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VALIDATION OF A PALLIATIVE OUTCOME SCALE AND APPLICATION FOR PEOPLE WITH HIV IN HAI PHONG

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The thesis can be found at:

1. National library
2. Hai Phong University of Medicine and Pharmacy library

LIST OF RESEARCH RELATED TO THE THESIS HAS BEEN PUBLISHED

1. **Pham VA**, Nguyen H, Krakauer EL, Harding R. "I Wish I Could Die So I Would Not Be in Pain": A Qualitative Study of Palliative Care Needs Among People With Cancer or HIV/AIDS in Vietnam and Their Caregivers. J Pain Symptom Manage. 2021 Aug;62(2):364-372. doi: 10.1016/j.jpainsymman. 2020.11.030. Epub 2020 Dec 4. PMID: 33285274.
2. Le DD, **Pham TVA**, Bui TTH, Than HNT, Pham VT, Luong NK, Harding R, Krakauer EL (**Le, Pham Thi Van Anh, Krakauer and Harding contributed equally**). Symptom prevalence, burden and correlates among people living with HIV in Vietnam: a two-centre self-report study. AIDS Care 2022;34: 887-893.
3. **Phạm Thị Vân Anh**, Bùi Minh Khôi, Lê Khắc Tùng, Phạm Văn Linh (2022), "Sử dụng thang đo kết quả giảm nhẹ trong chăm sóc toàn diện người sống với HIV tại Thuỷ Nguyên, Hải Phòng", Tạp chí Y học Việt Nam, Tập 515, số đặc biệt (phần 2), tr: 70- 76.
4. Pham Thi Van Anh, Richard Harding, Eric Krakauer. "Adaption of the POS to Vietnam:A mixed methods study to ensure local clinical utility". Poster in POS and IPOS Training Days in Cicely Saunder Institute of Palliative Care, Policy & Rehabilitation at King's College London and The Hull York Medical School, 15-16 May, 2023.

INTRODUCTION

In Vietnam, the lack of palliative care (PC) tools leads to a lack of evidence on the effectiveness of PC programs. As a result, policy makers cannot provide recommendations to improve the quality of care or develop standard operating procedures for PC.

Globally, the Palliative Care Outcome Scale (POS) has been developed and validated into many languages. The African Palliative Care Outcome Scale (APCA POS) has been validated by the African Palliative Care Association and has been evaluated as valuable and reliable, and it positively impacts the quality of care.

Is APCA POS appropriate in content and culture for palliative care evaluation for people with life-limiting illness in non-African resource-constrained countries such as Vietnam? How should the APCA POS be revised to be relevant for Vietnam, to become a Vietnamese POS or "VietPOS"? And what would be the results of using a VietPOS to inform clinical care for people with HIV (PWH)? We conducted a study named **"Validation of a Palliative Outcome Scale and application for people with HIV in Hai Phong"** with the following 2 objectives:

1. Validate a Vietnamese Palliative Outcome Scale (VietPOS) for people with cancer and HIV in Vietnam.

2. Apply VietPOS to assess palliative care outcomes of people with HIV in Hai Phong.

NEW CONTRIBUTION OF THE THESIS

To date, evidence on the effectiveness of PC in Vietnam is limited due to the lack of locally developed and validated by study instruments. The study's contributions are the first to develop and scientifically validate a palliative care tool in Vietnam, as well as demonstrate the significance of using the VietPOS tool in detecting and monitoring the palliative care needs and evaluating changes in the quality of life over time for HIV patients. The VietPOS tool is short but covers essential content for palliative care, and its ease of use makes it a useful tool in clinical care, quality assurance, and scientific research.

STRUCTURE OF THE THESIS

The main part of the thesis has 135 pages, consisting of the following sections:

Introduction: 1 page
Chapter 1: Background: 30 pages
Chapter 2: Research subjects and methodology: 25 pages
Chapter 3: Results: 42 pages
Chapter 4: Discussion: 33 pages
Conclusions and Recommendations: 3 pages

The thesis has 140 references including 16 Vietnamese references and 124 English references, 40 tables, 5 figures, 15 boxes, and 9 appendices.

Chapter 1 : BACKGROUND

1.1. Current sistuation and needs of palliative care in the world and in Vietnam

1.1.1. Definition of Palliative Care

In 2022, the Vietnamese Ministry of Health defined palliative care as "the prevention and relief of suffering of any kind – physical, psychological, social, or spiritual – experienced by adults and children living with serious health problems using best available evidence."

1.1.2. Current sistuation and needs of palliative care in the word and in Vietnam

Globally, an estimated 56.840.123 people have a need for palliative care for serious illnesses. Of the 53,000,000 adults in need of palliative care, 76% live in countries with middle to low incomes. The major illnesses that generate a need for palliative care are HIV infection (22.2%), cerebrovascular disease (14.1%), and dementia (12.2%). The most serious illnesses and conditions that generate a need for palliative care intervention are cancer, HIV/AIDS, cerebrovascular disease, dementia, and lung disease.

In Vietnam, significant achievements have been made in the field of palliative care. In terms of policy, the Ministry of Health issued Guidelines for Palliative Care for Cancer and AIDS Patients in 2006, and revised and expanded them in 2022 to include other groups such as drug-resistant tuberculosis patients, end-stage lung and heart failure patients, elderly people who are frail and susceptible to injury, trauma or serious illness. Opioid prescription regulations have been released closer to international standards, improving access to pain relief

medication. Basic and advanced training in palliative care has been provided to physicians, nurses, and healthcare workers throughout the country. Palliative care facilities have been established in hospitals nationwide. The current challenges facing the palliative care in Vietnam include the lack of a scientifically validated tool to evaluate the effectiveness of ongoing programs that is appropriate for local culture.

