very similar diagnostic accuracy of in-hospital mortality between APACHE II and III [28]. Clinical characteristics during the ICU stay included three items: invasive procedures and instruments, use of antibiotics, and isolation of multidrug-resistant organisms (MDROs). Invasive procedures and instruments included surgery, transplantation, endoscopy, bronchoscopy, continuous renal replacement therapy, indwelling catheters, central venous catheters, ventilators, and drainage tubes. Antibiotics comprised penicillin, carbapenem, cephalosporin, fluoroquinolone, and vancomycin. The isolation of multidrug-resistant bacteria included vancomycin-resistant enterococci (VRE), methicillin-resistant *Staphylococcus aureus* (MRSA), extended-spectrum beta-lactamase (ESBL), and MDR *Acinetobacter baumannii*. Data were collected from the date of hospitalization until the date of CRE colonization for the CRE-colonized group (CP-CRE group and non-CP-CRE group) and until the date of discharge from ICUs for the non-CRE group.

Data analysis

The collected data were analyzed using the SPSS/WIN software (version 25.0; IBM Corp., Armonk, NY, USA). A two-tailed test was performed with a significance level (α) of .05. The size and type of CP-CRE and participants' baseline characteristics were analyzed as frequency and percentage for categorical data and median and interquartile range for continuous data because they were not normally distributed.

Bivariate analysis was conducted using simple logistic analysis to compare the baseline characteristics between the two groups (CP-CRE group vs. non-CP-CRE or non-CRE group), and the unadjusted odds ratios (ORs) and associated 95.0% confidence intervals (CIs) were calculated. With all variables as significant factors at a significance level (α) of .05, the adjusted ORs and the associated 95.0% CIs were calculated through forward stepwise multiple logistic regression analysis after confirming no deviation from the assumption of multicollinearity with a coefficient of determination of less than .80 [29], and variance inflation factor of ranging from 1.03 to 1.19.

Ethical considerations

This study was conducted after receiving approval of exemption from review (No. 05-2021-127) from the Institutional Review Board (IRB) of Pusan National University Yangsan Hospital. All data were anonymized.

Results

Among the 137 patients in the CRE group in this study, 24 patients were included in the CP-CRE group, giving a CP-CRE positivity rate of 17.5%. The most common infectious agent in the CP-CRE group was *K. pneumoniae* (79.1%), followed by *Escherichia coli* (12.5%); in the non-CP-CRE group, *K. pneumoniae* (82.3%) was the most common, followed by *Enterobacter* spp. (8.8%) and *E. coli* (7.1%) (Table 1).

Table 2 presents the baseline characteristics of the participants. For the CP-CRE group, 62.5% were male, 20.8% were transferred from another medical institution, the median CCIS score was 1.5, 79.2% had an underlying disease, 50.0% underwent bronchoscopy, 41.7% received carbapenem antibiotics, and 79.2% had MDROs other

 Table 1 Microbiological Characteristics of CP-CRE and Non-CP-CRE.

Microorganisms	CP-CRE ($n = 24$)	Non-CP-CRE ($n = 113$)	Total (137)
	n (%)	n (%)	n (%)
Klebsiella pneumoniae	$ \begin{array}{c} 19 (79.1) \\ 3 (12.5) \\ 0 (0.0) \\ 0 (0.0) \\ 1 (4.2) \end{array} $	93 (82.3)	112 (81.8)
Escherichia coli		8 (7.1)	11 (8.0)
Enterobacter aerogens		6 (5.3)	6 (4.4)
Enterobacter cloacae		4 (3.5)	4 (2.9)
Citrobacter freundii		1 (0.9)	2 (1.5)
Serratia marcescens	1 (4.2)	0 (0.0)	1 (0.7)
Providencia rettgeri	0 (0.0)	1 (0.9)	1 (0.7)

CP-CRE = Carbapenemase producing carbapenem-resistant *Enterobacteriaceae*.

than CRE. There was no significant difference in variables between the CP-CRE and non-CP-CRE groups; however, the CP-CRE group had a higher median CCIS score (1.50 vs. 1.00, p = .044), bronchoscopy rate (50.0% vs. 26.5%, p = .027), and overall MDROs (except MRSA) isolation rate (79.2% vs. 34.5%, p < .001) than those in the non-CRE group (Table 2).

Table 3 shows the results of multiple logistic regression analyses to identify the CRE risk factors using variables that were significant in the simple logistic regression analysis for the CP-CRE and non-CRE groups as explanatory variables. In Model 1, regardless of the type of multidrug-resistant bacteria, isolation was used as an explanatory variable, and as a result, the risk factor for acquiring CP-CRE was confirmed as an isolate of multidrug-resistant bacteria, which was related to a 5.88 times increase the risk of acquiring CP-CRE (p = .001) relative to when multidrug-resistant bacteria were not isolated. In Model 2, when individual multidrug-resistant bacteria were included in the model, only VRE was identified as a risk factor for acquiring CP-CRE.

Discussion

In this study, CP-CRE was confirmed in 17.5% of patients in the CRE group. This result is similar to the 20.0% CP-CRE-positive rate [17] obtained in a study in patients with CRE admitted to ICUs and transplant wards of a single hospital in the United States. However, it is much lower than the 27.7% [18] reported in a study using a cohort of patients admitted to 127 veterans hospitals in the United States and the 31.5% reported by the US Centers for Disease Control and Prevention' Antibiotic Resistance Laboratory Network [30], and 44.7% of national surveillance report using both active surveillance cultures and clinical samples from 189 institutions in Korea [31]. This result may be related to the difference in the sample mix; colonized by or infected with CRE. The former two studies, including this study, targeted those colonized by CRE, while the latter three studies with higher positivity rates for CP-CRE examined the CRE-infected group or both. In particular, it showed a higher CP-CRE positivity rate in patients with bloodstream infections. Zou et al [19] study of patients with CRE bacteremia showed a CP-CRE-positive rate of 67.9%. In a cohort study of patients with CRE bacteremia at a tertiary hospital in Korea, the CP-CRE positivity rate was as high as 47.4% [32]. Therefore, even in the same CRE group, it seems that the CP-CRE positivity rate is higher in patients who are infected, especially in the bloodstream infection stage, compared with those at the colonized stage. Nevertheless, it is necessary to confirm this through repeated studies in various settings.

The major strain in the CP-CRE group in this study was K. pneumoniae, which supports the results of previous studies which reported that K. pneumoniae was the most common CP-CRE strain, regardless of whether it was a CP-CRE-colonized [21] or CP-CRE-infected group [18,19]. In addition, K. pneumoniae is the most common CP-CRE strain over the past 10 years from the analysis of national surveillance data in the Korea [31,33]. K. pneumoniae accounted for 62.8% [31] to 88.7% [21] of CP-CRE strains, and the result in this study was within this range. The next most frequently isolated strains were E. coli and Enterobacter spp., which is consistent with the previous reports using national surveillance data [31,33]. However, the rankings differed depending on the study. E. coli was found in 4.4% [18] to 20.0% [19,21] of the CP-CRE group, and Enterobacter spp. in 9.1% [19] to 13.1% [18]. In this study, only E. coli was detected in the CP-CRE group, whereas both strains were detected in the non-CP-CRE group.

For CP-CRE-related factors, some variables, such as invasive procedures and instruments, and antibiotics, were analyzed for

 Table 2 Comparison of Characteristics of Study Participants Among Three Groups.

