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EDITORIAL

Some reflections on the evolution of nursing over the past 50 years

When I reflect on the early days of my career, there are feelings of both embattlement with the day-to-day hierarchical nature of our professional environment and, at the same time, joy, as I went about delivering care to patients practising the profession I loved. We were at the bottom of a very big pile with very little power. This led to a perception of change only being brought about by conflict, a situation which to a degree exists until this day. We had internalised notions of being seen as followers and not leaders in changing health care. Of course, where we were at the beginning of this 50-year period was to a large degree shaped by our forebears, particularly following the Second World War which had such a significant effect on the delivery of health care and on the development of our profession.

Significant international and system developments which had a profound effect on the development of our profession begin with the 1948 Universal Declaration on Human Rights which was adopted by the General Assembly of the United Nations.[1] Included in the Declaration are amongst other things, the right to social security, health, and education, as well as racial equality, and equality between the sexes. The latter was to have a profound effect on the development of nursing as we became swept up in the women's movement and the rise of feminism in the 60s and 70s.

Health as a human right is fundamental to the concept of access to and indeed equity in health care. Universal access to health care in Australia was introduced as part of the reforms of the Whitlam Labor Government in 1975 under the rubric of Medibank – later Medicare. Its purpose is to provide free access for Australians to hospitals and, today, subsidised access to medical practitioners, nurse practitioners, optometrists, eligible midwives, and some dental services. Alongside Medicare is the Pharmaceutical Benefits Scheme which was introduced in 1948 by the Chifley Labor Government. In the post-war period we also saw profound societal changes such as smaller families, increases in the standard of living, the rise of feminism and changes in education. Nursing, as a female dominated profession, was affected by all these changes. Nurses played a significant role in universal access to health care as they were central to the implementation of new and expanded health services.

From the 1960s hospitals began to develop into the hospitals we know today. The role of the nurse intensified, and nurses needed to deliver care which was more than providing comfort. They needed to become technically competent and move to a plane where nursing diagnosis and interventions contributed to patient outcomes.

Along with the rise of the modern hospital we saw profound technological change, especially in clinical practice and treatment of so many conditions. If nurses were to maintain their role in patient care they had to become educated in the care of patients through enhanced treatments and resist the rise of technicians who cared for specific aspects of a patient's care. Wholistic care was paramount.

We now see demographic change in the form of an ageing society and the rise of degenerative disease occurring alongside the recrudescence of quiescent communicable diseases such as influenza and viral haemorrhagic fevers. We have experienced several epidemics in the past 30 years and now are coming out of the most virulent pandemic in 100 years. In addition, we also see a rise in non-communicable diseases.

It soon became evident that the educational preparation of nurses needed a radical overhaul. In the 70s and 80s there were several major drivers to transfer nursing education from the health sector into the education sector. The overwhelming reason in the beginning was the realisation that with rapid technological change taking place within the health system, nurses needed a much broader and deeper educational base if they were to function with technical competence whilst continuing their role in providing care to patients and their families. It was clear that if the profession were to contribute on an equal basis to the health care debate, there was need for them to have a more scientific education and to move from being unsophisticated epistemologists to possessing a more comprehensive understanding of the political economy of the health system and their potential to change it.

What was not as evident and did not play a part in the campaign was the gradual realisation by the funders of the public hospitals that nursing education in the form of apprenticeship training was a significant drain on the health budget. Students were paid to spend an increasing amount of time both sitting in classrooms and gaining clinical experience external to the hospital. Pressure was also applied by the local state/territory nursing boards in the form of gradually increasing the content in the curriculum. Furthermore, nursing education was a standalone system with no articulation to the mainstream education framework.

The campaign to transfer nursing education into the education sector began in 1973 with a small group of nurses representing all the major nursing organisations in Australia coming together to devise a plan of action.[2] Nursing

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leadership was paramount in achieving a consensus on how to proceed.

Following this meeting a document entitled The Goals in Nursing Education – Part II was developed and formed the basis for a concerted and highly organised national campaign. Lobbying materials were produced and a plan to approach every federal candidate was developed in each of the States and Territories. Truth needs propaganda as much as the opposite! The resistance from politicians was enormous, spurred on it seems by their constituents and their families.

The campaign began in the 70s which was around the time of the second wave of feminism which was part of a general liberation of all gender and sexually diverse groups. You may recall that Germaine Greer's seminal work The Female Eunuch was published in 1970 and this set the scene for women demanding the same rights as men enjoyed both in Australia and overseas.[3] We were caught up in that movement as with nursing being overwhelming female, the campaign to transfer nursing education became a feminist issue. Anne Summers, a famous Australian feminist, and author had a later role to play in this struggle.

During this period there were two cases in the Industrial Commission in 1969 and 1972 on equal pay. The first was equality of pay between the sexes,[4] and the latter equal pay for work of equal value.[5] Numerous cases to increase salaries for nurses were mounted during this period and more recently. Nurses became more aware of their centrality to the health system and demanded rightly to be properly remunerated. Cases for salaries and conditions which were more in line with similar occupations in the wider community continued at both state and national levels throughout the 1980s and 1990s until the present. Gradually nursing and midwifery wages caught up with expectations although time lags were frequent.

The campaign to transfer nursing education was long and hard and was waged during and between elections. Success was finally achieved nationally on 24 August 1984 when in principle support was given for the full transfer nationally. An Interdepartmental Committee was established in Canberra as this transfer involved the movement of state/territory health funds to federal education coffers. Anne Summers who at the time was head of the Office of the Status of Women in the Keating Government was a strong advocate and ensured that the process did not stall.

This campaign is emblematic for us on several levels. First and foremost, it showed that we have a tradition of formidable leaders in nursing and midwifery. It also showed that determination, hard work and consistent messages are required if a vision is to be realised. This campaign took the better part of 11 years with national elections coming and going and powerful forces opposing us. The Country Women's Association and some factions of the Parliamentary Labor Party as well as it seemed at the time the whole Parliamentary Liberal Party all fought against us. In addition to the presence of feminism in the debate, elements of class warfare also emerged. Opponents particularly from the union movement ran a campaign citing disadvantage for girls from lower socio-economic backgrounds not having the opportunity to be paid while they trained. Their prediction was that nursing would become an elite profession and that women would be denied a career which was flexible and sustaining to many families particularly during straightened economic times.

The transfer agreed to in 1984 was then debated at individual State and Territory level. Initially the programs were established in colleges of advanced education at diploma level, but the goal was bachelor level. Another battle ensued and this time the goal was accomplished quickly along with other changes to higher education. Thus, we were on the way to educational parity with other health professionals at an early stage which was to stand us in good stead down the track.

Once the question of the location of the foundational programs in nursing was settled, postgraduate programs gradually followed to the point today where we have large faculties of nursing and midwifery with a wide range of offerings. The effect of this has been to enhance access by nurses and midwives to education particularly specialist education. Online formats are readily available and those who live in the more sparsely populated areas of Australia have access to programs on the same basis (internet access permitting) as their metropolitan counterparts. Access to health care by the population is also enhanced as nurses and midwives gain qualifications which enable them to provide specialised care in a range of different settings.

The campaign by nurses for recognition by the Commonwealth as independent health care providers and specifically for access to Commonwealth reimbursement via Medicare was again a long-drawn-out affair and not as successful as the transfer of nursing education. Work began on Medicare and prescriber numbers for nurse practitioners and eligible midwives following the 2009 budget. This was eventually achieved but with significant barriers.

Another more successful campaign which was waged for approximately 20 years was the goal of national nursing and midwifery registration. In 2010, the National Registration and Accreditation Scheme was established. This scheme encompassed most of the health professions and provided for common registration and accreditation standards across the professions and had the effect of nurses and midwives being on an equal footing with other health professionals.

Finally, the issue of leadership over the past 50 years has been critical in achieving our goals and developing our profession. We need to ensure there are visionary nursing leaders throughout the profession. It goes without saying that we need cooperative relationships between the various

strands of nursing and midwifery, and we have good role models from our history in achieving this. With any group or organisation of like-minded individuals or professionals there is always the possibility of internal dissension. Nursing has certainly had its share of internecine fighting often played out in the courts. In recent times good sense has prevailed and the leaders of the various groupings have shown significant leadership in creating partnerships and making sure they are maintained.

Whilst we have achieved much in both the development of health care and of nursing and midwifery, there are still challenges in both areas. Policy development of the health workforce with its attendant competing imperatives is one of the significant contemporary challenges facing nursing and midwifery as we struggle to maintain professional standards and relevance at the same time.

I have pointed to the main developments leading to the evolution of our profession over the last 50 years. There are many factors which have influenced that progression. My view is that the transfer of nursing education into the mainstream and eventually into universities is the most critical factor in our development in my lifetime. I hope that I have illustrated that a broad scientific basis to our practice is the foundation of our past success and our future development.

We inherited a situation where powerful, innovative nursing leaders took advantage of the opportunities for nursing when they were presented. I am confident that this tradition will be carried on and that we have the nursing and midwifery leaders to guide our professions judiciously to increase access to health care for our community.

Rosemary Bryant AO
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Management of bleeding in trauma victims by Portuguese nurses in prehospital setting

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ABSTRACT

Introduction: External bleeding is the leading preventable cause of death from traumatic injuries. Implementation of guidelines for its control have been associated with a significant reduction in mortality. The objectives of this study were to provide a characterisation of trauma patients with external bleeding and to compare the outcomes from specific autonomous interventions applied by nurses in prehospital care.

Methods: A non-randomised prospective study was conducted in the Immediate Life Support Ambulances in Portugal, from 1 March 2019 to 30 April 2020. Patients were divided into two groups according to whether external bleeding was controlled or not on their arrival at the emergency room.

Results: A total of 189 patients were included in this study (73.0% men; mean age of 53.6 years). Among these patients, 140 (74.1%) had their external bleeding controlled by prehospital nurse's intervention. The average time of assistance at the incident site was 31.5 min. Patients with uncontrolled bleeding had a higher average rescue time (30.8 ±15.2 vs 33.7 ±13.0). Cryotherapy was administered to 15.9% of all patients and 93.3% of these patients arrived at the emergency room with controlled bleeding (p=0.01).

Discussion: Despite the substantial reduction in the number of patients who keep bleeding after prehospital care, it was observed that one fifth of patients have external bleeding on arrival at the emergency room. Cryotherapy has been shown to be effective in controlling external bleeding. Failure to use haemostatic agents may explain the ineffective control of more complex external bleeding.

Contribution to Emergency Nursing Practice: The current literature on management of bleeding in trauma patients is scarce and contradictory, especially in terms of interventions provided by

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prehospital teams led by a registered nurse. In addition, interventions vary from country to country.

This article increases awareness of autonomous interventions implemented by prehospital nurses to manage external bleeding.

Key implications for emergency nursing practice identified in this study suggest greater fluid therapy appears harmful while cryotherapy achieved the best results (control of the bleeding on emergency room arrival). This may contribute to the review of institutional algorithms and training in this area.

Keywords: Trauma; Patient Care Team; Prehospital Care; Haemorrhage; Nursing.

INTRODUCTION

Severe trauma is an international primary cause of death, with more than five million worldwide deaths each year.[1] Bleeding is the leading preventable cause of death from trauma injuries.[2,3] The implementation of specific guidelines to control external bleeding has been associated with a significant reduction in the number of deaths.[4]

The treatment of internal and external bleeding depends on the use of more specialised medical equipment.[5] To achieve a rapid surgical intervention to control bleeding, a short scene time, rapid response and rapid application of control methods provided by the prehospital services is required.[6] Interventions often used to control external bleeding may involve simple methods such as direct pressure, elevation of the injured area or cryotherapy (which decreases mucosal blood flow and helps haemostasis),[7] but also complex ones such as haemostatic dressings (contain agents to improve blood clotting),[8] or torniquet (a "life-saving" intervention).[9]

An essential task carried out by the rescue team is to minimise intervention and transportation time until the final and definitive treatment is administered.[10] The prehospital period is defined as the time elapsed between the injury and the admission to the emergency room. Out-of-hospital scene times greater than or equal to 20 minutes are associated with higher odds of mortality in patients with penetrating traumatic injuries, and it is for this reason that it is recommended that minimal time be spent in the out-of-hospital setting, allowing only essential procedures to be performed.[11] Therefore a systematic assessment, targeted hemodynamic management and rapid transportation to a trauma centre is crutial.[12] Therefore, it is essential to implement a model of trauma care delivery based on solid evidence-based principles within the healthcare system that are applied in all phases of care delivery.[13]

Prehospital nurses play an essential role, as they are responsible for the initial resuscitation, management and prevention of further bleeding and the avoidance of hypoxemia. Further, their care model includes diagnosis, monitoring and immediate bleeding control. Additionally, they are also responsible for further investigation of any unidentified source of bleeding, restricted volume replacement, and core temperature control.[14] However, these interventions are still understudied in the prehospital setting.[15]

STUDY OBJECTIVES

The objectives of this study were to: (1) characterise trauma patients with external bleeding, who are managed in the prehospital environment by a team composed of a registered nurse (leader) and an emergency technician; and (2) to evaluate the factors associated with the effectiveness of interventions applied by nurses to patients with external bleeding.

METHODS

This study was conducted in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.[16]

STUDY DESIGN

This was a non-randomised prospective study, conducted in Portugal. Data were prospectively collected from 1 March 2019 to 30 April 2020.

SETTING

The study was conducted in all (n=41) Immediate Life Support Ambulances (ASIV) operating in mainland Portugal. National Institute of Medical Emergency (INEM) is responsible for the coordination of the Integrated Medical Emergency System in mainland Portugal, providing prehospital emergency care to trauma victims and acute medical patients. INEM´s ambulances are able to provide assistance in place and during transport to the emergency room. There are two types of ambulances, basic life support ambulances, with a team of two emergency technicians and ASIV, with a team of nurse (team leader) and emergency technician.

PARTICIPANTS

Since we included the entire accessible population during a given time period, without specific sampling criteria, the study used convenience sampling. The sample included all trauma patients who fulfilled the following inclusion criteria: aged 18 years or older; with (suspected) injuries from blunt, penetrating, or blast mechanisms and; with active external bleeding. Patients were excluded if they show (suspected) injuries from heat or cold.

VARIABLES

The following clinical characteristics of the patients were collected by the registered nurses: day and time of incident, age, gender, physical location of trauma, type of trauma, mechanism of trauma, scene time, transportation time, vital signs, Shock Index (SI), Revised Trauma Score (RTS) and type of interventions implemented. External bleeding treatment implemented by ASIV nurses followed INEM institutional algorithms. INEM supervises all prehospital practices in Portugal. Interventions administered included: rewarming measures, immobilisation, elevation of the injured area, oxygen therapy, fluid therapy and hands-on therapies such as direct pressure, pressure/wound dressings, and cryotherapy. Cryotherapy involves the application of a cold substance, such as ice, on the skin, which promotes immediate vasoconstriction, reducing vascular spasms and slowing blood flow.[17]

DATA SOURCES

A data collection tool (Prehospital Rescued Victim's Clinical File) specifically designed by researchers for this purpose was used in order to describe the hemodynamic status of the trauma patients rescued, the interventions implemented, the time elapsed during the rescue and the time elapsed between the moment they left the incident site and the arrival at the reference emergency room. Prior to its application and to ensure data consistency, the principal investigator conducted specific training for all ASIV nurses so that they could fill in the questionnaire with information about the treatment given to trauma patients.

STATISTICAL METHODS

Continuous variables included mean and standard deviations (SD) while categorical variables included frequencies and percentages. To compare demographic data, clinical characteristics, and interventions employed by burses to control active bleeding, we used the McNemar test (paired nominal data – to compare results with similar injuries with and without bleedin g control), Student's t-test (continuous variables) and the χ^2 test or Fisher's exact test (categorical variables).[18] All interventions administered to control bleeding were included in stepwise multivariate logistic regression (Forward Conditional analysis), with bleeding controlled on arrival at the emergency room as a dependent variable. Previously, all assumptions (normality, multicollinearity, among others) were met. A 2-sided $p<0.05$ was considered statistically significant. All analyses were performed using SPSS statistical software- version 23.0 (IBM Corp).

ETHICAL CONSIDERATIONS

This study was approved by INEM as part of the project "Evidências para Não Arriscar MaisVidas: do pré-hospitalar ao serviço de urgência e a alta (MaisVidas)", with the reference: PROJ/UniCISE /2017/000.1 Additionally, the study received ethical approval from the Tondela Viseu Hospital Centre Ethics Committees. The exemption from the obligation to obtain the consent of patients was granted.

RESULTS

A total of 627 trauma patients were rescued by ASIV teams in Portugal during the period it took to conduct this study. However, only 189 (30.1%) trauma patients met the inclusion criteria, 19 patients were excluded because they died before arriving at the emergency room and 419 patients because they showed no active external bleeding. The patients were mostly men (73.0%; n=138) with a mean age of 53.6 (±19.1) years. 74.1% (n=140) of trauma patients arrived at the emergency room unit with controlled bleeding ($p<0.001$). Trauma patients with active external bleeding, on arrival at the emergency room, were slightly older than those with bleeding controlled (56.5±20.6 vs 52.6±19.1), however the difference was not statistically significant. The most frequent type of trauma with external bleeding was blunt force trauma (53.4%; n=101), followed by penetrating trauma (36.0%; n=68). External bleeding in blunt trauma was controlled in 49.3% (n=69) of the patients, whereas in cases involving penetrating trauma, external bleeding control was achieved in 37.1% (n=52) of the cases ($p<0.05$). As for the physical location of trauma, cranioencephalic trauma was the most common (56.6%; n=107), followed by lower limb trauma (46.0%; n=87). The average time it took the teams to provide assistance at the incident site was longer for patients whose bleeding was not controlled, with a higher mean value of approximately three minutes; however, it was observed that transport to the reference emergency room unit took longer for patients with controlled external bleeding. It was also noted that trauma situations were more common in autumn and summer, however, there was no relationship between seasons and the control of external bleeding (Table 1).

Patients with uncontrolled external bleeding, after the intervention of ASIV teams, show higher mean values of respiratory rate than patients with controlled external bleeding (18.27±4.2 vs 17.12±2.62; $p<0.05$). The initial mean systolic blood pressure, respiratory rate, and heart rate of patients with external bleeding and without active external

TABLE 1: DIFFERENCES IN DEMOGRAPHIC AND CLINICAL CHARACTERISTICS BETWEEN PATIENTS WITH CONTROLLED AND ACTIVE BLEEDING ON ARRIVAL AT THE EMERGENCY ROOM (N=189)

	Active bleeding before the ASIV nurses' intervention	Controlled bleeding on arrival at the emergency room	Active bleeding on arrival at the emergency room	p[a]
n (%)	189 (100)	140 (74.1)	49 (25.9)	<0.001[b]
Age, years	53.6 (19.5)	52.6 (19.1)	56.5 (20.6)	0.48
Gender, n (%)				
Male	138 (73)	101 (72.1)	37 (75.5)	0.64
Female	51 (27)	39 (27.9)	12 (24.5)	
Season, n (%)				
Winter	33 (17.5)	26 (18.6)	7 (14.3)	0.79
Spring	32 (16.9)	22 (15.7)	10 (20.4)	
Summer	62 (32.8)	47 (33.6)	15 (30.6)	
Autumn	62 (32.8)	45 (32.1)	17 (34.7)	
Location of trauma, n (%)				
Cranioencephalic	107 (56.6)	77 (55)	30 (61.2)	0.44
Neck	33 (17.5)	28 (20)	5 (10.2)	0.12
Thoracic	44 (23.3)	37 (26.4)	7 (14.3)	0.08
Abdominal	32 (16.9)	24 (17.1)	8 (16.3)	0.89
Pelvic	30 (15.9)	20 (14.3)	10 (20.4)	0.31
Upper limbs	67 (35.4)	54 (38.6)	13 (26.5)	0.12
Lower limbs	87 (46)	64 (45.7)	23 (46.9)	0.88
Spinal-cord	41 (21.7)	32 (22.9)	9 (18.4)	0.51
Type of trauma, n (%)				
Blunt	101 (53.4)	69 (49.3)	32 (65.3)	0.03[b]
Penetrating	68 (36)	52 (37.1)	16 (32.7)	
Blunt and penetrating	20 (10.6)	19 (13.6)	1 (2.0)	
On-site rescue elapsed time, minutes	31.5 (14.6)	30.7 (15.1)	33.7 (13.0)	0.49
Transportation time from incident site to emergency room, minutes	40 (25.3)	40.8 (25.6)	37.8 (24.3)	0.08
Vital parameters				
Initial Systolic Blood Pressure, mmHg	131.9 (27.5)	129.9 (27.2)	137.1 (27.6)	0.11
Final systolic blood pressure, mmHg	130.5 (22.6)	129 (22.6)	133.8 (21.5)	0.20
Initial respiratory rate	18.8 (3.5)	18.7 (3.5)	19.2 (3.3)	0.44
Final respiratory rate	17.3 (3.1)	17.1 (2.6)	18.2 (4.2)	0.02[b]
Initial heart rate	85.6 (17.1)	84.8 (16.0)	87.2 (19.6)	0.38
Final heart rate	82.2 (15.0)	81.3 (14.0)	83.9 (17.7)	0.35
Initial axillary temperature	36 (0.6)	36 (0.6)	36.0 (0.5)	0.87
Final axillary temperature	36 (0.4)	36.1 (0.4)	36.0 (0.3)	0.11
Initial Oxygen Saturation	97 (2.9)	97.1 (2.8)	96.9 (3.0)	0.60
Final Oxygen Saturation	98 (2.1)	97.4 (8.5)	97.6 (3.1)	0.83
Severity indices				
MGAP	23.7 (3.4)	23.6 (3.5)	24.3 (3.2)	0.23
Initial Shock Index	0.6 (0.1)	0.6 (0.1)	0.6 (0.1)	0.83
Final Shock Index	0.6 (0.1)	0.6 (0.1)	0.6 (0.1)	0.96
Initial Revised Trauma Score	7.6 (0.5)	7.6 (0.5)	7.6 (0.4)	0.54
Final Revised Trauma Score	7.7 (0.4)	7.6 (0.5)	7.7 (0.4)	0.86

[a] p values indicate differences between patients with controlled and active bleeding on arrival at the emergency room based on the results of a McNemar test, Student's t-test, χ^2 test, or Fisher exact test.

[b] Statistically significant.

MGAP (Mechanism, Glasgow coma scale, Age, and arterial Pressure)

TABLE 2: DIFFERENCES IN INTERVENTIONS IN PATIENTS WITH CONTROLLED AND ACTIVE BLEEDING ON ARRIVAL AT THE EMERGENCY ROOM (N=189)

	Active bleeding before the ASIV nurses' intervention n=189	Controlled bleeding on arrival at the emergency room n=140	Active bleeding on arrival at the emergency room n=49	p[a]
Rewarming measures, n (%)	157 (83.1)	119 (85.0)	38 (77.6)	0.34
Removing wet clothes	39 (20.6)	29 (20.7)	10 (20.4)	0.96
Drying the patient's body	26 (13.8)	18 (12.9)	8 (16.3)	0.54
Isothermal blanket	122 (64.6)	90 (64.3)	32 (65.3)	0.89
Blankets	26 (13.8)	20 (14.3)	6 (12.2)	0.72
Increasing ambient temperature	100 (52.9)	73 (52.1)	27 (55.1)	0.72
Heating pads	3 (1.6)	3 (2.1)	0 (0.0)	0.56
Warmed intravenous fluid	56 (29.6)	39 (27.9)	17 (34.7)	0.36
Immobilisation, n (%)	150 (79.4)	110 (78.6)	40 (81.6)	0.64
Elevation of the injured area, n (%)	18 (9.5)	13 (9.3)	5 (2.6) 10.2)	0.85
Oxygen therapy, n (%)	70 (37)	50 (35.7)	20 (40.8)	0.52
Volume of fluid therapy, n (%)				
0 ml	29 (15.3)	24 (17.1)	5 (10.2)	0.55
1 to 500 ml	106 (56.1)	79 (56.4)	27 (55.1)	
501 to 1000 ml	39 (20.6)	27 (19.3)	12 (24.5)	
1001 to 1500 ml	13 (6.9)	9 (6.4)	4 (8.2)	
1501to 2000 ml	2 (1.1)	1 (0.7)	1 (2.0)	
Physical measurements, n (%)				
Direct pressure	39 (20.6)	33 (23.6)	6 (12.2)	0.09
Wound dressing	91 (48.1)	70 (50.0)	21 (42.9)	0.38
Cryotherapy	30 (15.9)	28 (20.0)	2 (4.1)	0.01[b]

[a] p values indicate differences between patients with controlled and active bleeding on arrival at the emergency room according to the results of a χ^2 test, or Fisher exact test.

[b] Statistically significant.

bleeding tend to decrease after the nurses' intervention, and the SpO2 values increase in both groups of patients.

Based on the interventions administered to all trauma patients, the differences between patients with controlled and active bleeding on arrival in the emergency room are shown in Table 2.

The data show a significant association between cryotherapy and external bleeding control. Cryotherapy was administered to 15.9% (n=30) of the patients. 93.3% (n=28) of them arrived at the emergency room with controlled bleeding (p=0.01). This trend was also reinforced by the multivariate analysis which included all the interventions implemented and found that only cryotherapy was associated with bleeding control (p=0.02) (Table 3). According to this model, cryotherapy alone is responsible for an explained percentage of variance of 73.9%.

TABLE 3: ODDS RATIO FOR BLEEDING CONTROL IN PATIENTS WITH TRAUMA BASED ON CRYOTHERAPY INTERVENTION (N=189)

	OR	95% CI	p
Cryotherapy	5.93	1.35-25.90	0.02

OR: Odds Ratio; CI: confidence interval; p: statistically significant.

DISCUSSION

Among the 189 cases included in this prospective study, one fifth was still experiencing severe bleeding when they got to the emergency room. The interventions that were most frequently administered were rewarming measures (83.0%) (especially the use of isothermal blanket and increasing ambient temperature) and immobilisation (80.0%). Oxygen therapy and elevation of the injured area were also applied, as was warm fluid therapy. None of these measures revealed statistically significant differences for the two groups of patients, i.e., with controlled versus non-controlled bleeding on arrival at the emergency room. Physical interventions were also applied, namely wound dressing (48.0%), direct pressure (21.0%) and cryotherapy (16.0%). This last measure proved to be the only therapy with statistical significance, both in univariate and multivariate analyses. Patients who underwent cryotherapy were almost six times more likely to arrive at the emergency room with bleeding under control. Even so, it was found that cryotherapy was administered to only 16% of victims. Its application may not always be affordable or easy to implement in trauma victims, which may explain its reduced use as a bleeding control measure. Cryotherapy is a safe, non-invasive procedure,[19] although

supervision by healthcare professionals is required to avoid unnecessary skin damage.[20]

Age and gender were statistically similar between the two groups, and so were the values of systolic blood pressure, heart rate, MGAP and shock index. These results support the evidence found by other studies that point to the fact that vital signs are poor indicators of physiological compromise,[21-23] even though traditional vital signs (systolic blood pressure, heart rate and respiratory rate) are commonly highly valued during the initial evaluation of traumatised patients.[24,25] However, this study shows that there have been significant differences in respiratory rate, between patients with and without controlled bleeding, which may indicate an important relationship between hemodynamic compromise and the respiratory rate in patients whose bleeding has not yet been controlled. Understanding altered initial physiological outcomes may prove useful to predict outcome in trauma patients.[26]

The significant reduction in the number of patients with active external bleeding (74.1%, n=140; p<0.001) seems to demonstrate that the management of bleeding as a whole is more consistent than the sum of all available interventions. This is because the inability to demonstrate the effectiveness of each intervention contrasts with the overall capacity of all interventions to reduce the number of bleeding patients. It is the set of interventions that seems to improve this clinical condition and not the implementation of an isolated measure.[27] This research has shown that cryotherapy has contributed significantly to the control of bleeding and its use is associated with a decrease in the number of patients with active external bleeding. Despite the results observed with the application of cryotherapy to trauma patients, it is not possible to find evidence that prove its clinical efficacy.[28] This study obtained important results regarding to this measure, but more methodologically robust studies, such as clinical trials are needed to assess the risks, benefits and feasibility of cryotherapy as an intervention used by nurses in the pre-hospital setting to control bleeding. Although cryotherapy is the only statistically significant one, we should point out that direct pressure, although not significant, seems to be a simple, easy, immediate intervention with good results in controlling external bleeding.

It is important to recognise that not all the haemostatic options used for this purpose are available in ASIV in Portugal. This is the case, for instance, of haemostatic dressings, haemostatic agents, or anti-haemorrhagic pharmacological options like tranexamic acid, an important and recommended pharmacological option to control bleeding.[14, 29] Several studies have demonstrated the effectiveness of haemostatic dressings,[30-32] and haemostatic agents,[33, 34] in controlling bleeding. Other studies have also shown that direct compression itself increases its effectiveness when associated with topical haemostatic agents.[4] The use of tourniquets is also indicated in the control of uncontrolled external limb bleeding.[28] This measure is available in ASIV ambulances in Portugal, but this intervention wasn't used by nurses in any situation in our research (data not shown), even though almost half of the patients with active bleeding on arrival at the emergency room had experienced lower limb trauma injuries and one fourth of the patients experienced the same sort of trauma in the upper limbs. There have been concerns that the effectiveness of the tourniquet obtained in military settings may not be directly extrapolated to civilian patients due to differences in the pattern and severity of the injuries.[35] The existing civilian experience with tourniquet use has not been systematically assessed,[36,37] so it is important to understand whether the rescue teams have adequate training and experience in the application of turnstiles, and if this limitation may explain the difficulty in implementing this technique.