1.2. Methods of palliative care assessment

1.2.1. Roles of outcome measures in palliative care

Palliative care assessment tools are used for three purposes: clinical care, quality assurance, and research. Specifically, in clinical care, palliative care measurement tools are used to: (1) Describe the patient's initial state (level of pain, anxiety); (2) Evaluate the patient's symptoms and the needs or issues that the family and patient are facing; (3) Monitor changes in the patient's health status and QoL, support the patient and their family's ability to communicate with healthcare professionals; (4) Support clinical decision-making and evaluate the effectiveness of interventions, care, and services currently available.

1.2.2. Palliative care assessment tools

Many palliative care assessment tools have been developed, but they do not cover all content of palliative care and have a length that is not suitable for the frail characteristics of the populations needing palliative care. In this context, the Palliative Outcome Scale (POS) was born. POS is concise, consisting of only 10 questions selected based on high value and reliability, addressing all types of suffering: physical, psychological, social, and spiritual. In addition, POS leaves a blank space for the interviewee to list the main issues they are facing. POS has been validated in many languages in Europe, Asia, Africa, and Latin America. In particular, the African Palliative Care Association POS version has been validated in countries with limited resources and heavy disease burdens.

1.3. Validation procedure of POS and the use of POS in palliative care

1.3.1. Validation procedure of POS

The validation procedure of POS developed by Antunes and colleagues consists of 8 phases: conceptual definition or equivalence, forward translation, backward translation, expert review, cognitive debriefing, proof reading, psychometric testing, report and publication. In practice, researchers carried out this procedure in various ways depending on the cultural conditions of each country.

1.3.2. Use of POS and APCA POS in the world

Currently, POS is the most widely used CSGN outcomes assessment tool in the world, in both high-income and middle- and low-income countries. POS significantly improves patient care, is valued and accepted in various settings such as hospitals, communities, charitable clinics, outpatient centers, day care centers, and general practitioner clinics. POS is used to guide clinical care, monitor interventions, assess and improve quality. The APCA POS version, in particular, has contributed significantly to improving patient care, leading to changes in the organization of service delivery, staffing, patient and family-centered care. APCA POS has become a tool for advocacy, aiming to increase access to high-quality palliative care in countries with limited resources. Therefore, validation of the APCA POS scale in the context of Vietnam is necessary.

Chapter 2: METHODOLOGY

2.1. Research subject, setting and time

2.1.1. Research subjects

Validation study:

The research population consisted of any person with HIV infection at any stage, or any person with cancer that is incurable and at stage 3 or 4 according to 2010 TNM staging criteria.

Inclusion criteria:

Patients:

- At least 18 years and older,
- diagnosed with HIV (at any clinical stage) according to the guidelines of the Vietnamese Ministry of Health and/or diagnosed with stage 3,4 cancer,
- good command of the Vietnamese language,
- aware of their diagnosis, and agree to participate in the study.

Caregivers: Directly caring for people living with HIV and cancer, and agree to participate in the study.

Exclusion Criteria: Those who do not have the physical and mental health to participate in the interview.

VietPOS application study

Research subjects were people with HIV at Outpatient Clinic at Thuy Nguyen General hospital

Inclusion criteria: At least 18 years and olders, confirmed HIV diagnosis, being on ARVs, agree to participate in the study.

Exclusion Criteria: Those who do not have the physical and mental health to participate in the interview.

2.1.2. Research settings:

Validation study*:* Dong Da Hospital, K Hospital in Tam Hiep, Hue Central Hospital, Binh Dan Hospital, Hospital for Tropical Diseases in Ho Chi Minh City.

VietPOS application study: Thuy Nguyen General Hospital

2.1.3. Time: from January, 2015 to April, 2022

2.2. Research methods

2.2.1. Study design

Validation study: A cross-sectional descriptive study combining qualitative and quantitative methods.

VietPOS application study: Experimental study

2.2.2. Sample size

Validation study:

- Sample size for quantitative study to determine the most prevalent and severe symptoms: 1399 patients (832 cancer patients and 567 HIV patients).
- Sample size for qualitative study: 60 (21 cancer patients, 20 HIV patients, and 19 caregivers).

VietPOS application study: 50 HIV patients on ARV treatment.

2.2.2. Variables and indicators of the study

Validation study

Group of variables related to the most prevalent and distressing symptoms of research participants in quantitative study and palliative care needs emerged from qualitative study.

VietPOS application study

Group of variables realated to validity and reliability: correlation coefficient, Cronbach's alpha.

Group of variables related to application resuts: changes in mean scores of palliative care needs (physical, psychological, social and spiritual needs), quality of life, time to complete VietPOS.

2.3. Data collection tools

Validation study

Quantitative questionnaire, Memorial Symptom Assessment Scale-Short Form (MSAS-SF), qualitative interview questionnaire

VietPOS application study

VietPOS, WHOQOL-HIV BREF questionnaire

2.4. Evaluation criteria used in research

Validation study

Criteria for selecting symptoms to include in VietPOS: Based on the results of the MSAS-SF questionnaire: (1) symptoms with a prevalence rate of less than 25% and causing discomfort at the level of "quite a bit" and "very much" at a rate of 5% or higher for people with HIV and 10% or higher for cancer patients are selected; (2) symptoms that can be clinically managed; (3) distinguishable from other symptoms; (4) symptoms that do not meet the above criteria but are common and cause distress at the end of life.