Variables	CP-CRE (n = 24)	Non-CP-CRE $(n = 113)$	Non-CRE (n = 113)	CP-CRE vs. Non-C	P-CRE	CP-CRE vs. non-	CRE
	n (%) or median (IQR)	n (%) or median (IQR)	n (%) or median (IQR)	OR (95% CI)	р	OR (95% CI)	р
Demographic characte	ristics						
Men	15 (62.5)	76 (67.3)	67 (59.3)	.81 (.33-2.03)	.654	1.14 (.46-2.84)	.771
Age (years)	56.5 (24-69)	59.0 (26-67)	60.0 (28-74)	1.00 (.98-1.02)	.951	1.00 (.98-1.01)	.646
Clinical characteristics	at ICU admission						
Transfer from LTCF	4 (16.7)	7 (6.2)	7 (6.2)	.73 (.25-2.12)	.561	.88 (.30-2.59)	.817
APACHE II	19 (12-27)	21 (16-25)	16 (12-22)	.97 (.91-1.03)	.289	1.06 (1.00-1.14)	.069
CCIS	1.50 (0-3)	2.00 (0-3)	1.00 (0-2)	1.03 (.79–1.33)	.846	1.35 (1.01-1.82)	.044
Underlying disease							
DM	4 (16.7)	26 (23.0)	23 (20.4)	0.67 (.21-2.13)	.497	.78 (.24-2.51)	.681
CHD	11 (45.8)	44 (38.9)	56 (49.6)	1.33 (.55-3.22)	.532	.86 (.36-2.08)	.740
CRD	4 (16.7)	13 (11.5)	7 (6.2)	1.54 (.46-5.21)	.489	3.03 (.81-11.31)	.099
CLD	5 (20.8)	22 (19.5)	18 (15.9)	1.09 (.37-3.24)	.879	1.39 (.46-4.20)	.561
CKD	1 (4.2)	11 (9.7)	7 (6.2)	.40 (.05-3.28)	.396	.66 (.08-5.61)	.702
Cancer	4 (16.7)	19 (16.8)	9 (8.0)	.99 (.30-3.22)	.986	2.31 (.65-8.24)	.197
Any disease	19 (79.2)	82 (72.6)	80 (70.8)	1.44 (.49-4.18)	.506	1.57 (.54-4.55)	.408
Clinical characteristics	during ICU stay						
Invasive procedures/dev	vice						
Surgery	11 (45.8)	52 (46.0)	36 (31.9)	.99 (.41-2.40)	.987	1.81 (.74-4.43)	.194
Transplantation	4 (16.7)	18 (15.9)	13 (11.5)	1.06 (.32-3.46)	.929	1.54 (.46-5.21)	.489
Bronchoscopy	12 (50.0)	51 (45.1)	30 (26.5)	1.22 (.50-2.94)	.664	2.77 (1.12-6.82)	.027
Endoscopy	7 (29.2)	28 (24.8)	15 (13.3)	1.25 (.47–3.33)	.655	2.69 (.96-7.57)	.061
CRRT	6 (25.0)	41 (36.3)	25 (22.1)	.59 (.22–1.59)	.294	1.17 (.42–3.27)	.760
Urinary catheter	23 (95.8)	108 (95.6)	105 (92.9)	1.07 (.12-9.55)	.955	1.75 (.21–14.71)	.605
CVC	21 (87.5)	106 (93.8)	93 (82.3)	.46 (.11–1.93)	.291	1.51 (.41–5.54)	.538
MV	19 (79.2)	98 (86.7)	71 (62.8)	.58 (.19–1.79)	.345	2.25 (.78-6.47)	.133
Drainage tube	14 (58.3)	71 (62.8)	48 (42.5)	.83 (.34-2.03)	.680	1.90 (.78-4.63)	.160
Antibiotic treatment							
Penicillin	18 (75.0)	91 (80.5)	67 (59.3)	.73 (.26–2.04)	.543	2.06 (.76-5.58)	.156
Carbapenem	10 (41.7)	61 (54.0)	28 (24.8)	.61 (.25–1.49)	.276	2.17 (.87–5.43)	.098
Cephalosporin	20 (83.3)	84 (74.3)	80 (70.8)	1.73 (.55–5.47)	.354	2.06 (.66-6.50)	.216
Fluoroquinolone	17 (70.8)	78 (69.0)	62 (54.9)	1.09 (.42-2.86)	.862	2.00 (.77-5.19)	.156
Vancomycin	9 (37.5)	52 (46.0)	37 (32.7)	.70 (.29–1.74)	.447	1.23 (.49-3.08)	.654
MDROs carrier							
VRE	14 (58.3)	46 (40.7)	23 (20.4)	2.04 (.83-4.99)	.118	5.48 (2.16-13.91)	<.001
MRSA	2 (8.3)	20 (17.7)	6 (5.3)	.42 (.09–1.94)	.269	1.62 (.31-8.57)	.569
ESBL	7 (29.2)	46 (40.7)	13 (11.5)	.60 (.23–1.56)	.295	3.17 (1.11–9.08)	.032
MDR A. baumannii	6 (25.0)	31 (27.4)	10 (8.8)	.88 (.32–2.43)	.807	3.43 (1.11–10.62)	.032
Any MDROs	19 (79.2)	93 (82.3)	39 (34.5)	.82 (.27–2.45)	.718	7.21 (2.50-20.79)	<.001

APACHE = Acute physiology and chronic health evaluation; CCIS = Charlson comorbidity index score; CHD = Chronic heart disease; CI = Confidence interval; CKD = Chronic kidney disease; CLD = Chronic liver disease; CP-CRE = Carbapenemase producing carbapenem-resistant *Enterobacteriaceae*; CRD = Chronic respiratory disease; CRE = Carbapenem-resistant *Enterobacteriaceae*; CRT = Continuous renal replacement therapy; CVC = Central venous catheter; d = days; DM = Diabetes mellitus; Dx = Disease; ESBL = Extended spectrum beta-lactamase; IQR = Interquartile range; MDROs = Multidrug resistant organisms; MRSA = Methicillin resistant *Staphylococcus aureus*; OR = Odds ratio; VRE = Vancomycin resistant *Enterococci*.

Table 3 Multivariate Analysis of Risk Factors of CP-CRE: CP-CRE versus non-CRE.

Variables	В	SE	OR (95% CI)	р	VIF
Model 1					
Charlson comorbidity index	.27	.17	1.32 (.95-1.82)	.097	1.03
score					
Any MDROs isolated	1.77	.55	5.88 (1.99–17.43)	.001	1.12
Bronchoscopy	.66	.50	1.93 (.73–5.13)	.187	1.10
Model 2					
Charlson comorbidity index	.19	.17	1.21 (.86-1.70)	.280	1.11
score					
Vancomycin resistant	1.37	.51	3.92 (1.44–10.70)	.008	1.15
enterococci					
Extended spectrum	.76	.61	2.14 (.65-6.99)	.210	1.05
beta-lactamase					
MDR A. baumannii	.98	.68	2.67 (.70-10.13)	.150	1.14
Bronchoscopy	.51	.53	1.67 (.59-4.75)	.339	1.19

APACHE = Acute physiology and chronic health evaluation; CI = Confidence interval; HR = Hazard ratio; CP-CRE = Carbapenemase producing carbapenem-resistant *Enterobacteriaceae*; CRE = Carbapenem-resistant *Enterobacteriaceae*; SE = Standard error; VIF = Variance inflation factor.