Rescue time management remains a critical variable that should be considered during prehospital assistance.[14,38] Surgical intervention is the necessary and definitive treatment for patients with uncontrolled bleeding trauma but is only available in trauma centers.[39] Therefore, prehospital care should consider not only the administration of the necessary interventions, but also the management of the assistance time itself.[14,28] Many factors affect prehospital transport time, like the distance from a trauma centre and specific patient-related factors.[39] We believe that the timely management of interventions can increase the patients' probability of survival, however, this research was unable to find results to assess this phenomenon. On the other hand, it was observed that patients with uncontrolled external bleeding on arrival at the emergency room have an average rescue time at the incident site of approximately 33.7 minutes, three minutes more than patients with controlled bleeding. Other studies have shown a mean response time of less than 20 min.[39,40] They also proved that every additional minute in prehospital scene time independently correlates with a 1% increase in mortality.[39]

Trauma models are currently used by different countries to provide pre-hospital professionals with decision support during field triage. These models seek to outline the best methodology to be used to improve clinical decisions.[41] In addition, a multidisciplinary approach with clinical guidelines can ensure a uniform standard of care and thus improve outcomes for the patient with severe bleeding trauma.[14] Therefore, we believe that a model of trauma care adjusted to the pre-hospital reality can support providers not only in triage decisions, but also in clinical decision making to improve patient outcomes, particularly in bleeding control.

LIMITATIONS

Our study has some limitations. First, the number of events with confirmed active external bleeding was relatively low, despite the inclusion of a high number of trauma patients (608), which did not allow for more consistent conclusions. This lack of homogeneity may have affected the power of the statistical tests. Second, the impossibility to assess all the means usually used for active external bleeding control in trauma victims, since the ASIV in Portugal are not equipped with all the anti-haemorrhagic devices that are available in other contexts and countries. Finally, the conclusions of this investigation should be interpreted considering the outcomes found at emergency room arrival. More solid conclusions could be achieved using intra-hospital results.

IMPLICATIONS FOR EMERGENCY NURSING

The management of external bleeding is a priority in prehospital care for trauma patients. This study suggests that nurses should consider the following options in their clinical practice: (1) higher respiratory rate values seem to be an important predictor of hemodynamic instability resulting from uncontrolled active external bleeding; (2) cryotherapy has been proven to be successful in controlling external bleeding; (3) overall success may be explained with the concerted implementation of several types of interventions, and not with the isolated administration of specific interventions; (4) Haemostatic options should become part of the ASIV's protocols in the future. The approach to trauma patients remains controversial, so the rescue of each patient should depend on the articulation between the assessment of available evidence and the type of treatment available in each rescue ambulance.

CONCLUSION

This study shows that a significant number of patients continue to arrive at the emergency room with active external bleeding. More complicated haemorrhages require more effective interventions, so providing ambulances with more differentiated pharmacological and non-pharmacological options is a priority. Cryotherapy has been associated with high control of external bleeding, so evaluating its effectiveness in new investigations is also a priority.

Conflicts of interest: The authors have nothing to disclose.

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RESEARCH ARTICLES

Patient privacy: a qualitative study on the views and experiences of nurses and patients

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ABSTRACT

Objective: The aim of the study was to determine views and experiences of intensive care unit nurses and patients on the issue of protecting patient privacy.

Background: Intensive care should be delivered to protect the privacy of intensive care patients because these patients experience a loss of personal identity and significant limitations in physical activity and emotional expression. Intensive care patients may not be able to dress themselves; they may not communicate effectively without glasses and hearing aids; they cannot control the environment; they may not govern their actions, and they may not advocate for themselves. For these reasons, nurses should assume a primary role to protect patient privacy because they spend many hours with them and witness patients' loneliness, pain, and death as their primary caregivers.

Study design and methods: This is a qualitative study using a phenomenological method with data gathered through interview. The study was conducted with nurses (n = 14) and patients (n = 14) in the intensive care units of a state hospital in a metropolitan city in Turkey between 12 March 2018 – 4 October 2019. Data were collected from nurses and patients using semi-structured interview forms. Content analysis revealed categories, themes, and sub-themes. We have followed the Consolidated criteria for reporting qualitative research (COREQ).

Results: The categories explored in the study for both nurses and patients were the concepts of privacy, privacy protection and privacy violation. Some of the sub-themes were physical privacy, not sharing personal information, using screens or curtains, using aprons or sheets, insufficient number of nurses or excessive number of patients, and a lack of inspection and equipment.

Conclusion: This study shows that the acquired information and the awareness of privacy, protection of privacy, and violations of privacy were adequate among both nurses and patients. Some of the nurses in the study stated that institution-related violations occurred because of the inadequate numbers of nurses to provide care to an exceedingly large number of patients.

The implications for research, policy, and practice: Increasing awareness of nurses and patients on patients' rights and protection of privacy and violations of privacy and taking adequate measures to protect patient privacy increase both patient satisfaction and service quality in health.

What is already known about the topic?
- Privacy is a fundamental human right.
- Protection of patient privacy is the responsibility of healthcare professionals.

What this paper adds:

- The awareness of patient rights for privacy and privacy protection has been well established among patients and nurses, and both participating patients and nurses were knowledgeable of respective privacy violations.
- Institution-related factors such as the insufficient numbers of nurses, exceedingly large numbers of patients, problems with the main door access control systems in intensive care units, and the provision of care in smaller units than optimum ones are significant factors involved in the privacy violations of patients.
- Patients were reluctant to report privacy violations because they believed this could negatively affect their treatment and care.

Keywords: privacy, intensive care unit, patient, nurse, qualitative research

INTRODUCTION

Intensive care unit (ICU) patients are dependent on nurses for the provision of care 24/7 for their physical, mental, and social needs resulting from invasive interventions, family deprivation, limitations of movements, pain, mechanical ventilation, and memory disorders. Moreover, the protection of the patient's privacy may not be easy in ICUs because of the presence of many patients in the same environment witnessing the treatment and care of other patients and the incapacity of patients to communicate and make decisions to protect their privacy.[1,2,3] In this context, several principles and regulations have been developed by international and national organisations for the protection of patient privacy. Such principles and regulations may include ensuring the integrity of electronic or paper-based health report data, forbidding the disclosure of personal and confidential information, and the discipline of showing respect to patients' choices, empowering patients in decision making, and delivering appropriate and culture-related care. The implementation of such regulations and principles leads to the assumption of new responsibilities and ethical obligations by nurses to ensure the privacy and confidentiality of patients.[4,5,6,7,8]

'To respect the dignity, worth, equality, diversity, and privacy of all persons' is listed in the ethical codes of the World Health Organization.[4] Florence Nightingale's pledge has set various rules forth as an important guide for nurses and it is accepted as the first ethical code of nursing.[5] Privacy is emphasised in the original pledge as follows: 'I…will hold in confidence all personal matters committed to my keeping, and all family affairs coming to my knowledge in the practice of my calling'. The current privacy statement in the pledge has been reformulated as: 'I will keep all the information given to me about the individual confidential'.[6] The Code of Ethics for Nurses of the International Council of Nurses (ICNs) also states that nurses are responsible for respecting human rights.[7] The principles of autonomy, privacy and secrecy are stated in 'Ethical Principles and Responsibilities for Nurses' published by the Turkish Nurses Association (TNA). The respect for human dignity, informing the patient and obtaining his/her consent are mentioned under the principle of autonomy. The protection of all aspects of privacy and ensuring the privacy of personal information are also included under the principles of privacy and confidentiality.[8] The protection of patients' privacy increases patients' trust, satisfaction, and quality of healthcare services.

International studies have also indicated that patient privacy may not be adequately protected or even violated.[9,10,11,13] Roos et al. report that patients were satisfied when they had more social interaction and were cared for in multiple-bed rooms, but noted a lack of privacy.[9] Another study has shown that nurses may sometimes not feel like respecting patients' privacy adequately and that they may feel like invading the patient's intimacy.[12] The same study reported that patients' privacy was not protected appropriately in a way that the patient would wish. A study showed that 48% of the nurses expressed concern over the security of electronic health records due to security vulnerability associated with administrative issues, inadequate training, access by unauthorised users, inadequate auditing, poor communication with technology vendors, and the lack of adequate time for appropriate documentation.[13]

Some of studies on patient's privacy in Turkey concluded that nurses and healthcare professionals did not pay enough attention to patient privacy or it was violated,[14,15] while some studies showed that nurses had usually positive opinion about patient privacy.[14,16-18] Although patient privacy is important in all units of hospitals and in all healthcare facilities at all levels, it might have critical importance in ICUs because of the unique medical characteristics of the admitted patients and services provided. However, studies conducted with nurses on the 'protection of patient privacy' in ICUs in Turkey are very few.[19,20,21] The use of protective screens or curtains may not be attentively used for patients in ICUs. Patients and their relatives may not be provided with adequate information about the interventions and treatments, and not enough attention was paid to patient privacy while transferring the patients from one unit to the other. Lastly, healthcare professionals may not be observant regarding the presence of third parties in the environment while they are providing information to relatives about

patients.[18,19,21] A study by Özata et al. discussed the issues of patient privacy in ICUs and reported that unconscious patients received great care but patients were separated with curtains only.[19] Based on these discussions, it is not difficult to anticipate that physical conditions and care needs put intensive care patients in a vulnerable position concerning their privacy.

METHOD

STUDY DESIGN AND ETHICS

The aim of this study was to determine the experiences and views of the nurses and the patients in the ICUs on patient privacy.

This study used the phenomenology design, a qualitative research method. Based on the interpretive phenomenology model developed by Van-Manen, semi-structured interviews were conducted.[22] In the interpretive phenomenology model, the experiences of individuals regarding a phenomenon are transformed into a structure, where experiences are described in the words of the patients. This phenomenon relates to experiences of some personal significance, such as the development of an important relationship or a major life event. The researcher makes a description that defines the essence of people's experiences based on his/her own experiences and literature.[22]

The study was approved by the Non-Interventional Clinical Research Ethics Board of a state university (06.02.2018; GO 18/138-06). Written consent was obtained from the patients and the nurses. Written permission to conduct the study was obtained from the hospital administration.

PARTICIPANTS

The study was conducted between 12 March 2018 – 4 October 2019 with the nurses working in the cardiovascular surgery, anaesthesia reanimation, and neurosurgery ICUs of a state hospital, and with the patients who were transferred to the surgical clinics after receiving health care from these ICUs.

The sample of the study was obtained using the purposive sampling method, which reveals the facts and events. In this methodology, data saturation is reached to stop research when the concepts and processes that may be the answer to the research question start to repeat, and when repetitive answers are given to the questions.[23,24] Polkinghorne reports that researchers should conduct their interviews with five to 25 people who have experienced the phenomenon created by them.[25] Accordingly, semi-structured individual interviews were conducted with 14 nurses working in the ICUs and 14 patients receiving healthcare service from these units. The inclusion criteria for patients were (1) aged 18 or older, (2) no mental health conditions, and (3) no communication problems. Further, (1) work experience for more than one year, and (2) working in ICUs were the inclusion criteria for nurses.

DATA COLLECTION

The views and experiences of nurses and patients were obtained by using semi-structured interview forms developed for nurses and patients (Table 1). A pilot study was conducted with two hospitalised patients and two nurses in order to evaluate the data collection tools and the applicability of the study. No change was made in the questionnaire forms after the pilot study, and the data obtained from the nurses and patients who participated in the pre-application were included in the study.

TABLE 1: SEMI-STRUCTURED INDIVIDUAL INTERVIEW QUESTIONS

Questions for nurse
Could you please explain the definition of privacy and its place and importance in nursing practices?
Could you please give examples of your practices that cover patient privacy when you think about your working day in an intensive care unit?
Could you please give some examples of practices on patient privacy of one of your colleagues at your workplace who is a role model for you?
Could you please state if you have ever encountered situations where patient privacy was violated? If so, what procedures are to be followed in case of violations?
Questions for patient
What do you think has been done to protect your privacy during your stay in the intensive care unit?
Is there ever a situation that would prevent the protection of your privacy while you receive care in the intensive care unit? Or have you witnessed such a situation?
Do you think that there have been interventions performed on you even though you did not want them done?
What do you think should be done in cases where privacy is not protected in the intensive care unit?

The researcher (SA) informed the nurses about the study, and conducted face-to-face interviews with them in the nursing rooms of the ICUs where the nurses worked. The interviews started when the nurses felt ready. The interviews were recorded on a tape recorder using the semi-structured interview form. The researcher (SA) informed the patients about the study and conducted face-to-face interviews with them in their rooms when they were alone. Those patients sharing their rooms with other patients were interviewed in the nursing room of the clinics to ensure confidentiality. When the patient felt ready the interview was begun, recorded on a tape recorder, and followed the semi-structured interview form. Each interview with nurses and patients lasted for about 20 minutes.

DATA ANALYSIS

Frequency and percentage were used to analyse descriptive characteristics of nurses and patients. Data analysis steps were followed for converging patterns for qualitative data.[26] Qualitative data collected independently from each participant was analysed independently.[27] The recorded

semi-structured face to face individual interviews were transcribed by the researchers. After the transcripts were created, the recordings were re-listened to, to prevent errors. The data were analysed by using content analysis as recommended by Strauss and Corbin.[28] Content analysis is based on the inductive analysis of similar data and the combination and interpretation of the data within the framework of certain categories and themes. The researchers read the transcripts separately and developed themes. They read the transcripts again and exchanged ideas and opinions through open discussion meeting. Data collected from nurses and patients were analysed independently, and results were interpreted in line with research purposes. Then, the opinions of five experts on ethics, privacy, psychiatry and/or intensive care nursing were obtained to make sure that the categories, themes and sub-themes were created appropriately. The interviews were numbered to conceal the identities of the participants. For instance, (P1, 20A, F) means participant 1, female and aged 20 years old. Male participants were also coded with the letter 'M'.

VALIDITY AND RELIABILITY/RIGOUR

We have rigorously followed the consolidated criteria for reporting qualitative research (COREQ). The researchers in this study are experienced and trained in relation to qualitative research methods. A strict process of transcription, categorisation and analysis of results was carried out according to the usual methodology.

RESULTS

Table 2 shows the demographic characteristics of the participants. The mean age of the nurses was 29.1±5.2. The total working experience of the nurses was 6.2±4.5 years on average, and the working experience in the ICU was 4.2±2.9 years on average. The mean age of patients was 51.3±16.6 and their mean length of stay in the ICU was 4.5±3.7 days.

QUALITATIVE FINDINGS

The findings of qualitative data of nurses and patients were grouped into three categories: concept of privacy, protection of privacy and violation of privacy (Table 3, Table 4).

CATEGORY, THEMES AND SUB-THEMES INDICATING NURSES' VIEWS AND EXPERIENCES ON PATIENT PRIVACY

Category 1: the concept of privacy

Theme 1: perception of privacy

The nurses mentioned the physical dimension of privacy related to the body and stated that personal information should not be shared. They also mentioned the social dimension of privacy by indicating that privacy is a private concept.

TABLE 2. DESCRIPTIVE CHARACTERISTICS OF NURSES (N=14) AND PATIENTS (N=14)

Descriptive characteristics	n	%
Nurse		
Age (year): x̄ ±SD= 29.1±5.2; min=25 and max=41		
Total working time in nursing (year): x̄ ±SD= 6.21±4.5; min=2 and max =20		
Working time in the intensive care unit (year): x̄ ±SD= 4.28±2.9; min=1 and max =11		
Gender		
Female	11	78.6
Male	3	21.4
Educational level		
Vocational high school	3	21.4
Undergraduate	11	78.6
Received education on patient rights		
Yes	14	100
No	0	0
Time of education on patient rights		
Within the last year	10	71.3
During undergraduate education	4	28.7
Received education on privacy		
Yes	11	78.6
No	3	21.4
Time of education on privacy		
Within the last year	7	63.6
During undergraduate education	4	36.4
Patient		
Age (year): x̄ ±SD= 51,35±16,6; min=20 and max=74		
Length of stay in the intensive care unit (day): x̄ ±SD= 4.5±3.7; min=1 and max=15		
Gender		
Female	6	42.9
Male	8	57.1
Educational status		
Literate/illiterate	2	14.2
Primary school	5	35.8
High school	6	42.9
University	1	7.1

'Sometimes, questions can be specific to patients. For example, when suicidal patients come in, our Turkish society is likely to dig in why they are suicidal and what they have experienced. This is the privacy of the patient, it's up to him to tell or not. But we often dig into the issue, and of course this can be overwhelming for the patient. This is the privacy of the patient after all.' (P11, 26A, F)

TABLE 3. CATEGORIES, THEMES, AND SUB-THEMES INDICATING NURSES' VIEWS AND EXPERIENCES ON PATIENT PRIVACY

Category	Theme	Sub-Theme
Concept of privacy	Perception of privacy	Physical privacy (n:10) Non-share of personal information (n:7) Social privacy (n:3)
Protection of privacy	Physical interventions	Use of screen/curtain/ apron/bed cover (n:11) Preventing the presence of third parties (n:9)
	Respect for personal preferences	Receiving care from a same gender nurse (n:6) Religious preferences (n:5)
	Cognitive protection	Protection of personal information (n:8)
	Adopting model behaviours (n:9)	
Violation of privacy	Physical violation	Non-use of apron/curtain (n:12)
	Cognitive violation	Sharing personal information (n:5)
	Job-related violation (n:5)	
	Violation due to unprofessional conduct	Considering insignificant (n:5) Lack of education (n:3) Conscious-unconscious patient distinction (n:10)
	Institution-related violation	Insufficient number of nurses and high number of patients (n:2) Long working hours and working for many years (n:4) Lack of control (n:7) Lack of equipment (n:4)
	Consequences of violation	Verbal warning (n:8) Remaining silent (n:6)

TABLE 4. CATEGORIES, THEMES AND SUB-THEMES INDICATING PATIENTS' VIEWS AND EXPERIENCES ON PATIENT PRIVACY

Categories	Theme	Sub-Theme
Concept of privacy	Perception of privacy	Physical privacy (n:10) Non-share of personal information (n:4)
Protection of privacy	Physical interventions	Use of curtain/covering the body (n:12)
	Respect for personal preferences	Receiving care from a same gender nurse (n:3)
Violation of privacy	Physical violation	Non-use of curtain (n:5) Presence of third parties in the environment (n:2)
	Cognitive violation	Sharing personal information (n:3)
	Disrespect for patient integrity	Being scolded (n:3)
	Violation due to unprofessional conduct	Considering insignificant (n:4) Conscious-unconscious patient distinction (n:1)
	Institution-related violation	Insufficient number of nurses/high number of patients (n: 1) Lack of equipment (n: 4)
	Consequences of violation	Complaining/verbal warning (n:3) Compulsory acceptance of interventions (n:6) Feeling helpless (n: 2)

Category 2: privacy protection

Theme 1: physical interventions

The nurses indicated that they used a screen/curtain and apron/bed cover to protect patients' privacy. They ensured that the patient occupied a single room, if available in the unit, and they attempted to prevent third persons from entering the intensive care unit. Furthermore, nurses only allowed the necessary personnel required to provide patients' bodily care.

> 'While relatives of patients visit their patients, there is a cardiac arrest in the other bed. Or an urgent care needs to be taken. We take patients' relatives out right away.' (P9, 25A, M)

Theme 2: respect for personal preferences

With regard to the protection of privacy, the nurses reported that they paid attention to ensure that the patients would receive care from same-gender nurses, and they reported that they respected their religious preferences.

> 'Female patients especially do not want male personnel to enter. She does not want to be touched while her body is wiped. Or, while inserting a catheter, they ask whether there is a male nurse or a female nurse even during the procedures." (P11, 26A, F)

Theme 3: cognitive protection

Concerning the protection of privacy, the nurses stated that they protected the personal information of the patient.

> 'We try to keep other information private. We try to avoid showing the whole file of the patient to the relatives of the patient as much as we can. . .." (P2, 31A, F)

Theme 4: adopting model behaviours

The nurses indicated that they had colleagues who served as role models for them regarding interventions to protect patients' privacy, and they appreciated these nurses' example.

> 'I have friends who check the curtains of the patients' beds and check the patients before the relatives of the other patient visit, especially during the visiting hours, and I try to pay attention to them as much as I can." (P5, 39A, M)

Category 3: violation of privacy

Theme 1: physical violation

The nurses stated that the violations against the patient occurred in the form of not using curtains or an apron.

> 'For example, there are times when many of our patients have fever, so the privacy we show to those patients is unfortunately not enough. In other words, we act with the focus on the treatment we do, not the privacy of the patient.' (P13, 27A, F)

Theme 2: cognitive violation

The nurses reported that the violation of privacy occurred in the form of sharing the personal information of the patient with others.

> 'At the moment we learn the patients' diagnosis, we might ask: methanol intoxication... what happened?'. Without talking about patients' any other medical knowledge, we have guessed information about private lives of patients." (P14, 41A, F)

Theme 3: job-related violation

The nurses indicated that privacy violations occurred during emergency situations.

> 'If there is a life-threatening risk, you cannot think of much privacy, for example, when they bring patients hurriedly from the emergency. The woman patient is uncovered bottom to the top. You know, since you give priority to intervention, privacy is a bit in the background.' (P12, 25A, F)

Theme 4: Violation Due to Unprofessional Conduct

The nurses reported that education and training concerning the issue of privacy was inadequate, and that their approaches to the privacy of the unconscious patient were different. In addition, either they considered privacy insignificant or they forgot about it.

> 'Healthcare staff approach privacy with the same mindset. For example, consulting doctors come from many different units of the hospital to the intensive care unit for patient consultation. They do not pay attention to privacy. It is wrong. Education and training are essential in meeting privacy needs of patients." (P7, 25A, F)

Theme 5: institution-related violation

The nurses indicated that the violations of patient privacy were caused by institution-related deficiencies such as a shortage of nurses, too many patients, long working hours in the ICU, lack of equipment, and the failure of hospital administration to control the entrance and exits of the ICU.

> 'There is a little fatigue, a little weariness. This also affects the patient. The nurse is dealing with something at that moment. When the patient asks the nurse to take measures to protect her/his privacy, the nurse can yell at the patient directly.' (P11, 26A, F)

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Theme 6: consequences of violation

The nurses reported that in cases where privacy was violated, the health professional who committed the violation was warned verbally. Some of the staff ignored the violation, and no sanction was given by the administration. Furthermore, they stated that it was impossible to intervene in the situation if the person who committed the violation was an administrator or a doctor.

> 'We say this, but people do not want to say this in order to not offend each other. Or when you say this, you hurt them and you become the bad person." (P8, 29A, F)

CATEGORIES, THEMES AND SUB-THEMES INDICATING PATIENTS' VIEWS AND EXPERIENCES ON PATIENT PRIVACY

Category 1: concept of privacy

Theme 1: perception of privacy

The patients mentioned the physical dimension of privacy related to the body and the privacy of personal information.

> 'The person's own private information remains private, not shared with others, that is, not shared other than with necessary persons. It could be a doctor, a healthcare professional, for example, a medical intervention person. It may be a caregiver, or a family relative, or lesser third parties." (P9, 20A, F)

Category 2: protection of privacy

Theme 1: physical interventions

The patients stated that the nurses working in ICUs sometimes did not close the curtains and cover the patients' bodies while they were putting aprons on the patients and providing special procedures.

> 'The curtain was not pulled. So, everyone was on their own of course, I think they draw the curtains of those who want to change their clothes." (P11, 56A, M)

Theme 2: respect for personal preferences

The patients reported that nurses paid attention to ensure that the patients would receive care from their same-gender nurse in the interventions for the protection of privacy.

> '….they were all females. If he was a man, of course I would refuse.' (P6, 27A, F)

Category 3: violation of privacy

Theme 1: physical violation

The patients reported that the violation of privacy occurred since nurses did not use the curtains separating the patient beds, the entrance to the ICU was always busy with people coming in and going out, and there were third parties.

> 'Sometimes they closed the curtain and sometimes they didn't, but even if they closed the curtain, it was the same. The patients feel embarrassed when care is being given….' (P6, 27A, F)

Theme 2: cognitive violation

The patients stated that it was a violation of privacy when information about themselves or other patients could be heard by others.

> 'I mean, everybody hears each other, and we find out their private information….' (P9, 20A, F)

Theme 3: disrespect for patient integrity

The patients reported that they were scolded by the nurses and that the nurses spoke in unfriendly or disapproving language to them.

> 'You are warning them why they aren't careful. For example, when you say 'why didn't you close the curtain?', they say 'I closed the curtain, I am doing my duty, please do not interfere, do not make my job difficult, I got some other things to do' and they shut the patient down admonishingly." (P4, 51A, F)

Theme 4: violation due to unprofessional conduct

The patients stated that violations occurred since nurses considered privacy insignificant and treated unconscious patients differently.

> 'What, uncovered genital organs? Me lying there naked? Personnel feelings are insensitive. They don't even care whether I am embarrassed or not, they are not doing anything to help me." (P4, 51A, F)

Theme 5: institution-related violations

The patients indicated that the protection of privacy was hindered by too few nurses, too many patients and the lack of equipment such as curtains, sheets, or other coverings to protect patients' privacy in the unit.

> 'So, it is already a very crowded environment. Everyone sees each other. I guess they are trying to protect the privacy of patients, but they cannot prevent privacy violations involuntarily. There were some deficiencies as well of course. The curtains are not enough.' (P9, 20A, F)

Theme 6: consequences of violation

Despite the violations of their privacy, patients stated that they felt obligated to accept the interventions of the healthcare workers because they were concerned about being mistreated. They understood that a complaint or warning should be expressed in case of violation. But they felt quite helpless.

> 'He/she said I had a fever, and I didn't believe it. I begged, 'how come I have a fever while I'm freezing here? I am begging you please, I'm freezing. The healthcare person refused to cover me. They saw each part of my body but in the end, life comes first" (P8, 74A, F)

DISCUSSION

Patient privacy should be emphasised as a main concern for nurses providing care to ICU patients due to the fact that ICUs have special architectural structures such as more beds and patients in the same environment, an open and/or cramped space; there might be sudden changes in the health conditions of patients; vital care interventions are first priority; third parties might witness the treatment and care of the patient; and ICU patients usually have lack of ability to communicate. Nevertheless, the care provided to patients in ICUs should always adhere to the principles of privacy.[2,9,12,29] The WHO's 2000 report emphasises the importance of patient privacy. According to this report, one of the goals of the health system should be the maintenance of responsiveness to people's expectations in regard to non-health matters, reflecting the importance of respecting the dignity and autonomy of individuals along with the confidentiality of information while delivering prompt attention and amenities of good quality to the patient and empowering the patient for access to social support networks and for the choice of a provider. In this context, responsiveness may refer to reducing an insult to one's dignity and autonomy and to alleviating the fear and shame that would potentially be brought about by sickness.[30] Ensuring the security and the protection of patient privacy are critical responsibilities to be assumed by both institutions and all healthcare personnel including nurses.

In our study, under the main theme of the perception of privacy, most of the nurses and all the patients mentioned the physical dimension of privacy. When defining the concept of privacy, they mainly relate it with 'the body being naked or covered'. Furthermore, the participants indicated that keeping their personal information confidential was also related to privacy. In a study conducted with nurses and midwives, 68.1% of the participants defined privacy as the privacy of both body and information.[31] Many individuals may prefer to keep information about themselves private. Their reasons may be related to 'being condemned, stigmatised' or 'non-interest to others'.[32] Therefore, patient privacy is an important issue that is the responsibility of health professionals and should be protected in accordance with ethical principles.[3] According to a study conducted by Mohajjel-Aghdam et al. in Iran, 97.4% of nurses had awareness of the confidentiality of patient information and patient privacy.[33]

Patient-centred care might be a solution to solve witnessed privacy issues since it considers the patient's cultural traditions and habits in the planning and providing process of medical interventions to patients' privacy as well as the quality of healthcare services.[34-36] In our study, the nurses indicated that privacy was a personal issue that is specific to each patient and is dependent on the patient's culture and religion. These views are compatible with the information in the literature and the national/international principles on patient rights and privacy protection.[7,8,29,34-36] The nurses in our study reported that using a curtain or a screen for the protection of privacy before bodily care and interventional procedures or mobilisation were important. In one study 95.4% of patients reported that all staff took care of their personal privacy (such as closing the door while being examined, pulling the curtain or screen).[37] Although patients' right to privacy is ensured and protected by legislation, and the values for privacy such as 'safety and security' are included in Maslow's pyramid of needs,[38] the study participants stated that their health was prioritised during their treatment period, and therefore, the importance they attached to privacy was minimised.