Criteria for additional palliative care needs in VietPOS: based on the results of qualitative research, added palliative care needs that are not included in APCA POS.

VietPOS application study

Assessment of construct validity through correlation coefficients between VietPOS and WHOQOL-HIV BREF. Assessment of internal consistency through Cronbach's alpha coefficient (values of 0.7 or higher indicate good internal consistency). Assessment of suitability in applying VietPOS to HIV care process through significant changes in the mean scores of palliative care needs, quality of life, and VietPOS completion time. Changes are considered significant if the p-value is less than 0.05.

Data management: The collected data was entered into Epidata 3.1 software and processed using SPSS 16.0 software.

2.5. Research Ethics

The research proposal was reviewed and approved by the Ethics Board of the Partners Healthcare System in Boston, USA, the Vietnam Ministry of Health, and the Hai Phong University of Medicine and Pharmacy with code 2021P001160 (Appendix). The study was conducted in accordance with the research protocol and was approved by the scientific council at the participating hospitals. Study introduction documents and consent forms were detailed and ensured that all interviewees were provided with full information (Appendix). In-depth interviews were recorded with the consent and permission of the participants. The collected information was de-identified to ensure anonymity and confidentiality throughout the data analysis and report writing process.

Chapter 3: RESULTS

3.1. Validation palliative outcome scale for people with life-limitting illness in Vietnam

The APCA POS scale was translated from English to Vietnamese by two independent translators. After completing the forward translation, the two translators discussed to obtain the best translation to be handed over to two other translators for back translation. After the completion of the back translation, the two translators who performed the forward translation discussed once again to decide on the final Vietnamese version. The experts agreed that APCA POS provided relevant clinical information related to palliative care and covered the components considered important for palliative care.

Simultaneously, Vietnamese palliative care experts proposed expanding question 2 in APCA POS to measure common specific symptoms. Therefore, in phase 1, the MSAS-SF was used to determine the prevalence of the most common and distressing symptoms. The results of this prelance study were then added as a supplement to question 2 in the VietPOS.

Table 3.7. Ten most common symptoms in HIV patients and their distribution by degree of discomfort or frequency (N=567)

Rank	Physical symptoms	Prev-alebce %	Level of distress (%)				
			Not at all	A little bit	Some what	Quite a bit	Very much
2	Lack of energy	40.6	3.5	15.2	9.7	8.3	3.7
5	Drowsy	37.7	5.6	15.3	7.9	6.3	2.3
6	Lack of sleep	35.3	3.0	11.1	8.3	9.5	3.4
7	Numbness/Tingling	35.1	4.8	16.0	6.3	6.7	1.2
8	Dry mouth	31.4	5.1	16.0	4.8	4.4	1.1
10	Cough	29.6	4.4	13.4	5.8	4.8	1.2
	Psychological symptoms		Preva-lence %	Frequency (%)			
				Rarely	Occasi-onally	Freque-ntly	Almost constant
1	Worrying		41,4	5,6	20,3	13,4	2,1
3	Feeling nervous		40,4	6,3	25,0	7,4	1,6
4	Feeling sad		39,2	6,3	19,4	11,5	1,9
9	Feeling irritable		30,3	4,8	18,3	6,3	0,9

Comments: The 10 most common symptoms in HIV patients were: anxiety (41.4%), fatigue (40.6%), feeling irritable (40.4%), feeling sad (39.2%), drowsy (37.7%), lack of sleep (35.1%), numbness/tingling (35.1%), dry mouth (31.4%), feeling nervous (30.3%), hair loss (29.6%). All 4 psychological symptoms ranked highest on this list. The symptom of "worrying" had the highest frequency of occurrence at the level of "frequently" and "almost always" (15.5%).

Table 3.10. Ten most common symptoms in cancer patients and their distribution by degree of discomfort or frequency (N=832)

Rank	Physical symptoms	Prev-alebce %	Level of distress (%)				
			Not at all	A little bit	Some what	Quite a bit	Very much
1	**Pain**	70.0	1.7	11.9	24.5	27.3	4.6
2	**Lack of energy**	64.9	1.9	15.6	26.3	19.1	1.7
3	**Numbness/ tingling**	63.9	3.7	18.3	22.1	18.1	1.6
6	**Lack of sleep**	57.6	2.0	11.9	18.5	21.0	4.2
7	**Dry mouth**	51.0	1.6	20.9	16.6	11.2	0.7
8	**Weight loss**	50.5	4.4	20.6	13.9	9.7	1.8
9	**Change in food taste**	48.9	2.6	14.9	17.4	12.0	2.0
10	**Lack of appetite**	48.3	1.9	13.1	18.0	13.2	2.2
	Psychological symptoms		**Preva-lence %**	**Frequency (%)**			
				Rarely	**Occasio-nally**	**Frequent-ly**	**Almost constant**
4	**Worrying**		63.6	12.5	31.9	16.5	2.9
5	**Feeling sad**		59.7	8.5	29.8	19.0	2.0

Comment: Among the 10 most common symptoms in cancer patients, pain is the most prevalent symptom with the highest rate of occurrence (70%) and causing the most discomfort with 31.9% at the "quite a bit" and "very much" levels. Other common symptoms are fatigue (64.9%), numbness/tingling (64.1%), worrying (63.9%), feeling sad (59.7%), lack of sleep (57.8%), dry mouth (51.2%), weight loss (50.2%), changes in the way food taste (49.3%), and lack of appetite (48.7%). Feeling sad is the symptom with the highest rate of occurrence at the "frequent" and "almost constant" levels (21.0%).