correlations with CP-CRE depending on whether they were used [19–21] or their period of use [18]. In this study, only the model including this category was used because there was a difference

in the data collection period between the CRE group and non-CRE group, which may distort the results. After confirming the factors related to CP-CRE, there were no distinct characteristics between the CP-CRE and non-CP-CRE groups. However, when compared with the non-CRE group, the isolation of MDROs except for CRE, particularly VRE, was confirmed as a major risk factor. A previous study showed that the presence of MDRO colonization within one year in patients admitted to acute-care hospitals from long-term care facilities is a risk factor for new MDRO colonization [34]. However, it is difficult to find results suggesting that other types of MDRO are risk factors for CP-CRE. In a study conducted in Israel, other types of multidrug-resistant bacteria were associated with CP-CRE, but these were not identified as significant variables in the multiple logistic regression analysis [21]. Unlike other MDROs, VRE was derived as a risk factor for acquiring CRE. The reason may relate to the fact that the major reservoir of VRE and CRE is common in the lower gastrointestinal tract [35]. A healthy gastrointestinal microbiota can provide resistance to multi-drug resistant organisms such as VRE and CRE. However, antibiotic-mediated destruction of the intestinal microbiota and consequent loss of colonization resistance leads to antibiotic-resistant organisms' colonization and infection [36-38].

CCIS and bronchoscopy use were associated with CP-CRE in the univariate analysis but not with CP-CRE in multivariate analyses. The CCIS score of the CP-CRE group was higher than that of the non-CRE group in this study. In a study by Kassem et al [20] conducted in Israel, the CCIS score was significantly higher in the non-CP-CRE group than in the CP-CRE group, but multiple logistic regression analysis showed that CCIS was not related, which was consistent with the finding that it was not a risk factor for CP-CRE. CCIS is an index developed to predict the risk of death within one year of hospitalization based on the number of comorbidities and is often used to evaluate the prognosis or survival of patients [39]. Kassem et al [20] reported that as the CCIS score increased by 1 point, the in-hospital mortality rate increased by 1.09 times, indicating that CCIS reflects in-hospital mortality. The CCIS score has been reported to be related to increased mortality rates for the coronavirus disease in 2019 [40]. Regarding the relationship between bronchoscopy and CRE infection, Mehta and Muscarella [41] reported suspected cases of CRE infection due to inappropriate reprocessing of bronchoscopy following literature review and Internet searches. In these cases, the risk of CRE transmission due to bronchoscopy is underestimated, emphasizing the interest of healthcare workers and the importance of appropriate reprocessing of bronchoscopies [41]. In this study, the statistical power of the use of bronchoscopy was only 42.0%; therefore, it was not confirmed as a factor related to CP-CRE. Repeated studies using a larger sample are required in the future.

Clinical implications

As a result of this study, CP-CRE acquisition was found to occur frequently in patients admitted to the ICU. Factors that increase the risk of CP-CRE in patients with CRE were not identified, but the risk of CP-CRE increases when MDROs are isolated from patients without CRE. When a specific MDRO is identified in a patient, even though precautions such as contact isolation are applied, inappropriate or incomplete application of precaution or the patient's vulnerability to any kind of MDRO should be considered [21]. If MDROs are isolated from a patient for any reason, such patients require treatment with more thorough adherence to CRE prevention and management guidelines. Our findings added the importance of prevention and control of CRE acquisition and spread in the ICUs, as CP-CRE is more easily transmitted between patients by using a mobile genetic element than non-CP-CRE [5,15]. In addition, with the advancement of personalized care, CP-CRE/non-CP-CRE/ non-CRE stratification can better guide the prevention and control of CP-CRE acquisition.

Strengths and limitations

Management of CP-CRE through an understanding of the epidemiologic characteristics of CP-CRE is important to prevent the rapid transmission of CRE. In particular, when the CP-CRE test is difficult to perform or the patient refuses the test, the population at high risk of CP-CRE can be managed more effectively by identifying the characteristics that distinguish CP-CRE from non-CP-CRE or non-CRE. Given that studies on the epidemiologic characteristics of CP-CRE at home and abroad are very limited, the results of this study can improve understanding of the progression of CP-CRE among CRE-colonized patients or non-CRE patients admitted to ICUs.

However, careful interpretation of the results is required because of the following limitations. First, since this study is a secondary data analysis study using existing data, variables identified as CP-CRE-related factors in previous studies [20] but were not included in the primary data sources (for example, pressure ulcers and use of antibiotics prior to admission) were excluded from the explanatory variables. Second, data were collected from the date of hospitalization until the date of CRE colonization for the CRE colonized group (CP-CRE group, non-CP-CRE group) and until the date of discharge from the ICU for the non-CRE group, where differences in data collection time can influence the length of stay in the ICU. Therefore, the duration of ICU stav was not considered in this study. Consequently, while the length of stay in the ICU has been identified as a factor related to CP-CRE in previous studies [19], it was excluded as an explanatory variable in this study. Third, this study could not identify the factors related to the acquisition of CP-CRE among those with CRE colonization. This is thought to be because poor statistical power was expected when the sample size was calculated, and repeated studies using a larger sample are suggested in the future. Last, the primary data included ICU patients hospitalized in a single hospital, and the generalizability of the findings to other hospitals or settings may be limited.

Conclusion

As a result of this study, approximately 2 out of 10 patients who were colonized by CRE after admission to the ICU had CP-CRE, and the most common causative strain was *K. pneumoniae*. The CP-CRE group did not have any characteristics distinguishing it from the non-CP-CRE group; however, the isolation rate of multidrugresistant bacteria, especially VRE, was higher than that in the non-CRE group. When multidrug-resistant bacteria are primarily isolated from hospitalized patients, strict adherence to CRE prevention and management guidelines is required to prevent the rapid spread of CRE between patients. In the case of patients with isolated VRE, it is recommended to conduct a screening test to confirm the presence of CP-CRE colonization and isolate carriers promptly, according to the results.

Conflicts of interest

The authors declared no conflict of interest.

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Research Article

The Lived Experience of First-time Mothers with Congenital Heart Disease

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SUMMARY

Purpose: Nowadays most children with congenital heart disease (CHD) are expected to survive to adulthood. The healthcare focus needs to pay close attention to the important developmental tasks during their growth process. The women with CHD face some challenges in their critically developmental stages during pregnancy, delivery, and even motherhood. The lived experience of being a mother needs to be further concerned. This study aimed to explore the lived experience of first-time mothers with CHD.

Methods: Descriptive phenomenological design was adopted. Semi-structured interviews were conducted from April to August 2018 with 11 primiparous women with CHD, who were recruited from the pediatric and adult cardiology outpatient departments at a medical center and who had a child aged between 6 months and 3 years. Giorgi's phenomenological analysis method was employed.

Results: Six main themes arose from the analysis: (1) recognizing pregnancy risks, (2) performing self-care for health, (3) building self-worth from my baby, (4) adapting to postpartum life and adjusting priorities, (5) enjoying being a first-time mother, and (6) the factors contributing to success in high-risk childbirth.

Conclusions: The experiences that occurred prior to and after labor that were identified in this study can assist women with CHD to more capably prepare for and understand the process of becoming a mother, including recognition of the importance of a prepregnancy evaluation. The findings of this study can help women with CHD to better understand the path to becoming a mother and prepare themselves for the challenges that lie ahead.

