NEW EMBRACING APPROACH FOR BETTER ADVANCED CANCER PATIENT COMPREHENSIVE CARE

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Abstract

Introduction: Cancer patients have multiple and complex needs. Argentina has a medium-high cancer incidence. Only 14% of patients with palliative care needs have access to specialized services. This study aimed to develop and implement an integrated cancer care model in three hospitals and at home based care level.

Methods: The NECPAL2 was a prospective longitudinal observational study. We report a two-year healthcare intervention and its implementation process. The NECPAL tool was used as a screening instrument. Adult cancer patients were recruited and assessed. NECPAL+ patients are those with a positive surprise question - Would you be surprised if this patient dies in the next year? (no)– and, at least one indicator of advanced disease. Patients were reassessed periodically with validated scales. Feedback was given for clinical case management. The project was developed in three consecutive stages and six phases. Data were collected for statistical analysis with a prognosis and palliative approach.

Results: 2104 cancer patients screened. 681 were NECPAL+. 21% of them presented more than six parameters of severity or progression. The mean general survival was 8 months. 61.9% died within the follow-up period. Survival predictors were identified. Over 65% of patients were referred to palliative care; 10% received home-care. Areas for improvement were recognized. An implementation document was created.

Discussion: This study showed that a predictive model is feasible, improving chances for timely referral and needs approach. It provided the basis for further implementation research and should encourage policy-makers for embracing palliative model development for better cancer patient care.

Key words: palliative care, advanced cancer, public health, prognosis

Resumen

Nuevo enfoque para mejorar el cuidado integral del paciente con cáncer avanzado

Introducción: Los pacientes con cáncer tienen necesidades múltiples y complejas que se deben atender oportunamente en los distintos niveles del sistema sanitario. Argentina tiene una incidencia de cáncer media-alta pero solo el 14% de los pacientes acceden a cuidados paliativos. El objetivo de este estudio fue desarrollar e implementar un modelo multicéntrico de atención integral del paciente con cáncer avanzado.

Métodos: El NECPAL2 fue un estudio observacional longitudinal prospectivo de dos años. Se evaluaron

pacientes adultos con cáncer avanzado. Se utilizó la herramienta NECPAL como instrumento de cribado. Los pacientes NECPAL+ son aquellos con la pregunta sorpresa positiva -¿Le sorprendería que este paciente muriera en el próximo año? (no)- y, al menos, un indicador de enfermedad avanzada. Los pacientes fueron reevaluados periódicamente con escalas validadas para la gestión clínica de casos. El proyecto se desarrolló en tres etapas consecutivas y seis fases. Se analizaron los resultados con un enfoque pronóstico y paliativo.

Resultados: Se identificaron 2104 pacientes oncológicos, 681 eran NECPAL+. El 21% presentaba más de seis parámetros de gravedad o progresión. Más del 60% de los pacientes NECPAL+ tenían una evaluación inicial multidimensional completa y documentada. La supervivencia media general fue de 8 meses. El 61.9% falleció durante el periodo de seguimiento. Se identificaron predictores de supervivencia. Más del 65% fueron derivados a cuidados paliativos; el 10% recibió atención domiciliaria. Se reconocieron áreas de mejora. Se creó un documento de recomendaciones.

Discusión: Este estudio demostró que un modelo predictivo multicéntrico y en varios niveles es factible y mejora las posibilidades de derivación oportuna para atención paliativa. A pesar de las limitaciones este estudio puede inspirar políticas para mejorar la atención integral de pacientes con cáncer avanzado.

Palabras clave: cuidados paliativos, cáncer avanzado, salud pública, pronóstico

KEY POINTS
Current knowledge

- Cancer patients have multiple and complex needs that will be timely addressed at different healthcare system levels.
- These patients are late or not referred to specific services and die with unrelieved suffering.
- The NECPAL tool is validated for screening and early identification of patients with life-limiting diseases. It combines palliative and prognosis approach.

Contribution of the article to current knowledge

- We designed and implemented a demonstration cancer programme that could be replicated in different settings.

- We proposed a proactive palliative approach using the NECPAL as screening tool, and the continuity of care until death when possible.
- A predictive model was feasible improving chances for timely palliative care referral and needs approach.

In 2020, an estimated 19.3 million new cancer cases and nearly 10 million cancer deaths occurred worldwide[1]. Patients have multiple and complex needs that will be addressed at different healthcare system levels[2]. Argentina has a medium-high cancer incidence, with over 100 000 new cases per year[3]. It is ranked seventh in terms of incidence and third in terms of mortality among countries of Latin America[4]. Nowadays, only 14% of patients with palliative care (PC) needs have access to specialized services in the country[5]. The National Palliative Care Programme for cancer patients, launched by the National Cancer Institute in 2016, "promotes continuous and integrated care throughout the disease trajectory, focusing on the prevention and relief of suffering and achieving the best possible quality of life for patients and their families"[6]. So far, the number of cancer patients with palliative needs in Argentina remains unknown. There are no standardized screening processes for the early identification of the target population and their palliative needs. Furthermore, there is no systematic review and documentation model of interventions seeking better effectiveness and quality assessment. Consequently, patients with palliative care needs are late or not referred to specific services and die with unrelieved suffering.