3.1.3. Palliative care needs of cancer and HIV patients

Physical needs

Box 3.1-3.3 . Pain and physical symptoms in people with cancer and HIV

"Now I just hope to die without pain. Day and night, that's all I ask for. Buddha, please take me away gently, I don't ask for anything more" (ID41PWC).
"Breathless, couldn't sleep for 15 days, forced to sit" (ID07PWC).
"When the chemotherapy was administered, I feel nausea...I keep throwing up" (ID33PWC).
"My mother seems to have no energy left...she just lies there like a corpse" (ID43CPWC).
"My abdominal pain was unbearable that I had to look for drugs...unable to eat, painful swallowing, fatigue, dizziness, and diarrhea" (ID47 HIV patient).
"The medication was so strong that I couldn't bear it so I stopped taking it. Then I got sick again" (ID51PWH).

Comment: Cancer patients described horrible pain and wished for death as a way to escape it. In addition, they experienced fatigue, shortness of breath, and nausea. HIV patients suffered from symptoms caused by opportunistic infections and treatment side effects. Untreated symptoms lead to drug-seeking behavior, medication discontinuation, treatment failure, and disease rebound.

Psychological needs

Box 3. 4-3.5. Psychological issues in cancer and HIV patients

"I was completely devastated." (ID04PWC))
“I was surprised and shocked, I had tried it just a few times and still got infected."(ID12 HIV patient)
"I'm afraid of transmitting to others" (ID15PWH)
“ I intended to commit suicide and was going to jump off a building." (ID38PWC))
"I'm afraid of death and pain…my baby was only a few months old, I was worried about everything. I am the one who has to bear the greatest burden in the family." (ID41PWC)

Comment: Cancer and HIV patients both expressed sadness, depression, or shock when they received a diagnosis of a life-limiting illness. They worried about the disease, death, pain, leaving their families behind without anyone to care for them

Social needs

Box 3.6-3.7. Being rejected or stagmatization in cancer and HIV patients

"I feel worthless here…human life is so cheap..." (ID27PWC))
"I went to 6 hospitals and no one would accept me." (ID35PWC))
" Few people come by to visit, they scared of getting infected… and I also do not go anyone's house" (ID38PWC)
I think they're afraid of catching it so they don't come over." (ID38PWC)
"I live in a rural area where people held strong stigma against HIV... they wouldn't walk toward me or sit next to me" (ID15PWH)
"We haven't dear to reveal to our family, we're afraid they'll be superstitious and not accept us into the community... they'll avoid us and we won't be able to get government loans." (ID23 C PWH)

Comment: Cancer patients felt abandoned, and were not accepted at treatment facilities. HIV patients faced stigma and social isolation. They had to hide their HIV status to avoid compromising their integration and employment opportunities.

Box 3.8-3.9. Lack of emotional support from family and loved ones for cancer and HIV patients

"I've been lying here for three weeks, and no one has been taking care of me" (ID41PWC).
"When I feel sad, I have to bear it all alone. There's no one to share it with..." (ID44PWC).
"No one in my family cares about me. They keep their distance from me because they're afraid of catching the disease" (ID47PWH).
"I have to keep it a secret from my company too. I can't let anyone know" (ID55PWH).

Comment: Cancer patients lack regular support due to the prolonged nature of the disease. HIV patients experience a lack of support due to both stigma and fear of being stigmatized.

Box 3.10. Financial concerns of cancer and HIV patients

"I'm financially incapable now... I'm worried about basic needs such as food, drink, mortgage payments, and education expenses for my children... I don't want to go to the hospital because I don't have any money, and I want to commit suicide" (ID38PWC).
"I'm worried a lot. All the money had been used for medical expenses " (ID41PWC).
"I'm worried about the fact that I'm now unable to work, and I've lost a lot of money on expenses for my wife and children" (ID12PWH).
"At present, I'm renting a house where I live with my family of four, with three of us taking ARV medication" (ID56PWH)

Comment: Both cancer and HIV patients are concerned about the financial burden of treatment, as well as basic needs such as food, shelter, and education expenses. The decline in health also affects the family's income. Some financially incapable cancer patients contemplate suicide.

Spiritual needs

Box 3.12-3.13. Feeling at peace in cancer and HIV patients

"...If God calls me back, then I ask God to take me back to Him" (ID04PWC).

"I follow Buddhism... I used to believe, but now I don't believe anymore" (ID41PWC).

"I never feel peaceful…My father is over eighty years old, my mother is blind and no one takes care of me when I lie down" (ID44PWC).

"In general, I am lucky to find peace because my two children and my wife are not infected" (ID54PWH)

Comment: Some cancer patients find peace from their religious beliefs, from fulfilling their duties to their families before leaving this world. HIV-infected individuals find peace by accepting their illness and their loved ones stay safe from infection. However, uncontrolled pain has caused some patients to lose faith in religion.

Box 3.14-3.15. Information needs of cancer and HIV patients

"I want to confirm if I can still survive with chemotherapy this time...If I can live for another 5-6 months with chemotherapy, then I should. But if I die in 1-2 months, then let it be, leave the money to take care of my children" (ID41PWC).
"What are the results of my tests, and what is my current condition?" (ID19PWH).

Comment: Cancer and HIV patients want more information about their diagnosis, disease progression, prognosis, and treatment options**.**

3.1.3. The result of adjusting APCA POS to VietPOS: questions for patients:

(1) Based on the quantitative research results, additional symptoms have been included: lack of energy/fatigue, mouth problems (dryness, soreness), shortness of breath, nausea/vomiting, lack of appetite, and other symptoms.

