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Psychometric properties of the Brazilian version of the Nurses' Knowledge of High-Alert Medications scale: a pilot study

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Abstract

Background and Purpose: High-alert medication is considered to be a medication that presents a high risk of causing significant patient harm when used erroneously and its consequences can be fatal. The Nurse's Knowledge of High-Alert Medication scale (NKHAM) is a tool available to evaluate the knowledge of nurses in practice about this issue. **Aim:** This pilot study aimed to measure the reliability and known-groups validity of the Brazilian version of the NKHAM. **Methods:** This pilot psychometric study was carried out at the Faculty of Nursing and University Hospital of the University of Campinas, Sao Paulo, Brazil. Forty nursing students and 44 registered nurses working in complex clinical or surgical settings completed a sociodemographic questionnaire and the Brazilian version of the NKHAM. The KR-20 coefficient and Mann-Whitney test were used was used to establish reliability and known-groups validity. A significance level of ≤ 0.05 was adopted for all the analyses. **Results:** Analyses demonstrated preliminary acceptable reliability scores of 0.55 and 0.60 in domains A and B of NKHAM, respectively. A significant difference was found between the nursing students' and the registered nurses' knowledge of high alert medications, demonstrating the scale's ability to discriminate between the two groups. **Implication for Practice:** Although this is pilot study, results suggest that the Brazilian version of the NKHAM might be a reliable and valid tool to measure nurses'

knowledge of high-alert medications.

Keywords: Rating scales; Psychometrics; Medication errors; Patient safety; High-alert medication; Nursing.

Introduction

Lack of knowledge of nursing professionals is considered to be one of the major factors associated with errors in administering general medication (Brady, Malone, & Fleming, 2009; Hsaio et al., 2010; Lo, Yu, Chen, Wang, & Tang, 2012). Most medication errors (ME) cause no harm to patients, but serious injuries and deaths are usually due to incorrect administration of high-alert medications (HAM) (Cheragi, Manoocheri, Mohammadnejad, & Ehsani, 2013; Lu et al., 2013; Phillips et al., 2001), such as epinephrine, insulin, potassium chloride in acute care setting (Institute of Safe Medication and Practices, 2014). For this reason, studies have systematically shown the need for increasing training and knowledge of nurses, particularly focused on pharmacological knowledge, so as to improve the safety in administering medication, especially the HAM (Brady et al., 2009; Cheragi et al., 2013; Lu et al., 2013). It is also important to carry out objective evaluations of the nurses' knowledge in relation to the HAM, using valid and reliable instruments, as a strategy to identify priorities in nursing training in relation to use of HAM (Chen et al., 2014; Shafiei, Baratimarnani, Goharinezhad, Kalhor, & Azmal, 2014).

There is a current dearth of research investigating nurses' knowledge of HAMs in Brazil and no valid and reliable tool is available to measure this construct with nurses in this country. The Nurses' Knowledge of High-Alert Medications (NKHAM) is a tool that was developed and validated with 305 registered nurses in Taiwan. The instrument is composed of two sections; 1) items to evaluate nurses' knowledge about HAM, and 2) items to evaluate

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known errors related to administering medication. Section 1 is formed of four sub-parts; a) items about administering medication, b) items about medicine regulations, and c) items about co-factors related to errors, and d) items for self-evaluation.-This scale is considered to be a reliable (α=0.74) e valid instrument to measure nurses' knowledge of HAM (Hsaio et al., 2010). Initial tests showed that the NKHAM was sensitive to differences in HAMs knowledge between a group of registered nurses (n=30) and a group of student nurses (n=30) (63.8(12.9) vs. 53.0(14.5), t=3.01; p=0.004) (Hsaio et al., 2010) and was recently translated and culturally adapted to Brazilian nurses (Apolinario, Rodrigues, Silva, Secoli, & Lima, 2015) and the adaptation process showed the need to include three items. Considering the importance of measuring nurses' knowledge of HAMs to improve the quality of care provided and to maintain patients' safety, this study aimed to measure the reliability and known-group validity of the NKHAM in a pilot study in Brazil.