Making regulations or scheduling female and male nurses to provide care to the same gender patients might be an appropriate way to protect patients' privacy. In our study, both nurses and patient indicated that the nurses fulfilled the requests of their patients to receive care from a nurse of their own gender. In one study, it is stated that patients might be more comfortable if they receive the needed care and share their personal information with the nurses who are the same gender by quoting the saying: 'I would be more comfortable in terms of privacy and communication since I am the same gender'.[39] As reported in the literature, the patients in our study reported feeling embarrassed when they received care from nurses of the opposite gender. They preferred to receive care from nurses of the same gender, and they also expected nurses to be more careful about privacy, to communicate well with patients, and to be sensitive to the needs of unconscious patients.

The nurses reported that they shared the diagnosis of the patients, the reason for admission to the ICU, and the patients' private information with colleagues or others not related to the patients' care. Furthermore, patients in this study reported that information about themselves or other patients was mentioned in the ICU and heard by others. The study by Entzeridou et al. reported that the majority of participants agreed that they would be concerned about the likelihood of non-authorised third party access to their personal health information (48.8%) and that they would

worry about potential future discrimination, which may arise from disclosure of their health information (48.8%).[40] Reports from the literature indicate that nurses rank first among the primary care personnel in hospitals in terms of sharing information inappropriately with others. Reasons given are that nurses have different educational levels, stressors, and uncertainty about their roles and responsibilities.[41] However, the principles of 'Autonomy, Privacy and Secrecy' are among the ethical codes by which nurses must abide. Within the context of these principles, nurses are expected to evaluate the patient's information in accordance with the principles of 'do no harm' and 'usefulness'.[8]

The nurses in our study stated that the violations against the patient occurred in the form of not using curtains or an apron. Similar to the reasons indicated by the nurses, the patients stated that their privacy was violated because the curtains separating the patient beds were not closed and third parties were present in the environment due to high back-and-forth activity into the ICU. Indeed, some studies have reported that visiting practices could tire the patient, consume time and energy of staff, interfere with care and medical treatment by causing confusion, violate the privacy of other patients, increase the patients' physiological stress, and lead to security problems.[42-44] In the study on privacy, conducted by Ross et al. a patient stated: 'There are things you really shouldn't hear. There was a fellow patient that was told he only had a few weeks left. The curtains are not exactly soundproof.'[9] The nurses in this study reported that they considered the protection of patient privacy to be unimportant among employees. Or if there were only healthcare professionals in the unit, patient privacy was not a priority. Nurses also stated they did not take precautions to protect the privacy of unconscious patients. Patients stated that violations occurred since privacy was considered unimportant by nurses and unconscious patients were treated differently. It should be noted that when a person is hospitalised, this is often a very sudden change in their life. Fear and anxiety and changes in the patient's physical environment in the ICU may contribute to their lack of preparedness to protect their own privacy. Areas affected could be in communication and decision-making.[45] Therefore, nurses working in ICUs should make efforts to notice the intimate, sensitive and vulnerable aspects of the patients and should act to plan all patient care with a holistic approach, including when caring for unconscious patients.

In our study, some nurses could not take adequate measures to protect patient privacy because of the insufficient numbers of nurses, an exceedingly large number of patients, inadequate control of the main door access to ICU, and the availability of only relatively small units rather than optimum-sized ones for the provision of care. In a study conducted with healthcare professionals, 59.2% stated that 'the patients' right to privacy was not as important as the treatment of their disease.' and 83.2% stated that 'adequate care could not be given to the patient due to the high number of patients per nurse'.[46] Although the consequences of demanding and irregular working conditions lead to a decrease in work efficiency and a negative effect on nursing care, patients were reluctant to report privacy violations because they believed this could negatively impact their treatment and care. The study of Valizadeh and Ghasemi[47] showed that reported consequences of privacy violations for patients were nervousness (34.2%), annoyance (32.6%), discouragement (7.1%), disappointment (8.5%), insecurity (3.5%), sense of uncontrollability (2.7%), feeling of disability and futility (2.4%), and feeling guilty (3.6%). Another study reported that the patients remained silent due to 'fear of getting an angry response from health professionals' (55.7%), and 'worrying that the service they received would be negatively affected' (20%), respectively.[48]

CONCLUSION

Results of this study have revealed that patients and nurses had information and awareness about privacy, the protection of privacy, and the violations of privacy, and participants believed that the protection and the violation of privacy was a unique condition for the patient but a condition experienced more than once for nursing professionals. However, despite challenges in protecting the patient's privacy, nurses spend their best efforts to take stringent precautions for the protection of patient privacy, originating from their concern and empathy for patients. Considering such challenges, it can be suggested that patient privacy should be addressed further in nursing education and training. Furthermore, financial investments would be needed, and structural improvements should be implemented in critical patient units along with the recruitment of a nurse workforce of appropriate size. Given that privacy is a patient right and an ethical commitment of the professional, Kim et al. reported that nurses' awareness of privacy and confidential information exceeds the size of actual behaviors performed.[49]

We believe that the results of this study will advance the implementation of interventions to protect patient privacy in ICUs and will increase sensitivity in this regard. Based on the results of this study, we suggest that service trainings on the topic of patient privacy should be held on a regular basis and hospital administrations should put policies in place to ensure the protection of patient privacy in ICUs.

Limitations of the Study: The study has some limitations. The results are not generalisable because the study was conducted with a small sample in one centre using only a qualitative method. Patients may not have expressed their thoughts adequately because of the concerns that their care and treatment processes might be affected unfavorably. Conducting the patient interviews in the clinic before they were discharged from the hospital may have resulted in

such concerns. Because the patients were transferred from a complex and critical care unit to the clinic, they may have had some cognitive and emotional incapacity interfering with their willingness to express themselves appropriately. Participants might have felt some pressure to complete the interviews quickly so as not to interfere with the regular schedules and tasks in the hospital environment. Nurses may have had difficulties in expressing their feelings freely about patient privacy to avoid blaming the personnel.

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REVIEWS AND DISCUSSION PAPERS

Effectiveness of early mobilisation versus laxative use in reducing opioid induced constipation in post-operative orthopaedic patients: an integrative review

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ABSTRACT

Objective: To explore which nursing intervention: early mobilisation versus laxative use, is more effective in reducing constipation in post-operative orthopaedic patients who require strong analgesia.

Background: The use of opioids to manage pain in orthopaedic patients causes post-operative constipation. Nursing interventions used to relieve constipation in patients post-operatively include encouraging patients to eat a high fibre diet, to increase their hydration, to mobilise and to use laxatives. However, varying results have been demonstrated on the effects of early mobilisation and laxative use, specifically in managing opioid-induced constipation.

Study design and methods: An integrative literature review was used to identify articles from online databases between January 2000 and June 2020. Grey literature was also utilised. Data were quality appraised, extracted, and thematic analysis was used to synthesise the results.

Results: The use of laxatives was effective in some studies, while some studies found laxatives to be either ineffective or partially effective. Most of the studies and grey literature recommended early mobilisation, however not in isolation, but in conjunction with other interventions including increased fibre, fluid intake and laxative use.

Discussion: Although the benefits of early mobilisation have been identified, it is not advocated for independently and is usually advocated for in conjunction with other interventions such as a diet high in fibre, increased water intake along with laxative use. Laxatives used as the first line of constipation treatment are not always effective. Multiple doses are often required as they may not deal with the underlying cause of opioid-induced constipation.

Conclusion: This study determined there is no clear evidence to support a singular course of action; early mobilisation or laxative use. Each intervention potentially contributes to preventing constipation therefore both interventions should be utilised concurrently.

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Implications for research, policy, and practice: Post-operative constipation is an ongoing problem in this subset of patients. However, there is always a need for reviewing current practices and re-educating and reminding patients and staff of the benefits of a multipronged approach. Practices recommended include discouraging bedpans, following protocols, documentation and having an open dialogue with patients. Further research is needed to examine the effectiveness of early mobilisation only in relieving constipation in post-operative orthopaedic patients and orthopaedic patients in general who require strong analgesia.

What is already known about the topic?
- The continuous use of opioids to manage pain post-operatively in orthopaedic patients results in opioid-induced constipation.
- The advice given currently advocates a mix of pharmacological and non-pharmacological interventions to relieve constipation.

What this paper adds:
- There is no evidence that either early mobilisation or laxatives are effective in preventing post-operative constipation.
- Both interventions should be utilised concurrently.
- Research addressing whether early mobilisation only can relieve constipation is needed.

Keywords: Exercise; mobility: opioid-induced constipation; bowel management protocols; patient education; orthopaedic; post-operative.

INTRODUCTION

Nurses have a major role in ensuring patient wellbeing through optimal post-operative recovery and ensuring that iatrogenic problems are minimised or avoided. Opioids are a potent form of analgesia used to relieve acute pain and are the most common analgesic in perioperative pain management.[1-6] Efficient post-operative pain control is essential for decreasing stress related to surgery and facilitating the full recovery of physical function.[7,8] Pain control is also important in preventing the development of chronic pain, a decreased quality of life and morbidity.[9-12] Pain management also reduces costs by promoting early discharge from hospital.[7,11] However, some common side effects reported by patients receiving opioids are gastrointestinal dysfunction such as nausea and vomiting, ileus formation and constipation.[1,13-15] Constipation is also associated with an increased cost of care and use of hospital resources. It can result in severe health consequences such as reflux, rectal pain and burning, nausea and vomiting, haemorrhoid formation, bowel obstruction and rupture.[16-21]

Constipation, in general, is a widely recognised gastrointestinal disorder that affects a patient's wellbeing, quality of life and activities of daily living.[22,23] The standard Rome III criteria defines constipation as needing to meet one of five distinct criteria: the passage of fewer than three stools per week; a feeling of inadequate evacuation or anorectal obstruction; straining during defecation; the need for manual techniques to promote defecation; or the passage of hard or lumpy stool.[24] There is no generally accepted definition of opioid-induced constipation (OIC). However, most definitions consider a recent history of opioid use, together with symptoms of constipation described by the Rome III criteria.[2,24-26] Opioid-induced constipation occurs when opioid agonists bind to the mu receptors in the enteric nervous system.[20,27,28] This, in turn, results in stimulation of fluid absorption, inhibition of water and electrolyte excretion and increased non-propulsive contractions, which cause delayed gastrointestinal transit and hard, sparse stools.[15,20,27-29] An increased occurrence of OIC is linked to increased opioid prescription, and as little as one dose of opioid can cause acute OIC in patients.[2,14,15,30] It is estimated that between 2-28% of the population experience constipation.[31-34] However, constipation occurs in 40% – 60% of post-operative orthopaedic patients.[35-38] Of patients who take opioids, between 40% to 95% will develop OIC.[1] Even with the use of laxatives, 40-64% of patients using opioids for noncancer pain will still experience OIC.[39] Due to the high prevalence of constipation, health professionals need to take appropriate measures to manage constipation or prevent it from happening in post-operative orthopaedic patients.

Early mobilisation after surgery has been shown to reduce the incidence of post-operative complications such as constipation and decrease health issues related to quality of life.[40,41] Studies have demonstrated that physical exercise in the form of walking, resistance exercises and running can speed bowel transit time.[42-45] Pharmacological (the use of laxatives) and non-pharmacological (encouraging early mobilisation, encouraging patients to increase their fibre and fluid intake) are nursing interventions that have been recommended for preventing or reducing constipation in patients post-operatively.[1,28,46] A combination of these interventions is most commonly used to treat OIC.[47-52]

There is evidence that each of these interventions in isolation is effective in reducing constipation.[40,53-55] However, varying results have been obtained from studies which examined the effects of early mobilisation and laxative use in the management of opioid-induced constipation.[56-58] Some studies have indicated a positive effect of both interventions

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on preventing or managing constipation,[1,2,37,40,41,43,44,54,59-63] while other studies have highlighted these interventions to have little or no effect in preventing or managing constipation.[64-72] It, however, appears that early mobilisation is not emphasised as much as the use of laxatives to relieve constipation.[73-75] With OIC being so prevalent in post-operative orthopaedic patients, it is imperative to understand what interventions are most effective.

METHOD

AIM

This review aimed to undertake an integrative approach to examine which nursing intervention (early mobilisation versus laxative use) is more effective in reducing constipation in post-operative orthopaedic patients who require strong analgesia.

METHODOLOGY AND REVIEW PROTOCOL

The available studies that met the inclusion and exclusion criteria exploring early mobilisation and the effects of laxatives on constipation consisted of quantitative and qualitative research. The quantitative studies were few; therefore, an integrative review approach was used to analysis the literature on the effects of the two interventions. An integrative literature review is a non-experimental method whereby researchers systematically analyse, summarise and draw conclusions about a topic through the examination, categorisation and thematic analysis of quantitative and qualitative research studies on the topic.[76-78] This methodology was used to explore a broad range of literature (observational studies, clinical experts, randomised controlled trials, qualitative research and any other form of relevant evidence) in the study area.[78,79] Online databases relevant to nursing and healthcare were searched. These included CINAHL, Cochrane, Scopus, PubMed, Medline and Google Scholar.

The search was restricted to studies published from January 2000 till June 2020.To enhance the search, alternate spellings, synonyms and related words were identified and truncation was used to allow for different word variations. Search terms of each group were combined using the Boolean operator 'OR' and 'AND' as appropriate.

Group one: Early mobilisation, exercise, movement, physical activity, physical exercise, mobilisation, walking.

Group two: Constipation, bowel movement, bowel motility, bowel transit time, gastrointestinal transit, colon contraction, frequency of defecation, stool frequency, opioid-induced constipation.

Group three: Laxatives, use of laxatives, laxative use.

Group four: Analgesia, strong analgesia, analgesics, pain relief, pain relievers, pain killers, opioids.

From the library search, few articles were identified that used laxative use and mobility in this population. Therefore, a manual search of each article's reference list was performed and the 'cited by' feature was also used to find more articles. This yielded articles that were related to this study. Both interventions (early mobilisation and laxative use) were utilised in the included studies. However, limited studies examined the combined effect of early mobilisation and laxatives in reducing constipation in post-operative orthopaedic patients. Grey literature and a book chapter were also used to explore expert opinion and evidence-based practice recommendations for these two interventions.

Titles, aims and abstracts were screened according to the inclusion and exclusion criteria (Table 1) to determine the relevance of studies for the review. The full text was downloaded and reviewed for clarification in instances where the title and abstract did not provide enough information. Articles were limited to peer-reviewed academic journals published in English or with an English version available in full text. Grey literature was added if it also met the inclusion criteria.

TABLE 1: INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria	Exclusion criteria
• Quantitative, qualitative and mixed methods • Grey literature • Use of exercise or early mobilisation and laxatives in preventing or reducing constipation • Post-operative orthopaedic patients • Use of strong analgesia (opioids) • Age ≥ 18	• Known gastrointestinal disorder, bowel issues or diseases that can decrease bowel movement • Other forms of surgery other than orthopaedic surgery • Use of opioids without undergoing orthopaedic surgery • No use of opioids post-orthopaedic surgery • Studies not written in English language • Studies with subjects not related to the keywords • Age ≤ 18

PRISMA (PREFERRED REPORTING ITEMS FOR SYSTEMATIC REVIEWS AND META-ANALYSES) SCREENING

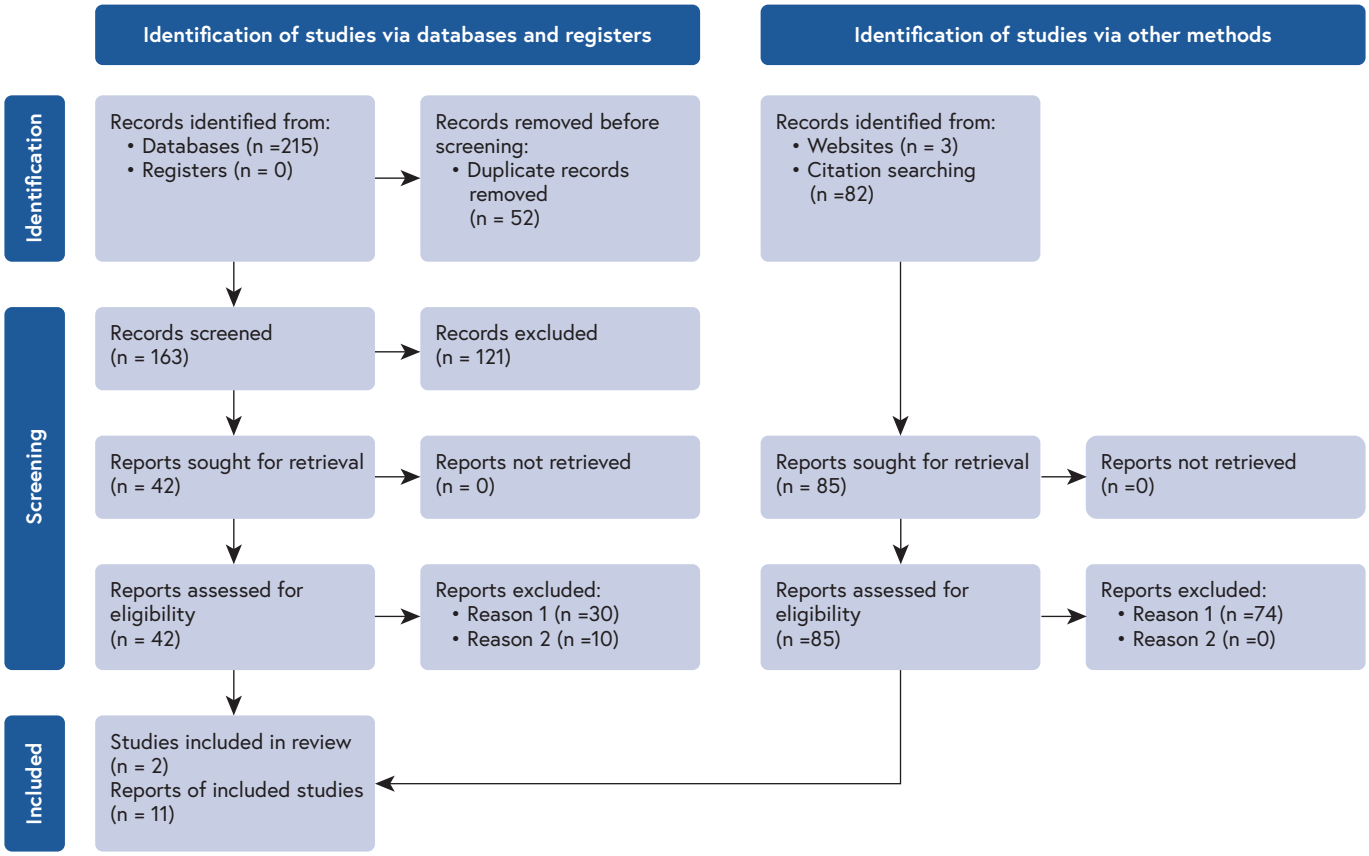
Across all six databases, the initial literature search using the keywords identified 215 potential articles located in CINAHL (= 81), Cochrane (= 14), Scopus (= 38), PubMed (= 0), Medline (= 1) and Google Scholar (=81). From manual searching and cross-referencing 82 articles and 3 grey materials were included. Duplicates were removed, which left 248 articles. The titles and abstracts of these articles were screened using the keywords, and 121 articles were excluded. The full text of 127 articles was assessed for eligibility with 114 articles excluded after the inclusion and exclusion criteria were applied. Finally, 13 studies were included in this review as illustrated in the PRISMA framework (summarised in Fig. 1). These articles met the inclusion and exclusion requirements for the selection outlined above.

QUALITY APPRAISAL

Eight articles were evaluated for methodological quality using the mixed methods appraisal tool (MMAT) version 2018.[80] One of the articles was evaluated using Joanna Briggs Institute (JBI) critical appraisal checklist for systematic reviews and research syntheses and the JBI opinion and text-critical appraisal tool was used for grey literature.[81] Each article was independently appraised by two reviewers. Observed discrepancies were discussed until an agreement was reached between both reviewers. A summary of the appraisal tool showed that of the articles all met more than 85% of the MMAT criteria (Table 2) therefore was deemed suitable. Of the grey literature 83% of the quality appraisal requirements were met (Table 3). The book chapter did not go through critical appraisal because it was from a peer-reviewed book and was deemed suitable.

DATA EXTRACTION AND DATA ANALYSIS

The studies included utilised different research designs, methodologies, interventions and outcome measures. Thus, relevant data from each study was extracted using a data collection tool consisting of study title and citation, methodology, study purpose, results, conclusion/recommendation/clinical implications and study limitations. Following the data analysis stages (data reduction, data display, data comparison, drawing of conclusion and verification) described by Whittemore and Knafl,[78] thematic analysis was performed on the data sample. An integrative review is a secondary research; therefore, ethical approval was not needed for this research.[82]



Key:
Reason 1: Does not meet the inclusion criteria
Reason 2: Written in other languages

*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).
**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reportng systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/

FIGURE 1: PRISMA FLOW CHART

TABLE 2. SUMMARY OF ARTICLES AND MMAT ANALYSIS

Study	Title	Method	Sample	MMAT out of 7	Main findings
Madsen, Magor[53]	Comparison of two bowel treatments to prevent constipation in post-surgical orthopaedic patients	Single-blind, parallel, randomised Participants were randomised into 2 groups (standard treatment and Movicol bowel treatment)	31 Orthopaedic patients undergoing hip and knee replacement surgery	7	Post-operatively, the Movicol bowel treatment group had a bowel movement earlier than the standard treatment group. There was no significant difference in gastrointestinal symptoms in both groups There was no increase in the length of hospital stay due to constipation in both groups. Thus, it is reasonable to retain the standard treatment (commercially available laxative products). However, Movicol is cheaper, causes a faster bowel movement and is ultimately less invasive.
Ross-Adjie, Monterosso[36]	Bowel management post major joint arthroplasty: results from a randomised controlled trial	Multisite cluster randomised trial in private secondary and tertiary hospitals Participants were randomised into control (routine bowel management) and intervention (bowel management as per Murdoch protocol) group and were examined over 13 months.	331 patients (who require total hip and total knee replacement) from 7 hospitals	6	The intervention group took six days less than the control group to return to normal bowel function and were more than seven times more likely to return to normal bowel function by day five post-operatively. The administration of the Murdoch bowel protocol results in a clinically and statistically significant reduction in time taken to return to normal bowel function in post-operative total hip and total knee replacement patients.
Neighbour[83]	Improving bowel care after surgery for hip fracture	3 audits were conducted in 2010, 2011 and 2013 to evaluate bowel care for older people after hip fracture.	Cohort of 40 people aged 60 and older after surgical fixation of hip fracture	6	The initial audit showed none of the patients had a stool-type chart and recorded information was not acted on. The 3rd audit showed all patients had a record of stool type. 75% of the participants skipped doses of laxatives. Nursing staff had an improved awareness of patient bowel habits with each successive audit. By the 3rd audit, patients with hip fracture were significantly less constipated and patient experience improved greatly. Maintenance of stool chart, reviewing opioid analgesia and taking action based on results from the stool chart is important.
Sendir, Büyükyilmaz[57]	Post-operative constipation risk assessment in Turkish orthopaedic patients	Descriptive correlational study Data was collected using a patient information form and constipation risk assessment scale (CRAS) on the 2nd post-operative day	83 patients hospitalised in the orthopaedic ward	7	Gender, mobility, pharmacological agents, increased age and low educational levels showed patients were of high risk for constipation. Orthopaedic patients are at moderate risk of constipation post-operatively. Nurses should be attuned to routinely assessing the post-operative risk of orthopaedic patients as well as other similar patient populations to implement safe and effective interventions.
Yue, Liu[84]	Randomised controlled trial of a comprehensive protocol for preventing constipation following total hip arthroplasty (THA)	Prospective Randomised controlled trial Participants were randomised to receive either preoperative education about lifestyle only or the combination of education with post-operative abdominal massage and polyethylene glycol 4000 (Forlax): a form of laxative	80 total hip arthroplasty patients	7	Patients who received combination treatment showed a significantly lower rate of post-operative constipation (25%) than those who received only post-operative education (55%). They also showed a significantly lower rate of enema rescue (12.5% vs 40%). 62.5% of the combination group had their 1st defecation within 2 post-operative days as opposed to the other group at 35.9%. The 2 groups were similar in terms of constipation rate, on post-operative days 15 and 30, rate of post-operative adverse events and rate of readmission within 30 days. The combination treatment (education with post-operative abdominal massage and polyethylene glycol 4000) can relieve constipation after THA, reduce the need for enema rescue and shorten time to the first defecation without sacrificing safety. Nurses play a very important role in this protocol, especially in preoperative education and post-operative abdominal massage

TABLE 2. SUMMARY OF ARTICLES AND MMAT ANALYSIS (CONTINUED)

Study	Title	Method	Sample	MMAT out of 7	Main findings
Marciniak, Toledo[58]	Lubiprostone vs Senna in post-operative orthopaedic surgery patients with opioid-induced constipation: A double-blind, active-comparator trial	Double-blind, randomised, active comparator trial Participants were randomised into 2 groups; Lubriprostone and Senna groups.	64 adults who were admitted in inpatient rehabilitation and required opioids for analgesia after orthopaedic procedures	7	There was no significant difference in both groups in mean change from baseline to Day 7 assessment of patient assessment of constipation. Participants in both groups demonstrated improvement in symptoms of constipation and quality of life. Multiple laxative medications may be required for constipation symptoms control in this setting as participants in both groups frequently required rescue medication. It is not known if the physical activity performed by the participants as part of their rehabilitation could have influenced the improvement in constipation symptoms.
Stienen, Smoll[85]	Constipation after thoracolumbar fusion surgery	A retrospective collection of data Participants were group into two groups: constipation and non-constipation group	99 patients undergoing thoraco-lumbar fusion surgery for degenerative lumbar spine disease with instability	7	44% of participants showed constipation post-surgery and had longer surgical procedures with higher estimated blood loss. Morphine given during surgery was more in the group with constipation but was statistically insignificant. Laxative use was relatively high in both groups but more frequent in the constipation group. The rate of constipation is high after thoracolumbar surgery and is related to longer surgery time, higher intraoperative blood loss, and higher morphine doses during the post-operative period. Although laxatives were frequently administered but seemed little helpful to prevent constipation. Minimal invasive spinal surgeries were suggested which could reduce the rate of constipation as surgery time is reduced, amount and duration of administration of morphine are reduced and there is faster mobilisation which is assumed to have a positive effect on the restoration of normal bowel function.
Davies, Green[86]	The use of opioids and laxatives, and incidence of constipation, in patients requiring neck-of-femur (NOF) surgery: a pilot study	Pilot study	46 patients who required emergency surgery for fracture NOF over 8 weeks in 2007 were included	7	All patients received opioid analgesia and constipation occurred in 71.7% of the patients. Prophylactic laxatives were prescribed for 20 patients and 12 of them developed constipation. Of the 26 patients who did not receive prophylaxis, 21 developed constipation. The study demonstrates age and nutritional status are significant factors influencing the occurrence of constipation, though the prophylactic use of laxatives did not alleviate the incidence of constipation. Prescribing of opioids should also be for a short period and at the lowest effective dose. Reducing opioid use can help to prevent constipation.

TABLE 3. SUMMARY OF ARTICLES AND JBI ANALYSIS

Study	Title	Method	Sample	JBI out of 6	Main findings
Sonneborn and Bui[56]	Opioid-induced constipation management in orthopaedic and trauma patients: treatment and the potential of nurse-initiated management	The review examined OIC, management with laxatives and the potential role of nurses in improving the management of OIC	55 articles were reviewed of which 39 articles were cited in the paper Review	6	Orthopaedic and trauma patients are at high risk of developing OIC due to reduced mobility and increased opioid use to manage pain. Clinicians need to balance adequate analgesia and minimise OIC symptoms. OIC can reduce the quality of life of patients and generate a greater demand on healthcare utilisation. The use of laxatives can mitigate symptoms. Nurses can undertake an active role in the management towards reducing the likelihood of the onset of OIC.
McDermott and Sullivan[91]	Managing constipation after surgery	N/A	N/A	5	This is a review by a professional RN with a Phd. Healthline aims to cover all facets of physical and mental health openly and objectively. This section defines constipation, states that narcotics such as opioids result in constipation in the orthopaedic population. This happens in 40% of the post-operative population. Walk around as soon as possible after surgery to help to heal, prevent DVT and constipation. Plan to take a stool softener docusate or fibre laxative Metamucil after surgery.
Elliot[90]	Post-Surgery: Maximising success	N/A	N/A	5	Orthopaedic surgeon gives open access advice on post-management orthopaedic care. Constipation after orthopaedic surgery can be severe. Constipation is due to: strong opioid pain medication; therefore, it is advised to take regular laxatives from the first evening post-surgery (generally Coloxyl and senna, two tabs morning and night) Early mobilisation – bowels respond to movement. Eat fruit and vegetables especially kiwi fruit and prunes. Plenty of oral fluids- A microlax enema is recommended if no bowel movement after three days.
Frisch[92]	Opioid-induced constipation management in orthopaedic and trauma patients	N/A	N/A	5	PeerWell gives management advice to those who have chronic musculoskeletal health issues. An orthopaedic surgeon defines constipation and states orthopaedic patients on pain medications have a 40% increased risk of constipation when combined with lack of exercise. Advice: encourage fibre, prunes, get moving as soon as possible and take laxatives.