(2) Based on the qualitative research results, three questions have been added: (1) "Have you been feeling sad (depressed) in the past 3 days?", (2) "Have you felt rejected or discriminated against because of your illness in the past 3 days?", (3) "Over the past 3 days, have you been concerned about lack of money to meet basic needs of you or your family?" (Examples of basic needs include treatment, food, tuition, transport, rent…).

3.2. Results of VietPOS application study

3.2.1. Internal consistency

The Cronbach's alpha coefficient was 0.692 for 14 questions for patients (pain, lack of energy/fatigue, mouth problems, shortness of breath, nausea or vomiting, lack of appetite, other symptoms).

3.2.2. Construct validity

Box 3.17-3.19.Correlations between VietPOS domains and WHO QOL HIV BREF domains

	VietPOS Physical-Psychological	VietPOS Spiritual	VietPOS Interpersonal
WHO Physical	-0.587**	-0.221	-0.055
WHO Psychological	-0.472**	-0.127	0.024
WHO Independence	-0.539**	-0.199	-0.077
WHO Social relationships	0.093	0.289**	-0.546**
WHO Environmental	-0.247	-0.266	-0.247
WHO Spirituality	-0.412**	-0.259	-0.059

** **p< 0,01**

Comment: There is an inverse correlation between the physical and psychological domains of VietPOS and the physical, psychological, and level of independence domains of WHOQOL-HIV BREF ($p<0.01$). There is also an inverse correlation between the social communication domain of VietPOS and the social domain of WHOQOL-HIV BREF ($p<0.01$). The lower the score in the domains of VietPOS (indicating fewer problems), the higher the score in the corresponding domains of WHOQOL-HIV BREF (indicating better QOL).

3.2.3. Results of application of VietPOS for PWH in Hai Phong

Tables 3.22-3.30. Changes in mean scores of palliative care needs of PWH after 7-10 days and after 28-30 days compared to the baseline scores.

Palliative care needs	Time point	Mean ±SD	Difference compared to T0 (mean ± SE)	Z test	P
Pain	T0	0.62 ± 1.16			
	T1	0.36 ± 0.78	0.26 ± 0.15	-1.713	0.087*
	T2	0.06 ± 0.24	0.56 ± 0.16	-3.264	0.001**
Other symtoms	T0	0.42 ± 0.58			
	T1	0.22 ± 0.31	0.20 ± 0.07	-3.247	0.001*
	T2	0.08 ± 0.14	0.34 ± 0.08	-4.493	<0.001**
Worrying	T0	0.88 ± 1.24			
	T1	0.20 ± 0.67	0.68 ± 0.17	-3.555	<0.001*
	T2	0.16 ± 0.47	0.72 ± 0.18	-3.483	<0.001**
Sad/depress	T0	0.66 ± 1.22			
	T1	0.12 ± 0.44	0.54 ± 0.17	-2.869	0.004*
	T2	0.04 ± 0.28	0.62 ± 0.17	-3.334	0.001**
Stigmatiza-tion	T0	0.88 ± 1.21			
	T1	0.14 ± 0.54	0.74 ± 0.16	-3.922	<0.001*
	T2	0.08 ± 0.44	0.80 ± 0.18	-3.907	<0.001**
Emotional support	T0	2.68 ± 1.85			
	T1	1.66 ± 1.49	1.02 ± 0.31	-3.165	0.001*
	T2	0.84 ± 0.91	1.84 ± 0.26	-5.087	<0.001**
Financial concerns	T0	1.94±1.48			
	T1	1.52±1.66	0.42±0.31	-1.430	0.153*
	T2	1.18 ± 1.29	0.76 ± 0.23	-2.972	0.003**
Feeling at peace	T0	2.16 ± 1.36			
	T1	1.26 ± 1.14	0.90 ± 0.23	-3.637	<0.001*
	T2	0.64 ± 0.63	1.52 ± 0.23	-5.001	0.001**
Information	T0	1.50 ± 1.13			
	T1	1.62 ± 1.50	-0.12 ± 0.56	-0.392	0.700*
	T2	0.80 ± 0.70	0.70 ± 0.16	-3.867	<0.001**

Wilcoxon Signed rank test; * p của T1 so với T0, ** p của T2 so với T0

Comment: After 7-10 days, there was a statistically significant decrease in the mean scores of the study subjects compared to the

baseline in terms of severity of symptoms (decreased by 0.20 ± 0.07, p=0.001), anxiety (decreased by 0.68 ± 0.17, p<0.001), sadness (decreased by 0.54 ± 0.17, p=0.04), stigma (decreased by 0.74 ± 0.16, p<0.001), emotional support (decreased by 1.02 ± 0.31, p=0.001), and feeling at peace (decreased by 0.90 ± 0.23, p<0.001).

After 28-30 days, there was a statistically significant decrease in the mean scores of the study subjects compared to the baseline in terms of pain severity (decreased by 0.56 ± 0.16, p=0.001), symptom severity (decreased by 0.34 ± 0.08, p<0.001), anxiety (decreased by 0.72± 0.18, p<0.001), sadness (decreased by 0.62 ± 0.17, p=0.01), stigma (decreased by 0.80 ± 0.18, p<0.001), emotional support (decreased by 0.76 ± 0.23, p=0.003), feeling at peace (decreased by 1.52 ± 0.23, p=0.001), and information (decreased by 0.70 ± 0.16, p<0.001).