The WHO defines PC as improving quality of life (QoL) through early detection and impeccable needs assessment, which will enable professionals to set an efficient, timely, continuous, and integrated care plan[7]. The practical PC approach should be an informed and always available option[8-10]. Furthermore, prognostic factors may contribute to achieving a more accurate multidimensional case management[11-13]. Simple well-validated predictive tools that identify individuals at high risk of death and comparative outcomes indicators are required[14,15].

Growing evidence shows that the NECPAL CCOMS-ICO© tool (in Spanish, NECesidades PALiativas; in English, Palliative Needs) is a validated screening instrument for the identification of patients with life-limiting diseases in need of PC[2, 10, 11, 16, 17]. It is based on the "surprise question" (SQ)- *Would you be surprised if this patient dies in the next year?*- and comprises professionals' consideration, patient or family's perceived need or desire, and other general or specific severity and clinical progression parameters. It assists healthcare professionals by encouraging systematic patient screening, estimating prevalence, and implementing assistance. It is the essence and first step in comprehensive care[12,18-20]. Moreover, some NECPAL parameters have been independently associated with mortality risk in different populations[11-13,21].

In 2015, we implemented a small-scale study, called NECPAL1, to test the feasibility of the screening tool and the continuity of care in one university hospital in Buenos Aires City[10]. That experience provided valuable insight to replicate and scale up this systematic approach as an effective and practical model for appropriate needs addressing into different settings.

The present study, called NECPAL2, aimed to design and implement an integrated PC model (PCM) in three hospitals in the same city. We report a two-year healthcare intervention and its implementation process. It is a demonstration multi-site and multi-level programme that includes patients' follow-up through hospital facilities and until death when possible. If home-care was feasible and consented to, it was provided by a home-based care team. This project included palliative and prognosis approaches.

Materials and methods

The NECPAL2 was a prospective longitudinal observational study. It was designed and implemented in public hospitals located in Buenos Aires from 2016 to 2018. Three palliative hospital-based care teams and one home-based care team were involved: the Medical Research Institute A. Lanari, the Institute of Oncology A. Roffo and C.B. Udaondo Hospital of Gastroenterology. The two first institutes are affiliated with the University of Buenos Aires; meanwhile, the third one depends on the City Government. Pallium Latinoamérica is a non-profit PC organization that runs a home-care programme within the city.

The project was developed in three consecutive stages and six phases (Figure 1): A) Preliminary stage (phase 1), B) Early Identification stage (phases 2 and 3), and C) Implementation stage (phases 4, 5 and 6) The NECPAL tool was used as screening instrument[10]. In addition, STROBE statement checklist for observational research guided this report[22].

Figura 1 | Implementation stages and phases of the Palliative Care Model (PCM)
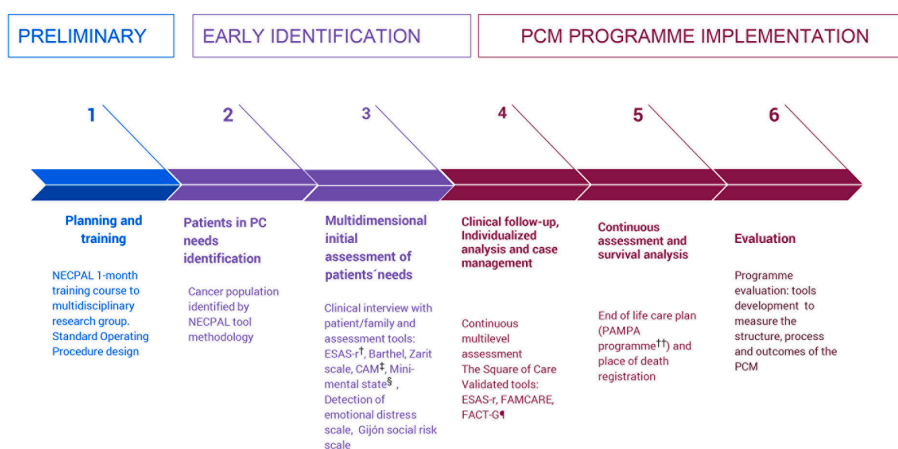
†ESAS-r: Edmonton Symptom Assessment System Spanish version
‡CAM: Confusion Assessment Method
§Mini-Mental State: Mini-Mental State Examination de Folstein (MMSE-30)
¶FACT-G scale: Functional Assessment of Cancer Therapy -General
††PAMPA © (Pallium Multidisciplinary Assistance Program) (Tripodoro, Goldraij, et al., 2019)

A) Preliminary stage: planning, preparing and training

Phase 1: A multidisciplinary research group was established. Researchers followed a specific one-month training course on implementation procedures and concurred with operational definitions based on the NECPAL systematic screening methodology[10, 23]. After ethical approvals, researchers, oncologists and PC teams discussed and agreed the protocol in each centre.