RESULTS

The goal of this review was to explore the effectiveness of mobilisation verses the effectiveness of laxatives. These were further broken into the source of information (article, book chapter and grey literature) they were retrieved from so triangulation between the three sources could ultimately be compared.

EFFECTIVENESS OF MOBILISATION

Of the articles, most of the studies (67%) promoted the effectiveness of mobilisation in relation to constipation.[36,57,58,86-88] Three studies emphasised that reliance on bedpans and lack of physical movement post-operatively were barriers to mobilisation, resulting in constipation.[57,86,87]

Two studies (22%) found a combination of pharmacological and non-pharmacological interventions were beneficial. Ross-Adjie, Monterosso noted that less constipation was reported after discharge when mobility was included daily as part of the Murdoch bowel protocol.[36] In agreeance, Yue, Liu inferred that constipation can be alleviated with non-pharmacological treatments, yet found that pharmacological treatments still tend to provide the most successful prevention of constipation.[88] One study (11%) by Marciniak, Toledo was inconclusive as it found constipation symptoms were improved in participants, but it was not clear if this was a result of the physical activity participants were involved in as part of their rehabilitation process (Table 2).[58]

Copanitsanou dissuades the use of bedpans and advocates that a daily toilet routine (e.g., every 2 hours) that promotes walking helps to mitigate constipation.[89] Remobilisation should begin immediately after surgery, once the patient is clinically stable. Copanitsanou also emphasised the importance of providing convenient access to toilets, reducing fasting times and promoting exercise/mobility by encouraging patients to sit at the edge of their beds and be engaged regularly in their everyday activities.[89]

Of the grey literature,[90-92] all sources emphasised the importance of early mobilisation after surgery, arguing that bowels respond to movement and early mobilisation and in turn will prevent post-operative constipation. Frisch described movement as a lotion to the bowel and encouraged post-operative orthopaedic patients to move within their pain comfort level.[92] It is important to increase movement any form of exercise, walking and taking the stairs all help in order to get regular bowel motions.[91,92]

EFFECTIVENESS OF LAXATIVES

From this review, it was found that the overall effectiveness of laxatives was mixed. From the articles, three studies (33%) were in favour of laxative use. Sendir, Büyükyilmaz found that laxatives safely preserve healthy bowel patterns when correctly used.[57] Laxatives such as Coloxyl and Senna and Movicol were most effective in relieving constipation, while Movicol recorded the fastest transit time for a bowel movement.[53] Marciniak, Toledo observed an improvement in bowel associated symptoms with the use of Senna and Lubiprostone they stated that the efficacy of laxatives in managing OIC is only 50%.[58]

Two studies (22%) advocated for a combination therapy approach with techniques such as post-operative massage, preoperative education and polyethylene glycol, and of the Murdoch bowel protocol (which included the use of Movicol and mobility) to be significant in preventing and relieving constipation.[36,88]

Although the above-mentioned studies found laxatives effective in relieving constipation symptoms when used alone or in combination with other interventions. The majority of studies (44%) had contrary results concluding that prophylactic use of laxatives does not reduce the incidence of constipation and that the true benefit of laxative administration for post-operative constipation was not remarkable.[85-86] The conclusion being that constipation as a result of OIC can be treated with laxatives, but symptoms will persist with continued opioid use, because opioids are the root cause of OIC.[56] Although laxatives were administered regularly to patients, it did not appear to relieve constipation because post-operative orthopaedic patients required multiple types of laxatives in multiple doses to manage constipation.[58,85,86] Sonneborn and Bui mentioned that inadequate evidence exists to direct health professionals on the most efficient laxative routine for the management of OIC.[56] Balancing sufficient analgesia and reducing OIC symptoms is a difficult challenge for clinicians.[56]

A solution would be that opioids and laxatives are taken together while opioids should be prescribed at the lowest effective dose for a short period and their use should be reviewed frequently to prevent constipation.[56,58,86,87] Diarrhoea is a common adverse effect of laxative use which should not be ignored.[86] Other adverse effects of opioid and laxative use were increased gastrointestinal symptoms such as abdominal bloating, nausea, discomfort and flatulence and these were reported more in the Movicol group even though it was not significant.[53]

Copanitsanou in an expert opinion piece concurred with the research findings presented in the empirical research articles and stated that the effectiveness of various laxatives does not vary greatly, and overuse of laxatives is a problem that should not be ignored.[89] Treatment with laxatives should usually be tailored to individual needs.[89] The grey literature encouraged the use of laxatives in post-operative orthopaedic patients and stated that laxatives such as Coloxyl and Senna; fibre laxatives like Psyllium; and stool softeners (Docusate) can help to alleviate constipation, while in cases of extreme constipation, suppositories, stimulant laxatives or enemas may be needed to induce bowel movements.[90-92] The Grey literature highlighted that laxatives should be taken from the first post-operative evening as it is better to have diarrhoea than to be constipated and the use of opioids should also be minimised.[90,91] The book chapter and grey literature mentioned diarrhoea as a common side-effect that the use of too many laxatives can induce.

Finally, this review separated the three forms of literature retrieved for triangulation and found that the grey literature and book chapter offer advice in favour of both treatment approaches and early mobilisation is liberally encouraged. Most of the articles promoted mobilisation; however, the exact benefit of this intervention was unsubstantiated from the articles reviewed.

DISCUSSION

This integrative review set out to explore which intervention, early mobilisation or laxative use is more effective in reducing constipation in post-operative orthopaedic patients who require strong analgesia. The review identified that although early mobility was encouraged in all the selected studies, grey literature and the book chapter, scant evidence exists as to the specific impact mobility provides as an isolated intervention for relieving constipation in this population. Rather, the merits of exercise are mentioned, in the prevention of all post-operative complications not only in preventing constipation.[43,44,54,59-62] Mobilisation is generally encouraged in conjunction with other interventions but is not solely advocated.[49,51,52] Only two studies stated that mobilisation possibly contributed to the participant's outcome.[36,86] Other studies could not distinguish if mobility was more important than laxatives.[53,56-58,85,87,88]

The significance that constipation in post-operative orthopaedic patients can be relieved with the use of early mobilisation was apparent in this review and correlates with the findings of other studies.[40,41] With the recommendation that patients with constipation need to increase their level of activity because aerobic exercise is necessary for constipation

management.[93-95] In contrast, immobility and bedrest cause constipation, thus emphasising the importance of discouraging bedrest and encouraging mobilisation as soon as possible.[96] This review found that the form of mobilisation is important because patients who had mobility issues and those who were mobilised in bed with the assistance of a device and a nurse were more prone to constipation.[57,86] It is important to mobilise patients out of bed, and the process of early mobilisation should progress to sitting out of bed, standing, walking and carrying out activities of daily living.[40,97,98] This literature review also identified that reduced mobility, encouraging bedrest and the use of bedpans increase the risk of constipation in post-operative orthopaedic patients.[57,86,87]

Mobility as an intervention is prevalent in the grey literature and book chapter, so this education is continually a message that is encouraged, even though the exact impact this advice has, is unknown. Mobility post-operatively is important advice; however, it is perhaps less effective when opioids are involved. It appears that early mobilisation is not emphasised as much as the use of laxatives to relieve constipation.[73-75] Rather, it is encouraged in conjunction with other modalities and interventions.

Laxatives were also explored in this review as to their effectiveness in relieving constipation in orthopaedic patients on opioids. The peer-reviewed articles in this review recorded contrasting results.[36,53,56-58,85,86,88] It was found that multiple doses of laxatives are required for constipation to be effectively managed in post-operative orthopaedic patients, which suggests that laxatives may not be as effective in managing constipation post-operatively in orthopaedic patients.[56,58,85,86] This concurs with literature that found the efficacy of laxatives in the management of OIC has been observed to be limited.[1,2,15,71] Evidence indicates that the problem of opioid induced constipation does not resolve over time.[56] This is possibly because laxatives have a nonspecific action and do not address the root cause of OIC.[1,56,72] Different forms of laxatives such as stool softeners, stimulants and bulk laxatives with varying modes of action exist. This is probably why multiple laxatives are required in post-operative orthopaedic patients to manage constipation.[1,2,37,58,63,86] However, insufficient evidence exists on the most efficient laxative routine for the management of OIC management.[56] Providing medication that addresses the root cause of OIC could be a more effective way of dealing with this problem. Examples of medications that deal with the root cause of OIC include methylnaltrexone bromide and oxycodone or naloxone, which are formulations containing opioid antagonists that act by blocking the effect of opioids on the gut.[1] However, some authors have found enemas, stimulants, or stool softeners to be effective.[1,2,37,63] Thus, it is recommended to use laxatives simultaneously with opioids, and when it is not effective in relieving OIC, medications like methylnaltrexone bromide and oxycodone or naloxone can be introduced.[1]

Some researchers recommend a combination approach. For example, Stienen, Smoll emphasised the need for a standardised protocol for pre-and post-operative administration of laxatives.[85] Bowel management protocols that clearly outline the sequence of administration of laxatives (for example Murdoch and Movicol protocol) have been shown in this review to be effective in the management of constipation. However, for the desired effect to be achieved, nurses need to adhere to the protocol as lack of adherence leads to constipation and the need for enemas.[53] Although the Murdoch bowel protocol utilised by Ross-Adjie, Monterosso had efficacy in this population it does include a combination of daily mobilisation, use of laxatives, increased intake of dietary fibre and fluid and adjustment of opioid doses as needed.[36] Ross-Adjie, Monterosso's study had limitations such as differences in the usual bowel regimen received by the control group and lack of clear definition of the usual bowel regimen.[36] These factors could have affected the overall results. Russell, Barnhart also found bowel management protocols were effective in managing constipation,[99] although the overuse of laxatives should not be ignored.[89] With the use of multiple doses of laxatives, patients are more prone to the adverse effects of laxatives, which probably causes them to decline the use of laxatives.[100] The use of laxatives causes diarrhoea, nausea, abdominal pain, vomiting, sudden urge to defecate, bloating/fullness, and gas which negatively impact the quality of life of patients.[72,100-103]

This review highlighted many factors besides opioids and the use of bedpans that need to be considered when identifying those at risk for post-operative constipation. For example, it is important to identify risk factors such as age (older) and gender (female) and presenting conditions such as diabetes mellitus.[57,86,88] Nutritional status or altered diet was a risk factor and in an inadequate fluid and fibre intake, such as those who experience preoperative fasting or the eating of hospital meals that are not based on individual requirements.[36,53,57,86,88,90,91] Consideration is needed of psychological issues such as reduced privacy, a change of environment, and extended hospitalisation, which can also contribute to constipation.[36,87,89] Not only is awareness needed, but nurses need to record and routinely monitor the status of their patients in relation to their bowel movements. Documentation is required so that bowel movements can be easily evaluated as to the effectiveness of the treatment given. Validated outcomes measures that can be used in assessing the effectiveness of the treatment given to treat OIC include a bowel function diary, bowel function index (BFI), Bristol Stool Form Scale (BSFS), and Patient Assessment of Constipation Quality of Life (PAC-QOL).[25,104-106] It is also important for nurses to regularly ask patients about their bowel movements and be actively interested in identifying a response to treatment.

All the sources used in this integrative review noted the importance of educating patients both pre-and post-surgery on the need for early mobilisation after surgery. Nurses need to be firm in encouraging patients to mobilise and get out of bed because of the poor health outcomes that have been related to immobility, including constipation. Nurses ideally educate patients on the importance of exercise and mobilisation, recovery and long-term outcomes.[8,9] Patients should also receive education about pharmacological interventions that are available.[8,7] Nurses are positioned to ensure adequate information is provided to patients to make informed decisions on the required prescribed laxatives.[8,7, 88] The patient's motivation to take laxatives is as important as the prescription of laxatives.[8,7] Sanguineti,Wild emphasised the need for nurses to encourage early mobilisation because it is associated with reduced post-operative complications and maximisation of functional levels.[107] Other interventions were also mentioned in this review in preventing and managing constipation, such as increasing fluid intake, eating food rich in fibre, and forming a normal toileting pattern, all of which correspond with other studies.[22,103,106]

LIMITATIONS

One of the major limitations of this review is the lack of literature available on the effectiveness of early mobilisation in preventing or relieving constipation in post-operative orthopaedic patients. No primary evidence on the effectiveness of early mobilisation in preventing or relieving constipation in post-operative orthopaedic patients was found, nor the exact formula of how much mobility is needed to be effective. The limited literature and evidence reveal the lack of evidence-based attention given to this issue. Differences in the definition of constipation between patients and health professionals could have also affected the results in the articles because some of the studies required self-report of constipation from patients. Patients defined constipation by focusing on stool consistency or straining during defecation, while clinicians described constipation based on the Rome III criteria.[1,24] Another limitation is that many of the studies included in this review had small sample sizes.

Further limitations may be that the search strategy may have resulted in pertinent material being excluded or missed during the search performed. Complexity exists in combining diverse methodologies, contributing to a lack of rigour, inaccuracy, and bias. However, quality appraisal was conducted all sources used in this review.

CONCLUSION

Nurses have an important role to play in the assessment and management of orthopaedic patients in relation to preventing constipation post-operatively. The current evidence gained from this review shows that both interventions should be utilised concurrently. Therefore, early mobilisation has its benefits and should be encouraged in post-operative patients; however, more research is required as to the exact amount required to promote bowel function. To relieve OIC, laxatives should be administered together with opioids, as some studies have found them effective. Constipation is a significant issue faced by post-operative orthopaedic patients, primarily when opioids are being used. Therefore, health professionals should be reminded of this ongoing problem and implement current effective measures to prevent and manage constipation in this population and can be applied to all post-operative populations that receive opioids.

SUGGESTIONS FOR FURTHER STUDIES

This integrated review has highlighted that further research is required to examine the effectiveness of early mobilisation only in relieving constipation in post-operative orthopaedic patients who require strong analgesia. Setting up a randomised controlled study comparing increased exercise and treatment as usual in this population could be beneficial. Qualitative studies that look at the attitudes and knowledge of nurses working on orthopaedic wards would also be beneficial.

CLINICAL IMPLICATIONS

The recommendations for practice drawn from this integrative review include the following three steps with associated interventions.

1. ASSESSMENT

- Evaluating the patient for risk factors.
- Baseline constipation assessment tailored to the individual, history of constipation, current hydration status, last bowel movement, the usual pattern of defecation and exercise.
- Early identification of constipation in post-operative orthopaedic patients.

2. TREATMENT

- Prescribing opioids at the lowest effective dose and daily review of medications (op ioids and laxatives) administered to patients.
- Administration of opioids and laxatives concurrently.
- Encouraging patients to get out of bed as soon as possible after surgery-no bedpans.
- Education advising early mobilisation, increase in fluid and fibre intake.
- The utilisation of bowel management protocols and adherence to the protocol.

3. EVALUATION

- Accurate documentation of bowel patterns of patients to identify patients at risk of constipation and to monitor the effectiveness of treatment provided.

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REVIEWS AND DISCUSSION PAPERS

Considerations when examining the psychometric properties of measurement instruments used in health

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ABSTRACT

Objective: To discuss and provide insights on how to critique the psychometric properties of measurement instruments used by nurses and nurse researchers.

Design and data sources: Methodological discussion paper that is based on our own experiences and research and is supported by literature.

Primary argument: Nurses routinely use a variety of measurement instruments during their everyday practice. They do so with the assumption that the instrument has been thoroughly validated and has been shown to be reliable. There is the real possibility that frontline nurses are using measurement instruments that have not been validated in their patient population or context. Critiquing the psychometric properties of measurement instruments is, however, particularly complex. Complicating matters, there are conflicting standards regarding the quality criteria needed for validating the psychometric properties of measurement instruments.

Conclusion: Nurses need to be aware of the limitations of the measurement instruments they use. Consequently, nurses need to have some understanding about the psychometric domains of measurement instruments and their associated measurement properties, as well as the quality criteria used for evaluating these measurement properties. Through discussing these aspects this paper aids frontline nurses and nurse researchers in critiquing the research literature regarding an instrument's psychometric properties. This paper equips nurses for making informed decisions when evaluating whether an instrument is suitable for use.

What is already known about the topic?
- There is the possibility that nurses are using measurement instruments that have not been validated in their patient population
- A measurement instrument's psychometric properties should be re-established when used in a different patient population or context to the index study

What this paper adds:
- This paper provides nurses and nurse researchers with the necessary information for critiquing the research literature regarding an instrument's psychometric properties
- This paper equips nurses to make informed decisions for effecting change in deciding whether an instrument is suitable for use

Key words: Measure, instrument, utility, validity, reliability, psychometric

INTRODUCTION

Measurement in research and health can be characterised as assigning a score to observations. In health, this is done in order to quantify a concept ([construct] e.g., falls or pressure injury risk) and in doing so, operationalise the construct.[1] Regardless of an instrument's purpose, however, it can be difficult for end users to quantify a measurement instrument's efficacy and in doing so, ascertain if they should use a particular instrument. This is because there are a variety of psychometric domains and associated measurement properties needing to be considered when determining the efficacy of an instrument. Complicating matters, inconsistent and ambiguous information can be found in the literature regarding the terminology and definitions surrounding the measurement properties of instruments. Inconsistent information can also be found in the literature regarding the various statistical tests and associated quality criteria used when examining these properties.[2] These inconstancies are a contemporary issue as 'every time a scale is used in a new context, or with a different group of people, it is necessary to re-establish its psychometric properties.'[3(p.161)] This is because an instrument's efficacy may be affected when used in a different patient context to the index study.[4] Instrument efficacy is an important consideration for nurse managers and clinical leaders who often implement instruments into clinical practice. There is the real possibility that frontline nurses are using measurement instruments that have not been validated in their patient population or context; which in part prompted this discussion paper.

BACKGROUND

This is the eighth paper in a series of articles surrounding methodological aspects of health research. The overarching aim of this series is to assist nurses in critiquing the research literature to support evidence-based practice. Previous papers in the series have focused on considerations for falls risk screening tool selection versus development,[5] research paradigms,[6] the research process,[7] quantitative research methods,[8] considerations when choosing a statistical method for data analysis,[9] conducting a critical review of the research literature,[10] and most recently, quality appraisal of the research literature.[11] In this paper we begin by providing some background context to psychometric properties of measurement instruments.

CLASSIFYING MEASUREMENT INSTRUMENTS USED IN HEALTH

When determining whether a measurement instrument is suitable for use, end users should first consider how the instrument is to be used, the concept to be measured and ultimately, how the instrument is classified.[12] This is because how an instrument is classified can impact on which psychometric properties should be considered and what quality appraisal guidelines should be used to assist with critically examining an instrument's measurement properties.[13-15] There are various ways to classify measurement instruments used in health. Some classification criteria include the purpose or function of the measure, scope of the measure (descriptive) and methodological (technical) aspects.[16] Having three broad categories, discriminative, predictive (diagnostic) and evaluative (assessment),[15,16] perhaps a classification system based on a measure's function is the most clinically meaningful for nurses.

LATENT VARIABLES AND CONSTRUCTS

A latent variable is a variable that cannot be directly observed such as pain. The presence of latent variables can be estimated through measuring their relationship with variables that can be observed.[17] Most constructs in research and health are made up of one or more latent variables. A primary goal of a measurement instrument used in health is to measure some underlying construct.[18] Consequently, a first step in choosing or developing a measurement instrument is understanding the construct being measured.[19] Identifying a construct's theoretical and empirical underpinnings is imperative here. This is because a construct needs to be systematically defined before it can be operationalised through the examination of measurable variables that when combined, quantify the construct.[1,17,20] For example, the construct or concept of falls risk cannot be directly observed but can be quantified by examining known patient characteristics that contribute to an increased risk for falls. In their prospective cohort study McKechnie, Fisher defined falls as an event which results in a person coming to rest inadvertently on the ground or floor or other lower level.[21] Using this definition, they collected data on observable variables (i.e., patient characteristics) at time of admission and first fall. The five resultant significant contributors to falls were then used to develop the Sydney Falls Risk Screening Tool through which the concept (construct) of falls risk is operationalised.

MEASUREMENT ERROR

Measurement error is the discrepancy between a measured value and the true or known value.[22] No instrument can be completely accurate; all instruments have some form of measurement error.[23] Measurement error can either be in the form of a systematic (constant, bias) error or random (chance) error.[23] Systematic error occurs when a measure has consistent scores but they are inaccurate.[19,20] For example, if you know your true weight is 75 kilograms but when repeatedly tested using the same instrument it is 76 kilograms, the one kilogram difference is a systematic measurement error. This can occur when an instrument is incorrectly calibrated. Random error occurs when: (i) the observer misreads or misinterprets the findings of an instrument;[20] (ii) there is a transient change in the

participant affecting the findings; or (iii) when there are instrument variations (intra-observer and inter-observer error).[23]

Classical measurement theory describes observed scores consisting of two components: a true fixed score and an unknown error variance being measurement error.[19,23] Consequently, the overarching aim of ensuring an instrument is valid and reliable is to minimise measurement error.[1] Measurement error can have an impact on a clinician's actions that were based on their interpretation of an instrument's finding which in turn, affects the instrument's clinical utility.[17]

AIM

To discuss and provide insights on how to critique the psychometric properties of measurement instruments used by nurses and nurse researchers.

DESIGN AND DATA SOURCES

Methodological discussion paper that is based on our own experiences and research and is supported by literature.

DISCUSSION

Determining whether a measurement instrument is suitable for use is not straightforward; there are several important considerations. Some include: (i) has the instrument been validated in the target population or context of intended use;[24] (ii) what is the instrument to be used for and how is it administered (i.e., screen, assessment or test); (iii) is the instrument in the public domain; (iv) how well has the concept (construct) been defined; (v) do the instrument's items reflect elements of the construct; and finally (vi) is there sufficient evidence for the instrument's psychometric properties.[1,23] Sample size of the index study and subsequent validation studies should also be considered. It has been recommended that a sample size of at least 400 subjects is required for precise estimates of reliability and validity coefficients,[25] however, this may depend on the number of items in the instrument.

PSYCHOMETRIC PROPERTIES OF MEASUREMENT INSTRUMENTS

There are three principal psychometric domains of measurement instruments needing consideration: reliability (i.e., consistency), validity (i.e., accuracy) and responsiveness (i.e., precision).[23,26] Within these three psychometric domains there are numerous measurement properties and associated statistical techniques needing consideration when examining the psychometric properties of an instrument. An instrument's interpretability and clinical utility (i.e., efficacy) are also a consideration.

The reliability and validity of an instrument are equally important.[1] By definition, however, an instrument can be deemed reliable but may not necessarily be valid and inversely, an instrument cannot be truly deemed valid unless it is reliable.[1,17,23,27] Nonetheless, validity and reliability are relative concepts; they are not all-or-nothing concepts being comprised of many measurement properties.[19,28] Figure 1 is a model that illustrates how the three principal psychometric domains of measurement instruments and their measurement properties relate, considering that an instrument used in health needs to have been shown to be reliable for it to be considered valid. In the model clinical utility is included as the outermost ring as it is an important overarching consideration when evaluating an instrument's efficacy; which is similar to the model for evaluating genetic tests in health.[29] This is because if a health-related instrument has no beneficial outcomes (such as, health, economic or clinical) the instrument's efficacy should be questioned, this is despite it being reliable and valid. Figure 2 shows the measurement properties represented in this model but as a general linear process illustrating when these measurement properties are a consideration during an instrument's development and validation.

There continues to be inconsistent and conflicting information in the literature regarding the terminology, definitions, various statistical tests and quality criteria surrounding the measurement properties of instruments. This is despite Mokkink, Terwee who used the Delphi technique to identify and define a taxonomy of measurement properties to be considered when evaluating health-related instruments.[26] For example, construct validity is described

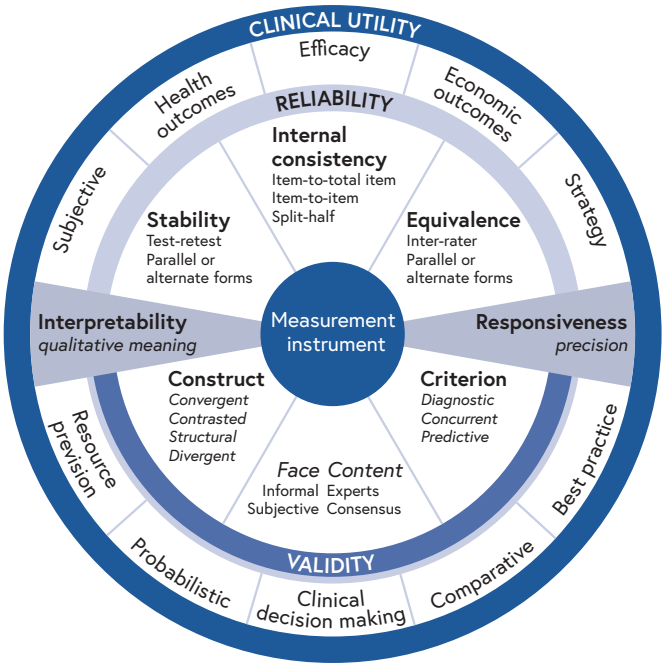

FIGURE 1: MODEL ILLUSTRATING DOMAINS OF MEASUREMENT INSTRUMENTS AND THEIR ASSOCIATED MEASUREMENT PROPERTIES

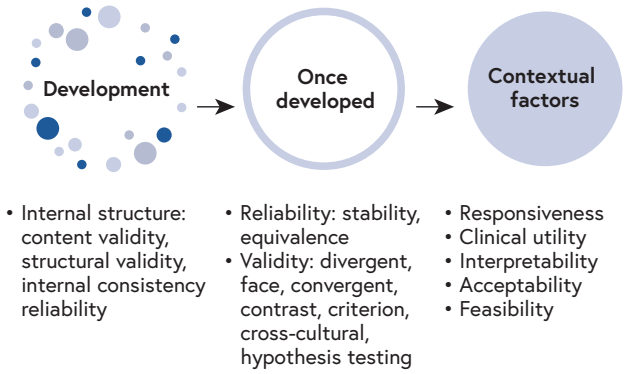

FIGURE 2: A GENERAL LINEAR PROCESS ILLUSTRATING WHEN AN INSTRUMENT'S MEASUREMENT PROPERTIES ARE A CONSIDERATION DURING AN INSTRUMENT'S DEVELOPMENT AND VALIDATION

by some authors as essential to the overall validity of any instrument and as such, overarches the other measurement properties of validity being translation (how accurately a construct has been operationalised) and criterion (the extent to which an instrument's score correlates with an external criterion) validity.[1,16,20,30] Other authors,[23,28] however, describe the measurement properties of validity as a tripartite model with construct, criterion and translation (face and content) validity being equally important. While some authors use equivalence to describe a defined measurement property of reliability,[23,31] other authors use measurement error,[26] which serves as another inconsistency. In this paper we have used the most widely referred to terminology in the research literature to describe the measurement properties of an instrument. When there is more than one term often used in the literature, we have made reference to both.

RELIABILITY

Reliability broadly refers to the consistency or stability of the measurement process across time, patients or observers (e.g., nurses).[16,31] Reliability estimates change when an instrument is administered by different users or when used in a variety of contexts or situations.[20,22] Being a function of measurement error, in classical test theory an instrument is said to be reliable when it measures the same thing twice and the same results are obtained and therefore, is free of random measurement error.[17,26] However, no measure can be perfectly reliable.[19] This is because reliability is not a unitary concept but rather an approximated concept that is determined through the evaluation of three underlying instrument properties: internal consistency, stability and equivalence.[17,28,31] The relative importance of these measurement properties, and therefore whether they are used to approximate reliability, depends on how the instrument is administered, who is to use the instrument, and in what context and patient population is it administered.[19,28] Reliability correlation coefficients are often used to approximate an instrument's reliability. In this instance, the reliability coefficient statistic indicates the extent to which the individual items of a scale are related and show the ratio between true score variance and observed score variance.[3] For instance, a reliability coefficient of 0.85 indicates that 15% of the observed variance is due to random measurement error.[16]

Internal reliability

Internal reliability is concerned with the extent to which an instrument is consistent within itself, evidenced by providing consistent results. Internal consistency or homogeneity reflects the extent to which the individual items within an instrument are interrelated and unidimensional in measuring the one domain or construct.[27,28] Unidimensionality of multidimensional scales is also a consideration.[18] For example, in an internally consistent unidimensional instrument each item equally contributes to the total score of the instrument and in the case of multidimensional scales, each subscale should measure different but related constructs.[23] Internal consistency can be measured by comparing the correlations amongst items in an instrument using techniques such as item-to-item and item-to-total item correlations, and the Split-half technique. While Cronbach's alpha is the most widely reported coefficient for internal consistency, it is known for underestimating true reliability.[32] McDonald's omega and Revelle's beta are alternatives statistical technique worth considering here.[32-34] Nonetheless, Zinbarg, Revelle advises that 'choosing among these [three] indices should be based on one's research question and considerations of dimensionality and equality of general factor loadings rather than which index is largest.'[35(p.132)] Quality criteria for Cronbach's alpha and other statistical techniques commonly used are provided in table 1.