Table 3.32. The difference between the mean scores of QOL domains at baseline and after 1 month (N=50)

QOL domains	Baseline	After 1 month	Z test	P value
Physical	15.10 ± 2.58	16.98 ± 1.74	-5.087	<0.001
Psychological	13.74 ± 1.80	15.52 ± 1.84	-5.260	<0.001
Independence	14.74 ± 2.09	16.56 ± 1.69	-5.091	<0.001
Social relationships	12.52 ± 1.63	14.20 ± 1.78	-5.006	<0.001
Environment	13.62 ± 1.44	15.01 ± 1.38	-5.466	<0.001
Spirituality	15.78 ± 2.86	17.42 ± 1.80	-4.764	<0.001

*Wilcoxon Signed rank test

Comment: After one month, the QOL of all subjects improved in all areas. These changes are significant with p <0.001.

Chapter 4: DISCUSSION

4.1. Validation of Palliative Outcome Scale for people with life-limiting illness in Vietnam

Our study has added the most common and burdensome symptoms for cancer and HIV patients in Vietnam to the VietPOS: pain, fatigue/weakness, shortness of breath, nausea/vomiting, loss of appetite, and mouth problems. These symptoms are also common in cancer and HIV patients in Africa. Specifically, this symptom list is also similar to the list of most common physical problems in the "Palliative Care Outcome Scale-Symptom" (POS-S) and the "Integrated Palliative Care Outcome Scale" (IPOS). These scales include symptoms of pain, shortness of breath, weakness or fatigue, nausea, vomiting, loss of appetite, constipation, mouth and dry mouth pain, restless sleep, and poor mobility. The physical symptoms in the VietPOS scale are among the 16 symptoms that require CSGN in the Global Atlas of Palliative Care.

The qualitative results showed that in addition to the palliative care needs included in the APCA POS such as pain, other symptoms, anxiety, emotional support, information, and peace, cancer and HIV patients in Vietnam have three additional needs: sadness, being rejected or stigmatized, and financial concerns. These needs have been incorporated into the VietPOS scale to ensure coverage of necessary content based on evidence of Vietnamese needs. In addition, the qualitative research results also show some similarities in the explanation of the concept of peace in African patients participating in the validation study of the APCA POS and Vietnamese patients participating in our study. This is a sense of peace that comes from awareness of oneself, relationships with others, spiritual faith, health, and healthcare.

VietPOS has some differences compared to APCA POS and other versions of POS worldwide.

Firstly, while APCA POS, POS version 1 and 2 only ask about symptoms in general, VietPOS specifies the list of common symptoms based on evidence in patients with life-limiting illness in Vietnam. This has also been proposed in German and Italian validation study.

Because symptoms are very common in patients with life-limiting illness and symptom management is the foundation of palliative care, Constantini and colleagues also believed that the future development of POS needs to consider evaluating symptoms. In addition, in the palliative care, symptoms of concern are not only common and distressing symptoms during the course of the illness, but also end-of-life symptoms such as difficulty breathing and pain. At the end of life, the patient's health status deteriorates rapidly, and these symptoms need to be monitored and evaluated regularly in order to alleviate the patient's suffering optimally. Therefore, in VietPOS, questions about pain and difficulty breathing have been included, although difficulty breathing is not among the most common and distressing symptoms from prevalence study.

Secondly, the VietPOS does not use the question "life worthwhile" but replaces it with "sadness/depression". The validated versions in Italy and Thailand also have similar replacements. This change is appropriate because sadness and depression are needs identified in both our qualitative and quantitative research. At the same time, evidence of the increasing prevalence and severity of depression in cancer and HIV patients also emphasizes the importance of this question.

Thirdly, VietPOS had a question about being rejected and stigmatized against. In Vietnam, stigma may not have been widespread toward cancer patients as much as toward HIV patients. However, the cancer patients in our study shared that they were avoided by other because a fear or a belief that cancer is contagious. This stigma led to feeling of isolation, shame and low self-esteem and may affect their ability to access to healthcare and their quality of life. Therefore, VietPOS raises awareness about cancer stigma and work towards reducing it, in order to support and empower those affected by the disease. The VietPOS addresses this neglected issue among cancer population.

Fourthly, VietPOS addresses financial concerns. Poverty, one of the social injustices, is a primary risk factor for suffering and

premature death. The National Guidelines on Palliative Care of Ministry of Health of Vietnam in 2022 mentioned interventions for social suffering. Therefore, VietPOS promotes Palliative Care meet the suffering of the poor, in line with national guidelines.

Thus, VietPOS has been revised by combining qualitative and quantitative methods. VietPOS is a measurement tool for assessing palliative care outcomes based on evidence of physical, psychological, social, and spiritual needs of people with life-limiting illness in Vietnam. The adaption process from APCA POS to VietPOS ensured content validity and covered what people with life-limiting illness in Vietnam need.

The VietPOS scale reflects the basic needs for assessment as described in the Palliative Care Guidelines of the Ministry of Health in 2022. Part 3, "Pain assessment and relief" corresponds to VietPOS question 1 (pain). Part 4.1, "Physical symptoms assessment and relief" corresponds to VietPOS question 2 (other symptoms). Part 4.2, "Psychological suffering assessment and relief" corresponds to VietPOS questions 3 and 4 (anxiety and sadness/depression). Part 4.3, "Social suffering assessment and treatment" corresponds to VietPOS questions 5, 6, and 7 (rejection /discrimination, emotional support, lack of money for basic needs). Part 4.4, "Spiritual suffering assessment and treatment" corresponds to VietPOS question 9 (peace).