B) Early Identification stage

Phase 2: Patients with PC needs identification

Accessible population and sample definition: All ≥18-year-old in/out cancer patients assisted by oncologists, gynecologists, urologists and clinicians at the three centres between June 2016 and July 2018. The sample was defined by the NECPAL CCOMS-ICO 3.0 methodology[23]. Oncologists, oncology nurses, gynecologists, urologists and clinicians were interviewed and asked about adult cancer patients under their care. Additionally, professionals consulted patients' clinical records for sociodemographic or medical information within the meeting. Interviews lasted 10 minutes on average for each case.

NECPAL tool methodology: This instrument offers a non-dichotomous multifactorial, quantitative and qualitative assessment method that incorporates subjective perception and the SQ: *Would you be surprised if this patient dies in the next year?* Positive answers (SQ+) meant that the doctor would not be surprised. Table 1 summarizes specific indicators and the usage of healthcare resources[23]. Patients considered NECPAL positive (+) are those SQ+ patients who also fulfilled at least one of the other indicators of the tool. Cancer patients were stratified into four levels[10]. Level 0 with cancer diagnosis; Level 1 cancer with advanced chronic disease; Level 2 cancer with SQ+; Level 3 cancer with SQ+ and at least one indicator (NECPAL+). The screening was repeated monthly for new patients' enrollment, including previous NECPAL negative (-) patients whose health condition might have changed. Advanced cancer patients (NECPAL+) who accepted participation were interviewed and followed up until death or study clinical cut-off (phase 3).

Operational definitions:

I. Advanced stage of the disease: with progressive and gradual course, with varying degrees of impairment of autonomy and QoL. Variable response to a specific treatment, progressing towards death in the medium term.

II. Advanced oncological disease: (based on NECPAL criteria) (at least one criterion is required)

- Confirmed diagnosis of metastatic cancer (stage IV) or stage III with poor response or contraindication to a specific treatment, evolutionary flare-up during treatment or metastatic involvement of vital organs (CNS, liver, massive pulmonary).

- Significant functional impairment (Palliative Performance Scale (PPS) < 50%)[24].

- Persistent poorly controlled or refractory symptoms, despite optimization of specific treatment.

III. Terminal oncological stage: an advanced disease in an evolutionary and irreversible phase with multiple symptoms, emotional impact, loss of autonomy, with little or no capacity to respond to specific treatment and with a life prognosis limited to weeks or months, in a context of progressive fragility.

Phase 3: Multidimensional initial assessment of NECPAL+ patients' needs

Meetings were appointed between patient-family and researcher for an initial assessment. Semi-structured clinical interviews explored patients' and families' multidimensional needs according to a qualitative-quantitative approach[25]. Each interview lasted for about 40-50 minutes. The following validated scales were applied for systematic assessment: ESAS-r, Zarit scale, Barthel, Confusion Assessment Method (CAM), Mini-Mental state, Detection of emotional distress scale, Gijón Social Risk Scale[26-33]. When the patient had documented cognitive or conscious state impairment, or severe language disorder, interviews were conducted with the patient's primary carer. In this case, self-administrable scales for patients were not applied. Data were collected on specific encoded registers, and identified PC needs were summarized in the patient's medical history after feedback to the oncologist in charge.

C) Implementation Stage

Phase 4: Clinical follow-up, Individualized analysis and case management

The Square of Care model guided the individual assessment[25]. It describes the six essential steps in providing care: review, information sharing, decision making, care planning, care delivery and confirmation. Assessment feedback was timely given to treating physicians or teams who would seek the best answer to each patient's needs. Case management ensured continuity of care according to individual complex needs. Patients were referred to the hospital PC service or the home-based care team if appropriate.

Patients and families were reassessed, at least, quarterly using a follow-up set of scales: ESAS-r, FAMCARE scale and QoL FACT-G questionnaire[34,35]. Register forms with qualitative data were complemented with field

Tabla 1 | General indicators of severity and progression and disease-specific indicators of NECPAL CCOMS-ICO© tool V 3.0[23]

The NECPAL tool indicators	
Choice, request or need of Palliative Approach	Has the patient or the main caregiver requested palliative/comfort treatments exclusively or suggests limitation of therapeutic effort? Do healthcare professionals consider that the patient requires palliative care or palliative treatment at this moment?
Functional markers	Serious established functional dependence (Barthel Score <20) Loss of two or more ADLs† even though there is adequate therapeutic intervention or clinical perception of functional decline (sustained, intense/severe, progressive, irreversible) not related to concurrent conditions
Nutritional markers	Serum albumin <2.5 g/dL, not related to acute episodes of unbalance Weight loss >10% or clinical perception of nutritional decline (sustained, intense/severe, progressive, irreversible) not related to concurrent conditions
Emotional	Presence of emotional distress with psychological symptoms (sustained, intense/severe, progressive) not related to acute concurrent conditions
Geriatric syndromes in the last 6 months	Persistent pressure ulcers (stages III–IV), recurrent infections (>1), delirium, persistent dysphagia, falls (>2)
Comorbidity	*Charlson* Index (≥ 2)
Additional factors on use of resources	Two or more urgent (unplanned) hospital (or skilled nursing facilities) admissions due to chronic disease in the last year. Need of complex/intense continuing care, either at an institution or at home
Cancer (1 single criterion)	Confirmed diagnosis of metastatic cancer who present low response or contraindication of specific treatment, progressive outbreak during treatment or metastatic affectation of vital organs. Significant functional deterioration (palliative performance scale, PPS <50%) Persistent, troublesome symptoms, despite optimal treatment of underlying condition(s).
Chronic pulmonary disease (≥ 2 criteria)	Breathlessness at rest or on minimal exertion between exacerbations. Difficult physical or psychological symptoms despite optimal tolerated therapy. $FEV1^{‡}$ <30% or criteria of restricted severe deficit: $FVC^{§}$ <40%/ $DLCO^{¶}$ <40%. Accomplishment of oxygen therapy at home criteria. Recurrent hospital admissions (>3 admissions in 12 months due to exacerbations)
Chronic heart disease (≥ 2 criteria)	Heart failure NYHA†† stage III or IV, severe valve disease or inoperable coronary artery disease. Shortness of breath at rest or minimal exertion. Difficult physical or psychological symptoms despite optimal tolerated therapy. Ejection fraction severely affected (<30%) or severe pulmonary hypertension (>60 mm Hg). Renal failure (GFR‡‡ <30 L/min). Repeated hospital admissions with symptoms of heart failure/ischemic heart disease (>3 in the last year)