Background and Conceptual Framework

The importance of evaluating the quality of care provided in health services has been increasingly recommended over the past few decades. This has been particularly observed after the American Institute of Medicine published a landmark book suggesting that the number of deaths caused by medication errors (ME) was between 44,000 and 98,000 each year, representing one of the main causes of deaths in the USA (Kohn, Corrigan, & Donaldson, 2000). The act of medicating has since been pointed out to be a threat to the quality of care and patients' safety, especially if the high frequency of use, the high costs and clinical consequences from ME are to be considered (Kohn, Corrigan, & Donaldson, 2000. Aiming to promote specific improvements on health procedures of high risk, several programs were initiated over the past few years, such as World Alliance for Patient Safety from the World Health Organization (WHO, 2017) and the International Patient Safety Goals from the Joint Commission International (The

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Joint Commission, 2016).

The act of medicating is considered to be a combination of knowledge, skills, performance, values and attitudes (Sulosaari, Suhonen, & Leino-Kilpi, 2011). A ME can occur at any step of the medication process (Beckett, Sheehan, & Reddam, 2012; Smeulers et al., 2015; WHO, 2017). However, the preparation and administration steps, which are more commonly carried out by nursing stuff, represent one third of all ME that causes harm to patients in hospitals (Beckett et al., 2012; Engels & Ciarkowski, 2015). Numerous authors have investigated the reasons for ME and found that these are the result of multiple system and individual factors (Brady et al., 2009; Keers et al., 2013). Previous studies have shown human factors to be mostly associated with lack of theoretical knowledge (Brady et al., 2009; Hsaio et al., 2010) and drug calculation skills (Brady et al., 2009; Keers et al., 2013). In a retrospective study of 364 ME, with 60% of errors caused by nursing professionals, the most common causes for the ME were associated to staff inexperience and medication reconciliation errors (Beckett et al., 2012). A systematic review has found that the main causes of ME in intravenous medication were slips and lapses, followed by knowledge-based mistakes and deliberate violations (Keers et al, 2013).

High-alert medication is considered to be a “medication that bears a heightened risk of causing significant patient harm when used in error” (Institute for Healthcare Improvement; 2012). This does not imply that errors with HAM occur more often than other medications, but that when an error does occur, the consequences can be more severe and even fatal (Cohen, Smetzer, Tuohy, & Kilo, 2007). The Institute for Safe Medication and Practices has developed some recommendations to reduce errors by considering the specificities of different scenarios of clinical practice, such as acute care and long-term facilities, and communities’ care settings. Converging with the items of the NKHAM, the recommendations for acute care setting relate to specific medications as epinephrine, insulin,

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opium, potassium chloride, which requires special attention in all steps of drug administration (Institute for Safe Medication and Practices, 2014). A case-control study carried out in three major hospitals in the U.S.A. showed that the use of HAM was an independent predictor of harm to patients (Beckett et al., 2012). In Brazil, a retrospective study involving 112 hospitalised patient records identified 14.3% of adverse effects to medication, 93% of which were related to HAM (Roque & Melo, 2012). Although these account for about for 5% of all ME, HAM represent 57% of all serious adverse medication events (Beckett et al., 2012).

It is important to measure the level of knowledge of nurses about HAM in order to improve the quality of care provided and there is a lack of a valid and reliable tool to carry out such assessment in Brazil. Therefore, this pilot study aimed to evaluate the preliminary psychometric properties of the Nurses´ Knowledge of High Alert Medications (NKHAM) for use with Brazilian nurses.

Method

This pilot psychometric study was carried out at the Faculty of Nursing and University Hospital of the University of Campinas, Sao Paulo, Brazil. This public university receives 40 new nursing students every year for a four-year Bachelor of Science (BSc) and teaching training course. These students have their placements at the aforementioned University Hospital, which attends patients through the national public health system with high complex health needs and employs 44 registered nurses. Participants were nursing students of the 6th and 9th semesters' cohorts, as well as registered nurses working for more than 12 months in high complex clinical or surgical settings (Intensive Care Unit; Bone Marrow Transplant Unit; and General Clinic and Surgical Care Units). These two groups were expected to show different levels of knowledge of HAMs through the NKHAM as they were likely to have different length of exposure to the administration of HAMs. Those registered

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nurses who were in sick leave or maternity leave during the period of the study were excluded.

The sample size for known-groups validity test (registered nurses vs. nursing students) was estimated using unpaired Student's t-test (Machin, Campbell, Fayers, & Pinol, 1997; Zar, 1984). Estimates for this test were obtained from a convenient sample of 24 individuals (12 registered nurses and 12 nursing students) who were not part of the final pilot psychometric study. Considering 80% Power and 95% Confidence Interval, a sample of 44 registered nurses and 40 nursing students was therefore considered sufficient.