External reliability

External reliability is concerned with measuring the extent to which an instrument varies when used at different times (stability) and by different observers (equivalence).[30]

Stability

Stability or repeatability reliability refers to the stability of a measure over time which is examined using the test-retest statistical technique.[20] The test-retest technique may not be suitable for phenomena that are likely to change over time, such as falls risk.[30] This technique examines whether a self-rated (intra-rater) or observer rated (intra-observer) measure produces constant results when used by/on the same patient under similar circumstances but taken/administered at two different points in time.[27] This measures the degree of random measurement error an instrument might have when the measure is repeated.[36] The test-retest intervals should be far enough apart to mitigate the effects of fatigue or patient learning, but close enough to avoid genuine changes in the construct being measured;[19] **two to 14 days is usually adequate.**[3,37]

Intra-class correlation coefficient (ICC) is the most commonly used indices to measure consistency of scores when continuous measures are used.[19,24,38] See table 1 for ICC criteria when examining stability. ICC is now preferred over Pearson and rank-order (Spearman) correlation coefficients as these statistical techniques can exaggerate the impression of reliability and measure the strength of a relation between two variables not the agreement between them.[3,16,39] Being a product–moment correlation, the tetrachoric correlation can also be used which describes the linear relation between two continuous variables that have both been measured on a dichotomous scale.[40] Parallel and alternate forms can also be used to approximate stability which are discussed next under equivalence.[23]

Equivalence

Equivalence, equal in value or worth, is concerned with the agreement or consistency among observers who use the same instrument and when altered forms of an instrument are used.[23]

Inter-rater reliability: Inter-rater or inter-observer reliability involves examining the strength of agreement or level of consensus between two or more observers (raters) when they are observing the same variable and rating their observations using the same instrument.[27] Percent agreement, tetrachoric correlation or Kappa (see table 1) are used to measure inter-rater reliability of categorical and nominal data.[23,38] Cohen's weighted kappa is commonly used for comparing agreement between two raters while Fleiss' kappa is used when there are more than two raters.[1,28] Modified Kappa, which is an 'index of agreement among experts that indicates beyond chance that the item is relevant', can also be used when there are two or more raters.[41(p.1276)] For measuring relationships between scores, Pearson's correlation coefficient can be used for continuous data and Spearman's rank correlation for ordinal data. Information regarding agreement and bias amongst raters can be evaluated by mean differences and confidence intervals.[28] Finally, ICC can be used to examine intra-class and inter-rater reliabilities (i.e., strength of agreement) when examining interval-level data.[23,42,43] In this instance, the ICC

TABLE 1: MEASUREMENT PROPERTIES FOR RELIABILITY AND COMMONLY USED STATISTICAL TESTS AND CRITERIA

Measurement properties & their aspects	Definition/purpose	Statistical test and criteria	Considerations
Reliability: consistent results and stability of an instrument			
Internal consistency	Extent to which items within an instrument are unidimensional and interrelated in measuring the same construct (aka homogeneity)	• Split-half & Cronbach's a (scale randomly split): <0.70 = low/ inadequate; 0.70-0.80 = adequate; ≥0.8 = desired/excellent[2] BUT >0.70 generally interpreted as sufficient[3,24,27,45,46] AND EFA or CFA performed with adequate sample size[24,33] • Item-to-total (omitting one item), Pearson correlation: >0.2[3] to >0.3[47] considered as adequate • inter-item correlation: coefficients ranging from 0.15 to 0.50 is considered as acceptable[18]	• A Cronbach's a statistic >0.90 may indicate redundancy of one or more items which could be removed without affecting the scale's reliability[3,48] BUT >0.95 has also been recommended for this.[23,24] However, Bland and Altman[49] recommends that for research purposes Cronbach's a statistic >0.80 is suitable and for clinical practice >0.90 is acceptable but >0.95 is desired. For psychological or achievement tests an a >0.80 is desirable[50] • The greater the number of items in a scale, the higher the Cronbach's a coefficient tends to be[1,16] • Interpretation: reliability coefficient <0.5 = high and >0.9 low measurement error[23] • Sample size: recommendations vary from 4 to 10 subjects per variable but >100 subjects is needed to ensure stability for factor analysis[24] and total number of subjects should exceed total number of variables by 50[30]
Stability test-retest	• The ability of a measure to produce the same results when used at two different points in time (aka repeatability reliability)	ICC, weighted Kappa & Tetrachoric correlation coefficient: generally 0.01-0.20 = slight agreement; 0.21-0.50 = fair/poor; 0.50-0.74 = moderate; 0.75-0.89 = strong; >0.90 = excellent agreement/reliability[19,38,51] BUT for most purposes <0.40 = poor; 0.40-0.59 = fair; 0.60-0.74 = good; ≥0.75 = excellent agreement[52,53]	• ICC criteria is arbitrary as acceptable reliability is a judgement call dependent on how the instrument and what test statistic is used[16,19,20,52] • Terwee, Bot[24] recommends 0.70 should be considered as minimum criteria for measures of external reliability in a sample size of 50 patients. For clinical measurements and ongoing progress measurement in treatment situations the ICC test-retest for reliability should exceed 0.90[54] • Must report what ICC is measuring (consistency or agreement) and classification of ICC (model and form) used[24,43,55] • The magnitude of both Pearson's correlations and ICCs can be influenced by the range of scores and presence of extreme values[56] • Salkind[27] comments that for inter-rater Kappa nothing less than 90% agreement should be accepted
Equivalence inter-rater	• Examining whether the same results are obtained when two or more observers use the same instrument		
Parallel/ alternate forms	• Examines results consistency when altered versions of the same instrument or alternate instruments are used to measure the same construct		

Abbreviations: ICC, intra-class correlation coefficient; EFA, exploratory factor analysis; CFA, confirmatory factor analysis.

measures the proportion of variance of an observation that is the result of between and within subject variance in the true scores.[28,44]

Parallel and **alternate forms** reliability: parallel forms of reliability are applicable when scale items from the same 'pool' are used to develop two differing instruments.[23,30] Alternate forms is applicable when two versions of the same measuring instrument are used to measure the same construct.[19,20,27] The equivalence between the two instruments is examined to determine which set of questions or instrument is best to use. Correlation coefficients and Student's *t*-test can be used for this.[19]

Summary of reliability evidence

- Internal consistency: same population, individual instrument items.
- Stability (test-retest): same observer (intra-rater) or same patient (intra-individual), same instrument, different times.
- Equivalence (inter-rater): different observers, same population, same instrument, same time.
- Equivalence (parallel/alternate forms): same observer, same population, different instruments or forms, same time.

VALIDITY

Validity broadly refers to the accuracy of an instrument and is subsequently concerned with systematic measurement error.[19] A measurement instrument's validity is the extent to which it is estimated to have correctly measured a construct (e.g., fall risk) it purports to measure within the context of which it was used.[22,26,28] This estimate is based on inferences made in determining whether the results of an instrument are accurate.[17] Therefore, validity is different to reliability in that, validity is not a property of the instrument itself (i.e., the item inventory) but rather inferences or interpretations of the test score that should be contextually relevant, meaningful and useful.[1,28] Consequently, an instrument's validity can only truly be evaluated within the context, circumstances and population of intended use.[3,19] Measurement properties of validity include face, content, construct and criterion validity. During instrument development the items used need to be based on some theoretical underpinnings (content validity) after which the instrument's construct (construct validity) can be examined and finally, the instrument can then be compared to an external criterion (criterion validity) (see figures 1 and 2).[16]

Face validity

Face validity is primarily concerned with whether an instrument superficially appears to, or 'looks like' it is going to, measure the concept (construct) it purports to measure.[19,26] That is, the operationalisation of a construct.[20]

While face and content validity are closely related, having face validity does not guarantee that the item inventory of an instrument represents the theoretical domain of the construct (i.e., content validity). Face validity is more concerned with the language/syntax of individual items and the flow/organisation of an instrument in its entirety.[30] Examining an instrument's face validity is a subjective assessment after an instrument is developed, usually by those who administer it. Consequently, face validity is the weakest measurement property of validity.[19,30]

Content validity

Content validity relates to how well an instrument's content domain (item inventory) truly represents the theoretical domain (e.g., what it means to be at risk of falls) of the latent construct, such as falls risk, it purports to measure in the context of its intended use.[22,31] More simply, how accurately a construct has been operationalised while still representing the construct that is being measured.[20,28] Content validity is more a qualitative judgement opposed to an absolute value.[17] The overall goal of examining content validity is to remove redundant items of an instrument so a minimal number of items remain while still defining and operationalising the construct, and retaining face validity.[23,28] Content validity generally evolves out of the process of planning and developing an instrument. For instance, a systemic review of the research literature can assist with initially generating an instrument's items. Following this, subject matter experts (such as, patients, researchers or clinicians) are often engaged through focus groups, questionnaires, interviews or the Delphi technique to generate new items and review existing ones.[1,19,28] The RAND/UCLA disagreement index can be used to quantify agreement amongst raters in Delphi studies and the Content Validity Index can be used when multi-item scales are being rated (see table 2).[19,41,57]

The series of studies used to develop the Sydney Falls Risk Screening Tool is a good example of research techniques that could be used to ensure the face and content validity of an instrument. In the first instance an integrative review that used a systematic search strategy to identify quantitative papers was undertaken.[58] This was followed by a retrospective nonequivalent case-control study that further described the characteristics of patients who fall in the target patient population and context.[59] The patent characteristics identified in the review and case-control study formed the basis for the items included in a modified Delphi study.[57] Participants had the ability to add additional patient characteristics that they believed contributed to falls in questionnaire round one. The resultant list of patient characteristics were then examined in a multisite prospective cohort study from which the five-item Sydney Falls Risk Screening Tool was developed.[21]

Construct validity

Construct validity refers to whether an instrument measures an underlying construct, as defined by theory, which it purports to measure based on the established variables that define the construct.[1,27] Exploratory and confirmatory factor analysis techniques are a consideration here as these statistical techniques can be used to examine dimensionality.[32] Exploratory factor analysis (EFA) can be used to examine linear relationships of underlying factors that explain a construct.[19] This is important for item pruning, when introducing new items and when evaluating revised instruments (structural validity).[32] With EFA there are no prior assumptions regarding the relationships between factors and as such, EFA can be thought of as theory-generating.[19] Conversely, confirmatory factor analysis (CFA) can be thought of as theory-testing as it is used to examine if sample data fit a previously determined factor structure of a construct.[19,24] Consequently, with CFA a model is proposed at the outset and the hypothesis, number of factors encountered and which variables should load onto each factor are all known.[19]

Exploratory Structural Equation Modeling (ESEM) is another consideration during instrument development and validation.[28] ESEM incorporates some advantages of the less restrictive EFA (i.e., allowing cross-loadings) and advanced aspects of CFA (i.e., goodness-of-fit or multi-group models) creating a synergy between the two.[60] Measurement properties for and associated quality criteria for construct validity, and associated statistical techniques for examining construct validity, are provided in table 2.

Criterion validity

Criterion validity of an instrument examines the extent to which an instrument's score correlates with some external criterion. A key factor in establishing criterion validity is the quality of the criterion.[27] Consequently, criterion validity, as well as convergent and divergent (discriminative) validity, can be difficult to evaluate when there is no 'gold standard' measure.[2] In this case, these aspects of validity can 'represent a form of construct validity in which the relationship to another measure is hypothesised' or a well-established reference standard may be used.[19, 36(p.194)]

The criterion can either be another instrument, a discrete but related variable or an outcome that will occur in the future. Concurrent validity is studied when two instruments, one new and one the criterion (accepted reference standard), examine the same concept at the same time while attempting to identify the same existing condition.[1,20,26] Predictive validity explores how well a measure of a construct predicts some future criterion being an outcome score, event or behaviour.[16,23,28] For example, the ability of a falls risk screening tool to predict patients who end up falling.

The primary criterion-related evidence in health is an instrument's classification or discriminatory accuracy in differentiating patients with and without a specific condition, that is, its diagnostic validity.[19] Consequently, measures of sensitivity and specificity are used as criterion-related evidence for validity (see table 2).[28] Correlation coefficients, regression modelling and the ICC can also be used to examine criterion validity.[19]

RESPONSIVENESS

An instrument's ability to detect or track clinically meaningful patient change over time (such as, between hospital admission and discharge) in a discrete patient condition is of interest in health.[2,24,26] This relates to an instrument's responsiveness, that is, its precision.[36] While an instrument's responsiveness is a relative concept being dependent on its reliability and validity, instrument responsiveness is a consideration when deciding whether it should be implemented into clinical practice.

Husted, Cook describe responsiveness as having two aspects.[72] Firstly, internal responsiveness which relates to the ability of an instrument to measure change over a pre-determined period of time, or change before and after a treatment with a known effect.[72] An instrument's internal responsiveness can be measured using student's paired *t*-test and measures of effect size (i.e., magnitude of difference/change/effects between treatments or relationship between variables) (see table 3). External responsiveness is the same as internal responsiveness but is used when the responsiveness of two instruments are compared, usually a new instrument against an external standard or reference instrument.[72(p.459)] Measures of sensitivity and specificity, Pearson's correlation coefficient and regression modelling can be used to examine external responsiveness as these statistical methods indicate how change in two measures vary together.[72]

Of consideration when examining an instrument's responsiveness is its floor and ceiling effects 'as they indicate limits to the range of detectable change beyond which no further improvement or deterioration can be noted.'[36(p.194)] Floor and ceiling effects of an instrument are measured by examining the proportion of patients that achieve the lowest and highest possible score.[24] Patient characteristics, such as age and acuity, can have confounding effects on the floor and ceiling attributes of an instrument and therefore need to be considered.[73]

INTERPRETABILITY

By providing useful and informative information, a measurement instrument can contribute to a clinician's decision making in identifying patients who will and will not benefit from particular actions.[79] This information needs to be contextually relevant to be of worth; that is, have clinical meaningfulness.[79,80] Interpretability of information provided

TABLE 2: MEASUREMENT PROPERTIES FOR VALIDITY AND COMMONLY USED STATISTICAL TESTS AND CRITERIA

Measurement properties & their aspects	Definition/purpose	Statistical test and criteria	Considerations
Validity: accuracy of an instrument			
Face & content validity: how accurately a construct has been operationalised while still reflecting the construct being measured			
Face	• Assesses whether an instrument superficially appears to measure the concept it purports to measure	• Item-level content validity index (I-CVI): Lynn[61] average criteria = 1.00 with 3 to 5 raters; >0.78 for 6 to 10 raters[62] AND • Scale-level content validity index (S-CVI): >0.90 = acceptable agreement[63,64] but other authors[65] recommend ≥0.80 agreement is acceptable • All items are relevant to: (i) measurement aim; (ii) the construct being measured; (iii) the target population; (iv) the context of use; (v) together comprehensively reflect the construct to be measured; AND (vi) investigators or experts were involved in item selection[24,45]	• Lynn[61] suggests a minimum of 3 experts and more than 10 is probably unnecessary for I-CVI analysis; 2 raters are used in S-VCI analysis • Lynn[61] suggests a 4-point ordinal scale be used to prevent an ambivalent midpoint for CVI analysis where 1 = irrelevant and 4 = extremely relevant. The CVI of a scale item is the proportion of experts who rate the item as a 3 or 4.
Content	• Examines the relevance of individual items in an instrument		
Construct validity: a measure of the underlying construct based on the established variables that define the construct			
Structural	• The degree to which an instrument's items and scores reflect the dimensionality of the construct being measured so facilitating the removal of redundant items (pruning).	• Classical test theory, item response theory and Rasch modeling[66]: EFA/CFA[19,45], ESEM[28,60], CFI, TLI[45,67]	• EFA loadings: >0.32 = poor; 0.45 = fair; 0.55 = good; 0.63 = very good; >0.70 = excellent.[68] These criteria are considered a rough guideline for CFA studies[69] • Generally, factor loadings >0.40 are considered meaningful[30]; some researchers use >0.30[19] • Cutoff values for acceptable fit between the hypothesised model and observed continuous data: CFI/TLI = close to 0.95 or higher; SRMR = close to 0.08 or lower; RMSEA = close to 0.06 or lower[70] • Correlation statistics quantify the association between two measurement instruments and indicate how accurately one rating can be predicted from another, they do not indicate agreement[16] • Correlation criteria depends on the measurement property and statistic used[16] • Salkind 27 suggest general correlation criteria as: <0.20 = extremely poor; 0.21-0.40 = week; 0.41-0.60 = moderate; 0.61-0.80 = strong; >0.81 very strong
Contrasted groups	• To examine contrasting groups where one group is expected to score high and one low (aka extreme groups)	• ANOVA, Student's t-test and regression[19]	
Convergent	• The extent to which the similarities (sensitivity) between two instruments measure the same construct. High correlations are expected.	• Correlation statistics: ≤0.40 = poor; 0.41-0.75 = adequate; ≥75 = excellent[2]; DeVon, Block[30] recommends ≥0.45 analysis.	
Divergent (discriminate)	• To examine the differences (specificity) between two instruments that measure the same construct and that conforms to a priori hypotheses. Low correlations are expected.	• Correlation statistics: DeVon, Block[30] recommends ≤0.45.	
Hypothesis testing	• To examine if an instrument measures the construct being based on the theoretical underpinnings used to develop the instrument	• Formal and discrete hypothesis formulated AND at least 75% of the results are in accordance with the hypotheses[24]	
Cross-cultural	• The degree to which the performance of the items on a translated or culturally adapted instrument reflect the original version	• Differential item functioning AND multiple group factor analysis[45,67]	
Criterion validity: extent to which an instrument's score correlates with an external criterion			
Concurrent	• Examines the correlation between a new and a validated instrument at the same time	1. Convincing evidence that the gold standard instrument has been identified[24] AND 2. AUC: AUC generic standard: ≤0.5 = no discrimination; >0.5-0.7 = poor; ≥0.7-0.8 = acceptable; ≥0.8-0.9 excellent; ≥0.90 = outstanding discrimination[71] BUT for criterion validity: ≥0.70 is acceptable[67]; OR 3. Correlation with gold standard: ≥0.70 is acceptable[24]	• Sensitivity and specificity criteria are arbitrary as the chosen criteria depends on how the measure is to be used, what is being measured and in what context • Consider other sensitivity and specificity statistics: PPV, NPV, DOR and LR[16,28]
Predictive	• Examines the ability of an instrument to predict some future criterion		

Abbreviations: AUC, area under the curve; PPV, positive predictive value; NPV, negative predictive value; DOR, diagnostic odds ratio; LR, likelihood ratio; EFA, exploratory factor analysis; CFA, confirmatory factor analysis; ESEM, Exploratory Structural Equation Modeling; CFI, Comparative Fit Index; SRMR, standardised root mean squared residual; RMSEA, root mean squared error of approximation; TLI, Tucker-Lewis index.

TABLE 3: MEASUREMENT PROPERTIES FOR RESPONSIVENESS AND COMMONLY USED STATISTICAL TESTS AND CRITERIA

Domain & measurement properties	Definition/purpose	Statistical test and criteria	Considerations
Responsiveness (precision): an instrument's ability to detect clinically important change over time in the construct to be measured			
Internal	An instrument's ability to measure change over a pre-determined period	1. Effect size: standardised effect size, standardised response mean (SRM), Guyatt's Index benchmark values: 0.20 = small; 0.50 = moderate; 0.80 = large responsiveness[16,73] 2. Effect size: Pearson's correlation & Chi-square/ ANOVA/multiple regression: small = 0.10/0.10/0.20; medium = 0.30/0.25/0.15; large = 0.50/0.40/0.35, respectively[73,74] 3. Student's paired t-test[2,16]	• SRM an estimate of change in the measure relative to the between patient variability in change scores • Guyatt's index examines repeated observations of the measure in clinically stable subjects providing information on MIC change on the measure[71] • t-test used to test the hypothesis that there was no statistically significant change in the average response on the measure over the two time points
External	A comparison of two instrument's responsiveness	1. AUC: AUC generic standards as per table 2 BUT for measuring responsiveness ≥0.70 is acceptable regarding MIC and MDC[24,67] 2. Pearson correlation coefficient 3. Regression models	
Floor/ceiling effects	An instruments limits in detecting change beyond which no further improvement or deterioration can be noted	• ≤15% = adequate for number of respondents either achieving the minimum (floor) or maximum (ceiling) score[75] with a sample size >50 participants[24]	Other authors recommend[2,36] or have used ≤20% in their studies[76,77]

Abbreviations: ANOVA, analysis of variance; MIC, minimal important change; MDC, minimal detectable change; AUC, area under the curve.

by an instrument is a consideration here. Mokkink, Terwee describe interpretability as, 'the degree to which one can assign qualitative meaning – that is, clinical or commonly understood connotations – to an instrument's quantitative scores or change in scores.'[26(p.743)] That is, how clinically meaningful is an instrument's resultant score and are there consistent definitions and classifications for interpreting the results.[36] Some authors suggest that interpretability should be one of the principal psychometric domains (i.e., validity, reliability, responsiveness) needing consideration when deciding whether an instrument should be used in health.[24,26,36] Information in the index study, such as mean, SD and minimal important change, can aid in interpreting the clinical meaningfulness of a measurement instrument's score.[24] Interpretability is an important foundation for an instrument's clinical utility.

CLINICAL UTILITY

Utility is generally described as a subjective outcome measure of satisfaction regarding how beneficial an action, intervention, product, or process is.[80] The clinical utility of a measurement instrument refers to what extent the instrument contributes to beneficial health outcomes relative to best practice alternatives.[79] These beneficial outcomes are not solely patient dependent but multidimensional that could include economic, clinical, administrative and subjective domains.[36,80] Acceptability (respondent burden [the patient]) and feasibility (administrative burden [effort, time, expense, disruption]) of a patient or staff completing an instrument are important considerations here.[2,36]

As clinical utility is not a measurement property of an instrument, instruments do not have clinical utility per se; it is best-practice outcomes that determines the clinical utility of an instrument.[81] The clinical utility of an instrument is, however, dependent on its reliability, validity and responsiveness. For instance, clinical utility of a falls risk screening tool is dependent on its predictive validity resulting in appropriate allocation of resources for preventing falls. Bossuyt, Reitsma describes clinical utility of health-related diagnostic tests as having four key elements:[79] (i) individual and societal health outcomes; (ii) probabilistic (reliability as measured by diversity of outcomes); (iii) strategy being management strategy for testing and subsequent clinical actions; and (iv) comparative being relative to some comparator strategy, best practice or clinical actions.

Clinical utility is rarely quantified as it is a subjective concept and is context dependent.[80] There are, however, some clinical utility indices that can be used to quantify the expected gain in the utility of a test.[82] These indices can be used for tests 'if the clinical situation can be described by pre-test probability of disease and the ratio of the cost of erroneously treating individuals without the disease to the net benefit of correctly treating individuals with the disease.'[82(p.564)]

IMPLICATIONS FOR RESEARCH, POLICY AND PRACTICE

Nurse researchers and frontline nurses use a variety of measurement instruments during their everyday practice. They do so with the assumption that the instrument has been rigorously validated and has been shown to be reliable. However, determining whether an instrument is valid and reliable is complex. Nonetheless, nurses need to question the efficacy of the instruments they use. This is because there is the real possibility that nurses are using measurement instruments that have poor clinical utility. The discussion in this paper can enable frontline nurses and nurse researchers to confidently critique the research literature regarding an instrument's psychometric properties and therefore, make informed decisions regarding whether it is suitable for use. Some recent studies that have examined the psychometric properties of health-related measurement instruments is provided in supplementary file 1. These papers provide some working examples describing what nurses should consider when critiquing the literature regarding the efficacy of a measurement instrument.

CONCLUSION

Fundamentally, nurses are caught between the clinical need to use an array of measurement instruments and the availability of contextually validated ones; falls risk screening tools are an example of this. Consequently, nurses need to be aware of the limitations of the measurement instruments they use. However, there continues to be inconsistent and conflicting information regarding the terminology and quality criteria surrounding the psychometric measurement properties of measurement instruments. These properties and their associated quality criteria have been discussed in this paper. This paper empowers nurses to confidently question the suitability of measurement instruments they may use.

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REVIEWS AND DISCUSSION PAPERS

The factors that act as barriers and enablers to the implementation of voluntary assisted dying services in acute care health settings: a systematic mixed studies review and secondary analysis

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ABSTRACT

Objective: To explore the barriers to, and enablers of, implementation of voluntary assisted dying into acute care health settings and identify the strategies that contribute to successful implementation in these settings.

Background: In jurisdictions where voluntary assisted dying is legal, some people choose to end their lives in acute care health settings. How voluntary assisted dying is integrated as an end-of-life option for patients in these settings is an emerging area for implementation research.

Study Design and Methods: A two-phase process was adopted. First, a systematic mixed studies review was undertaken to identify themes associated with the provision of voluntary assisted dying. The electronic databases ProQuest Central, Embase, and CINAHL including Medline were searched in June and July 2019. For inclusion, a study must have been published between 1997-2019 and undertaken in an acute care health setting in a jurisdiction where voluntary assisted dying is legally permitted. Study participants were those involved, directly or indirectly, with voluntary assisted dying. All studies were assessed for the risk of bias using the Mixed Methods Assessment Appraisal Tool. Data from the included articles were synthesised into descriptive themes. Themes were then deductively analysed using the Consolidated Framework for Implementation Research to identify possible barriers and enablers and generate strategies that support the implementation of voluntary assisted dying in acute care health settings.

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Results: Nine articles were included in the review. Seven articles were quantitative studies that collected cross-sectional survey data. There were two qualitative studies. Four themes were identified: 1) putting the law into practice requires knowledge and understanding gained through education, 2) helping people die using VAD is complex, 3) the how of enacting VAD, and 4) participating in voluntary assisted dying is deeply personal for clinicians. Barriers to implementation included: a lack of understanding of legal obligations associated with voluntary assisted dying and poorly defined roles. Enablers to implementation included: open and inclusive conversations about the process and building social capital through communities of practice.

Discussion: The provision of voluntary assisted dying is multifactorial and complex. Its implementation in the acute care setting requires strategies built on an understanding of the enabling legislation and recognition of contextual and individual characteristics that contribute to its complexity.

What is already known about the topic?

- Increasing numbers of jurisdictions worldwide are legalising voluntary assisted dying (VAD)
- Some patients have a preference to be supported in VAD in an acute care health setting
- In jurisdictions where VAD is permitted, some acute care health settings have implemented structured programs to guide the practice of healthcare professionals
- There is limited research exploring how VAD is implemented in acute care health settings

What this paper adds:

- Clinicians' understanding of their legal and operational responsibilities is critical to addressing barriers to the implementation of VAD
- Education, policies, and procedures around VAD should be collaboratively developed by clinicians and legal-ethical experts
- Building social capital through a robust system of clinician support and reflection is required to continually improve the processes associated with VAD

Keywords: Voluntary assisted dying, implementation, acute care, hospital, mixed studies review, end-of-life care.

BACKGROUND

The process of dying is an inevitable part of life. As people seek greater involvement with their care and treatment decisions, how people die is changing.[1] In some jurisdictions voluntary assisted dying (VAD) has emerged as a legal option permitting people who are suffering at the end of their life control over the time and to some extent, the place and manner of their death. Terms used to describe this option include voluntary euthanasia, physician-assisted suicide,[2] physician-assisted dying,[3] death with dignity,[4] medical assistance in dying (MAiD),[5] and voluntary assisted dying.[6] For clarity and consistency, in this article the term voluntary assisted dying (VAD) encompasses all of the above. VAD involves assisting a person to end their life by self-administering a lethal dose of a prescribed medication or permitting a healthcare practitioner to administer a lethal medication.[7]

While most people prefer to die at home,[8] people frequently die in a hospital where the resources needed to manage distressing symptoms such as shortness of breath or pain that may present near the end of life are accessible.[9] It is likely, therefore, that in those jurisdictions where new laws permitting VAD are passed, acute care health settings will be tasked with implementing VAD services and developing the resources needed to operationalise the legal framework.

Five Australian states have now passed voluntary assisted dying legislation. In each, there has been a designated period between enacting the law and its commencement, to enable the implementation into healthcare practice. The factors relevant to implementing a law are generally more heterogeneous and broader in scope than those typically associated with implementing the findings of biomedical or health research.[10] As the public debate has consistently shown, VAD is divisive and contested. Healthcare practitioners also have personal views about the law, so how they engage with the legal processes will affect implementation.[11-13]

While previous reviews have explored healthcare providers' experiences consideration must also be given to the intensity of required resources and education of those involved in VAD, to more fully guide health service managers and others responsible for implementing VAD.[14-17] Through a systematic review of this research literature, followed by a secondary analysis using a theoretical implementation framework, insights into potential factors that may act as barriers and enablers to VAD practice may be identified, and strategies to support implementation recommended.