(continua)

(continuación)

Serious chronic liver disease (1 single criterion)	Advanced cirrhosis: stage Child C, MELD-Na[§§] Score >30 or with one or more of the following medical complications: diuretic-resistant ascites, hepatorenal syndrome or upper gastrointestinal bleeding due to portal hypertension with failed response to treatment. Hepatocellular carcinoma: present, in stage C or D (BCLC[¶¶])
Serious chronic renal disease (1 single criterion)	Serious renal failures (GFR <15) in patients to whom substitutive treatment or transplant is contraindicated
Chronic neurological diseases (1): CVA[†††] (1 single criterion)	During acute and subacute phases (<3 months post stroke): persistent vegetative or minimally conscious state >3 days. During the chronic phase (>3 months post stroke): repeated medical complications (aspiration pneumonia, pyelonephritis, recurrent febrile episodes, pressure ulcers stages 3-4 or dementia with severe criteria post stroke)
Chronic neurological diseases (2): MND[‡‡‡], multiple sclerosis and Parkinson (≥ 2 criteria)	Progressive deterioration in physical and/or cognitive function despite optimal therapy. Complex and difficult symptoms. Speech problems with increasing difficulty communicating. Progressive dysphagia Recurrent aspiration pneumonia, breathless or respiratory failure
Dementia (≥ 2 of the following criteria)	Severity criteria: GDS/FAST[§§§] 6c or more. Progression criteria: loss of two or more ADLs in the last 6 months, despite adequate therapeutic intervention or difficulty swallowing, or denial to eat, in patients who will not receive enteral or parenteral nutrition. Use of resources criteria: multiple admissions (>3 in 12 months, due to concurrent processes- aspiration pneumonia, pyelonephritis, sepsis, etc.- that cause functional and/or cognitive decline)

[†]ADL: activities of daily living; [‡]FEV1: forced expiratory volume in 1 s; [§]FVC: forced vital capacity; [¶]DLCO: diffusing capacity of the lung for carbon monoxide; [††]NYHA: New York Heart Association; [‡‡]GFR: glomerular filtration rate; [§§]MELD-Na: Model for end-stage liver disease - sodium; [¶¶]BCLC: Barcelona clinic liver cancer; [†††]CVA: cerebrovascular accident; [‡‡‡]MND: motor neuron disease; [§§§]GDS/FAST: Global Deterioration Scale/Functional Assessment

notes and encoded to ensure patient and family confidentiality. All clinical information was included in clinical records available for professionals in charge.

Phase 5: Continuous assessment and survival analysis

Assessment of the different dimensions on health-related QoL was carried out, longitudinally measuring the clinical impact of the palliative intervention according to the clinical situation and recommended criteria (symptom control, QoL, caregiver burden, sedation, use of resources, survival and place of death).

When appropriate, we assisted dying patients under a specific care plan based on international standards[36]. The PAMPA© (from Spanish acronym *Programa Asistencial Multidisciplinario Pallium*) care plan for the last days

of life was founded on global evidence that identifies the ten key principles for the best care for the dying person and incorporates the 40 outcomes that support quality and safety in individualized patient care (*The international 10/40 Model*)[37,38]. A multivariate model with significant indicators in univariate analysis was calculated. Kaplan-Meier survival curves were generated from the date of NECPAL+ identification until death or the last control of that patient. The clinical cut-off was established two years after the first NECPAL+ patient was identified (1st July 2018)[11].

Phase 6: Evaluation

Programme evaluation involved a comprehensive assessment of each stage to identify areas for improve-

ment and guarantee the accomplishment of operational aspects and goals achievement. Adjustments were made according to detected needs regarding planning, staff training, interview method, follow-up process, registration accuracy, data collection and analysis, and monitoring of results.

A PC programme can be evaluated using a similar method to that used for PC services; that is, by looking at its structure, activities and outcomes using a quantitative and/or qualitative approach and setting up indicators[39]. Descriptive statistics were carried out to establish PCM indicators to measure structure, process and outcomes of PC resources involved in the project. This PCM was guided by a 23-quality indicator panel developed for our research group in a previous project (10 for structure, 12 for process, 1 for outcome)[10,40].