Procedure

The study was approved by the Ethics Committees of the Faculty of Nursing and University Hospital of the University of Campinas. Prior to data collection, participants were given the Participant Information Sheet and Consent Form. The data collection was carried out by the same researcher, face-to-face, after consent was given by participants. Data was collected from 40 nursing students and 44 registered nurses.

Group of nursing students (n=40): participants were first asked about their gender, age, semester of study and course type (BSc plus teaching training or only BSc), extra nursing activities (specific training), and about previous specific training on HAMs. After that, individuals completed the Brazilian version of the NKHAM (parts A and B).

Group of registered nurses (n=44): participants were first asked about their gender, age, any further degrees (e.g. specialty, master, doctorate), length of clinical experience as registered nurse, length of time working in hospital setting, unit of work, previous training on HAMs. After that, individuals completed the Brazilian version of the NKHAM (parts A and B).

Measurement tools

Nurses' Knowledge of High-Alert Medications - NKHAM

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The NKHAM was developed by Hsaio et al. (2010) aiming to provide a valid and reliable to tool to measure nurses' knowledge of HAMs. As mentioned before, this instrument has two sections: Section 1 evaluates nurses' knowledge about HAMs and Section 2 evaluates known errors related to administering medication (Table 1).

<Insert Chart 1 here>

The 20 dichotomous items from parts A and B were developed based on a broad literature review and expert advice (Hsaio et al., 2010). These two parts form a short self-responding questionnaire with dichotomous items, in which each correct answer gives sums five points, with a maximum of 100 points. The higher the total scores are, the higher is the levels of knowledge of HAMs. These two parts of the instrument were culturally adapted for Brazilian registered nurses. The Brazilian version of the NKHAM showed satisfactory results in the process of translation and cultural adaptation in Brazil and includes three new items: two for part A and one for part B (Apolinario et al., 2015). Having said that, the Brazilian version of the NKHAM is composed of 23 items, 12 in part A and 11 in part B. Each correct answer sums 5 points, totalling a maximum of 115 points, of which 60 corresponds to part A and 55 to part B.

Data Analysis

The data collected was analysed using SAS 9.3. The data was first analysed descriptively using relative and absolute frequencies. Reliability was estimated using Kuder–Richardson 20 (KR-20) for dichotomous variables (Kuder & Richardson, 1937). We also assessed item-total correlations and scale reliability coefficient if an item was deleted to assess whether any items needed to be excluded. The scale validity was established using known groups. Non-paired t-test was used to compare the total scores between undergraduate nursing students and registered nurses in practice and it was hypothesised that the two groups would have different levels of knowledge of HAM, considering their clinical experience. Mann-

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Whitney test was used to compare the scores in parts A and B between the two samples since these were normally distributed. A significance level of ≤ 0.05 was adopted for all the analyses.

Ethical Aspects

Permission to use the NKHAM was obtained from the copyright holders and written informed consent was obtained from the subjects who participated in the study. The ethics' committee of the Medical Sciences School approved the study (protocol number 442.552/2013) and the participants were informed about its voluntary nature, the confidentiality of the data and they were instructed that they could refuse participation at any point of the study.

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Results

The study sample was formed by 84 individuals, being 40 undergraduate nursing students and 44 registered nurses currently working at a university hospital in Sao Paulo, Brazil. Participants' sociodemographic details are shown in Table 1. The registered nurses' group was significantly older than the undergraduate nursing students' group (p=0.0001). Among the undergraduate nursing students, only 22% (n=8) reported having received specific knowledge about HAM during their undergraduate training. The majority of the registered nurses' group were working at intensive care units (66%), with mean time of 10.7 years of experience. About 70.5% (n=33) of this group did not receive any training about HAM throughout their training and career periods.

Participants completed all 23 items, with a mean success rate of 63.6% (55.2% for part A and 72.1% for part B). The majority of the respondents, nurses and students, (57%, 48 out of 84) had a total score of up to 80 points (up to 70% success rate), and 40% (34 out of 84) had a total score between 80 and 100 points (70 to 89% success rate). Only 3% (3 out of 84) had

a score higher than 100 points (>90% success rate). Participants' performance is shown in Table 2.