STUDY DESIGN

This study aimed to explore the factors that may act as barriers and enablers to the implementation of VAD in acute care health settings. A two-phase process was adopted. In Phase 1, a systematic mixed studies review using the steps described by Pluye and Hong was undertaken to identify themes associated with the provision of VAD.[18] The study protocol was registered with PROSPERO (Registration Number CRD42020155526) and reported following the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement.[19]

In Phase 2, the inductively developed themes from Phase 1 were subjected to deductive analysis using the Consolidated Framework for Implementation Research (CFIR) implementation science framework to identify factors that may act as barriers and enablers to suggest strategies to support the implementation of voluntary assisted dying in acute care health settings.[20]

OBJECTIVE

To explore the factors that act as barriers to and enablers of, the implementation of voluntary assisted dying into acute care health settings, and to identify strategies that facilitate implementation in these settings.

METHODS

PHASE 1: FORMULATE THE REVIEW QUESTIONS

The research questions were:

(i) What are the factors that act as barriers and enablers to the implementation of VAD services in an acute care health setting?

(ii) What implementation strategies contribute to the integration of VAD practice in an acute care health setting?

PHASE 1: DEFINE THE ELIGIBILITY CRITERIA

The review included primary research studies that used qualitative, quantitative, and mixed methods designs. Studies were included when VAD was implemented or undertaken in an acute care health setting which included hospitals, hospices, and palliative care services. Included studies were those where the participants were healthcare practitioners who may be involved either directly, or indirectly with VAD. The US state of Oregon has permitted VAD since October 1997.[21] Therefore, studies published after its *Death with Dignity Act* commenced operation were eligible. Included studies were published in English. Those published in grey literature were excluded. The Netherlands and Belgium are the only jurisdictions in the world that permit children to access VAD, and only in specific circumstances.[22] Because of their limited application, studies relating to children and VAD were excluded.

PHASE 1: APPLY AN EXTENSIVE SEARCH STRATEGY IN MULTIPLE INFORMATION SOURCES

A systematic database search strategy was designed and employed. Based upon their expertise in healthcare and law, the research team collectively decided upon relevant key search terms and alternatives. Under the guidance of a specialist health librarian, comprehensive search terms were generated (see Table 1. A reproducible search strategy for each database has been included in the supplementary file for this article). Acknowledging that the factors that affect the implementation of a law are more heterogeneous than those associated with the implementation of research evidence,[10] the terms barrier and enabler were not included as specific search terms. This was to ensure that a broader range of primary research articles where the factors affecting implementation were highlighted could be captured. The searches included subject headings and related keywords that were joined using Boolean operators AND, OR and NOT. Limiters reflecting the inclusion criteria were applied to ensure that irrelevant studies were not captured. The electronic databases ProQuest Central, Embase, and CINAHL including Medline were searched in June and July 2019. As a combination of electronic and manual searching is the most comprehensive method for retrieving relevant studies,[23] reference lists of included articles were manually screened to identify additional studies.

TABLE 1: KEY TERMS USED TO SEARCH THE DATABASES

Key terms for search	Alternative key terms for search
Assisted suicide	medically assisted suicide; voluntary assisted death; voluntary assisted dying; physician assisted suicide; physician assisted death; medical assistance in dying; voluntary euthanasia; right to die; voluntary active euthanasia; aid in dying.
Hospital	health services; acute care; tertiary care; hospice; healthcare.

PHASE 1: IDENTIFY AND SELECT RELEVANT STUDIES

The records were imported to an Excel database and duplicates were removed. Two researchers (JH, JD) independently screened the titles and abstracts according to the review inclusion and exclusion criteria and then met to compare the results and finalise the list of articles for full-text screening. At this point, articles were excluded if they did not relate to how VAD is implemented or undertaken if VAD was not legal at the time data were collected, or if VAD was not conducted in an acute care health setting. Where there was uncertainty regarding inclusion, this was resolved by mutual agreement. A third researcher (SL) reviewed the selected articles to confirm their suitability for inclusion.

PHASE 1: APPRAISE THE STUDY QUALITY USING THE MMAT

The Mixed Methods Assessment Tool (MMAT) was chosen to appraise the articles because it enables evaluation of the quality of various methodologies and has established validity and reliability.[24] The MMAT includes two generic screening questions and an additional five assessment criteria that are applied to the specific study design. Two researchers independently appraised the quality of each included article. The research team then met to discuss the outcomes and resolve any discrepancies.

PHASE 1: EXTRACTING DATA AND SYNTHESISING THEMES FROM THE STUDIES

To extract the data needed to inform our results, the research team developed a data extraction tool in an Excel spreadsheet. The data that were extracted included the country and setting where the study took place, the study approach and design, study participants and its key findings related to the implementation or operation of VAD. After pilot testing the tool, two researchers (JH, JD) each extracted the data from the nine articles and then met with the research team to discuss the results and settle any discrepancies.

Pluye and Hong describe three methods for synthesising research findings from the included studies.[18] This review followed a process of convergent qualitative design where results from studies that included qualitative, quantitative, and mixed methods are transformed into qualitative findings and then into themes.[18] To synthesise themes from the data, study findings or results of each study were entered verbatim into an Excel spreadsheet. Each line in the sheet represented one sentence of text from these findings. This allowed researchers to become immersed in the data and capture the meaning and context of each sentence to generate codes. These inductive codes were then compared and contrasted so that those including similar concepts could be grouped and organised into sub-themes and higher-order descriptive themes. Because we did not impose *a priori* framework implied by the research questions, this produced an authentic synthesis of the articles' findings. To move beyond the descriptive themes, the synthesised data were deductively analysed using the CFIR domains to generate propositions about the barriers, enablers, and potential strategies to support the implementation of VAD services and the subsequent practice.

PHASE 2: GENERATE POTENTIAL BARRIERS AND ENABLERS

Four of the CFIR domains were used as a framework in Phase 2. They were the characteristics of the intervention, the inner context, the outer context, and the individual. The fifth domain describes processes that are common across organisational change models.[20] Its focus is on implementation efforts, and as our review sought to identify factors affecting implementation rather than implementation itself, this domain was excluded from the analysis. Rather, by analysing the descriptive themes through the modified framework, researchers could identify potential barriers and enablers to the integration of VAD into an acute care health setting and recommend implementation strategies.

RESULTS

The search yielded 1,796 articles, with 1,729 after duplicates were removed. The process of selection is outlined in Figure 1 (PRISMA flow diagram). Nine articles were identified for inclusion in the review. Seven of these articles were quantitative studies that collected cross-sectional survey data.[2,16,25-29] There were two qualitative studies.[30,31] For most studies it was possible to answer the MMAT quality criteria affirmatively (Yes (Y) 82%; Cannot Tell (CT) 13%; No (N) 5%). The methodological quality of the studies was generally high. The two qualitative studies clearly described the process used to recruit study participants and used grounded theory approaches appropriate to answer the research questions.[30,31] Coherence between the data, analysis and interpretation was apparent. The seven quantitative studies collected data using cross-sectional surveys which are suitable for generating descriptive statements about a phenomenon such as exploring attitudes or experiences of voluntary assisted dying. Hogg et al. recruited participants from a single site, but all other studies recruited nationally.[16] While all reported descriptive statistics, their exploratory design limited the need for further statistical analysis. A detailed presentation of the criteria ratings is provided in the Supplementary file for this article.

Studies were conducted in the US state of Vermont,[30] Canada,[16,26] Belgium,[27,28,31] and the Netherlands.[2,25,29] VAD has been legal in Belgium and the Netherlands for nearly 20 years which may explain why more research has emanated from these countries. The samples included physicians, nurses, and pharmacy staff, which are the professions most likely to have direct contact with people requesting VAD. Two studies also included allied health professionals – social workers,[30] and physiotherapists, occupational therapists and other allied health professionals,[16] reflecting the multidisciplinary nature of VAD in some settings.

The studies included explicitly addressed the experiences,[2,30] attitudes,[2,25-27] involvement,[25,28-30] knowledge,[16,26] and perceptions,[16,29] of clinicians who experienced caring for patients seeking VAD. A descriptive summary of the studies is presented in Table 2.

Five of the studies explored the experiences of nurses with VAD.[25,27-29,31] These studies demonstrate that nurses find participating in VAD or VAD preparations emotionally challenging. Also, that balancing the dense procedural

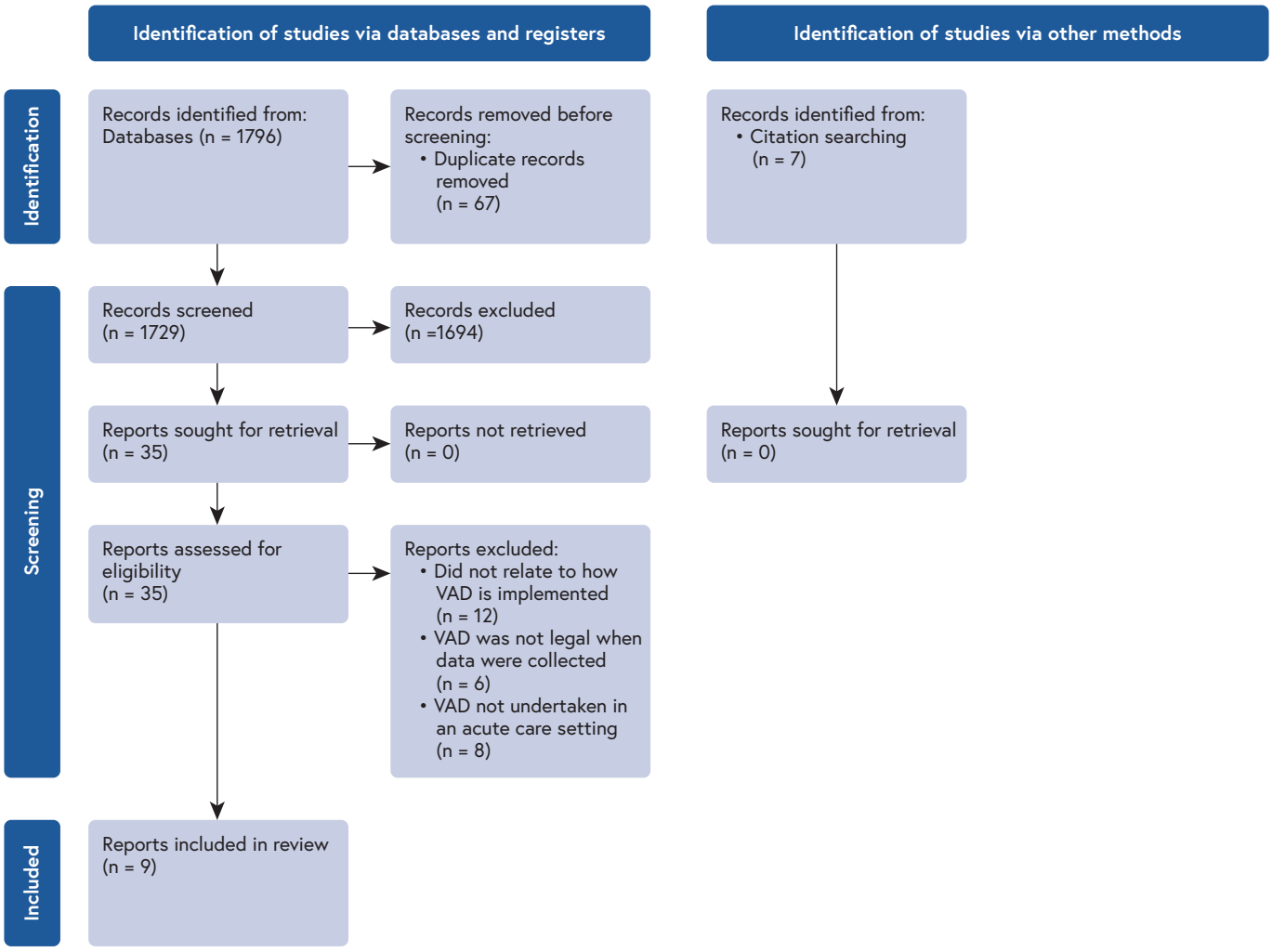

FIGURE 1: PRISMA FLOW DIAGRAM MODIFIED FROM: PAGE MJ, MCKENZIE JE, BOSSUYT PM, BOUTRON I, HOFFMANN TC, MULROW CD, ET AL. THE PRISMA 2020 STATEMENT: AN UPDATED GUIDELINE FOR REPORTING SYSTEMATIC REVIEWS. *BMJ* 2021;372:N71

aspects of the practice, with providing patient-centred care is difficult.[31] The extent to which nurses can communicate openly with physicians responsible for prescribing or administering a VAD substance influences their experience of the process.[28] Importantly, researchers also highlighted that nurses were often unfamiliar with the legal requirements of VAD.[25,27,28]

These findings were not confined to nurses. Physicians and pharmacists similarly found the process complex and time-consuming.[2] Knowledge of the law relieved some of this burden, but conversations with patients and their families about voluntary assisted dying were frequently perceived as difficult.[16,26] Understanding the individual's motivation for seeking VAD made this easier.[2,26]

Nine sub-themes and four descriptive themes emerged from the synthesis: 1) putting the law into practice requires knowledge and understanding gained through education, 2) helping people die using VAD is complex, 3) the how of enacting VAD, and 4) participating in VAD is deeply personal for clinicians. Examples of the codes and the associated text that informed the genesis sub-theme and descriptive themes are set out in Table 3.

Four descriptive interconnected themes were synthesised from the literature. Central to the implementation of a new VAD service is knowledge and understanding of the law and its requirements. Acknowledging the range of people involved in VAD and how VAD practices fit with their usual work, contributes to complexity. Enacting VAD, therefore, requires role clarification and unambiguous communication. Finally, the nature of VAD challenges deeply held beliefs and values about the world, for patients, families, and staff. Clinicians need opportunities to reflect on what VAD means to them at a personal, as well as professional level.

THEME 1: PUTTING THE LAW INTO PRACTICE REQUIRES KNOWLEDGE AND UNDERSTANDING GAINED THROUGH EDUCATION

All jurisdictions have strict eligibility criteria that limit who can access VAD. Authority to assess whether a person meets the eligibility criteria usually rests with physicians, although in Canada nurse practitioners can also conduct eligibility assessments. To undertake this important gate-keeping function, these clinicians must have sound knowledge and

TABLE 2: DESCRIPTIVE SUMMARY OF THE STUDIES INCLUDED IN THE REVIEW

Study & geographic location	Approach	Sample & context	Key findings	Answers to the RQ – what factors may act as barriers and enablers
Buchbinder et al. (2019) Vermont, USA	Data collection: Qualitative semi-structured interviews Method of analysis: Grounded theory	37 physicians, nurses and social workers who had clinical experience with VAD in Vermont	There are five domains where clinicians engaged with VAD: clinical communication; Act 39 protocol; prescribing medication; planning for death; professional education	Provider's communication with patients – need to understand reasons for seeking voluntary assisted dying Important to understand the requirements of the law, but this was complex and time-consuming Support with prescribing is often required, including how to source the medication once prescribed. Support for patients on the day – additional challenges associated with self-administration The need for support from colleagues
Denier et al. (2009) Flanders, Belgium	Data collection: Qualitative semi-structured interviews Method of analysis: Grounded theory	82 nurses with experience caring for patients requesting VAD	Nurses' involvement in VAD depends on whether they assume a procedural, action-focussed, or existential-interpretive perspective	Nurses participate in voluntary assisted dying in different ways • Organising the process. Reliance on checklists needed detailed protocols • Others focussed on ensuring they had the right attitude to support the patient. The two perspectives are not mutually exclusive (complementary dimensions of care) Phases associated with voluntary assisted dying are interrelated, not necessarily linear and/or distinct. Communication about the process, also communication about how patients and their families are experiencing the process Processes underpin the overall experience of voluntary assisted dying. It permits the existential-interpretive perspective to flourish.
Francke et al. (2016) Netherlands	Data collection: Questionnaire Method of analysis: Quantitative descriptive analysis and multivariate logistic regression analysis	587 nurses who worked in general or academic hospitals, home care, nursing homes or elderly care homes	Nurses want to be involved in VAD decision-making. Some nurses are not aware that they are not legally permitted to administer VAD drugs	Nursing staff believe that there are gaps in legal knowledge One-third of respondents would not administer voluntary assisted dying Nursing roles are restricted to caring for the patient and family Few nurses in the study had actively participated in voluntary assisted dying or been present Professional guidelines set out nurses legal obligations
Gallagher et al. (2018) Canada	Data collection: Web-based survey Method of analysis: descriptive and inferential statistics	1,040 hospital pharmacy staff	The majority of respondents, particularly technicians and assistants, were supportive of VAD, but most lacked education about the topic	Pharmacists need additional education around Medical Assistance in Dying (MAiD), and this should start in entry to practice programs Knowledge of the law was a predictor of support Important to the pharmacist that people seeking MAiD consented – i.e. voluntary, no coercion
Hogg et al. (2018) Canada	Data collection: Survey Method of analysis: Quantitative descriptive analysis	125 nurses and allied health professionals working in a large urban multi-site rehabilitation centre	Education for healthcare providers is critical to ensure they understand the relevant hospital policy and guidelines and improve compliance with VAD implementation	Lack of knowledge about MAiD leaves clinicians unprepared to handle conversations relating to MAiD – eager for more education Education about policies and guidelines, but also about difficult conversations with patients. Clinicians are generally supportive, but intent and readiness to participate is less apparent Clinicians don't know where additional help/support can be accessed MAiD generates intense emotions and conflicting personal opinions.

TABLE 2: DESCRIPTIVE SUMMARY OF THE STUDIES INCLUDED IN THE REVIEW CONTINUED

Study & geographic location	Approach	Sample & context	Key findings	Answers to the RQ – what factors may act as barriers and enablers
Inghelbrecht et al. (2009) Flanders, Belgium	Data collection: Questionnaire Method of analysis: Quantitative descriptive analysis and logistic regression analysis	3,321 nurses who had clinical experience caring for patients	Nurses are generally supportive of voluntary assisted dying for terminally ill patients, however, there is uncertainty about their role in its performance The separated attitudes and roles Support for VAD is higher than the agreement to administer	The sample was a general population of nurses rather than those with experience of EoL care The majority of nurses accepted VAD for people with a terminal illness with extreme uncontrollable pain Two-thirds disagreed that administering the drugs was a nursing role. Rather their tasks were restricted to patient and family care A substantial number (43%) said they would administer – but this is prohibited by law. Nurses should not be required to participate. Conscientious objection is permissible Positive attitude associated with personal and direct confrontation with pain and suffering of their patients. Uncertainty about roles.
Inghelbrecht et al. (2010) Flanders, Belgium	Data collection: Survey Method of analysis: Quantitative descriptive analysis and logistic regression analysis	1,678 nurses who had cared for patients for whom a life-ending decision may be required	Over half of the nurses surveyed had been involved in a VAD decision. Some nurses administered medications beyond the legal boundaries of their profession	More than two-thirds of nurses reported that the patient expressed their wish about VAD to them. Nearly two-thirds were involved in the decision-making process 40% of nurses were involved in the preparation, and one third were present. Consultation between physicians and nurses was important, however, not much actual shared decision-making. Seemed to be a lack of clarity in relation to the purpose of some medication prescriptions – nurses may have overestimated the actual life shortening effect of the drug they administered.
Kouwenhouven et al. (2014) Netherlands	Data collection: Questionnaire Method of analysis: Quantitative descriptive analysis and qualitative content analysis	793 physicians who were likely to be involved in end of life decision-making.	Dutch physicians perceive a difference between VAD that is self-administered by patients and practitioner administration. The choice of method is predominantly the physicians.	How voluntary assisted dying is completed is frequently not discussed with patients if they were unfamiliar with the process. Assumptions about patients' wishes and whether it was too burdensome Understanding of suffering
Van Bruchem-van de Scheur et al. (2008) Netherlands	Data collection: Questionnaire Method of analysis: Quantitative descriptive analysis and qualitative content analysis.	1,509 nurses employed in hospitals, home care organisations and nursing homes who had experienced a request for VAD in the past two years.	The majority of nurses stated that obtaining intravenous access and preparing VAD medications are not accepted as nursing tasks.	Nurses' understanding of the broader legal framework, including reporting obligations, was limited. Different views about whether preparing voluntary assisted dying medications is a nursing role Nurses in this study were reluctant to participate in voluntary assisted dying decision-making Lack of clarity about nursing roles – inserting an intravenous cannula may or may not be a nursing task.

TABLE 3: OVERVIEW OF THEMES, SUB-THEMES, AND CODES

Theme	Sub-theme	Codes	Text examples
Putting the law into practice requires knowledge & understanding gained through education	Knowing and understanding the law	Nurses' knowledge of the law	Not all respondents are convinced that their colleagues are familiar with the relevant legal rules: less than half (43%) agree with the statement that most nurses know which actions they are allowed to perform in the case of euthanasia (Francke et al. 2016).
		VAD law is complex	All providers emphasised that understanding the law is time-consuming and that it is difficult to grasp the details before beginning the process (Buchbinder et al. 2019).
		Understanding eligibility criteria for VAD	Clinicians achieved the highest average scores (84%) on survey questions relating to eligibility criteria (Hogg et al. 2018).
		Pharmacy staff knowledge of the law	Pharmacists and pharmacy technicians obtained similar results for their knowledge of provincial legislation (for pharmacists, mean 2.7 [SD 1.1], median 3 [IQR 2]; for technicians/assistants, mean 3.0 [SD1.2], median 3 [IQR 2]; t(1038) = 3.1, p = 0.002) (Gallagher et al. 2019).
		Knowledge of the law	Average grade scores were consistent and showed minimal differences among nurses and allied health professionals when comparing grade scores with professional background and years of clinical experience (Hogg et al. 2018).
		Familiarity with policy	When asked whether they knew of their hospitals' policies regarding MAiD, the majority of both pharmacists (460/595, 77%) and technicians/assistants (266/423, 63%) reported working at hospitals that permitted MAiD (Gallagher et al. 2018).
	Translation to practice depends on education	Opportunities for education are limited	Providers lamented the lack of formal education, training, and institutional support around Act 39, and reported seeking out information through informal professional networks and advocacy organisations, such as Compassion and Choices' 'Doc2Doc' program (Buchbinder et al. 2019).
		Willingness to participate in VAD education	All responses shared a common theme that was related to education. Specifically, all sixteen participants expressed interest in further education on MAiD. Examples of comments included 'staff in service would be a great idea', 'need a pamphlet on all units …', '[n]eed more training regarding MAiD – scenario training/practice", etc. (Hogg et al. 2018).
Helping people die using VAD is complex	Clarifying responsibility for VAD processes	VAD processes are complex	Nurses are aware that VAD affects many people, including the patient and their family, grandchildren, children, and staff. The needs of all hospital staff, not just clinicians must be considered (Denier et al. 2009).
		VAD processes are multidisciplinary	While the burdens of prescribing fell primarily to physicians, nurses, and social workers, when available, occasionally helped to identify pharmacies and determine insurance coverage (Buchbinder et al. 2019).
		VAD tasks undertaken by nurses	In addition, respondents were asked about involvement in the preparations for euthanasia. Very few (3% or less) say that they have ever brought the lethal drugs from the pharmacy, connected the infusion line, dissolved the drugs and/or prepared the syringe (Francke et al. 2016).
		VAD tasks undertaken by physicians	While physicians prescribe life-ending medications they may not always administer them or be present when a nurse administers them (Inghelbrecht et al. 2010).
		Pharmacy staff may not know if they're dispensing VAD medications	When asked if they had ever dispensed a prescription for MAiD after it became legal, 18% (n = 107) of pharmacists were sure they had, and 78% (n = 471) were sure they had not, whereas 15% (n = 63) of technicians/assistants were sure they had, and 58% (n = 249) were sure they had not. The remaining respondents were unsure (Gallagher et al. 2018).
	Keeping patients as the focus of care	Understanding what VAD care involves	Participants emphasised that reassuring patients that they would be there for them and exploring their reasons for requesting AID were important first steps (Buchbinder et al. 2019).
		Nurses' primary role is to care for patients	The nurse guides, counsels, and supports the patient and the family rather than organising the care process (Denier et al. 2009).
		Reasons for choosing VAD	When physicians were confronted with several statements and asked, which statement(s) could be a reason for them to choose for physician administration of VAD medication (physician-assisted suicide) over self-administration by the patient, 67 – 69% agreed with the statements 'PAS underlines the patient's autonomy, free choice and/or own responsibility (Kouwenhoven et al. 2014).

TABLE 3: OVERVIEW OF THEMES, SUB-THEMES, AND CODES CONTINUED

Theme	Sub-theme	Codes	Text examples
The how of enacting VAD	Developing sound therapeutic communication	Patients discuss VAD with nurses	Of the nurses whose patients received euthanasia, 69% (84/122) reported that the patient had expressed his or her wishes about euthanasia to them (Inglhelbrecht et al. 2010).
		Understanding requests for VAD	Providers were particularly attuned to probing for concerns about finances or being a burden on others due to terminal illness and often framed Act 39 as a last-resort option (Buchbinder et al.2019).
		Clinical communication is important but challenging	Most respondents are in support of MAiD and respondents expressed mixed feelings when it comes to ease of having MAiD related conversations (Hogg et al. 2018).
	Promoting interdisciplinary communication	Nurses' involvement in VAD discussions	Almost a quarter (22.6%) of the nurses approved of the proposal to regulate physicians' obligation to consult a nurse before making their decisions about situations where a nurse is involved in the daily care of the patient (Van Bruchem-van de Scheur et al. 2008).
		Good interdisciplinary communication is important	Respondents were asked whether they wished to be told if a prescription they were dispensing would be used for MAiD: 87% (n = 531/607) of pharmacists and 54% (n = 233/430) of technicians/assistants said yes (Gallagher et al. 2018).
Participating in VAD is deeply personal for clinicians	Attitudes and beliefs influence clinician's participation in VAD	Willingness to participate in VAD	Religious nurses – of any denomination – and nurses who rated their religion as important in their professional attitudes towards euthanasia and other end-of-life decisions were more opposed to euthanasia than nonreligious nurses and those nurses who rated their religion as not important (Inghelbrecht et al. 2009).
		Pharmacy staff are generally supportive of VAD	Both groups were very supportive of MAiD in terms of values (Figure 2). One-sample t-tests showed that means were significantly different from the neutral response on the scale, in the direction indicating that respondents were supportive of MAiD (Gallagher et al. 2018).
	Limiting moral distress	Participating in VAD has an emotional toll	Eighteen per cent (n = 33) had moral considerations for not discussing the option of PAS, for example, 'to burden the patient in this phase with the responsibility for physician-assisted suicide felt like walking away from my own responsibility.' Another 15% (n = 28) stated that the (presumed) patient's wish was euthanasia (Kouwenhoven et al. 2014)
		Getting it right	Closure for these nurses is a very personal process; it happens on its own terms and may involve continuous contact with the patient's family. [Attending the funeral] "it is also important for me, for coming to terms with it and for knowing "Did I do this right" ' (Denier et al. 2009)
	Fulfilling professional roles	Nurses' views on non-clinical VAD related roles	The nurses held diverging opinions about membership of regional euthanasia review committees: 45% out of the 1172 nurses supported membership of nurses on these committees, 8.9% were against, and 41.6% had no opinion about the issue (Van Bruchem-van de Scheur et al. 2008)
		Physicians assume different VAD related roles	Several physicians expressed a commitment to educating colleagues about the process, both formally and informally, illustrating that the provider's role in VAD does not necessarily end with a patient's death (Buchbinder et al. 2018)
		Participation in VAD is influenced by professional experience	Moreover, being a registered nurse, working in an academic or general hospital or in a nursing home, having cared for terminally ill patients in the previous two years, and working in a specialised palliative care team/department is associated with having been actually involved in decisions concerning euthanasia (Francke et al. 2016)

understanding of the law. Knowing the law is not the same as knowing how it should be applied and assessing eligibility criteria may extend beyond the clinicians' areas of clinical expertise. Buchbinder et al, for example, found that in Vermont physicians are required 'to determine who counts as a state resident, which sometimes put physicians in an uncomfortable position because determining residency lay outside the scope of their professional judgement' (p. 638).[30]

To varying degrees, laws also prescribe processes and procedures for undertaking VAD so all those who participate must have this legal knowledge. Importantly, the law will prescribe who is authorised to administer VAD medications. Inghelbrecht et al. found that in Belgium nurses occasionally administered VAD medications to patients who lacked decision-making capacity.[28] The Belgium law, however, requires a patient to have decision-making capacity at the time they request VAD and authorises physicians, but not nurses, to administer the VAD medication. Similarly, a quarter of nurses (n=587) surveyed in the Netherlands did not know if they were permitted to administer VAD medications,[25] suggesting a lack of awareness of the restrictions VAD laws place on their practice. Gaps in legal knowledge may be addressed with more or better education.

The need for education that focuses on improving clinicians' knowledge of VAD law, policies and guidelines was evident in four studies.[16,25,26,30] This is particularly important because more knowledge about VAD law and policy increased clinicians' support for the practice and patient requests.[16,26] The type and format of VAD educational resources will depend on the particular needs of the health service, clinicians, and patients, and are essential for supporting those involved to understand how the law works in practice.

