

Case Report

## **Advanced Practice Nurse Role in Clinical Trials for Cancer Patients: Description of a Continuous Improvement Project in Chile**

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### **Abstract**

#### **Background:**

The Pan American Health Organization (PAHO) established guidelines aiming to provide access and universal health coverage, through recommendations incorporating nursing models to support the development and strengthening of the different health systems<sup>1</sup>

#### **Case Presentation:**

The nurse navigator in oncology works direct and jointly with people, ensuring that each patient receives proper information and education related with the prescribed treatments, and that the given instructions guide the patient to the circuit of care that each person requires through the pathways of cancer treatment. To achieve this, we have worked on implementing a nurse navigator model, based on the expertise of a practice nurse to optimize access to clinical trials for people with oncological malignancies.

#### **Discussion:**

The nurse navigator intervention was applied to 326 adults in the context of clinical trial cancer patients. The average age was 62 years, and the most frequent sex was male.

The information collected showed that the follow-up of the navigator optimizes patient care times, while early and continuous education decreases the perception of patient's anxiety in the therapeutic indication.

### **Conclusion:**

The role of the advanced practice nurse is relevant for the cancer patient's experience and traceability, using a model such as the nurse navigator since the earliest steps of the clinical research processes. More research is required to determine whether this tool increases the access or dissemination of clinical studies. This Chilean model in research in cancer is pioneer in Latin-America.

### **Introduction**

The Management Model for the Operation of the Oncology Network of Chile (2018)<sup>2</sup>, clearly defines the development of follow up actions and the implementation of pillars based on nursing models. At Fundacion Arturo Lopez Perez – OECI Cancer Center (FALP), the focus on the clinical trials' development requires an active role of the advance practice nurse, becoming a major support for the patient that will participate in an assay in a comprehensive way.

In the scope review of the nurse navigator, "navigation" is described as a process where individualized support is provided to patients, families, and caregivers to overcome difficulties in different health systems and to facilitate timely access to health care and psychosocial services. This process is guided by a nursing professional, called "nurse navigator", who has specific clinical knowledge in the area, communicates assertively, and can provide education and resources facilitating informed decision making, and ensuring quality care during all phases of cancer, a concept coined since the 1980s in the United States<sup>3</sup>.

For nurse navigators there are roles and principles that define their actions such as patient-centered care, focused on promoting the mobility of the individual through the continuum of care, decreasing access barriers<sup>4</sup>.

This definition becomes imperative in the management of the patient participating in clinical trials, being an area of very low knowledge in the regional reality and in a context of new treatment weapons.

Clinical trials evaluate new therapeutic options to advance in cancer treatment. They also provide cancer patients' participation for excellence care processes conducted by highly qualified teams,

but unfortunately, the access to them is limited and restricted. In Chile, there is currently no spread information of these trials, so the common population is not usually aware of them prior to their information due to medical recommendations<sup>5,6,7</sup>.

## Report

A continuous improvement project was developed, implementing a nurse navigator pilot model for patients of the Clinical Trial Unit at FALP to evaluate the impact of a close follow-up process by a nursing team. 323 adults with solid tumor malignancies, consulting at FALP between August 2023 and May 2024 were included.

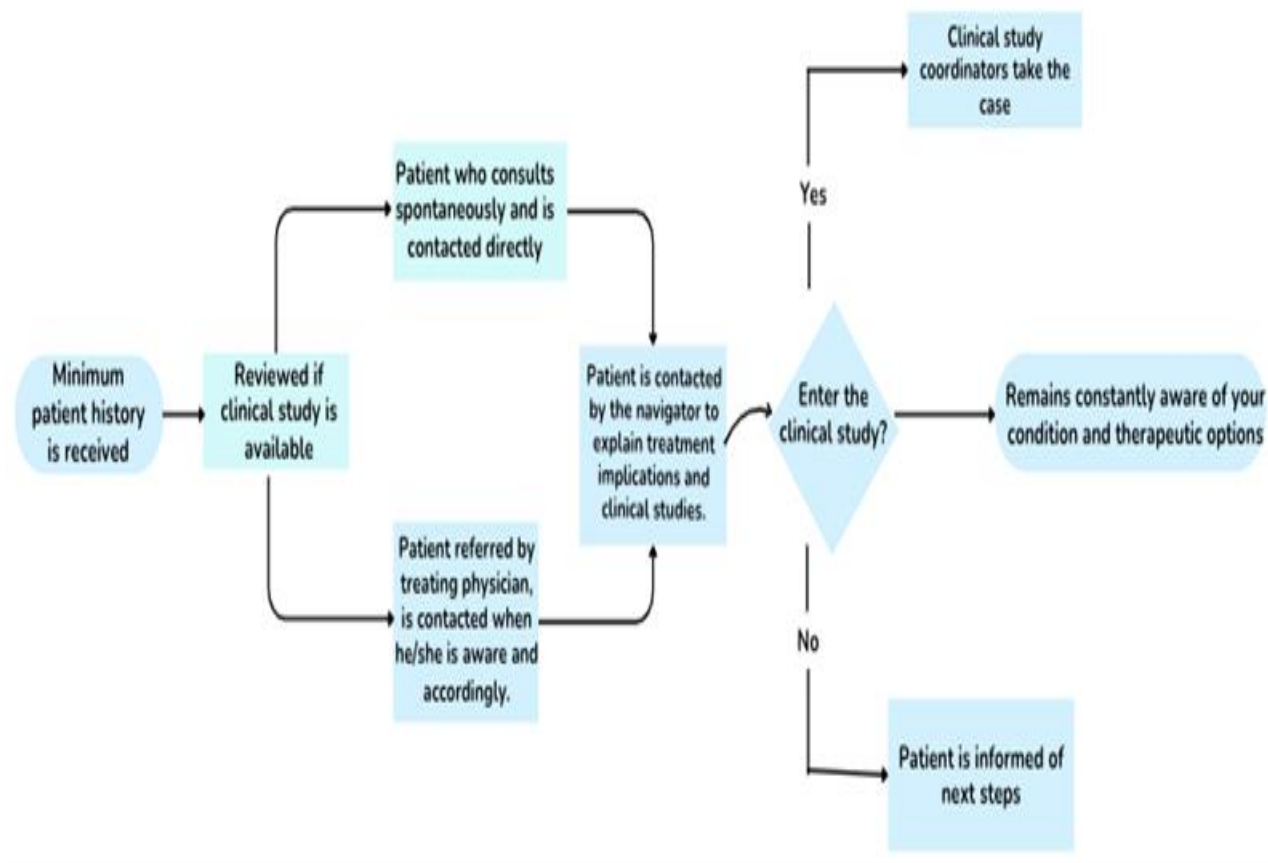
People were accompanied on an average of two times, where the activities applied to the local reality were<sup>8</sup>:

- Perform/complete anamnesis.
- Education before starting cancer treatment: explanation of the medical indication.
- Accompaniment: providing access to both spontaneous and scheduled care in consultations for resolution of doubts and follow-up from nursing, prior to the start of the screening process of a clinical trial.

Adults with malignancies were accompanied and demographic data was collected from the digital medical records, which are summarized below:

| Procedence   | Gender | Number of patients | Age (average) | Main diagnostic                     |
|--|--------|--------------------|---------------|-------------------------------------|
| Patients consulting spontaneously/extra-institutional referral | Female | 77                 | 58            | Digestive tumors                    |
|  | Male   | 59                 | 64            | Digestive and urological tumors     |
| Patients referred by the institution's oncology committee      | Female | 71                 | 57            | Dermatological and digestive tumors |
|  | Male   | 116                | 69            | Dermatological tumors               |

The patient navigation study is based on the interventions described by the American Cancer Society, which are summarized in the following diagram:



Regarding the results obtained, there is a high emotional burden with respect to the experiences related to the diagnosis process and the beginning of treatment<sup>9,10</sup>. Education about administrative difficulties derived from their care and the adverse events associated with their therapies reduces anxiety.

With respect to the time for a first attention in the context of clinical studies, there was no previous collected information about the time from the referral from a multidisciplinary committee to FALP Clinical Trials Unit. Currently, this process has an average of 6 days for the first oncological attention for patients that can attend the site. The most relevant variation in this item is to be able to have an updated registry of people with indications for clinical studies, and their decision regarding referral.

Likewise, an online consultation form was also generated on the institutional web page for patients who spontaneously want to request about clinical studies, which has allowed direct contact with the unit, and when required, a background review by a medical oncologist provides adequate and expeditious guidance for the patients and relatives.

Respecting to the educational needs delivered by the nurse navigator<sup>10</sup>, it can be evidenced that patients need both formal and incidental education, with greater development of the incidental by requirement, reviewing mainly topics of generalities of clinical studies, understanding of the indications given by the oncologists and in some cases education about their therapeutic processes. The presence of the nurse navigator increases collaboration with the multidisciplinary team for continuous improvement of care.

Within the spontaneous feedback given by the patients followed by the nurse navigator, the feature most frequently described as a qualitative need is containment, in turn, the most frequently described requirement for follow-up in consultation is education.

## **Conclusions**

During this pilot of nurse navigator in the context of adult oncology care in clinical research, a tool was created to register and follow up in real time the patients referred or consulted for clinical studies, as well as to generate a traceability of the care times, thus improving the control of the patients' timeline and their overall care<sup>11,12,13</sup>.

During the development of the oncology navigation follow-up in research, it can be concluded that there are multiple edges of care that can be intervened by the clinical nurse specialist, as seen in international models, such as the preventive approach, the importance of the first contact, the need for therapeutic follow-up, education, follow-up, and communication with the interdisciplinary team, among others.

Another relevant point is that the implementation of a nursing role that responds to the national Chilean cancer legislation, allowing innovation in the care provided to cancer patients who receive their care at FALP supported by nursing care in the disease process<sup>2</sup>.

Finally, the role of the nurse navigator in oncology, especially for the clinical nurse specialist, can be a connection both for the flow of the patient through the institution, and even in the future, for the passage through all levels of care (increasing the public and private connection, since FALP primarily serves patients referred from the public health service), improving care and clinical outcomes, as has been amply demonstrated in international experiences.

## Key Words

Nurse navigator, advanced practice nursing, clinical trials, oncology care.

## Conflict of interests

CC: Advisory board: Gilead; Research MSD, AZ, Roche, BMS, GSK, Athenex, Sanofi, Abbvie, Amgen, Bayer, Biontech, Daiichi Sankyo INC, Exelixis, Novartis, F Hoffmann LaRoche, PharmaMar, Zymeworks, Congent Biosciences, Pfizer, Dizai Pharma

CG: none

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