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Introduction

Congenital heart disease (CHD) is the most common congenital circulatory malformation in newborns. Depending on its severity, it affects normal life functions. The prevalence of CHD in screened children by year from 2002 to 2018 ranged from 5.1/1,000 to 7.3/1,000 in Taiwan [1]. However, due to the development of medical technology, more than 90.0% of patients can survive into adulthood,

but long-term follow-up is required [2]. The needs of these patients with respect to the physical, mental, social, and spiritual aspects of life are a worthy object of study. One of the major life events that women with CHD are likely to experience is becoming pregnant and being a mother.

Men with CHD are concerned about their performance during sexual intercourse, whereas women with CHD are concerned about problems related to pregnancy and childbearing [3,4]. Upon reaching childbearing age, women with CHD must prepare for pregnancy if they desire it. Women with differing heart disease severity face different levels of pregnancy risk. Studies examining the hemodynamic changes in women with CHD during their pregnancy have indicated that the cardiac output of these women is 30–50.0% higher than that of themselves when they are not pregnant, and this higher cardiac output can lead to elevated risk of cardiovascular diseases [5]. Additionally, compared with their

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counterparts without CHD, women with CHD are more likely to experience pregnancy complications and have their children inheriting CHD [6]. When the mother has chronic diseases or delayed childbirth, the child's risk of CHD will also increase [7]. In summary, CHD is a medical condition that can threaten the health of both mother and baby. According to the aforementioned difficulties faced by women with CHD during their pregnancy and during labor, their physical discomfort and more importantly their psychological stress during pregnancy should both not be overlooked [4]. However, the conviction resulting from the wish to become a mother can be a strong force, and this force can sustain the mother-to-be in their long battle against various preconception and postconception challenges not faced by women without CHD [8]. In an effort to pursue higher quality of life and prepare for the hazardous events that may occur during pregnancy, women with CHD pay great attention to their health during pregnancy [9]. Nevertheless, women with CHD remain uncertain whether they will be able to maintain their health with regard to the high risks they face.

The maternal role theories of Rubin [10] and Mercer [11] state that being a mother is an important step in women's personal development. After the child is born, the woman inhabits the role of mother. The mother-infant relationship and attachment are typically established between the primary caretaker and infant within their first year of interaction. The unconscious behaviors of a mother originate from her exploration of the attachment relationship between herself and her child. A healthy attachment relationship involves a reciprocal process between a mother and her child, and the mother-child attachment relationship affects the mother's emotions, the child's temperament, and the child's future development [12]. Nevertheless, chronic diseases can threaten the functioning of a woman in her socialized role. When a mother cannot take care of her child in the way she wants, she may experience negative emotions such as anxiety, depression, or guilt. Many women diagnosed with diseases wish to be become a good mother [9]. However, the physical and psychological burdens caused by their diseases may lessen their child-rearing ability. Women still expect to be able to raise children. Some women with CHD even think that being a mother is more important than properly caring for their condition. Being a mother can make women with CHD feel that they belong in society [8].

The label "disease" sometimes causes people to overemphasize the pathological characteristics of an individual and to ignore that individual's unique personal traits and advantages. Understanding and analyzing the processes that women with CHD go through to become a mother is crucial and necessary. Quality of life, health promotion, lifestyle, and pregnancy risk are some of the topics often discussed in relation to women with CHD in nursing studies. However, studies examining the lived experience of first-time mothers with CHD are relatively rare [4,8,9]. We conducted qualitative interviews to examine the upbringing of women with CHD, their life experiences after becoming a mother for the first time, their thoughts and feelings, and how these perceptions affected their execution of the maternal role. We hoped to explore the essence of lived experience of first-time mothers with CHD.

Methods

Design

141

Participants and setting

Purposive sampling was used to select participants. The participants were recruited from the pediatric and adult CHD specialist outpatient clinic at a medical center in Northern Taiwan. Mercer's [11,13] maternal role theory states that the mother's experience of the childbirth process will affect her ability to perform the maternal role at 6 months postpartum, and parent-child attachment will begin to shift when the child is approximately 3 years old. The inclusion criteria were as follows: (1) primiparous women with CHD and a child aged between 6 months and 3 years; (2) women who lived with their biological child(ren) and were one of the primary caretakers of their child(ren); (3) women who were classified as having class II, III, or IV cardiovascular diseases according to the classification principles stated in the mWHO Classification of Maternal Cardiovascular Risk; (4) women with CHD not caused by chromosomal and genetic abnormalities (e.g., Marfan syndrome and Down syndrome) and with no other chronic disease or comorbidity; (5) women who could communicate in Taiwanese Mandarin could understand the theme of the interview.

The interview questions were developed based on the combination of literature review and the practical experiences of the researcher (the first author), and the suggestions provided by qualitative experts (the third, fourth and fifth authors) (Table 1). Before the study was begun, a pilot study with one participant interviewed was conducted to confirm the appropriateness and feasibility of the original interview guidelines met the aims of the study.

The formal data collection period with the original interview guidelines lasted from April to August 2018. The interviews with 11 women with CHD (coded A-K) provided detailed information on the individual's experience, views, and feelings of the first-time mothers with CHD. Characteristics of the study participants are shown in Table 2. The CHD conditions of the participants included both acyanotic and cyanotic heart diseases. Regarding their Modified World Health Organization (mWHO) severity, the majority of the participants (7/11, 63.6%) had class II cardiovascular diseases, with the others having class III (2/11, 18.2%), including diagnoses of transposition of the great arteries and total cavopulmonary connection or class IV (2/11, 18.2%) cardiovascular diseases, including diagnoses of atrial septal defect and tetralogy of Fallot. The participants were aged between 22 and 46 years, with an average age of 34.5 years. Among the participants, 81.8% was planned pregnancy and 72.7% was natural insemination. The participants had a total of 13 children, and two of the participants had twins. Regarding the demographic characteristics of their children, six (46.2%) of the children were male. The children weighed 1,176–2,954 g at birth, and their average age upon recruitment of their mother into the study was approximately 22.7 months.

Data collection

Before commencing data collection, the researcher (the first author) briefed women who met the inclusion criteria about the content, purposes, and procedures of the current study in person. After obtaining the women's informed consent, the researchers then negotiated with each participant to schedule a suitable time and place for a one-to-one interview. Each participant was to be interviewed once. At the beginning of each interview, the researcher engaged in nonstructured conversation with the participant, so that the participant could relax before the main part of the interview started. Each interview lasted 1–2 hours, and the interviews were conducted in the participants' home or the café nearby their home. The interviews were recorded using a voice recorder. Nonverbal behaviors during the interviews—such as participants' tone of voice, expressions, and movements—were

This study employed a descriptive phenomenological design applying Giorgi's (2009) phenomenological method with in-depth interviews to understand the lived experience of women with CHD on their first-time motherhood.

Table 1 Interview Questions.

- 1. How did you feel when you discovered you were going to become a mother? What is the significance of becoming a mother to you?
- 2. This was the first time you became a mother. How did your actual feelings on becoming a mother differ from your expected feelings?
- 3. This is your first child. What feelings did the child give you? How did your life change after you become a mother?
- 4. The journey to becoming a mother is not an easy one. Can you share your experience of proactively seeking medical care and the types of medical resources that you accessed? Do you have any suggestions for women with CHD who are planning to have children?
- 5. Hospitals currently provide some relevant medical resources to aid women with CHD to fulfill their maternal role. What is your opinion of this? Do you have any suggestions?