THEME 2: HELPING PEOPLE DIE USING VAD IS COMPLEX

This theme highlights that VAD laws, and their associated processes, are perceived as complex, consequently how VAD-related roles and tasks are allocated is uncertain. In the US state of Vermont, physicians reported finding it difficult to 'grasp the details before beginning the process' (p. 638).[30] This included identifying the necessary administrative forms, prescribing the correct type and dose of medication, and where it might be dispensed. As complying with procedural requirements was time-consuming, nurses or social workers often assisted by finding eligible witnesses or completing VAD-related paperwork.[30] In these circumstances being able to access detailed policies or guidelines can serve as a procedural checklist and provide reassurance that all requirements have been met.[31]

After the VAD procedural processes have been completed, planning for the death was also perceived as a time-consuming and challenging task.[30] Even if not required to administer VAD medication, a physician or nurse may be asked to be present when the medication is taken, or be available to coordinate and provide after-death care.[30] Kouwenhoven et al. found that physicians in the Netherlands preferred to administer the VAD medication themselves which, to some extent, avoids this issue.[2] The research highlights that participating in VAD requires a collaborative multidisciplinary team from the first patient request to after the patient has died, but there are many points where this can be challenging. At each step in the process, however, the needs of the patient must be forefront.

The ability to end the suffering that some patients experience at the end of life was very important to clinicians who participated in VAD.[2,16,27,30] How this occurred was also important. Denier et al. found that for the 'patient's life … [to] end in a good way' it was imperative that all 'practical arrangements' were made (p.267).[31] Although the need to cover all steps in the process was important, for some, VAD entails much more than mechanically following procedures. A Belgium nurse summed it up by saying '[I would not need a protocol] because I believe that it is something that you cannot put down on paper. It is different for every patient. Every patient has different needs' (p.269).[31] So, while acute care health services must develop policies that make transparent the complexities of the relevant legal framework, how they are enacted will ultimately depend on those people who are caring for the patient.

THEME 3: THE HOW OF ENACTING VAD

The third theme encompassed how VAD was enacted with a particular focus on communication between clinicians and patients considering VAD, and also between healthcare team members. Ways of talking about VAD, while infused with experience and expertise, require adaptation to attend to the patient's specific needs. Buchbinder et al. for example, reported that clinicians were attuned to exploring a person's reasons for requesting VAD.[30] Requests motivated by financial concerns, or fear of becoming a burden, prompt further exploration to ensure the person's request is voluntary and not coerced. Even if coercion is not a concern, requests for VAD can initiate broader end-of-life conversations. As one physician stated '[t]here are more people who can say… "[c]an I have that death pill?" than who can say, "[w]hat can you do for me while I'm dying that I'm not gonna suffer?"' (p.638).[30] Statements such as these, invite conversations about other unresolved issues, potential palliative care options, or eligibility for VAD.

In this context, having the correct information was important because ensuring that the patient 'received all the necessary information to make a good decision' (p.267) was central to good end-of-life care.[31] However, complex policies designed to enact the law can make it difficult for clinicians to know what to say. In the survey of Canadian clinicians, a lack of knowledge about VAD policies and procedures resulted in respondents expressing 'mixed feelings' about having VAD-related conversations with patients (p.45).[16] Mixed feelings

may reflect concerns about possible misunderstandings about rules and regulations or miscommunication around expectations of the process. In these circumstances, clinicians may be hesitant to participate in VAD. Conversely, when they are comfortable with their knowledge of the law, and the associated VAD policies and procedures, clinicians felt better equipped to talk openly with patients about VAD and end-of-life choices.[2,26]

How VAD information, patient requests, and ways of participating, are communicated between clinicians was a notable concern. For example, in Belgium, interdisciplinary communication is underscored by the legislative requirement for an attending physician to discuss a patient's request for VAD with the nursing team. Even with this legal requirement, Belgium nurses generally would prefer that information about VAD processes was shared more frequently.[28] Although this point was reiterated by nurses in the Netherlands,[25] others felt that mandating this type of communication was not required.[29] The importance of accurate and open communication in healthcare is well recognised, as are the challenges around end-of-life communication.[32] The complexity of VAD law and its associated processes contributes an additional layer of intricacy. Enacting VAD involves navigating these challenges so that the process as a whole works well and the patient's life ends in a good way.[31]

THEME 4: PARTICIPATING IN VAD IS DEEPLY PERSONAL FOR CLINICIANS

The fourth theme reminds us that clinicians bring a diverse array of attitudes, beliefs, and values to their role. Some, like compassion, empathy and caring are embedded in, and inseparable from quality healthcare directed at prolonging life and relieving suffering. VAD challenges this position by enabling people to intentionally hasten their death, and for some clinicians, this choice can conflict with their deeply held and personal beliefs. Inghelbrecht et al. found that nurses who rated their religion as important in their professional attitude were more opposed to VAD than those nurses for whom religion was not an important factor.[27] For these nurses access to good palliative care or sedation were seen as preferable to VAD. Religiosity also influenced the degree to which nurses sought to be involved in VAD requests. Francke et al. showed that nursing staff who have 'religious or other beliefs that they considered important for their attitude towards end-of-life decisions, were more likely to agree with the statement that a physician should discuss euthanasia requests with them' (p.787).[25]

Participating in VAD is deeply emotive and the need to limit moral distress requires strategies to help manage the desire to participate in VAD, with the need to shield those who were highly vulnerable. In the Netherlands, both self-administration by the patient and administration by a physician are permitted. Kouwenhoven et al. found that while self-administration was less psychologically burdensome for physicians, in the majority of cases this option was not discussed with the patient because physicians believed that assisting with a person's death was their responsibility.[2] In other cases, physicians delegated the task of administering life-ending medications to nurses.[28] Although this only occurred in a minority of cases, it is prohibited by law. The authors in this study surmised that nurses assumed this active role out of concern for their frailer patients who were suffering. However, it left them in a vulnerable position where complying with a physician's medication order is also an illegal act.[28] This also highlights the potential conflict between personal and professional interests.

How professional roles are cast impacts VAD participation. For example, van Bruchem-van der Scheur et al. found that the majority of nurses surveyed believed that inserting an infusion needle and preparing VAD medications were not nursing tasks.[29] Positing that preparing for VAD may be 'too emotionally draining' (p.195) and that the 'extraordinary moral character' of VAD places it outside the professional domain of nurses (p.196). Professional attitudes to VAD, however, have evolved. Seventy-four per cent of Canadian pharmacists surveyed by Gallagher et al. accepted VAD as a part of healthcare.[26] In this setting, those clinicians holding negative attitudes to VAD made efforts to ensure that this did not impact their professional work.[26] For example, a pharmacist who was not supportive of VAD might still dispense the medication or refer to another colleague who is less reluctant to participate.[26] Clinicians take their professional VAD responsibilities seriously as confirmed by Denier et al.'s findings that nurses expressed that having the 'right attitude' and knowing that the process was completed correctly were important features of participating in VAD (p.267).[31]

SECONDARY ANALYSIS USING THE CONSOLIDATED FRAMEWORK FOR IMPLEMENTATION RESEARCH

The studies included in the review highlight the multifactorial and complex nature of VAD, but do not specifically address how this may affect implementation. Potential barriers and enablers to the implementation of VAD, therefore, were identified by deductively analysing the Phase 1 descriptive themes using four of the CFIR domains and are set out in Table 4.

Domain 1: The intervention

The first domain in the CFIR refers to the characteristics of the intervention being implemented and includes core elements, such as requirements of the law, and adaptable elements, such as VAD policy.[20] Knowing the law is a clear enabler for the implementation of VAD in acute care health settings. The legitimacy of the source of information is considered an enabler to implementation.[20] While clinicians

TABLE 4: USING THE CFIR TO IDENTIFY POSSIBLE BARRIERS AND ENABLERS

Theme	Phase 1	Phase 2				
	Subtheme	CFIR Domains				Example of a barrier (B) and enabler (E)
		1 Intervention	2 Outer Setting	3 Inner Setting	4 Individual	
Putting the law into practice requires knowledge & understanding gained through education	Knowing and understanding the law	✓		✓	✓	B: Not knowing what the law requires; perception that the law has been imposed on practice E: Developing VAD policies that align with organisations values and clearly describe how to meet legislative requirements
	Translation to practice depends upon education			✓	✓	B: Inaccessible or poorly targeted educational resources E: HCPs willingness to participate in VAD education
Helping people die using VAD is complex	Clarifying responsibility for VAD processes	✓	✓	✓	✓	B: Multiple procedural, clinical, technical, and legal steps E: Well-structured and accessible checklists or protocols
	Keeping patients as the focus of care			✓	✓	B: Closely following procedures and tasks may limit ethical considerations of patient and family concerns E: Open and inclusive conversations about the process, key decision points and associated requirements for each patient
The how of enacting VAD	Developing sound therapeutic communication			✓	✓	B: Identifying patient needs can be challenging E: A belief that VAD is an appropriate option in the circumstances
	Promoting interdisciplinary communication			✓	✓	B: Poorly defined and developed intersubjective relationships E: Acknowledging and using the skills and contribution of all members of the multidisciplinary team
Participating in VAD is deeply personal for clinicians	Attitudes and beliefs influence clinicians' participation in VAD				✓	B: Limited experience providing end-of-life care in an acute care setting E: Connections with external organisations that support VAD
	Limiting moral distress			✓	✓	B: Lack of support to conscientiously object E: Feeling that the patient's life has ended in a good way
	Fulfilling professional roles		✓	✓	✓	B: Limiting the roles of those who can participate in VAD E: Building social capital in the organisation through communities of practice

will acknowledge that the law is a legitimate foundation to inform their practice, its translation into local hospital policy and procedures will also require evidence of legitimacy. To address this potential barrier, the development of institution or service-specific policies that encapsulate the law, through active consultation with legal and clinical experts can create an 'adaptable periphery' (p.3)[20] which is critical to implementation.

Domain 2: Outer setting

Implementing VAD services in an acute care health setting will be influenced by external economic, political, and social contexts – 'the outer setting'.[20] The decision to, and practice of, actively ending a life carries social and political meaning that is less evident in most other healthcare practices. For example, the legislative appointment of an external body with oversight of each VAD case demonstrates that the

practice of VAD extends beyond the social context of the hospital and the therapeutic relationships between clinicians and patients.[33] Damschroder et al. observe that organisations that support staff to embrace 'external boundary-spanning roles' are more likely to quickly implement new practices (p.7).[20] Allocating a role focused on supporting the relationship between the internal hospital context and the external oversight body, to a senior clinician may enable implementation.

For clinicians involved in VAD, alignment of their practice with their disciplinary professional values and responsibilities will be critical to implementation. As VAD is gradually introduced to new jurisdictions, there is greater pressure for professional bodies that represent clinicians' interests to create overarching policy positions and statements that guide clinicians who choose to participate in VAD. In the absence of a professional voice in this legal-political space, clinicians draw upon their religious beliefs and values, confounding implementation. In these circumstances, peer learning and support can be implementation enablers.[30]

Domain 3: Inner setting

The inner setting is influenced by how the actions of individual clinicians are differentiated and coordinated to produce holistic care that meets patients' needs.[20] While clinicians frequently work in multidisciplinary teams to ensure that patients receive the complex quality care they deserve, VAD encompasses unique procedural, clinical, technical, legal, and humanistic elements that must be effectively negotiated. Damschroder et al. describe the way that labour is divided among teams as 'functional differentiation' and note that 'the more stable teams are, the more likely implementation will be successful' (p.7).[20] Achieving functional differentiation in the provision of VAD must account for its emotive and contentious nature, which can result in clinicians feeling ambivalent about taking on roles they would usually see as routine.

A commitment to education, and being open to learning about VAD, is considered essential.[16,30] The resources available to support learning influence implementation,[20] therefore, investment in educational programs is an important enabler. Learning programs could focus on the law and how the law has been translated into the procedure; provide opportunities to discuss how the procedure aligns with professional policies and values; and offer simulated learning to multidisciplinary teams to develop the intersubjective communication skills required to negotiate the emerging contingencies associated with the VAD process and procedure.

Domain 4: Individuals

In addition to their professional codes, the clinicians involved with VAD carry their own beliefs and values. As the provision of VAD requires a multidisciplinary team, implementation strategies need to account for the different stances, preferences, and abilities of all clinicians. Given the emotive nature of VAD, successful implementation will require clinicians who are open to learning about VAD and what it means to the patient. Initially, organisations may consider a process to select clinicians with a specific skill set to implement VAD or at least provide an option for clinicians to conscientiously object.

DISCUSSION

How to implement VAD in an acute care health setting is a relatively new area of exploration. Using a two-phase approach where inductive themes in the literature were deductively analysed using the CFIR, potential barriers and enablers can be identified, and associated implementation strategies generated.

In regard to the intervention, clinicians must perceive VAD as an appropriate 'fit' for their practice. The challenge here is that in essence, VAD is a legal procedure that is situated in a healthcare setting, and laws are frequently perceived as not a good fit for healthcare.[34] Furthermore, VAD laws seek to balance eligibility for access with safeguards to ensure the law is not abused. In some instances, complying with the safeguards creates significant barriers.[35] If clinicians perceive that a law, or the systems that operationalise it, have been imposed on their practice, rather than being internally developed as a solution to a problem, implementation may be resisted.

To ensure that clinicians can meet their legal obligations, institution-specific policies and procedures should be developed collaboratively and use consistent language that aligns with the services underlying values.[36] This has been demonstrated in a community palliative care service in Victoria, Australia, that when reviewing their organisational policies to accommodate the requirements of their state's law, ensured that client-centred values remained central.[37] These strategies may be considered as changes to the inner context and will assist clinicians to make sense of the law and reassure them that they are protected if they comply with their prescribed legal obligations. In the Netherlands, for example, VAD is not punishable if physicians have met the requirements of due care. In contrast, while nurses might routinely administer medications to relieve a person's suffering at the end of life, VAD laws generally do not permit them to administer medication with the intention of ending a life. It is important, therefore, that procedural guidelines also describe the legal boundaries of practice for all members of the interdisciplinary team.

Once developed, VAD policies and procedures must be supported locally by a suite of educational resources and made available to those who may be either directly or indirectly involved in VAD. The type and format of VAD educational resources will depend on the needs of the health service, clinicians, and patients. O'Conner and Philips report the use of informal sessions (referred to as 'fireside chats') to support more formal educational resources provided to staff working in a community palliative care service.[37] Research to evaluate whether educational resources and innovative strategies such as 'fireside chats' that are designed to support clinicians' understanding of how the law works in practice is essential.

Policies, recommendations, and guidelines such as those generated by professional associations or bodies form part of the outer setting. These statements are likely to resonate with some clinicians, and organisations that are aware of their stance can take steps to address potential areas of conflict that might act as a barrier. There is also a need for leadership within professional organisations; to begin professional debates about the merits and limitations of VAD in our society more broadly. For example, Palliative Care Australia has published guiding principles for those who provide care to those living with a life-limiting illness. These principles seek to ensure people have access to appropriate care at the end of life, and also to maintain appropriate, respectful, and cooperative relationships between healthcare professionals.[38] Contributions to professional debate are critical to informing the broader community's decisions about VAD legislation.

In regard to the individuals involved, effective collaboration is required to develop clear guidelines or protocols that set out how responsibility for VAD-related tasks or processes are allocated or delegated. While helping to achieve functional differentiation, they must also be flexible enough to accommodate different levels of participation as clinicians' attitudes to their involvement in VAD evolve. Mills et al. report that units or wards with a culture of open communication were more likely to be perceived as supportive of a range of different perspectives,[39] yet how clinicians develop the skills to work collaboratively, yet critically, in the highly contingent area of VAD requires further investigation.

Despite the importance of multidisciplinary care, the interaction between different disciplines may be fragmented. Entrenched cultural practices, such as views about the value of information to be communicated,[40] and organisation factors such as the physical layout of hospitals and staff scheduling that can result in physical and psychological segregation of different professions,[41] contribute to this fragmentation. Clear and timely interdisciplinary communication is pivotal for intersubjectivity and the provision of VAD. Although there have been concerted efforts to nudge the cultural change required to improve interdisciplinary communication,[42] additional strategies that are VAD-specific need to be considered. This might include structuring dedicated VAD teams. Collaborating on a team has been shown to relieve the tension that sometimes exists between providers as a result of the hierarchy and the conflicts that can arise across disciplines.[43] They also divide responsibilities among team members and alleviate the pressure experienced if one person feels as though they are responsible for doing it all.[44] Simulated learning is used to develop relational coordination in multidisciplinary emergency department teams and may also have value for VAD practice.[45]

When clinicians report that participating in VAD is deeply rewarding, this is likely because VAD aligns with deeply held values and beliefs.[46] For others, actively helping a person to end their life can generate substantial moral distress.[5] It is important, therefore, that clinicians are permitted and supported to choose their level of engagement with VAD. A recent literature review exploring the physician responses to participating in VAD found a universal lack of professional advice and support to help clinicians to deal with the emotional response generated by requests for VAD or coping with the impact.[47] Similarly, when nurses' perspectives are not respected or considered by other members of the multidisciplinary team, their experience of caring for patients seeking VAD is negatively affected.[47] Other contextual factors that support nurses to fulfil their caring responsibilities, and limit the moral distress associated with VAD include recognising the amount of time needed to effectively engage with patients.[48] Caring for patients who seek VAD involves significant emotional labour, and informal and formal support structures for all members of the team, as well as those who choose not to be involved, are necessary to foster sensitive and holistic care.[48]

Based on the preceding discussion we propose an implementation plan that recommends strategies to support the implementation of VAD in an acute care health setting (See Table 5). Further research will be undertaken to validate the plan.

STUDY LIMITATIONS

This two-phase study has used a systematic, and largely inductive, process to identify the common themes found in a diverse group of research studies investigating VAD. Rather than limit our researcher gaze to studies informed by implementation theory and frameworks, we focused more broadly on reported experiences associated with the introduction of VAD into the health setting. This approach generated more evidence for review and subsequent secondary analysis. It is important to recognise that this method has identified potential barriers and enablers that can assist clinicians, managers, implementation scientists and others in their deliberations about the implementation of VAD in their respective workplaces. However, the

TABLE 5: POSSIBLE VAD IMPLEMENTATION PLAN

Theme	Intervention	Outer Setting	Inner Setting	Individual
Theme 1: Putting the law into practice requires knowledge and understanding gained through education	Extract key clinical responsibilities (e.g. assessing eligibility for VAD) and procedural obligations (e.g. witnessing documents and reporting) from the enabling legislation.		Draft policies and procedures in consultation with legal experts and in collaboration with clinicians from a variety of disciplines. Develop, promote and evaluate VAD education for clinicians, and other staff.	Held to account for understanding legal and clinical requirements – possibly a credential.
Theme 2: Helping people die using VAD is complex	Identify roles that are specified in legal procedures.	Identify relevant professional position statements and guidelines.	Build a coalition of interested staff. Roles for other staff are discussed and negotiated by the team. Clearly articulated policies and guidance for conscientious objection to avoid requiring clinicians to comply with conflicting positions.	Commit to openness to other views and engage in discussion.
Theme 3: The how of enacting VAD		Access to resources developed by external agencies. Support compliance with legal reporting obligations.	Communication training to enhance staff intersubjectivity. Audit VAD deaths and provide feedback. Access to legal/ethical experts for consultation. Update record systems to align with the procedure. Include cases in morbidity & mortality meetings. Provide clinical supervision.	Attend communication training. Attend educational meetings with experienced providers when available.
Theme 4: Participating in VAD is deeply personal for clinicians		Encourage engagement with communities of practice.	Identify and prepare champions/ advocates. Make work-based psychologists and spiritual staff available for staff consultation. Structured and transparent processes and support for those clinicians choosing to participate in VAD as well as though who have a conscientious objection.	Reflect on personal views. Consult with workplace psychology or spiritual advisor. Support peers.

inductive nature of the methodology means that some implementation barriers, enablers and/or strategies may have been overlooked. As such, the recommendations of this study should be treated as tentative.

CONCLUSION

The number of jurisdictions where VAD is legal has steadily increased. Acute care health settings and the clinicians who work within them play an essential role in facilitating access to voluntary assisted dying for eligible patients. This study sought to identify the factors that act as barriers and enablers to the implementation of voluntary assisted dying in acute care health settings.

Thematic analysis of the articles included in the review demonstrated the complexity associated with the provision of VAD. It highlighted that the dense procedural and technical requirements associated with VAD can expose the inherent vulnerability of caring clinicians. Furthermore, the importance of clear communication, between clinicians and patients, and also between members of interdisciplinary healthcare teams was emphasised. It also reminded us that clinicians bring a diverse array of attitudes, beliefs, and values to their roles. Consequently, while some clinicians find that participating in VAD can be rewarding, it can also take an emotional toll.

Viewing these results through the CFIR implementation framework lens, allowed for potential barriers and enablers to be seen and implementation strategies to be suggested. It is apparent that educational resources to enhance knowledge of the law are imperative, however, the most important strategies to enable the successful implementation are those that recognise that VAD is a deeply personal and relational practice. Consequently, there is a need to ensure institutional policies clearly articulate the legal obligations, and also align with the underlying values of the organisation. Successful implementation requires strategies that promote collaborative interdisciplinary teamwork and support individual clinicians to practice in a way that is congruent with their underlying beliefs and values. That is, supporting those who wish to participate in VAD, as well as those who have a conscientious objection to participating in any part or all of the process.

Experience has shown that participating in VAD is not likely to become a routine procedure in any acute care health setting. However, its impact on those who participate cannot be understated. By ensuring that clinicians are adequately supported, people seeking VAD can gain control over the timing and manner of their death.

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REVIEWS AND DISCUSSION PAPERS

Validity of the Edinburgh Postnatal Depression Scale for screening pregnant and postpartum adolescents: a systematic review

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ABSTRACT

Objective: To examine the validity of the Edinburgh Postnatal Depression Scale (EPDS) for screening depression in pregnant and postpartum adolescents.

Background: The incidence of postpartum depression (PPD) in 15 to 19-year olds is double the rate reported among mothers older than 25 years. EPDS threshold scores that indicate possible depression among adolescents have not been established and may differ from those validated for adults.

Study design and methods: A systematic review of the literature between 1987 and 2020 was conducted using five databases: CINAHL, EMBASE, MEDLINE, MIDIRS and PsycInfo. Studies that sampled adolescent mothers in the perinatal period, that screened for depressive symptoms using the EPDS, and which assessed the validity of the tool were included. The studies were grouped according to their methodology with results presented as a narrative synthesis. Two researchers independently reviewed search results, study selection and data extraction, and undertook quality appraisals using the Quality Assessment of Diagnostic Accuracy Studies checklist.

Results: Five studies that sampled a total of 1,241 participants were included in the review: four validated the EPDS against diagnostic reference standards and one against other depression screening tools. The EPDS demonstrated high levels of sensitivity and specificity although optimal cut-off scores for possible depression were between 2 and 7 points lower than that recommended for adult samples. Overall performance of the EPDS was equivalent or better when compared to other screening tools.

Discussion: The standard EPDS cut-off score (≥12) does not identify all adolescents at high risk of depression during the perinatal period. Scores of ≥9 may be more appropriate. However, different reference standards and sampling methods used in the studies compromise the review's strength of evidence.

Conclusion: Despite development of the EPDS more than 30 years ago, research into its validity among adolescents is still in its infancy. This review makes an important contribution to that body of evidence by revealing its limitations and highlighting trends upon which further research can build.

Implications for research, policy and practice: Although Australian guidelines for perinatal depression screening are some of the most detailed in the world, limited guidance is offered for EPDS use among adolescents. The findings of this review

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raise important points for that guidance and for practitioners. Concerns for possible depression in adolescents should be triggered at an advisory EPDS cut-off score of ≥9. Further research is needed to confirm or refute these findings.

What is already known about the topic?

- Postpartum depression (PPD) among adolescents is prevalent and a recognised public health concern due to its significant association with morbidity.
- Perinatal screening for depression using validated instruments, including the Edinburgh Postnatal Depression Scale (EPDS), is recommended in national and international guidance.
- There is no validated version of the EPDS for adolescents although there is evidence to suggest that cut-off scores indicative of possible depression may need to be lower than those recommended for adults.

What this paper adds:

- The paper synthesises evidence that demonstrates the EPDS is a valid scale for perinatal screening of depression in adolescents.
- It identifies lower cut-off scores for suspected depression among adolescents compared to adults, and also highlights score differences in the pre and postnatal periods.
- The paper provides advisory screening guidance for practitioners and emphasises the importance of monitoring for depressive symptoms in perinatal adolescents at every healthcare encounter.

Key words: Adolescent mothers, antenatal depression, postpartum depression, psychometric properties, rating scales.

INTRODUCTION

Nearly 16 million adolescent women give birth every year, accounting for 11% of births worldwide.[1] However, they carry 23% of the overall disease burden from pregnancy and childbirth in terms of disability adjusted life years.[2] Common mental health problems during the perinatal period (prenatal to one year postnatal) include substance abuse, eating disorders, anxiety and depression.[3] The prevalence of depression is significantly higher in adolescent mothers compared to adult mothers, ranging from 14 to 53% and 6.9 to 16.7% respectively.[3] The probability of having used illicit drugs is also greater in adolescent mothers, as is smoking during pregnancy and suffering physical abuse from partners.[4]

Adolescence is often a tumultuous period in a person's life characterised by changes in hormones and neurotransmitter levels, which influence how we experience emotions. Mood can change rapidly and frequently, and strong emotions may emerge not previously experienced. Feeling depressed as an adolescent mother may therefore include different features compared to adult mothers such as fear, transition difficulties, feeling overwhelmed and confused, low self-esteem, rejection by peers and a sense of abandonment and isolation.[5] Postpartum depression (PPD) is a particularly common and frequent disorder among this group and is recognised as a public health concern due to its significant association with morbidity.[3]

Over the first two decades of this century, increasing attention has focused on perinatal mental health screening in Australia. The National Perinatal Depression Program was launched in 2001, followed by the Perinatal Mental Health Action Plan in 2008.[6] The first Australian national guidelines for perinatal mental healthcare were published in 2011,[7] which recommended antenatal and postnatal screening for depression. Clinical practice guidelines issued in 2012 reiterated these recommendations, for which an update was published in 2017.[8] Between 2000 and 2017 the percentage of Australian women not screened for depression during the perinatal period fell from 40.6 to 1.7%, and the percentage who were screened in both the antenatal and postnatal periods increased from 21.3 to 79.3%.[9] Despite these improvements, one-in-five women (21%) are still not screened at both time points in line with clinical guidance.[9]

There has also been a 40% reduction in the rate of teenage pregnancy in Australia between 2006 and 2017, from 17.6 to 9.2 live births per 1,000 females aged 15-19.[10] However, there is wide variation across different populations with a rate of 53 live births per 1,000 among adolescents who identify as Aboriginal or Torres Strait Islander.[11] The rate is also higher among those who live in remote areas, are socially disadvantaged with unstable housing and who receive social welfare.[11] Struggles with mental health issues among these young mothers are not uncommon but there are recognised barriers to adequate care including a lack of resources, adequately trained professionals, and the social stigma associated with mental disorders, although the greatest impediment is inaccurate assessment.[12] Often, individuals are either not diagnosed or misdiagnosed.

Studies that examine screening for depression in adolescent mothers have used various instruments including the Center for Epidemiological Studies Depression Scale (CES-D) and the Beck Depression Inventory (BDI).[13,14] The psychometric properties of both scales demonstrate their suitability for use among adolescent mothers, but neither focuses on

the measurement of symptoms that are specific to PPD. In contrast, the Edinburgh Postnatal Depression Scale (EPDS) was created especially for screening PPD symptoms.[15] The EPDS was originally developed in the United Kingdom (UK), has been translated into more than 50 languages and is now used extensively throughout the world.[16]

Although initially developed for identifying possible symptoms of depression in the postnatal period, the EPDS has been adequately tested among adult samples to also identify symptoms in the antenatal period.[17] The scale contains 10-items that capture data on depressive symptoms experienced over the preceding seven days, excluding somatic symptoms which can be confused with physiological changes in pregnant or postpartum women. The most typically used threshold score to identify mothers with major depressive disorder is ≥12. Shorter versions of the tool have also been created including the EPDS 2-item, 3-item and 7-item.[5]

Few psychometric data on the full or shortened versions of the EPDS among pregnant or adolescent mothers have been reported. To date, there is no validated version or any other measure of PPD in any language for adolescents,[3] although there is some evidence to suggest that cut-off scores lower than ≥12 may be advisable among this population.[5]

Australian clinical practice guidelines recommend use of the EPDS to screen for depression during the perinatal period and advise formal psychiatric assessment for scores of 13 or more, with repeated screening within a 2 to 4-week period for scores of between 10 and 12.[8] The guidelines advise that appropriately translated versions of the EPDS should be used when necessary with culturally relevant cut-off scores, but advice is not tailored to adolescents who are mentioned only as examples of complex presentations for which inter-professional collaboration is recommended.[8] Accurate screening for PPD among adolescents remains an important clinical challenge. This paper therefore presents a systematic review that considered the suitability of the EPDS for use among this group. Specific objectives were to:

- appraise the validity of the EPDS as a screening tool for pregnant and postpartum adolescents;
- identify the optimal EPDS threshold scores that indicate possible PPD in adolescents.