Statistics analysis and ethical approval:

Quantitative data were imported into IBM-SPSS version 22, SPSS Inc. Chicago, IL and Stata V12 (Statistical Package for Social Sciences) for descriptive statistical analysis.

Ethical approval for this study was obtained from the Ethics Committees of each institution involved. The Necpal2 study was registered at the National Ministry of Health (RENIS IS001867/IS001871), and funded by the Argentine National Cancer Institute and *Pallium Latinoamérica*.

Results

A total of 2104 cancer patients were screened. Table 2 characterizes the total population profile per hospital and condition. Furthermore, the flowchart depicts the recruitment process in stratification levels per hospital (Figure 2).

Overall, 681 patients were NECPAL+ (32.3%). Within the three hospital samples, every patient who was SQ+ (Level 2) had at least one general parameter of decline or specific parameter of advanced disease, either cancer or other life-limiting condition (Level 3). Therefore, they were

sorted and presented as Level 2 and 3. All NEC-PAL+ patients were followed up for two years after first identification.

The information was gathered at each of the three hospitals. The data are presented disaggregated per group and hospital due to the heterogeneity of the sample. Comparison between the three hospitals information was beyond this project scope. The demographic and clinical parameters of NECPAL+ patients underwent descriptive analysis (Table 3). According to distribution, continuous variables were expressed as mean values, standard deviation, median, and range. Almost 70% of the patients were recruited at the oncology department in the gastroenterology hospital. At the other centres, participation of different cancer services was heterogeneous.

More than 60% of NECPAL+ patients had a full documented initial assessment. Besides, 65% to 89% of NECPAL+ patients were referred to a PC specialised team. 10% of these patients received home-based care. Home-care delivery was not available beyond Buenos Aires city. Thus, the referral was limited due to geographical factors. Roffo and Udaondo are referral centres and have no geographic service area. Several patients came from outside the city (30-40 kilometers away), either for assistance or specialist consultation. In those cases, follow-up was erratic, and homecare was not an option.

The percentage of patients who presented one or more parameters according to the NEC-PAL tool is summarized in Figure 3. Most of the patients (79%) presented less than six parameters in the whole sample (60% Lanari, 86.6% Udaondo and 89% Roffo Hospital). However, 21% of the patients presented six or more NECPAL tool parameters (40% Lanari, 13.4% Udaondo and 11% Roffo Hospital).

Tabla 2 | Socio-demographic characteristics of the total population profile per hospital and condition

Total population profile per hospital and condition	Lanari Institute		Roffo Institute		Udaondo Hospital	
	In-patients	Out-patients	In-patients	Out-patients	In-patients	Out-patients
Age (years)	77	76	57	64	60.5	61
(Mean and range)	(50-93)	(27-99)	(27-82)	(26-89)	(22-99)	(21-92)
Female / Male Ratio	1.1		1.1		0.9	

Figura 2 | Stratification of the recruitment process flowchart
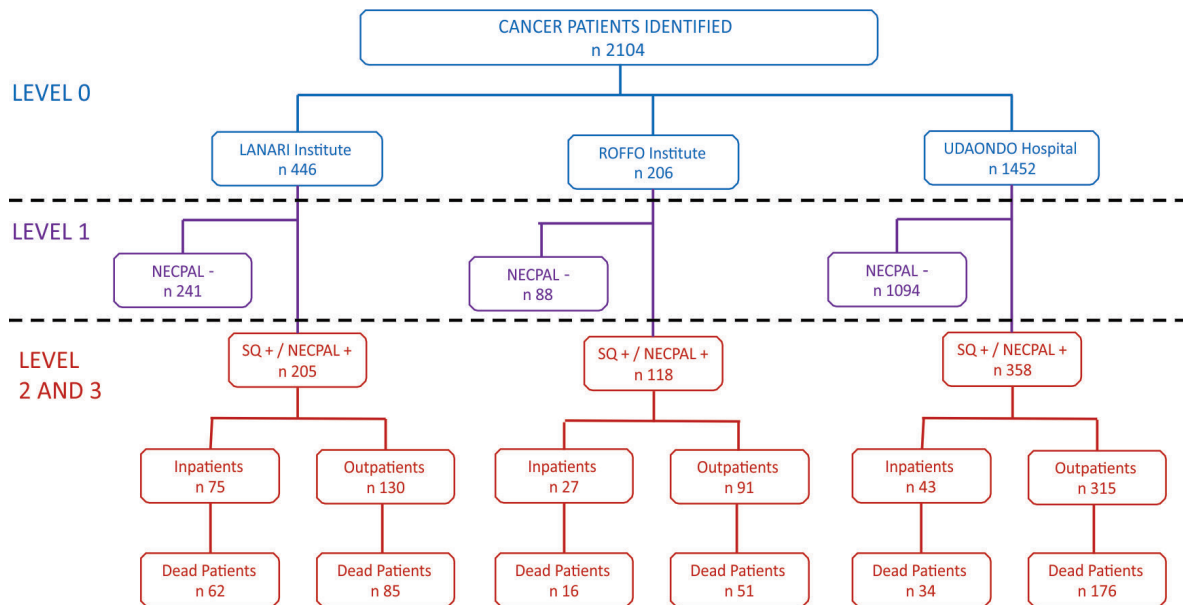
SQ: surprise question; NECPAL+: patients with SQ+ plus at least another parameter of severity or progression; NECPAL−: patients with negative SQ

Within the 2-year follow-up period, 422 NECPAL+ patients died (61.9%). Survival analysis and Kaplan-Meier curves were published in a preliminary report[12]. Patients referred to other centres or those lost to follow-up were censored. Hospital-specific survival analysis allows for local interpretation but it is omitted here. Predictable prognostic factors and logistic regression details can be found elsewhere[12].