CHD: congenital heart disease.

observed and recorded. To add to the comprehensiveness of the interview data, the researcher also recorded the interactions that occurred during the interview sessions and their own reflections on the interviews. The voice-recording file of each interview was transcribed into text within 24 hours of the interview for data processing and analysis. The research groups (all authors) then sorted, coded, and categorized the collected data of individual participants separately. Data collection and analysis were repeated until the point of data saturation, and participant recruitment was halted when no additional themes could be generated from the data analysis and when there was overlap of themes.

Data analysis

The researchers used contrast, induction, and comparison methods to gradually develop the conceptions and themes of the interview content. For the data analysis, the five-step empirical phenomenological analysis method proposed by Giorgi [14] was employed. The analysis steps are as follows: (1) Phenological data were collected, and all transcripts were read to gain a global sense of the data. (2) The meaningful analysis units were identified. Then, by using trained sensitivity and an open attitude, a series of meaning units expressed in the words of the participants was identified. (3) The descriptive raw data were transformed into meaning units through the process of reflection and imaginative variation by using technical language in the field; these meaning units were then used as the basis for interpretation of the research question. (4) The themes were abstracted into key meanings; the basic features of each phenomenon were confirmed. (5) The specific structured descriptions of each participant were combined. In the general description of situated structure, the key meanings were compiled to form structured descriptions. The core concepts were captured by using phenomenological reduction and developed into the research results [14,15]. The process of data analysis from meaning units to theme is illustrated by an exemplar in Table 3.

Ethical considerations

Ethical approval for the study was obtained from the institutional review board of the medical center (Approval No. 201712164RINC). The ethical principles were met through oral and written information about the study to the participants. Potential participants were called by the first author to query their interest in participating in the study. Participants were informed that the study was voluntary, and they could refuse participation in the study or withdraw at any time without affecting their treatment. Written consent was obtained. In the transcribed material and reports, codes were allocated to each participant and identifying information was removed.

Rigor

To ensure the validity and reliability of the study, the researchers conducted the study in accordance with the research guidelines for qualitative studies proposed by Lincoln and Guba [16]. The phenomenological qualitative research method was used to collect data. The research questions were designed by an expert panel comprising a cardiologist, experts on CHD in children and adults, and experts on child developmental psychology. Interviews were conducted to investigate the first-time motherhood experiences of women with CHD, after which the voice-recording files were transcribed into text. The interview processes were properly recorded, and the records were ensured to reflect the actual interviews. Purposive sampling method was employed in the current study to ascertain the scope of participant selection. Understanding was obtained through listening; this understanding was used to identify problems; and assistance was provided accordingly. The following interview content was especially crucial: (1) the experiences of the participants regarding how they solved shared problems, and (2) the participants' expression of their needs and perceived processes. The results of the current study are applicable to the female population with CHD. The written records were crosschecked against the original records and revised accordingly. When conducting the research, we recorded our reflections in a daily diary. The purpose of this was to help us avoid bias by clarifying self-awareness and emphasizing the essences of phenomena. After objective analysis of the data, the results were cross-checked against the content of this reflection diary, ensuring the consistency and dependability of the data analysis.

Results

In the text analysis process, the researchers reduced the meaning phrases of women with CHD to a coherent text. The researchers then transformed the 251 meaning units into technical languages, after which the content was coded and classified into 33 categories. Subsequently, the researchers integrated the categories into 18 subthemes of the current study. Finally, the subthemes were abstracted into six core concepts—the themes of the study (Table 4).

Theme 1: Recognizing pregnancy risks

When women with CHD who participated in this study did not routinely seek relevant medical treatment, they did not have clear understanding of their own health status. Patients' poor understanding of their CHD also resulted in discrepancy between patientperceived severity and professionally evaluated severity. Additionally, fear of pregnancy or unplanned pregnancies was observed among the women with CHD because of a lack of contraceptive and childbearing knowledge (D-26 in Table 4).

Table 2 Demographic and Clinical Characteristics of the Study Participants (N = 11).

Characteristics	N / Mean (SD, min-max)
Age (years)	34.2 (6.7, 22-46)
Education	
Master	4
College	4
Undergraduate	2
Vocational	1
Pregnancy intention	
Planned	9
Unplanned	2
Types of insemination	
Natural	8
Artificial	3
Numbers of children born	
Singleton	9
Twins	2
Diagnosis	
ASD	2
VSD	2
TOF	2
TGA	1
SV	1
DORV	1
COA	1
PDA	1
mWHO class	
II	7
III	2
IV	2

ASD: atrial septal defect; VSD: ventricular septal defect; TOF: tetralogy of fallot; TGA: transposition of the great arteries; SV: single ventricle; DORV: double outlet right ventricle; COA: coarctation of aorta; PDA: patent ductus arteriosus; mWHO class: modified World Health Organization Classification of Maternal Cardiovascular Risk.

Once the participants had confirmed their pregnancy, they began to worry about the risk to their health and their child's health. The participants were scared that their CHD would hamper the development of their child. Because of uncertainties surrounding their own health and that of their child, they often experienced entangled thoughts, feelings of contradiction, and emotional conflict during their pregnancy. Most of the participants were concerned that their child would inherit their CHD; the next most common reflections were concerns about other uncertain risk factors and description of feelings of discomfort. In their reports, the women expressed negative emotions including worry and nervousness. If they could, most of the women with CHD acquired more detailed or additional and self-funded medical examinations; they only felt at ease if the examination results revealed that their child was healthy (I-12 in Table 4).

Theme 2: Performing self-care for health

When the participants were preparing themselves to be mothers, they began to pay more attention to their CHD-related health problems and better take care of themselves. They proactively visited hospital to seek help from physicians with the hope that they could obtain information relevant to pregnancy before conception. Additionally, they arranged for a preconception evaluation and other relevant medical examinations as well as discussing with physicians the possible symptoms and risks that could emerge during pregnancy. During pregnancy, they often worried about their future health and that of the unborn baby. They proactively sought to acquire knowledge and took precautions beneficial to the baby and themselves; they obtained disease information, took precautions for the pregnancy and labor, and acquired child-rearing knowledge. They aimed to optimize their body condition and eliminate risk factors with the aim of ensuring the safe and healthy delivery of their baby. In pursuit of these goals, they visited Chinese medicine clinics, sought advice from physicians and senior family members, adjusted their daily routine, and paid more attention to sleep and regular exercise (H-24, E-31, H-74, and A-37 in Table 4).

Additionally, the women with CHD believed that they played a crucial role in the growth process of their children and that they were closely connected to their children. Therefore, the women's consciousness over their health continued until they decided it was enough. After the first pregnancy of the participants, numerous factors affected their decision to get pregnant again, including the complications that occurred during the first pregnancy, physicians' evaluation of their health, and their self-evaluation of their health and the health condition of their children. The results revealed that after the participants experienced pregnancy, they understood the importance of regular follow-up visits and health maintenance (C-15 and G-27 in Table 4).

Theme 3: Building self-worth from my baby

The participants reported their perseverance and determination to achieve their goal. When physicians stated that pregnancy and childbirth were high-risk activities for them or recommended against pregnancy, the participants felt that if they took this advice, they would miss something in their lives. It was similar to having their rights deprived or being labeled as separate from ordinary people. Regardless of whether the participants perceived the effect of their CHD on their lives, they stated that they wanted to be indistinguishable from other mothers. Furthermore, they did not want their disease to affect their personal relationships and interactions with other family members. From the moment they confirmed their pregnancy, the participants prepared themselves for all types of challenges and did not want to give up, regardless of the number of adversities they would encounter. Regarding the risks of pregnancy and labor, the participants described the challenges and hazard level of their pregnancy.