METHODS

The Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy was used to design and execute the review.[18] It is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement extensions for Diagnostic Test Accuracy studies (PRISMA-DTA).[19] An *a priori* protocol was prepared for the review and is available on request from the corresponding author. Completed DTA checklists are available online (Appendix A).

SEARCH STRATEGY

A preliminary search of the Cochrane library was undertaken to ensure no other related systematic reviews had been conducted. A population, intervention and outcome (PIO) analysis was then performed to identify index terms using the medical subject headings (MeSH) thesaurus and associated free-text terms,[20] which were expanded and combined in the search strategy using Boolean operators (Table 1). This strategy was applied to the Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medline, EMBASE, Maternity and Infant Care Database (MIDIRS) and PsycInfo in August 2020. Forward citation tracking of retrieved articles was also conducted by hand searching reference lists.

TABLE 1 PIO ANALYSIS SEARCH TERMS

	Population		Intervention		Outcome
Index terms/MeSH	Pregnancy in adolescence/ Adolescent pregnancy		Psychometrics		Postpartum depression
Free-text terms	Adolescent mother* OR Pubescen* mother* OR Child bearing* OR Child-bearing OR childbearing* OR teen* mother* OR young* mother*	AND	Rating scale* OR Rating tool* OR Rating instrument* OR Measurement scal* OR Measurement tool* OR Measurement instrument* OR Assessment scal* OR Assessment tool* OR Assessment instrument* OR Screening scal* OR Screening tool* OR Screening instrument* OR Depression adj3/n3 scale* OR Depress* adj3/n3 detect* OR Psychometric* adj2/n2 scal* OR Mood* adj3/n3 scale* OR Mental adj3/n3 scale* OR Postnatal scale* OR Postpartum scale* OR Edinburgh adj2/n2 scale* OR EPDS	AND	PPD OR Postpartum adj3/n3 depres* OR Postnatal* adj3/n3 depress* OR Perinatal* adj3/n3 depress* OR Puerperal adj3/n3 depress* OR Postnatal depression OR PND

INCLUSION CRITERIA AND STUDY SELECTION

Studies were included if they reported quantitative research that sampled adolescent mothers aged between 13 and 19 years who were pregnant or in the postpartum period, which screened for depressive symptoms or PPD using any version of the EPDS, and which considered the validity of the tool. Only studies reported in the English language between 1987, when the EPDS was first published, and 2020 were included. Qualitative designs, expert opinion or consensus statements were excluded.

Both authors (FB and AG) independently assessed titles, abstracts and full-text articles against eligibility criteria. The resulting indecision and disagreement regarding the eligibility criteria of individual titles, abstracts, and full-text articles were discussed and excluded by agreement amongst the two authors. Selection decisions were agreed through discussion and full-text copies of the included articles were uploaded into Covidence for analysis (www.covidence.org).

DATA EXTRACTION AND ANALYSIS

A data extraction template captured methodological details from each study including country of origin, study aim and index test, design and reference standard, sample and setting, and key findings. Index test extractions included the EPDS version(s) being tested and other validated tests used for comparative purposes. Reference standard extractions included the assessment instrument, diagnostic classification system and the diagnoses used for analysis purposes. Sample extractions included the sampling method, demographic and stage of pregnancy data (antenatal or time postnatal). Key findings extractions were of the principal diagnostic accuracy measures including sensitivity, specificity, positive and negative predictive values, receiver operator curve statistics and optimum cut-off scores.

Four different diagnostic reference standards were used across the studies resulting in different classifications of depression e.g. minor and major depression combined, and major depressive episode alone. There were also important differences in study samples, being exclusively pregnant or postpartum adolescents. These differences between reference standards and participants precluded a meta-analysis.[21]

The studies were initially grouped according to assessment of the EPDS against a diagnostic reference standard or against another depression screening tool. Within and between group comparisons of study contexts, methods and diagnostic accuracy results were then undertaken to provide a narrative synthesis of the results.

QUALITY APPRAISAL

Quality appraisal of the studies was undertaken using the Quality Assessment of Diagnostic Accuracy Studies checklist (QUADAS 2019).[22] The Cochrane handbook recommends using 11 of the 14 original QUADAS quality items for DTA reviews and adding additional items for particular topics or contexts.[18] The QUADAS is principally designed to appraise studies in which the accuracy of a test such as the EPDS is measured against a diagnostic reference standard, rather than when two or more screening tests are compared with each other. Because some of the studies in this review undertook comparisons of different screening tests, adjustments were made to the wording of some QUADAS items to include the reference standard or comparison test e.g., was the reference standard/comparison test independent of the index test?

The checklist included space for a description and judgement against each quality item. The description provided a succinct statement of the stated facts from a study upon which each judgement was based. Judgements were rated as 'yes', 'can't tell', 'no' or 'N/A'. QUADAS ratings were completed separately by each author (FB and AG) with any disagreements resolved through discussion. Results are provided as a narrative summary.

RESULTS

SEARCH OUTCOMES

The literature search returned 3,588 studies. After the removal of duplicates, and title and abstract screening, 53 studies were retrieved for full text review from which five met eligibility criteria and were included in the review (Figure 1).

STUDY CHARACTERISTICS

Table 2 presents the characteristics of included studies. They collectively sampled 1,241 participants with mean ages from 15 to 17 years across the studies, and individual sample sizes from 59 to 807. Three studies were conducted in the USA one in Mexico and one in Brazil. [5,23-26] Study designs included one randomised controlled trial (RCT) and four cross sectional surveys.5,[5,23-25] Two studies assessed the EPDS among pregnant adolescents and three assessed its use among adolescent mothers during the postpartum period.[5,23-26]

Participants were sampled from public services in their respective countries, typically prenatal hospital-based clinics and postnatal community services. Two studies from the USA included participants from the teen parenting program of a public school system.[23,24] Four of the studies assessed the EPDS against a diagnostic reference standard,[5,24-26] although different reference standards were used in each study. Three of these four studies also assessed EPDS performance against other screening tests.[5,24,26] The fifth study used the CES-D as a concurrent validity check for the EPDS without a diagnostic reference standard.[23]

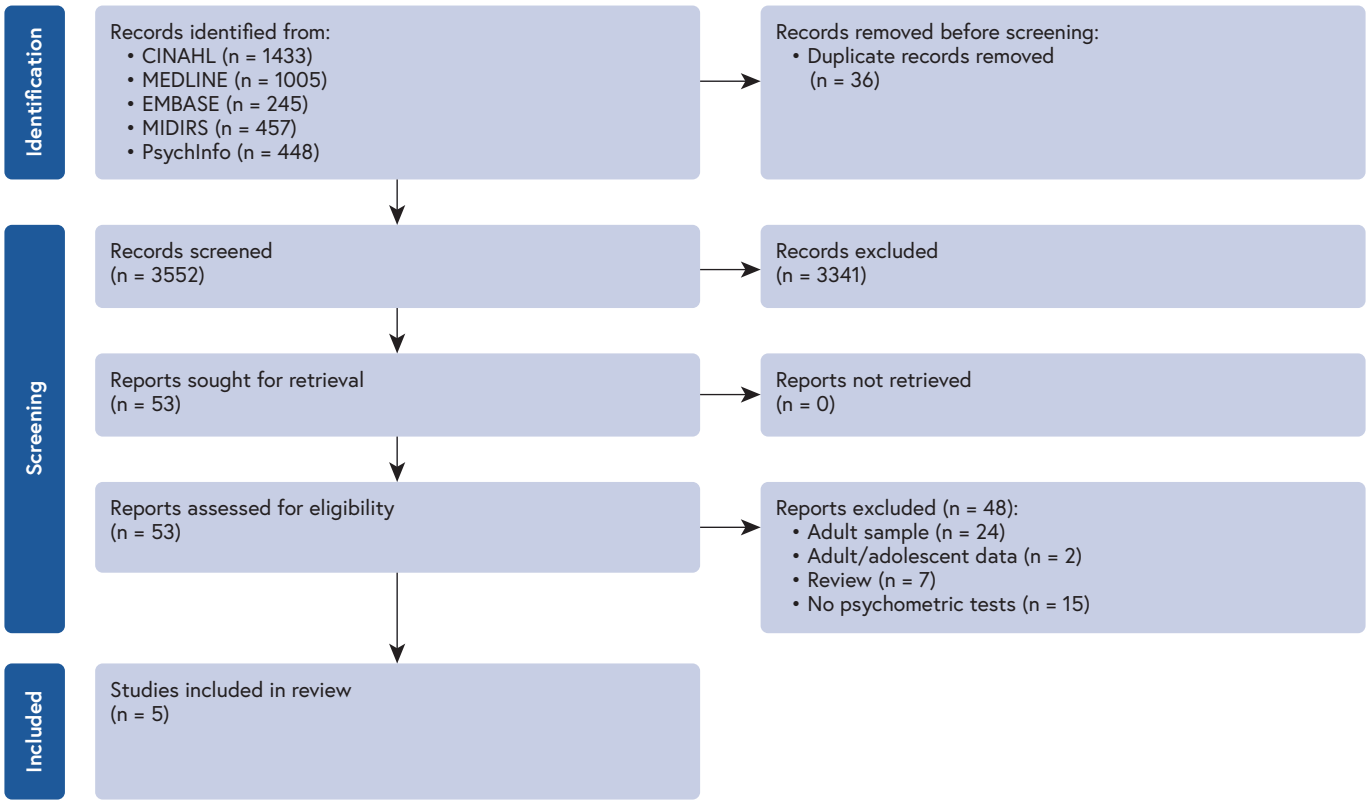

FIGURE 1 PRISMA FLOWCHART[27]

TABLE 2 STUDY CHARACTERISTICS

Authors and country	Aim and index test	Design and reference standard	Sample and setting	Key findings
Alvarado-Esquivel et al, (2014)25 Mexico	To validate a Spanish translated Mexican version of the EPDS in pregnant adolescents	Cross-sectional survey using DSM-IV psychiatrist assessment as a reference standard Major and minor depression diagnoses included in analyses.	Random selection of 120 pregnant adolescents from a prenatal hospital clinic in Durango City, Mexico (mean age 15.9 years ± 1.0)	• Sensitivity 70.4% and specificity 84.9% • Positive predictive value 47.6% and negative value 91.0% • AUC 0.81 (95% CI: 0.56-1.07) • Optimal cut-off score 8/9
Logsdon et al (2009)23 United States of America	To assess the psychometric properties of the EPDS among adolescent mothers	Cross-sectional survey using the CES-D as a concurrent validity check without a diagnostic reference standard	Convenience sample of 149 adolescent mothers from two community hospitals and one public school for pregnant and parenting teens in southern United States (postpartum 4-6 weeks, mean age 16 years ± 1.19)	Principal components analysis • Factor 1 anxiety (Alpha 0.82, loading range 0.61-0.80) • Factor 2 depression (Alpha 0.82, loading range 0.51-0.82) Item analysis • Total items >0.44 (moderate) • Inter-items 0.23-0.72 (moderate to strong) Concurrent validity • Correlation with CES-D r=0.77 (mid-level) Internal consistency • Cronbach's alpha 0.88

TABLE 2 STUDY CHARACTERISTICS

Authors and country	Aim and index test	Design and reference standard	Sample and setting	Key findings
Logsdon and Myers (2010)24 United States of America	To establish whether the EPDS or CES-D 20- and 30-item is more efficient at predicting major depressive disorder in adolescent mothers, and to assess their psychometric properties	Cross-sectional survey using the KSADS-PL as a reference standard, which incorporates DSM-IV diagnoses Diagnosis of major depressive disorder included in analyses	Convenience sample of 59 adolescent mothers from a public school for pregnant and parenting teens in southern United States (postpartum 4-6 weeks, mean age 16.38 years ± 1.34)	Diagnosis • Reference standard 16.9% • EPDS (traditional cut-off 12) 12.5% • CES-D20 (traditional cut-off 16) 32.2% • CES-D30 (using cut-off 24) 30.5% • EPDS, CES-D 20 and 30 all significantly correlated with one another (p<0.001), but reference standard not correlated with any Sensitivity, specificity and AUC • EPDS cut-off of 5 produced similar results to cut-off of 12 in adult population (sensitivity 0.8, specificity 0.6) • AUC 0.68 (95% CI 0.51-0.84, p=0.041) • CES-D20 similar to adult population cut-off of 16 (sensitivity 0.7, specificity 0.5) • AUC 0.62 (95% CI 0.47-0.80, p=0.201) • CES-D30 optimal cut-off of 16 (sensitivity 1.0, specificity 0.27) • AUC 0.60 (95% CI 0.45-0.77, p=0.343)
Martins et al (2015)26 Brazil	To identify the best cut-off scores of the EPDS and BDI in pregnant adolescents	Cross-sectional survey using MINI psychologist assessment as a reference standard, which is consistent with DSM-IV criteria Diagnosis of major depressive episode included in analyses	Consecutive sample of 807 pregnant adolescents from 47 primary care units and three obstetric clinics in Pelotas, Southern Brazil (mean age 17.3 years ± 1.4)	EPDS • Sensitivity 81.1% and specificity 82.7% • Positive predictive value 43.6% and negative value 93.3% • AUC 0.90 (95% CI 0.87 - 0.92) • Optimal cut-off score ≥10 BDI • Sensitivity 86.7% and specificity 73.8% • Positive predictive value 37.0% and negative value 92.8% • AUC 0.87 (95% CI 0.84 - 0.89) • Optimal cut-off score ≥11
Venkatesh et al, (2014)5 United States of America	To evaluate the accuracy of the EPDS and three subscales for identifying postpartum depression among primiparous adolescent mothers	Randomised controlled trial that used the KID-SCID as a reference standard, which incorporates DSM-IV diagnoses Diagnosis of major depressive disorder included in analyses	Randomisation of 106 adolescent mothers to an interpersonal theory intervention to prevent depression or a control group that received a guidebook as a didactic intervention: both five sessions (assessed at 6-weeks, 3 and 6-months postpartum, mean age 16 years, range 13-18). Because the intervention was designed to prevent depression, adolescents with psychiatric disorders including depression were excluded.	Overall scores across three time points • EPDS full 10-item AUC 0.94 (95% CI 0.91 - 0.99) • EPDS 7-item AUC 0.96 (95% CI 0.92 - 0.99) • EPDS 3-item AUC 0.81 (95% CI 0.73 - 0.88) • EPDS 2-item AUC 0.90 (95% CI 0.93 - 0.97) Standard cut-off score ≥10 • Full EPDS, 7- and 2-item performed satisfactorily AUC >0.85 • 3-item performed less well AUC=0.72 Optimal cut-off score ≥9 • Full EPDS improved AUC 0.90 Optimal cut-off score ≥7 • EPDS 7-item improved AUC 0.89 Sensitivity and specificity • EPDS full at standard cut-off: overall sensitivity 80%, specificity 92% and at optimal cut-off sensitivity 90%, specificity 90% • EPDS 7-item at standard cut-off: overall sensitivity 77%, specificity 96% and at optimal cut-off sensitivity 90%, specificity 87% • EPDS 2-item sensitivity 87%, specificity 83% • EPDS 3-item sensitivity 74%, specificity 70%

Key: AUC = area under the curve, BDI = Beck depression inventory, CES-D = Center for Epidemiological Studies-Depression scale, DSM-IV = Diagnostic and Statistical Manual version 4, EPDS = Edinburgh Postnatal Depression Scale, KID-SCID = Structured Clinical Interview for DSM-IV Childhood Disorders, KSADS-PL = Schedule for Affective Disorders and Schizophrenia for School Age Children-Present and Lifetime Version, MINI = Mini International Neuropsychiatric Interview

QUALITY OF STUDIES

Table 3 presents quality appraisal results. The overall quality of the body of evidence was considered good although, it was not possible to rate one item in four studies and another item in three studies due to insufficient information: whether EPDS results were interpreted without knowledge of reference standard results and the representativeness of samples.[5,23-26] Whether EPDS results were interpreted blind of the reference standard, rests on whether participants knew their diagnosis before completing the EPDS. Detail on the sequencing of tests and the disclosure of results to participants was not provided in sufficient detail to judge. The samples may be representative of those who will receive the EPDS in practice, given the studies' inclusion of pregnant and postpartum adolescents attending public ante and postnatal services, but in three studies the sampling method is not clear.[5,23,24] One of these studies also had an unexplained incomplete data set,[5] indicating withdrawals from the study, which may further undermine representativeness.

There was also insufficient information to judge whether assessors were blind to index text results in two studies,[5,23] and one study, although meeting six criteria, provided insufficient information to rate the remaining five criteria.[23] However, with the exception of unexplained withdrawals, these are all problems identified with the reporting of studies and it is unclear whether the omission of information hides deeper methodological problems. No study was excluded based on its quality appraisal but results are accounted for in the synthesis of evidence and the conclusions drawn. Completed appraisals are available online (Appendix B).

REVIEW FINDINGS

Reported findings include sensitivity, specificity, positive and negative predictive values, and area under the receiver operator curve statistics. Sensitivity is the true positive rate and specificity the true negative rate of clinically diagnosed depression in the participants. Positive predictive values represent the probability that individuals who screened positively with the EPDS truly had depression, or truly didn't for negative predictive values. All these values change depending on the EPDS cut-off score that was used to determine the likely presence of depression. Choosing a cut-off score that increases sensitivity will result in decreased specificity. Area under the receiver operator curve statistics are the result of computing true positive versus false positive scores across a range of cut-off values, which allows optimal cut-off scores to be identified for clinical use.[28] Findings are presented for studies that assessed EPDS performance against a diagnostic reference standard, followed by studies that assessed performance against another depression screening tool.

ASSESSMENT AGAINST A DIAGNOSTIC REFERENCE STANDARD

Venkatesh et al.[5] assessed the full 10-item, 7-item, 3-item and 2-item EPDS scales among adolescent mothers using the Structured Clinical Interview for DSM-IV Childhood Diagnoses (KID-SCID) as their reference standard. The diagnosis of major depressive disorder was used for diagnostic accuracy tests. Against a standard cut-off score of ≥10, the full 10-item, 7-item and 2-item scales performed satisfactorily (area under the curve [AUC]=>0.85). The 3-item scale performed less well (AUC=0.72). When adjusting the cut-off score to ≥9, performance of the full EPDS improved

TABLE 3 QUALITY APPRAISALS

QUADAS appraisal items[22]	Alvardo-Esquivel et al (2014)[25]	Logsdon et al (2009)[23]	Logsdon and Myers (2010)[24]	Martins et al (2015)[26]	Venkatesh et al (2014)[5]
1. Representative spectrum	Y	?	Y	?	?
2. Acceptable reference standard/comparison	Y	Y	Y	Y	Y
3. Acceptable delay between tests	Y	?	Y	Y	Y
4. Partial verification avoided	Y	?	Y	Y	Y
5. Differential verification avoided	Y	Y	Y	Y	Y
6. Incorporation avoided	Y	Y	Y	Y	Y
7. Index test results blinded	Y	?	Y	Y	?
8. Reference standard/comparison test results blinded	?	?	Y	?	?
9. Relevant clinical information	Y	Y	Y	Y	Y
10. Uninterpretable results reported	Y	Y	Y	Y	Y
11. Withdrawals explained	Y	Y	Y	Y	N

Key: Y=yes, ?=can't tell, N=no, N/A=not applicable

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(AUC=0.90), as did performance of the 7-item scale with a cut-off score of ≥7 (AUC=0.89). Sensitivity of the full EPDS at ≥10 cut-off was 80% and specificity 92%, but sensitivity improved with a ≥9 cut-off (90%). All other sensitivity values and most specificity values reduced for the 7-, 3- and 2-item scales.

Logsdon and Myers assessed the full 10-item EPDS scale among adolescent mothers using the Kiddie Schedule for Affective Disorders and Schizophrenia,[24] Present and Lifetime version (KSADS-PL) as their reference standard, which incorporates DSM-IV diagnoses. The diagnosis of major depressive disorder (MDD) was used for diagnostic accuracy tests. Using a traditional cut-off score of ≥12, the EPDS identified MDD in 12.5% of the sample compared to 16.9% identified by the KSADS-PL (non-significant correlation). However, when the EPDS cut-off was reduced to ≥5, it produced similar sensitivity (0.8) and specificity (0.6) results among their adolescent sample as those found among adult samples using a ≥12 cut-off (AUC=0.68, 95% CI 0.51-0.84, *p*=0.041).

Alvarado-Esquivel et al.[25] assessed the full 10-item EPDS scale among pregnant adolescents using the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) as their reference standard. The combined diagnoses of minor and major depression were used for diagnostic accuracy tests. Sensitivity was 70.4% and specificity was 84.9%. Positive and negative predictive values were 47.6% and 91.0% respectively. Optimal sensitivity and specificity were found at a cut-off score of between 8 and 9 (AUC 0.81, 95% CI 0.56-1.07).

Martins et al.[26] assessed the EPDS full 10-item scale among pregnant adolescents using the Mini-International Neuropsychiatric Interview (MINI) as their reference standard, which is consistent with DSM-IV criteria. The diagnosis of major depressive episode was used for diagnostic accuracy tests. Sensitivity was 81.8% and specificity was 82.7%. Positive and negative predictive values were 43.6% and 93.3% respectively. Optimal sensitivity and specificity were found at a cut-off score of ≥10 (AUC 0.90, 95% CI 0.87-0.92).

ASSESSMENT AGAINST ANOTHER DEPRESSION SCREENING TOOLS

Logsdon et al.[23] assessed the full 10-item EPDS scale among adolescent mothers against the Center for Epidemiological Studies Depression Scale (CES-D). The concurrent validity correlation with the CES-D was *r*=0.77 (mid-level), and test characteristic curves for both scales suggested that the items in each scale were well aligned to one another. Principal component analysis of the EPDS identified two factors: anxiety (Alpha 0.82, loading range 0.61-0.80), and depression (Alpha 0.82, loading range 0.51-0.82). The internal consistency of the EPDS was 0.88 (Cronbach's alpha), which did not improve with the removal of any item.

Logsdon and Myers,[24] and Martins et al.[26] also assessed the CES-D and the Beck Depression Inventory (BDI) respectively against their reference standards (KSADS-PL and MINI). Results can therefore be compared with the EPDS performance. The CES-D 20-and 30-item scales both identified a greater proportion of cases diagnosed by the reference standard than the EPDS (32.2% and 30.5% versus 12.5%) but, as with the EPDS, these were non-significantly correlated with the KSADS-PL. CES-D 20-and 30-item AUC scores were no better than for the EPDS and did not reach statistical significance. The BDI had a slightly improved sensitivity value than the EPDS (86.7% versus 81.1%) but positive predictive values for the EPDS were higher than the BDI values at all cut-off points. The BDI and EPDS AUC scores were similar (0.90 versus 0.87).

DISCUSSION

The objectives of this review were to appraise the validity of the EPDS as a screening tool for depression among pregnant and postpartum adolescents, and to identify optimal EPDS threshold scores indicative of possible depression. Age-specific screening for adolescent depression during the perinatal period remains an important priority, particularly given its adverse, and possibly lifelong effects on mother and child.[3] Against this backdrop, the paucity of available literature is a striking feature of this review. This may reflect the general tendency for women to have children later in life, and a corresponding decline in pregnancies at a younger age, thereby shifting the lens of inquiry away from adolescents.[29] There was also a noted tendency for the age of mothers in the articles screened for this review to be a purely descriptive characteristic, rather than a variable to stratify samples across which results could be compared. This was particularly so before the year 2000 and persisted to some degree beyond that time point. For example, Santos et al.[30] reported an EPDS validation study in which 22.2% (n=84) of their sample were under the age of 20 years although no attempt was made to consider optimal EPDS cut-off points across age groups.

The four studies in this review that calculated optimal cut-off scores all reported a lower value than that traditionally used among adult samples (≥12).[5,24-26] Optimal values ranged from 2 to 7 points lower, and the extremes of this range differentiated between pre and postnatal adolescents. Optimal postpartum scores were 7 points lower and prenatal scores were 2 points lower.[24,26] This may be an artifact of ethnic and geographical differences between study samples,[31] and may also be due to a type I error for the postpartum score. The study by Logsdon and Myers from which that result emerged had a sample size between 44 and 92% smaller than the other studies (n=59).[24] However, the pre-postnatal cut-off difference is consistent with the origins of the EPDS, which was designed to screen for the increased vulnerability of women to psychiatric disorder in the months following childbirth.[15] It is also known that incident depression, new cases in people with no history of depression, is higher in the postnatal period.[32] The findings of this review may point to a greater incidence and intensity

of depressive feelings in postpartum adolescents compared to prenatal adolescents. Regardless of this uncertainty, the consistent trend toward lower scores across these studies suggests that the standard cut-off for the EPDS may not accurately identify adolescents who are at high risk of depression during the perinatal period.

Three other points of interest are noteworthy from these four studies that compared the EPDS with a diagnostic reference standard. Sensitivity and specificity were high except in the Logsdon and Myers study where neither the EPDS, CES-D or BDI correlated with the KSDAS-PL reference standard, although they significantly correlated with each other.[24] Again, uncertainty surrounds this finding because of the small sample size and the possibility this time, of a type II error. Larger samples may generate improved sensitivity and specificity values against the KSDAS-PL. Venkatesh et al.[5] reported valid results not only for the full 10-item EPDS but also for the shorter 7- and 2-item versions. In services with limited time and resources this is an important finding and may advantage the EPDS over other scales. The studies by Logsdon and Myers,[24] and Martins et al.[26] point to other EPDS advantages. Receiver operator curve results and AUC statistics indicated that the overall performance of the EPDS 10-item was equivalent to that of the CES-D 20- and 30-item instruments,[24] and performed better than the BDI.[26]

The literature emphasises the importance of screening for both anxiety and depression in postpartum women,[33,34] and more specifically, that adolescent mothers' feelings of depression include an anxiety component.[35,36] Principal component analysis of the EPDS performed by Logsdon et al.[24] identified two components labelled anxiety and depressive symptoms, which lend further weight to the value of the EPDS as a screening instrument among adolescents. The two factor structure is also supported by the work of Ross et al.[34] who sampled adult mothers.

Australian guidelines for perinatal depression screening are some of the most detailed in the world,[8] and whilst they acknowledge the importance of culturally relevant cut-off scores when using the EPDS, little is said about the tool's implications for adolescents. The findings of this review do not provide definitive evidence to offer greater specificity, but they do raise important points for policy makers and practitioners. Guideline recommendations to undertake formal psychiatric assessment for scores of 13 or more,[8] with repeated screening within a two to four week period for scores of between 10 and 12, are not in line with the findings of this review. They suggest that concerns for possible depression among perinatal adolescents should be triggered at lower EPDS values. Leaving to one side the Logsdon and Myers study that may contain sampling bias,[24] the weight of evidence points to a need for formal psychiatric assessment at scores of ≥9 among adolescents. With a young woman's consent, such assessments can realise treatment benefits and in the most extreme cases, may save lives.

LIMITATIONS

The availability of only five studies is a limitation of this review. Given the increased prevalence of depression in adolescents during the perinatal period, its potential consequences for mother and child, and a recognition that threshold scores for screening instruments among this group may need to be lowered, it is surprising that so few studies have addressed this important challenge. Conclusions drawn and recommendations made should therefore be viewed as preliminary. However, this is an important review output that provides a marker for the strength of the evidence base. The relative importance of the preliminary findings is also underlined by a 'good' quality appraisal for the overall body of evidence.

The transcultural applicability of the results is uncertain, although the EPDS has been translated and validated for use among adults in 50 languages around the world.[16] Confidence in the review's findings is supported by the consistent trend toward lower cut-off EPDS scores among adolescents from studies conducted in North and South America. However, it is not possible to accurately deduce whether or how much those scores should be lowered for different geographical settings and languages.

CONCLUSION

The consistent, systematic use of an accurate method to screen for depression among adolescents during the perinatal period is a pre-requisite for improved diagnosis, the selection of effective interventions, and the amelioration of the burden and risks associated with the condition. The EPDS is a valid, brief, easy to administer tool that can support those endeavours. Despite its development more than 30 years ago, research into its psychometric properties for use among adolescents is still in its infancy. This review makes an important contribution to that body of evidence by revealing its limits, but also highlighting trends that suggest different scoring systems may be necessary, both in the pre and postnatal period, from those recommended for adults. Researchers should build on this knowledge to further study and publish data on the psychometric properties of the tool for pregnant and postpartum adolescents. The absence of more definitive conclusions does not negate the importance of monitoring for depressive symptoms in perinatal adolescents at every healthcare encounter.[37]

IMPLICATIONS FOR RESEARCH, POLICY AND PRACTICE

Although Australian guidelines for perinatal depression screening are some of the most detailed in the world, limited guidance is offered for EPDS use among adolescents. The findings of this review raise important points for that guidance, for practitioners and for research. The evidence

suggests that concerns for possible depression in adolescents should be triggered at an advisory EPDS cut-off score of ≥9, and that this score may need to be lower for postpartum compared to pregnant adolescents. The existing evidence base is insufficiently mature to allow meta-analyses. More primary research with improved reporting standards is needed to confirm or refute the findings of this review.

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