The best predictors of mortality were: nutritional and functional decline with PPS≤ 50, persistent symptoms, functional dependence, poor treatment response, primary cancer diagnosis and condition (in/outpatients). Only three variables remained significant in multivariate analysis: low response to treatment, PPS ≤ 50 and condition (in/outpatients).

The place of death was recorded in 50% to 66% of deaths occurring within the follow-up period. The PAMPA© care plan for the last days of life was comprehensively documented in 91 dying patients (21%). Only two hospitals (Lanari Institute and Udaondo Hospital) and the homecare team had had previous experience with this care plan. Care principles and outcomes

were recorded on the patients' clinical records. Telephone case management was appropriately documented, including post-bereavement calls to the families. PAMPA© outcomes clinical audit has already been published[36].

In the evaluation phase, we identified areas for improvement that would allow building a formal quality improvement process and providing feedback to attendant teams and stakeholders:

- Define the target population profile
- Identify available healthcare services and models of continuity of care across settings (hospital, outpatients' facilities, home care services).
- Suggest clinical guidelines and protocols for healthcare delivery.
- Select validated tools for multidimensional assessment and end-of-life care plan.
- Define existing standards of health care practice.

Structure, process and outcomes indicators were recommended. Process indicators regarding patient-family care and teamwork, as well as pain assessment (outcome indicator) were

Tabla 3 | Socio-demographic characteristics of NECPAL+ patients with primary cancer diagnoses and NECPAL parameters per hospital

	Total NECPAL+ (n 681)	Lanari Institute (n 205)		Roffo Institute (n 118)		Udaondo Hospital (n 358)	
		In-patient (n 75)	Out patient (n 130)	In-patient (n 27)	Out patient (n 91)	In-patient (n 43)	Out patient (n 315)
Female	339 (50%)	35 (47%)	72 (56%)	9 (33%)	53 (59%)	19 (44%)	150 (48%)
Age (mean/range)	65 (23-99)	76 (50-93)	76 (38-99)	56 (27-77)	63 (33-81)	60 (32-99)	59 (23-91)
Nutritional decline	259 (38%)	42 (56%)	37 (29%)	10 (37%)	19 (21%)	23 (53%)	128 (41%)
Functional decline	266 (39%)	54 (72%)	66 (51%)	18 (67%)	33 (37%)	17 (40%)	76 (24%)
Functional dependence	89 (13%)	24 (32%)	17 (13%)	8 (30%)	5 (6%)	7 (16%)	27 (9%)
Breast cancer	36 (5%)	7 (9%)	24 (19%)	4 (15%)	1 (1%)	0	0
Lung cancer	118 (17%)	8 (11%)	23 (18%)	3 (11%)	83 (92%)	43 (100%)	305 (97%)
Gastro-intestinal cancer	413 (61%)	31 (41%)	25 (19%)	7 (26%)	1 (1%)	0	0
Genitourinary cancer	35 (5%)	8 (11%)	22 (17%)	2 (7%)	3 (3%)	0	0
Hematologic cancer	11 (2%)	5 (7%)	6 (5%)	0	0	0	0
Gynecologic Cancer	12 (2%)	1 (1%)	7 (5%)	4 (15%)	0	0	0
Other	40 (6%)	9 (12%)	19 (15%)	7 (26%)	2 (2%)	0	3 (1%)
Unknown primary site	16 (2%)	6 (8%)	3 (2%)	0	0	0	6 (2%)
Initial assessment completed		170/205 (82.9%)		72/118 (61%)		244/358 (68,2%)	
Referred to PC hospital services		182/205 (88.7%)		92/118 (78.6%)		232/358 (64.8%)	
Referred to PC homecare service		45/205 (22%)		1/118		10/358 (2.8%)	
Total deaths		147/205 (71.7%)		67/118 (56.8%)		210/358 (58.7%)	
Total deaths at home				119/350* (34%)			
PAMPA© End of life care plan		66/147 (44.9%)		0		27/210 (12.9%)	
Mean survival (months)		3		8		11	
Mean general survival (months)				8			

PAMPA © (Pallium Multidisciplinary Assistance Program)[36]
*350/424 (74 deaths without specific data)