The healthy birth of their child was critical for each participant. In addition to their feelings of concern for their child, the child's arrival served as a proof of their own value. As the participants saw it, when they understood and were willing to face the risks of pregnancy and childbirth, and when they finally became a mother, they proved to others that they could do what others thought they could not. The arrival of their child gave new value to their existence that allowed their life to remain meaningful. Other people may not be able to understand the goals and expectations that these women had during their suffering, but these women were able to enhance their self-value through the arrival of their child (H-20, B-16, and F-19 in Table 4).

Theme 4: Adapting to postpartum life and adjusting priorities

Most of the women with CHD focused on themselves before they became pregnant. After the conception, they began to imagine and construct a vision of how they would live and interact with their child in the future. However, their imagined life of being a mother was different from their actual life. Once a woman becomes a mother, she seldom has the time and space for her own life activities. Therefore, regardless of whether the participants were employed (i.e., full-time employment or full-time mother), they faced maternal role conflict. Poor quality of sleep and overfatigue affected their health, leading to cardiac discomfort and negative emotions. Nonetheless, the participants prioritized taking care of their child and ignored the discomfort caused by their disease (K-16 and B-8 in Table 4).

Table 3 An Examplar for the Process of Data Analysis from Meaning Units to Ti

Meaning unit	Category	Subtheme	Theme
" Every time the doctor said that I had to exercise several times a week and go to the dentist to prevent tooth decay. The doctor would remind me every time I went back to the clinic, but I did not do it once" (I-12)	Overlooking the influence of CHD on personal health	Lack of regard to CHD	Recognizing pregnancy risks
"Actually, I <u>had not tracked my heart</u> . I would not know how serious my heart condition <u>was but that I was</u> <u>pregnant</u> Until I was pregnant and giving birth, the doctor explained my heart to me. He gave me a handbook with detailed information on it, so I really <u>understood my heart</u> condition." (D-26)	Incomplete knowledge of CHD	Lack of regard to CHD	Recognizing pregnancy risks
"Yes, I was not worried about my danger. I have been thinking about what to do with my child. I was afraid that my child would be hypoxic just like the doctor said. It would cause many major diseases in the brain. I have been thinking about this problem" (G-17)	Worried about the baby's health	Uncertainties surrounding safety during pregnancy	Recognizing pregnancy risks
"We didn't particularly want to challenge. It's just that we would <u>be</u> <u>disappointed</u> at that time <u>It's not</u> <u>that we chose not have a child</u> , but because we have been told that we <u>can't have a child</u> . We still have <u>been</u> <u>disappointed</u> " (H-9)	Scared of losing the baby	Uncertainties surrounding safety during pregnancy	Recognizing pregnancy risks
"I felt that my <u>physical health was</u> <u>unstable</u> I was not sure if I could <u>bear the risks of pregnancy and</u> <u>childbirth</u> . The degree of this risk was <u>beyond my prediction</u> , so I felt that <u>pregnancy was dangerous for my</u> <u>life</u> ." (D-6)	Uneasy about unpredictable events during pregnancy	Uncertainties surrounding safety during pregnancy	Recognizing pregnancy risks

The underline: meaning unit.

me undernne: meaning unit.

The parenting attitude or concepts of an individual can be influenced by the parenting attitude or concepts of his or her own mother. Participants described their own mothers' experiences of caring for them. Because of CHD, their mothers paid more attention to them than they would have to a child without CHD and tried hard to protect them. The participants wanted to protect and care for their own children in the same way. Their own upbringing had a certain importance in the memory of the women with CHD; they perhaps adopted their mothers' child-rearing concepts and experience and transformed them into something of their own. Nevertheless, each participant had unique opinions, feelings, and expectations regarding the way their children should handle things and express emotions. In the worlds of these mothers, their children were the most important things in their lives (K-18, B-29, and F-30 in Table 4).

Theme 5: Enjoying being a first-time mother

The women with CHD realized that they were becoming a mother; this realization usually arrived when their fetus started to move or when the baby was delivered. When the fetus began to move, the expectant mother started to feel that there was a little life growing inside them and that the life needed her protection. Additionally, an amazing interaction occurred between mother and child; when the child exhibited behaviors that indicated his or her need for the mother, the mother felt that she was the center of the child's life. Throughout this process, the participants felt that they were needed by their child and considered the child's need and desire for their mother to be a gift from the child to themselves. Therefore, a strong desire to protect her child was generated. Consequently, the mothers were willing to lavish unimaginable love and care on their children. They hoped that they could record every moment that they spent interacting with their child; the child's growth record would be representative of the work that the mother had performed. The birth of the child brought a great sense of achievement and fulfillment for the participants. They had great expectations for their healthy babies. Equally, they were grateful and appreciative for the arrival of their babies. The women with CHD were thankful that their child was willing to enter the world and their life, granting them novel experiences and feelings. Such a state of mind differentiated the mothers with CHD from other family members and resulted in a close relationship between mother and child, causing their emotional bond and interactions to be more intense and profound (H-73 and D-17 in Table 4).

Theme 6: Factors contributing to success in high-risk childbirth

The participants experienced the processes of pregnancy, delivery, and child caring, and they expressed the importance of coordination between internal and external resources. The primiparous women with CHD believed in the professional evaluation and suggestions provided by their CHD medical team. However, the method and attitude that medical personnel chose to adopt when conveying decisions and suggestions could strongly interfere the feelings and opinions of the participants, thereby leading to differing opinions of the women with CHD when they **Table 4** Identified Themes, Subthemes, and Quotes from the Interviews.