VietPOS meets the global development trend of the palliative outcome scale. The most important questions identified by palliative care experts worldwide have been encompassed in VietPOS. Additionally, there is a growing demand worldwide for a more comprehensive version (incorporating more symptoms and addressing spiritual issues for diverse populations) to enhance its utility. As a result, a new version of POS has been developed, called the Integrated Palliative Care Outcome Scale – IPOS. The IPOS toolkit represents a novel development, integrating the most crucial questions from POS, POS-S, and APCA African POS. IPOS has been welcomed by patients and experts as a more rational and concise approach, capturing their most significant concerns regarding symptoms while expanding to

include information needs, practical concerns, worries, distress, family concerns, and overall sense of peace. Several countries, including Germany, Sweden, Greece, Romania, Israel, Japan, China, Turkey, Poland, France, Italy, and Portugal, are in the process of validating IPOS. VietPOS has followed this trend and has been developed to address the expansion of symptoms, financial worries related to basic needs, anxiety, sadness/depression, and the general sense of peace as a spiritual need. The content of VietPOS shares many similarities with the content of IPOS.

4.2. Results of VietPOS application study for PWH in Hai Phong

4.2.1. Validity and reliability

In the VietPOS application study, we evaluated the internal consistency of VietPOS in an HIV patients in Hai Phong. The study showed that the Cronbach's alpha coefficient was 0.692 for 14 questions for patients. Therefore, the internal consistency was at a moderate level. Although the small sample size influenced the analysis results, these initial results were similar to those of the validated POS study. The original POS scale had a Cronbach's alpha coefficient of 0.65 for the patient version. The Spanish and Argentine versions had Cronbach's alpha coefficients ranging from 0.62 to 0.69 for the patient version. APCA POS had a Cronbach's alpha coefficient of 0.6. The Italian version had a Cronbach's alpha coefficient (95% CI) of 0.67 (0.59-0.73) for 10 components of POS.

For construct validity, the research indicated a negative correlation between the physical and psychological domains of VietPOS and the physical, psychological, and level of independence domains of WHOQoL HIV BREF, between the social communication domain of VietPOS and the social domain of WHOQoL HIV BREF, and between the mental domain of VietPOS and the social domain of WHOQoL HIV BREF. The WHOQoL HIV BREF scale consists of 31 questions that have been proven to be valid and reliable and widely used in PWH in Vietnam. The average time to complete the WHOQoL HIV BREF is 15 minutes. Due to the frailty of the target population requiring care and support, selecting a short but comprehensive measurement scale that covers all domains of care and support PWH

will be prioritized. The VietPOS scale meets this requirement with a completion time of 10 minutes for the first time and decreasing to 4-5 minutes for subsequent times.

4.2.2. Results of application study for palliative care needs

This study provides the first evidence of the use of a palliative care assessment tool to monitor the health outcomes of HIV patients undergoing ARV treatment in Vietnam.

Overall, we observed improvements in all aspects covered by the VietPOS after one month of integrating the use of the VietPOS scale in routine care for patients at the outpatient clinic of Thuy Nguyen General Hospital. This has also been observed in other studies using the POS scale for HIV and cancer patients worldwide.

In our study, the most significant improvement was observed in the aspect of "emotional support" (improved by 1.84 points) and "feeling at peace" (improved by 1.52 points). The improvement was lower in the aspects of "stigmatization" (reduced by 0.80 points), "financial concern" (reduced by 0.76 points), "feeling worried" (reduced by 0.72 points), "information" (improved by 0.70 points), "feeling sad" (reduced by 0.62 points), "pain" (reduced by 0.56 points), and "other symptoms" (reduced by 0.34 points). All of these changes were statistically significant. These results are consistent with the findings from a randomized controlled trial conducted by nurses on HIV patients in Africa using the APCA POS scale. In that study, Keira Lowther found improvements in all components of the APCA POS scale, including pain, symptoms, anxiety, peacefulness, support, and advice in both the control and intervention groups. The most significant improvement in the intervention group was observed in the ability to share emotions and feel that life is worth living. There was no improvement in these two aspects in the control group at the end of the study.

In our study and Keira Lowther's study, significant improvements were observed in psychological, social, and emotional aspects. However, Charles Hongoro et al. recorded significant changes in physical and psychological aspects. In this study, the mean scores for pain (decreased by 51%), symptoms (decreased by 56%), and anxiety

(decreased by 53%) were significantly reduced. Conversely, the mean scores for other social and emotional aspects showed lower improvements: emotional support (decreased by 15%), quality of life (decreased by 15%), peace (decreased by 9%), and access to help and advice (decreased by 23%). These differences may indicate that HIV patients in our study, mostly in clinical stage 1, are healthier than those in other studies.

In our study, after one month, the proportion of HIV patients satisfied with their health increased from 28% to 46%, the proportion of "very satisfied" increased from 0% to 46%, and the proportion dissatisfied decreased from 12% to 0%. After one month, the proportion of patients with good and very good health-related quality of life (HRQoL) increased from 20% to 60%, the proportion of patients with poor HRQoL decreased from 14% to 2%, and the proportion of patients with very poor HRQoL decreased from 2% to 0%. The average scores in the six domains of HRQoL, which are physical, psychological, level of independence, social relationships, environment, and spirituality, also significantly improved ($p < 0.001$). Our study's results were similar to those of other studies on HIV patients such as Keira Lowther, Victoria Simms who studied 438 HIV patients in 11 outpatient clinics in Kenya and Uganda, which showed that physical and mental health subgroups improved over time in the care program. A study by Richard Harding et al. in Tanzania showed a significant improvement in HRQoL in the intervention group compared to the control group in the physical (1.46 vs. 0.54, $p=0.002$) and psychological (1.13 vs. 0.26, $p=0.006$) domains.