Figura 3 | Distribution of NECPAL parameters per hospital
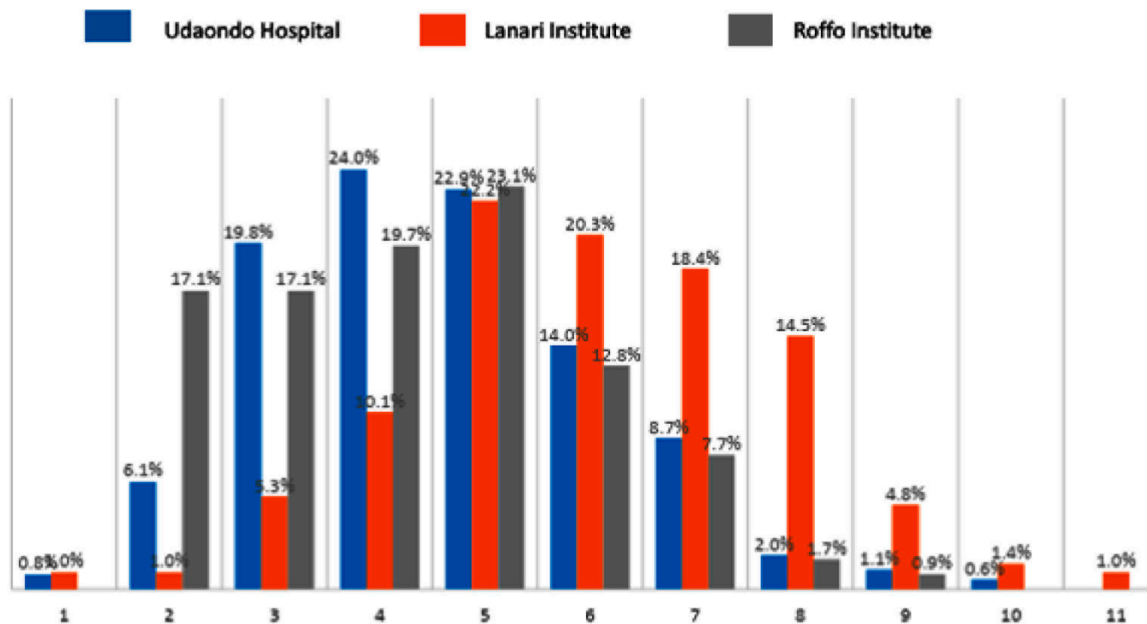
reported in clinical records. Therefore, findings are not comparative in terms of the quality of resources themselves, but rather descriptive of examined areas.

As a project deliverable, we created a Palliative Approach Model of Implementation (MAP in Spanish) document with recommendations.

Discussion

The strength of this study is the design and implementation of a demonstration programme that could be replicated in different settings and sites in Argentina. We proposed a proactive palliative approach and the continuity of care until death, which is still not guaranteed in the national healthcare system. We believe that the MAP can be customized and reproduced in other centres with similar characteristics in the country. Besides study limitations, we believe this model should inspire new cancer care-related national policies. NECPAL2 study contributes to existing evidence by amplifying our previous studies results on a multi-site and multi-level scale. It was feasible and measurable. It improved communication among professionals and services and enabled ethical discussion and better quality management.

Critical aspects of contributions analysis are pointed out below:

Early patient identification and need assessment. The NECPAL tool proved to be helpful in the early identification of cancer patients with palliative needs and multidimensional needs assessment. The SQ is widely recognized as a straightforward and effective technique for identifying individuals who are more likely to require PC in their final year of life[41-42]. The twelve-month SQ accurately predicts death in cancer patients admitted to the hospital[43]. However, when the time frame is reduced (12, 6, 3 or 1 month before death), its specificity increases while its sensitivity decreases. Further research is needed to understand how the SQ is used in practice and whether consistency and accuracy could be improved in our setting. Nevertheless, in this study, the SQ and NECPAL parameters were appealing tools for screening patients for PC referral[42]. It promoted reflexive thinking about potential survival or mortality and triggered a systematic and comprehensive search for unmet needs, including non-physical domains and integrating patient expressed necessities[2]. Surprisingly, in our sample, SQ+ and NECPAL+ patients were coincident. Probably, more experienced or trained physicians are likely to have implicitly in mind advanced cancer indicators, on which they base their answer to the SQ. The presence of one or more NECPAL indicators comes to confirm professionals' perceptions.

Feasibility and acceptability. The screening methodology and follow-up process were feasible and accepted by healthcare professionals within the research settings. They found the tool practical and easy to complete in a short time in comparison to other prognostic techniques or needs assessment tools[42]. Furthermore, they agreed that it enabled a multidimensional assessment without additional burden for patients or families.

Case management improvement and PC integration. Systematic screening prompted reflexive analysis and holistic case management and improved timely access and referral to PC services. The programme implementation resulted in a time-efficient method to assess patients and their families, leading to a more sensitive awareness of their needs and better use of resources to meet them. According to current practice in the country, this PCM had four to six times increased patients' chances of receiving PC, regardless of the care setting[5].

Hui et al. support the need to expand outpatient PC services in cancer centres and improve early PC referral[20,44,45]. However, the availability of a PC team does not always mean enough or timely PC attention. Therefore, explicit criteria for referral are needed.