Theme/subtheme	Quotes from the interviews
Recognizing pregnancy risks	
Lack of regard to CHD Uncertainties surrounding safety during pregnancy	"That's right! That's why I said it wasn't planned. I didn't know how severe my condition was? Yes! Actually, it was really severe. I had the surgery at a really young age, when I was 6 years old. I didn't really understand my medical condition until I recently gave birth I feel that I have better understanding of it now. I was given a booklet, which had a detailed explanation of the condition, including the classification levels you just mentioned" (D-26) "I was quite worried during that time; I was worried that my baby would have the same medical condition as I do. Because my heart is slightly slightly positioned to the right. That's right! I was worried he would have the same medical condition as me, and whether he would have a genetic disease. Dr. A told me that my child would be prone to genetic diseases and that my medical condition is likely to cause genetic diseases in my children, so
Performing self-care for health Desire to become a mother	 was quite worked. After 1 gave birth to hy baby, i and send him for some medical examinations; he was examined by Dr. A and Dr. B Of course I was worried; no parent wants their children to suffer." (I-12) "We have been discussing whether to be pregnant Anyway, I might have been too happy at that time, Just tell him yes, I'm OK, I'm fine. At that time my physical condition was really good, and I
Proactive medical-care-seeking behaviors	didn't know why I believed in my situation, so I told him, just try it! Anyway, I think I would return to the clinic regularly." (H-24) "I did visit Chinese physicians for health promotion treatment. I still think that Chinese medicine and Western medicine are very different." (E-31) "Because I wasn't sure exactly what kind of influence this medical condition has like on pregnancy and overall health and I was thinking "Bight Liust have to give birth first
The importance of an evaluation before conceiving	About my condition we'll see what happens." But after I gave birth inst. About my condition we'll see what happens." But after I gave birth, I realized that I wanted to be with him as he grew up! [chokes up]" (H-74) "I think the first priority is still consulting the doctor. If the doctor gives me the green light after an evaluation, I would ask the doctor if there're any precautions I should take things like that. And you also need to be cautious during your pregnancy. You need to take extra precautions in everything you do. For example, when I was pregnant, my mother reminded me not to ride a motorcycle, because the roads in Taiwan are uneven, and riding
Reflecting on health during pregnancy and labor	a motorcycle on an uneven road would not do the baby any good. You must be careful in everything when you are on the way to becoming a mother." (A-37) "It's better not to get pregnant that I take the medicine. But doctor tells me to eat every day. If I want to get pregnant, I have to stop for at least half a year. Quitting the medication is also risky for me, but I really want to have a second child. I have talked to the doctor three times, and the nurse thinks I am too anxious" (G-27)
Building self-worth from my baby	
The hope of not being treated differently The most important decision in my life	"Actually, I was just asking the question out of boredom. I asked if there was anything I could still do. And then I asked about more important things, and then I was asked about I asked the doctor about the possibility of getting pregnant, and then I was a bit regretful when I heard that, because I felt like I was already different from normal people." (H-20) "I just felt that I wanted to have children, and everything I did was because I wanted to have children, so I need to move in that direction! Frankly, sometimes I did feel that I should just give up the idea of having children But then grain. I thought that was the only
The need to prove to myself that I can do it	time I could work toward having children. If I waited until I was 40 or 50 years old, it would be impossible for me to have a child. That's why I felt I should work as hard as possible and see what happens. If my efforts were unfruitful in the end, I could at least say that I had no regrets. That's why I didn't give up throughout the whole process, and I ended up having two children (twins), one boy and one girl." (B-16) "After I gave birth to my child, I felt like I had achieved something impossible. Because 8 th months after I was born, I was diagnosed with double outlet right ventricle with transposition of the great arteries. Given the medical technology in the 1980s, this medical condition was basically incurable. At that time, the doctor told my mother that I could only wait for a heart transplant. That's why giving birth was like achieving something that others didn't think I was capable of. And I was the first person in my family to get married and have children, my family members were quite shocked by that. People in the older generation think that giving birth to an abnormal child means that the mother did something wrong in her previous life. Therefore, this is like a sort of vengeance for me." (F-
Adapting to postpartum life and adjusting priorities The meaning of freedom and responsibility	19) "Maybe mothers are maybe you are biologically wired to wake up once you hear your baby cry. That's a maternal instinct. The father doesn't have it. He just sleeps so deeply. So I don't wake him up unless I have to attend to two babies (twins). Of course, he would help if I woke him up. But the truth is that I am the main caregiver, while he plays a passive assistent role." (K. 19)
The inheritance and transformation of child-rearing experience	"I did think about what is most important to me. I thought about work, but then I thought, no, that's not mine, that belongs to the country. In the end, I feel that being a mother is the most important task for me right now." (B-29) "For example, my classmates invited me to go hiking. Actually, I knew I shouldn't hike, but my mom made me go. During the hike I cried and vomited, but my mom followed behind me and said: "It's okay! Let's take it slow." I think the parents of children with CHD are very pitiful. They have a hard time, but I don't think it is necessary for them to be so negative.

Table 4	(continued)
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Theme/subtheme	Quotes from the interviews
The priorities of becoming a mother	Your child will be happy because you have to [pretend to] be happy, but in fact you are unhappy and your heart is not happy. (laugh)" (F-30) "I was definitely swamped by my workload for a while just taking care of the baby. Before giving birth, I just focused on carrying the baby; throughout the whole pregnancy, I just hoped to deliver the baby safely. So I didn't actually realize that there is a lot of caring work to be done after the baby is delivered and that I need to prioritize the baby all the time Midnight was especially terrible, because the babies had an inverted day—night rhythm. Right, and I was really overwhelmed when both babies cried at the same time." (K- 16) "Because both of going to work and taking care of my baby are so tiring, arrhythmia become the last consideration " (R 8)
Enjoving being a first-time mother	Decomes the last consideration. (B-8)
The joy and affection of welcoming a child	"I felt that I had formed some sort of comradeship with the baby in my tummy, right from the beginning. It wasn't easy so I think that my feelings toward my baby they're kind of exceptional and special." (H-73)
Strengthening the sense of commitment to being a mother	"You would really there was an invisible force that made you you actually gave love to the child selflessly! This was guite unexpected." (D-17)
Factors contributing to success in high-risk childbirth	
Understanding and help from the employer	"My boss would let me take children to work. If my work is really over, I'll stay keep doing it, I won't insist that I have to walk on time. I am very grateful to the boss for his tolerance." (A-28)
Support and encouragement from family	"Without help from my family, it would have been hard for us to handle everything well. Help from parents made a big difference. When I was waiting for my delivery at around the 34th or 36th week, I was afraid that I'd deliver prematurely, so I went and stayed at a hotel in Taipei. If my sister hadn't kept me company, I would've been scared to go to Taipei
The overall professionalism of medical care	alone." (E-18) "The examination by Dr. A really eased my mind. That's why I said that sometimes the doctors' words really make you feel confident, more confident. Otherwise, you feel so frightened and scared, because you don't know what will happen in the future." (I-69)

CHD: congenital heart disease.

were considering getting pregnant and delivering a baby. Helpful medical personnel and a positive medical care environment could lead to a sense of stability in the women with CHD; by contrast, subpar medical care services and environment could lead to confusion, anxiety, and uncertainties in the participants during their decision-making process. Throughout the whole process, the women with CHD hoped that their spouse or family members would be by their side, somewhat relieving their anxiety and fear. After they gave birth, the primiparous women with CHD were faced with various unfamiliar tasks and even a sense of fatigue. The understanding and help offered by the women's employers at this time relieved them from the dilemma of having to juggle work and family. Additionally, the company and assistance in taking care of the newborn offered by family members partially lifted the physical and mental burdens on the mothers that were caused by fatigue and the hectic situation; these efforts helped the participants tremendously in both the mental and practical aspects. The women desired support and company from their spouse most of all, followed by that from, members from their family and lastly member of their spouse's family; this indicates the significance and influence of the spouse during the process of pregnancy and child caring. In addition to depending on family relationships and familiarity, the women's preference of company was dependent on the role the women played in their family, their status in their family, the personality of family members, and familial relationships (A-28, E-18, and I-69 in Table 4).

Discussion

The study results indicated that the themes could be divided into two categories: those related to chronology and resource utilization. The first five themes—namely recognizing pregnancy risks, performing self-care for health, building self-worth from my baby, adapting to postpartum life and adjusting priorities, and enjoying being a first-time mother—represent a dynamic and continuous process, whereas the theme factors contributing to success in high-risk childbirth link the preconception lives of the women with CHD to their postpartum lives and are considered representative of resource utilization. The lived experience of the new mothers appeared to embody the participants' personal traits and upbringing. The statements and behaviors of each participant revealed their distinct personality and demonstrated their uniqueness. Even though the life of the participants had been made different by their disease from that of their counterparts without diseases, the essence of the maternal role is the same for all. The processes of carrying and nurturing a child strengthened the maternal role in the primiparous women with CHD, resulting in apparently more intense mother—child interaction and expressions. The results of the current study are consistent with the maternal role theory proposed by Rubin [10] and Mercer [11].