<Insert Table 2 here>

Reliability

Results from the reliability test using KR20 coefficient is shown in Table 3.

<Insert table 3 here>

Known-groups validity

The known-groups validity test of the Brazilian version of the NKHAM showed that the total scores of the parts A and B of the scale were significantly higher among registered nurses than in the undergraduate nursing students' group. This suggests that the scale is able to discriminate the knowledge on HAM between the two groups of participants (Table 4).

<Insert Table 4 here>

Discussion

This is the first study investigating the psychometric properties of the Brazilian version of the NKHAM scale (Apolinario et al., 2015). It was hypothesised that registered nurses and undergraduate nursing students would have different levels of knowledge on HAM. Statistical tests showed the scale to be reliable and valid for measuring the knowledge of HAM among these individuals, as this was able to discriminate between the two groups and provided high levels of internal validity. In addition, the application of this questionnaire was shown to be practical and therefore valuable for use in clinical practice to measure nurses' knowledge about HAM in Brazil (Apolinario et al., 2015). The availability of such instrument in Brazil will contribute improving quality of care and safety for patients, as well as to help increase confidence of nurses in using HAM.

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Although using a small sample, the internal consistency of the Brazilian version of the NKHAM was supported by the results from the KR20 coefficient. These corroborate the findings of the original study, which provided a KR-20 of 0.74, even though the authors did not provide the reliability scores for part A and B (Hsaio et al., 2010) and the Brazilian version has three additional items to reflect Brazilian clinical practice, as per suggested by the expert panel in the first study phase published previously (two items in Part A and one in Part B of the instrument) (Apolinario et al., 2015). Considering the nature of the scale variables – dichotomous – the reliability scores are indeed expected to be considerably lower than the average. This is acknowledged in similar tests, such as the Morisky-Green test, for which the threshold of reliability is as low as 0.61 (Morisky, Green, & Levine, 1986). Other knowledge measurement scales that used such tests, for instance the Breastfeeding Knowledge Questionnaire (Tamim et al., 2016), also showed low reliability scores (0.65). The latter is a widely used questionnaire to measure knowledge of breastfeeding. It is important to highlight that, although the items in Parts A (1; 4; 5; 11; and 12) and B (1 and 3) had low item-total correlation, removing such items did not affect the total reliability scores of the scale.

The known-groups validity scores, confirmed by the significant differences between the two investigated groups, suggest that the Brazilian version of the instrument is adequate to discriminate knowledge levels of HAM in registered nurses and nursing students. The findings relating to the measure's construct validity coincide with those observed in the study, which gave rise to the NKHAM (Hsaio et al., 2010). Although differences were expected between the two investigated groups in relation to training and clinical practice, the study participants mostly reported not having received lectures (77.8%) or other specific training (70.5%) about HAM previously. The differences in the scores of knowledge about HAM might be associated with their differences in working experience in registered nurses

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(mean time of 10.7 years). Similarly, Engels and Ciarkowski (2015) have found in a research with 778 general health professionals of University of Michigan Health System that almost 30% of the participants had received knowledge about HAM within their work environment. These authors have advocated for the importance of continuous training related to HAM for allied health professionals at work.

It is important to highlight that the total scores of the Brazilian version of the NKHAM range from 0-115, differing from the original scale due to the addition of three items, as previously mentioned. In addition, following the example of the original scale, cut-off points were not established for the Brazilian version of the NKHAM, nor were norm-referenced or criterion-referenced cut-offs. However, considering the importance of this scale for use in the training of nurses for their use of high-alert medications, it is important that future studies propose cut-off scores for establishing knowledge threshold so that more accurate knowledge scores can be quantified.

Despite its contributions, this pilot study used a small, non-probabilistic sample of participants and therefore interpretations should be made with caution. These may have had an influence on the reliability scores of the instrument. In addition, the study was conducted with a sample of nursing clinicians from one public health hospital in Brazil, meaning that the findings may not be generalizable to those nurses working on private hospitals, as there might be differences in training and practice.