Integration of primary care and hospital-level care is a constant challenge in a fragmented healthcare system[46]. We proposed a flexible care network even in hospitals with no specific geographical influence. The non-profit organization synergy, combined with the addition of a home-based programme, enabled us to provide a coordinated response even without administrative facilities.

Regular interviews with professionals and information interchange encouraged PC integration into the clinical and social services and facilitated continuous care across different healthcare services and levels. Moreover, routine screening exercises, documented multidimensional care priorities and case discussions launched cultural changes in oncologists' perspectives regarding the unit of care and the role of PC in practice. Future qualitative research should be conducted to look more deeply into this interpretation.

The importance of integrating PC into the healthcare system and providing specialized PC is now recognized by experts to ensure effective service delivery for people with PC needs throughout the continuum of care[15, 45, 47-50]. Clear referral criteria, interdisciplinary patient care rounds and embedded oncology–PC clinics are examples of potential strategies to promote care integration. PC would benefit nearly 80% of advanced cancer patients, enhancing their QoL, relieving patient and caregivers' distress, and even improving survival[51].

The National Palliative Care Programme promotes accessibility and integration with oncology in Argentina. Its actions are based on inclusion, equity, and quality principles. However, national recommendations focused on the know-how of that integration are lacking[6].

Symptom management and communication facilitation. Multidimensional assessment tools aided in eliciting patients' needs and care preferences, thereby in improving communication and clinical decisions with patients and families[52]. A comprehensive evaluation of needs provided oncologists, clinicians, and other specialists with dynamic information about the unit of care, enabling them to understand the patients' changing situation. From a pragmatic point of view, this approach combined palliative and prognosis evaluation, supporting physicians in their daily practice at clinical and organizational levels[53,54].

The NECPAL tool and methodology are based on international standards and evidence, conducting a good practice approach to prevent and alleviate suffering at the end-of-life. Additionally, NECPAL parameters played a crucial role in prognosis prediction[13]. Despite the uncertainty in survival, this model proved to assist with prognosis and mortality risk assessment, and it might help clinical decision-making by providing an approximate time frame of survival[12].

Our mortality analysis along the follow-up period showed that NECPAL+ patients died within the first year (mean global survival: eight months). These survival rates were higher than those in our previous study (mean global survival: four months)[11]. This result raises a new question about the potential impact of the systematic approach and reflexive SQ on earlier PC referrals[42].

In the new version of NECPAL 4.0 prognosis, identified needs, functional decline, nutritional

decline, multimorbidity, increased use of resources, and specific indicators of disease progression were all significant as prognostic indicators[13]. In this way, the group of patients that presented more than six positive parameters (21%) would be expected to have a life expectancy of about four months (following Stage III of NECPAL 4.0)[13]. Healthcare plans and new integrated and patient-centered care models have been developed globally and tested in other countries[53,54].

Information record for monitoring and outcomes evaluation. Data collected would allow scoring and monitoring needs and symptoms over follow-up and objective evaluation of the effectiveness of interventions. Because of their complexities, all implementation research should consider context-dependent factors that might influence outcomes[55]. Keeping in mind the characteristics of each hospital, screening NECPAL parameters associated with survival analysis allowed us to build a tailored PCM based on patients´ needs and the resources available in each hospital and in the community.

Quality end-of-life care using international standards[36]. The active participation of patients and families in this program encouraged us to carry out a continuous review. Our PCM allowed us to evaluate and refine content towards effectiveness for future implementation research projects. Bridging the gap between quality improvement implementers and researchers can increase the generalizability of interventions, accelerate the spread of practical approaches, and strengthen implementers' local work[51, 56].

This programme did not constitute a response to the gap between the country's need and supply of PC. Because identifying at-risk individuals with PC needs was based on clinical judgement, selection bias should be assumed. The number of cancer patients with palliative needs in Argentina remains still unknown. Subjective and objective information and the success of the screening process depended on the professionals' commitment to the research. The SQ may help with reflective thinking and increase PC referral more than usual. However, it is not necessarily a bias because the catalytic effect of the SQ has been described as a reflective induction of early PC referral[12].

In the geographic area, these three hospitals, in particular, do not have integrated primary care teams. In this PCM, the place of death was not always a choice. A substantial number of cancer patients recruited did not live in the city nor the home-care programme geographic area of coverage. All qualitative and quantitative data supported clinical decision making and case management as a healthcare intervention. Because we prioritized the PCM design and implementation process, we decided not to report clinical findings related to validated tools and quality indicator outcomes. They will be addressed in future research reports. Further research is needed to measure clinical impact.

The implementation of this programme was limited to an accessible population within hospitals with trained PC teams. Thus, results are poorly generalizable. However, it provided the basis for further implementation research and should encourage policymakers for embracing PCM development and network building for better cancer patient care.

In 2014, the World Health Assembly called to improve access to PC as a core component of health systems, emphasizing on primary health care and community/home-based care[7]. In addition, it recommended building evidence of PC models that are effective in low- and middle-income settings. Furthermore, policymakers should use a needs-based approach to identify patients who require PC and integrate measurement tools into healthcare professionals' practice. Encouraging adequate resources for PC programmes and research, particularly in resource-constrained countries, undertakes the next steps in PCM quality improvement efforts[57].

Conflicts of interest: None to declare

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