The results related to recognizing pregnancy risks revealed the deficiency in the attention of the women with CHD toward their CHD. Clinical observation revealed that most of the women with CHD attended a follow-up session at the outpatient clinic before their conception or mid-gestation, which has been long since their last hospital visit for CHD. Similarly, Yeh et al. [17] reported that most patients with CHD overlooked the importance of long-term tracking after the age of 10 years. The leading causes of tracking cessation include personal factors, the lack of continuous care services, inconsistent in the professionalism of medical personnel, and the lack of a comprehensive referral program [17–19]. CHD requires long-term, regular, and consistent tracking. A systematically planned transition program for adolescents with CHD is needed to reduce the management risk of loss to follow-up and strengthen their self-care ability [3,17].

The age distribution of the participants in the present study was 22–46 years old. Furenäs et al. [20] conducted a survey of cardiac, obstetric, and neonatal complications with pregnancies in women with CHD and found that advanced maternal age did not seem to affect complication rate. In addition to the age above 35 years, higher mWHO class or other psychosocial factors influencing on the mothers may be taken into consideration. During pregnancy and

labor, women with CHD are more likely than those without to sustain cardiovascular injury [7,21]. Despite their regular attendance of follow-up sessions, approximately 60% of young female patients with CHD did not discuss sex-related topics (e.g., pregnancy, labor, and contraception) with medical care personnel [22]. Aside from not realizing the importance of regular check-ups, women with CHD often overlook the possible impacts that CHD may have on pregnancy [19]. The lack of understanding regarding CHD as a medical condition and unplanned pregnancy can both increase the level of uncertainty and risk associated with the pregnancy of women with CHD. From the beginning of gestation to labor, negative emotions such as anxiety and uncertainty are consistently present. The possibility that any child would inherit CHD is one of the leading causes of negative emotions; stress and anxiety can affect the physical and mental health of women with CHD during the pregnancy [7,22–26]. This finding is consistent with that obtained in the present study.

The results regarding performing self-care for health revealed the desire of the women with CHD to become a mother as well as their worry and sadness caused by the possibility of not being able to do so. Such desire caused them to be unhesitant in trying to get pregnant [8]. Therefore, before their attempt to get pregnant, they visited hospitals to seek medical advice and used that advice as a basis for evaluating the health of any potential baby and whether they could overcome the risk associated with pregnancy [23]. At this stage, the women with CHD understood that an evaluation before conception was a crucial medical examination that could lower the risks of pregnancy and labor. Previous studies have also demonstrated that a comprehensive evaluation can predict the probability and potential severity of pregnancy complications to a relatively high degree of accuracy, and women with CHD can be given clear information on how to prepare for the pregnancy process and symptoms to monitor during the process [27,28]. In the present study, the participants proactively sought medical treatment and learned about CHD care, pregnancy, and health promotion behaviors, which was in stark contrast to their previously passive treatment-seeking behavior. This was consistent with the anticipatory stage in the maternal role theory proposed by of Rubin [10] and Mercer [29]. Additionally, Plutzer and Keirse [30] revealed that the focus of primiparous mothers mostly lies in the maintenance and enhancement of personal health. Preparations for the maternal role promote the abilities and protective mindset needed for maternal behaviors during pregnancy.

Traditional Chinese medicine is natural without the burden of chemical synthesis and mainly nourishes the body. Therefore, if patients use Western medicine with contraindications or strong side effects, Chinese medicine treatment may become an alternative to Western medicine treatment. Chinese medicine is more commonly used in Taiwan to nourish, invigorate, and adjust the body [31,32]. Some women who have experienced infertility, miscarriage, or want to have a smooth pregnancy may also turn to traditional Chinese medicine to recuperate their body. The participants in the present study are consistent with regulating the behavior of the body.

The maternal role requires a woman to protect her child from harm and from being threatened by her own medical condition [8]. In this study, this was exhibited in the attention the participants paid to their own health condition. Women with CHD do not wish to be seen differently by society but can feel differences between them and women without CHD. The limitations and differences experienced in their daily lives may have caused the participants to feel that their disease controlled their lives and caused them to crave recognition [33]. Pregnancy also poses a certain health risk for women. During this period, maternal resilience emerges. For the sake of their child, the participants had to stop their medications in certain circumstances, which is consistent with a qualitative synthesis of maternal resilience by Vallido et al. [9]. At this time, they identified themselves as a mother first and a CHD patient second.

The enjoying being a first-time mother theme indicated that emotional exchange is crucial to a healthy mother—child relationship [26]. The mother—child interactions that occurred after the child was born enriched the family life of the women with CHD. Compared with people from western countries, people from Asian countries express affection in more subtle and humble ways [34]. Asian mothers may not often verbally express their love and affection for their children, but they are responsive to the needs of their children. The participants with CHD in this study who gave birth considered their child a precious gift. To return the love that they received from their child, they devoted their affection, protection, and attention to their child without reservation; this was an exclusive relationship between a mother and baby.

Finally, the factors contributing to success in high-risk childbirth in the present study indicate the existence of three resources of social support: support from the family, employer, and medical care team. For women with CHD who are on their way to becoming a mother, apart from spousal financial and emotional support, spousal participation in the pregnancy and labor processes plays a critical role in providing the women with courage and confidence for the long journey [35]. Understanding from the employer can mitigate the time pressure problems faced by working women. As for medical personnel, they were providers of knowledge, suggestions, and guidance in the eyes of the participants. Suggestions from the medical care team affected the emotions of the patients. Excluding minor cases in which medical interventions and suggestions have resulted in stress, almost all relevant studies have indicated that the appropriate employment of medical resources improves the safety of patients and effectively reduces or prevents possible risk factors [28].

Limitations

The sample in the current study included only primiparous women with CHD who were recruited from a single medical center and whose children were aged 6 months to 3 years. Therefore, the present results cannot be generalized to the whole female population with CHD. Because the participants of this study came from various counties and cities of Taiwan, the researchers left the choice of interview venue to the participants. Some of the participant brought her children along because no one was available to babysit. The interviews were sometimes interrupted because the participants needed to attend emergencies related to their children. This can be considered an environmental limitation of the current study.

Conclusion

The findings of this study presented that the women with CHD reported a consistent set of core concepts regarding their process of becoming a mother for the first time. Six main themes related to the feelings and experiences of the women with CHD in becoming a mother for the first time were identified. These themes indicate that from the preparing for pregnancy stage, to the pregnancy and labor stage, and to the child-rearing stage, the women with CHD did not experience only a single emotion during the entire process. At every stage, they experienced the emotion cycle of worry, joy, fear, and ease. In other words, their emotions were complex and ever changing. Therefore, appropriate social support and intervention are necessary during this period. The findings provide relevant parties with better understanding of the emotional course in events experienced by women with CHD during their pregnancy. The results also indicate the importance and unique contribution of this study in the research area of women with CHD.

Author contributions

Study conception and design: YTL, CWL, PFM and CWC; data collection: YTL and YMS; data analysis: YTL, PFM, YMS and CWC; manuscript drafting: YTL and CWC; and funding: CWC. All authors approved the final version for submission.

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Conflict of interest

The authors declare that there is no conflict of interest.

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