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Implication for practice

This study contributes to the advance of research in nurses' knowledge of HAM in their clinical practice, as well as scale development within this field of research. Despite the need for further psychometric testing, the availability of such valid and reliable measurement

scale will help nurses in direct contact with HAM to measure their knowledge about such medication and how to improve their day-to-day practice in order to prevent adverse effects and harm to patients. This instrument may also be useful to measure quality of care in health institutions and direct specific training aiming to improve patients' safety. Further studies using the Brazilian version of the NKHAM should focus on carrying out future psychometric assessments, with larger sample of participants, aiming to build the scale profile and the suitability of the scale for use in diverse clinical settings.

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Chart 1. Items of the Taiwan version of the Nurses´ Knowledge High Alert Medication (Hsaio et al., 2010)

Section 1: Nurses' knowledge	
Part A: Drug administration	10 dichotomous items evaluating knowledge of que access and dosage of medications
Part B: Drug regulation	10 dichotomous items evaluating how the HAMs should be stored, dispatched and prescribed
Part C: Contributing factors	Considers personal factors and previous work experience (such as age, degree, length of work), as well as training which might contribute to nurses' knowledge of HAMs
Part D: Self-Evaluation	Subjective evaluation of the individual about three factors associated with HAMs: 1) Obstacles encountered (14 obstacles presented in multiple answer-items); 2. Level of knowledge (five levels of knowledge rated from "sufficient" to "extremely insufficient"; and 3. Need for training (rated as "necessary", "no comments", "not necessary")
Section 2: Error events	Individuals are asked to describe a known error in administering medication, with information about the nature of the error and possible consequences for the patient. This anonymous.

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TABLE 1. SOCIODEMOGRAPHIC AND QUALIFICATION PROFILE OF UNDERGRADUATE NURSING STUDENTS (N=40) AND REGISTERED NURSES (N=44) PARTICIPATING IN THE STUDY

Registered nurses (n=44)	
Gender *n(%)*	
Female	38 (86.0)
Male	2 (5)
Age *(mean)*	37.3 (±7.5)
Specialization geral	
Yes (concluded or on-going)	33 (75)
No	11(25)
Masters' degree *n (%)*	
Yes (concluded or on-going)	7 (15.8)
No	37 (84.0)

Doctorate (PhD)	
Yes (concluded or on-going)	2 (4.6)
No	42 (95.5)
Training/continuous education related to HAM	
Yes	13 (29.5)
No	31 (70.5)
Length of nursing clinical practice *(years)*	10.7 (±8.17)
Current work	
Intensive care unit	65.91%
Bone marrow transplantation unit	11.36%
Clinical or surgical units	22.73%
Undergraduate nursing students (n=40)	
Gender *n(%)*	
Female	38 (95.0)
Male	6 (13,64)

Age *(mean)*	22.7 (±1.8)
Undergraduate course in Nurse *n(%)*	
General Bachelor	6 (15.4)
Bachelor and Teaching	33 (84.6)
Number of semesters of undergraduate courses completed at the time of the study *n(%)*	
01/jun	18 (46)
07/set	21 (53.0)
Practical classes *n(%)*	
Yes	10 (25)
No	30 (75)
Lectures/course of HAM during undergraduate training n(%)	
Yes	8 (22.2)
No	28 (77.8)

HAM – High alert medication

TABLE 2. KNOWLEDGE OF PARTICIPANTS ON PARTS A AND B OF THE BRAZILIAN VERSION OF THE NKHAM

Item	Question	Correct answer T/F	Correct answer (%)	Errors /Don't know (%)	Rank
Part A	**Conhecimento sobre administração de medicamentos**				
11	The concentrations of heparin administered subcutaneously and/or intravenously are the same, and therefore, can be interchanged.	F	94	1.2/4.8	1
7	The injectable electrolytes sodium gluconate 10% and calcium chloride 10% are the same drug and therefore they can be interchanged.	F	84.5	1.2/ 14.3	2
2	In emergencies, such as ventricular fibrillation, 19.1% potassium chloride must be infused via intravenous route.	F	72.6	7.1/20.2	3
1	"cc" or "ml" are the units of measurement used in the insulin	F	65.5	28.6/5.9	4

	syringe scale.				
8	For fast infusion, it is better to add potassium chloride 19.1% to the Ringer's solution.	F	59.5	1.2/39.3	5
12	The prescription of medication with a zero after the decimal point (10.0 ml) improves safety in drug administration.	F	57.1	32.1/10.7	6
3	Sodium chloride at 3% - 500ml must be pushed fast via intravenous route in patients with low levels of sodium serum.	F	51.2	10.7/38.1	7
6	For patients with slight allergic reactions, the adequate treatment is 1 ampoule of adrenaline, at a 1:1000 concentration, by a fast IV infusion.	F	47.6	10.7/41.7	8
4	Usually, the implantable venous system (Port-a-Cath ®) can be used for blood draw and medication infusion.	F	42.9	46.4/10.7	9
5	Insulin syringes can be replaced with 1ml syringes.	F	35.7	63.1/1.2	10
9	In emergency situations, potassium chloride 10% - 10ml must be infused via intravenous route in approximately 1 to 2 minutes.	F	35.7	20.2/44.1	11