The clinical message from this study is that multidimensional issues (including pain, symptoms, psychological distress, social and spiritual) can be effectively managed with palliative care and quality of life can be improved.

Time to complete

The VietPOS questionnaire had 10 questions for patients, the average time to complete it for the first time is 10 minutes, and subsequent times are 4-5 minutes when patients understand the structure and how to answer the questions. In Argentina, patients

completed the POS for the first time in 12 minutes, the second time in 9 minutes, and healthcare workers completed it in 6 minutes. In Africa, the time for patients to complete POS for the first time was 7 minutes, and the second time was 5 minutes.

During the study, we found VietPOS to be short, easy to understand, and easy to use. VietPOS helps to quickly screen palliative care needs. From there, the care team will identify those who benefit the most and identify the most feasible and priority intervention goals. VietPOS can be integrated into patient records along with decision-support tools for doctors, nurses, and other care providers to provide patient-centered care.

In summary, the VietPOS was adapted based on evidence from patients with life-limiting illness in Vietnam, which has face validity. With just 10 short questions for the patients, VietPOS can be used to track changes in the HIV patients' care needs over time. The VietPOS also detected significantly improvement in physical, psychological, social, spiritual, and overall health and quality of life of the patients.

4.3. Limitations.

Our study has some limitations. Firstly, the study evaluated the VietPOS in terms of construct validity, internal consistency using a small sample size of 50 people, which may not fully reflect the validity and reliability of the VietPOS. Therefore, these stages need to be continued on a larger sample size in the HIV population and other populations that require palliative care. Secondly, the application study was conducted on a small sample size and without a control group. This leads to an inability to draw conclusions about the causal relationship of changes in care outcomes. However, conducting palliative care studies on people with life-limiting illnesses is not always feasible with large sample sizes. The lack of a control group in the study is partly related to the researcher's concerns about discovering patients in need of care without availability of effective intervention.

CONCLUSIONS

1. Validation of Palliative Outcome Scale for people with cancer and HIV in Vietnam

The Vietnam Palliative Outcome Scale - VietPOS is the result of applying the modified APCA POS from Africa as the following:

o VietPOS adds common symptoms experienced by cancer and HIV patients: lack of energy/ fatigue, mouth problems, shortness of breath, nausea/vomiting, and lack of appetite, other symptoms

o The social aspect of the VietPOS scale is expanded to cover issues such as sadness/ depression, rejection/stigmatization due to illness; financial concerns for basic needs of oneself and family.

o VietPOS includes questions on what matter the patients the most

2. Results of VietPOS application study for HIV patients in Hai Phong

The results of VietPOS application study research in evaluating palliative care for HIV patients at the outpatient clinic of Thuy Nguyen General Hospital are as follows:

The Cronbach's alpha coefficient is 0.692 for 14 questions for patients.

There is a negative correlation between the physical and psychological domains of VietPOS and the physical, psychological, and level of independence domains of WHOQOL-HIV BREF (correlation coefficients of -0.587, -0.472, and -0.539, $p < 0.01$), between the social communication domain of VietPOS and the social domain of WHOQOL-HIV BREF (correlation coefficient of -0.546, $p < 0.01$), and between the mental domain of VietPOS and the social domain of WHOQOL-HIV BREF (correlation coefficient of -0.289, $p < 0.01$).

The VietPOS assists healthcare professionals in identifying the needs of PWH, enabling targeted care to improve various aspects of their health.

Within a week, significant improvements were observed in various symptoms, including reductions in anxiety (0.68 ± 0.17 points, $p<0.001$), sadness (0.54 ± 0.17 points, $p=0.004$), and perceived stigma (0.74 ± 0.16 points, $p<0.001$), as well as enhancements in emotional support (1.02 ± 0.31 points, $p=0.001$) and overall well-being (0.90 ± 0.23 points, $p<0.001$).

After one month, there were notable improvements in pain (0.56 ± 0.16 points, $p=0.001$), other symptoms (0.34 ± 0.08 points, $p<0.001$), anxiety (0.72 ± 0.18 points, $p<0.001$), sadness (0.62 ± 0.17 points, $p=0.001$), stigma (0.80 ± 0.18 points, $p<0.001$), emotional support (1.84 ± 0.26 points, $p<0.001$), financial anxiety (0.76 ± 0.23 points,

p=0.003), overall well-being (1.52 ± 0.23 points, p<0.001), and access to information (0.70 ± 0.16 points, p<0.001). The most significant improvements were observed in emotional and mental support. These findings have important implications in the field of palliative care.

The completion time for VietPOS decreased from 10 minutes initially to 5 minutes in subsequent visits.

The satisfaction rate of HIV patients regarding their health increased from 28% initially to 46% after one month. The percentage of HIV patients who rated their quality of life as good or very good increased from 20% initially to 60% after one month. The improvement was significant in all areas of physical, psychological, social, level of independence, environment, and spirituality (p<0.001).

RECOMMENDATIONS

1. It is necessary to test reliability and validity of VietPOS on appropriate sample sizes and different populations, such as cancer and other chronic illnesses.
2. It would be useful and feasible to integrate VietPOS into the standard medical records of HIV patients to assess, support, and monitor changes in their care needs and the outcomes of care interventions.
3. Develop user guides and clinical decision-making tools for the VietPOS scale based on patient scores.