10	For the calculation of the antineoplastic chemotherapeutic dose, body weight is used for adults and the body mass index is used for children.	F	23.8	26.2/50	12
Parte B	**Regulamentação de medicamentos**				
3	For more convenience, heparin and insulin must be stored together in the refrigerator.	F	93.9	2.4/4.8	1
4	Use "ampoule" or "flask" for dose measurement, instead of "mg" or "g".	F	85.7	5.9/8.3	2
2	Use different labels in similar medications.	T	80.9	14.3/4.8	3
5	If any ward stores muscle relaxant for tracheal intubation, it is recommended that this medication be kept with other drugs of the unit and be easily accessible to nursing professionals.	F	76.2	11.9/11.9	4
6	The potassium chloride is frequently used, that is why it must be easily and freely accessible to nursing professionals.	F	70.2	26.2/3.6	5
9	For paediatric dosage, use a teaspoon as a dose measure for the	F	70.2	4.8/25	6

	medication.				
8	It is indicated that each medication have different concentrations so that nursing professionals can correctly choose.	F	66.7	11.9/21.4	7
11	The use of "if needed" for high-alert medication is safer, as it allows nurses to administer medication according to patients' clinical condition.	F	60.7	17.9/21.4	8
10	Use 'U' instead of "unit" to express the drug dose.	F	54.8	22.6/22.6	9
7	If the patient can tolerate, it is recommended that potassium chloride be administered orally instead of intravenously.	T	51.2	15,5/33.3	10
1	Use a fentanyl patch as a controlled drug.	T	25	20.2/54.8	11

T/F: True/False

ACCEP

TABLE 3. ITEM-TOTAL CORRELATIONS AND KR- 20 COEFFICIENT SCORES FOR EACH OF THE ITEMS OF PARTS A AND B OF THE BRAZILIAN VERSION OF THE NURSES´ KNOWLEDGE HIGHT ALERT MEDICATION

	Brazilian version of NKHAM				
Part A	**Item-total correlation**	**KR20 scores**	**Part B**	**Item-total correlation**	**KR20 scores**
Item 1.	0.02	0.58	Item 1.	0.06	0.62
Item 2.	0.43	0.47	Item 2.	0.23	0.58
Item 3.	0.35	0.49	Item 3.	0.14	0.60
Item 4.	0.12	0.55	Item 4.	0.25	0.58
Item 5.	0.15	0.54	Item 5..	0.47	0.53
Item 6.	0.21	0.53	Item 6.	0.30	0.57
Item 7.	0.28	0.52	Item 7.	0.35	0.55
Item 8.	0.29	0.51	Item 8.	0.08	0.62

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Item 9.	0.43	0.47	Item 9.	0.24	0.58
Item 10.	0.39	0.49	Item 10.	0.36	0.55
Item 11.	-0.01	0.56	Item 11.	0.43	0.53
Item 12.	0.02	0.58	-	-	-
Total Score Part A					0.55
Total Score Part B					0.60
TOTAL SCORES					**0.68**

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TABLE 4. KNOWLEDGE LEVELS IN THE NURSES´ KNOWLEDGE HIGHT ALERT MEDICATION REPORTED BY REGISTERED NURSES AND UNDERGRADUATE NURSING STUDENTS

Brazilian version of the do NKHAM	**Registered nurses (n=44)**	**Undergraduate nursing students (n=40)**	**p-value**
	Mean (sd)	**Mean (sd)**	
Total scores	78.6 (15.5)	60.6 (16.4)	<0,0001*
Part A: Knowledge of drug administration	37.8 (9.6)	28.4 (11)	0,0003**
Part B: Regulation of drugs	40.8 (9.9)	32.2 (10)	0,0002**

** T-test; ** Mann-Whitney*

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