Optimizing efficiency in oncology day hospitals

ONCOptimal

A scientific initiative of:

eco Fundación para la Excelencia y la Calidad de la Oncología

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Contents

LIST OF ABBREVIATIONS

A

AECC: Spanish Association Against Cancer

Aenor. Spanish Association for Standardization and Certification

APEAS: Study on patient safety in Primary Healthcare

ASHP: American Society of Hospital Pharmacists

B

BCMA: Bar Coded Medication Administration

BD: Becton Dickinson

C

CC.AA: Autonomous Communities

CCCN: Comprehensive Cancer Centers Network

CGE: General Nursing Council

CICC: Centrally inserted central catheters

CPOE: Computerized physician order entry

CSTD: Closed Systems Transfer Devices

CT: Clinical trials

CVC: Central venous catheter

D

DB-SUA: Basic document on safety of use and accessibility

DERS: Dose error reduction software

E

EFQM: European Foundation for Quality Management

EHMA: European Health Management Association

EMA: European Medicines Agency

ENEAS: National Study on Hospitalization-Related Adverse Events

E

ECO Foundation: Foundation for Excellence and Quality in Oncology

G

GEDEFO: Spanish Oncology Pharmacy Group

GEPAC: Spanish Cancer Patients Group

H

HD: Hazardous drugs

I

IDIS: Institute for the Development and Integration of Healthcare

IOM: Institute of Medicine

ISMP: Institute for Safe Medication Practices

ISO: International Organization for Standardization

M

MAGIC: Michigan Appropriateness Guide for Intravenous Catheters

MSCBS: Ministry of Health, Consumer Affairs and Social Welfare

MVC: Medial venous catheter

N

NCC MERP: National Coordinating Council for Medication Error Reporting and Prevention

NHS: Nacional Health Service

NPS: Net Promotor Score

O

ODH: Oncology Day Hospital

OECD: Organisation for Economic Co-operation and Development

P

PDA: personal digital assistant

PICC: Peripherally inserted central venous catheter

PSIRLS: Patient Safety Incident Reporting and Learning System

Q

QOPI: Quality Oncology Practice Initiative

S

SEDISA: Spanish Society of Health Managers

SEEO: SSpanish Society of Oncology Nursing

SEFH: Spanish Society of Hospital Pharmacy

SNS: National Health System

SEOM: Spanish Society of Medical Oncology

U

UNE: A Spanish Standard

V

VTBI: volume to be infused

W

WHO: World Health Organization

1 EXECUTIVE SUMMARY

1.1 ONCOPTIMAL PROJECT

The **ONCOptimal** project (Optimizing the efficiency of oncology day hospitals) is a collaborative initiative between several entities related to the field of Oncology. The main goal was to **draw up a report of recommendations on optimizing efficiency in oncology day hospitals (ODH)** in Spain.

PARTICIPATING ENTITIES

- Foundation for Excellence and Quality in Oncology (ECO Foundation)
- Spanish Society of Health Managers (SEDISA)
- Spanish Society of Hospital Pharmacy (SEFH)
- General Nursing Council (CGE)

With the collaboration of the following patients associations:

- Spanish Association Against Cancer (AECC)
- Spanish Cancer Patients Group (GEPAC)

ONCOPTIMAL PROJECT PHASES

1- Creation of a scientific committee

ECO Foundation	Ruth Vera García Juan Antonio Virizuela Echaburu Ana Laura Ortega Granados
SEDISA	Candela Calle Rodríguez Dulce Ramírez Puerta
CGE	Diego Ayuso Murillo José Luis Cobos Serrano
SEFH	M.ª Estela Moreno Martínez Estefanía Zhan Zhou

2- Analysis of the situation:

a. **Review of the scientific evidence**
b. **Conducting of two national surveys** on the care situation:
   - Survey aimed at healthcare professionals from ODHs
     - 212 healthcare professionals belonging to
     - 116 public, private or subsidised Spanish centres
   - Survey of oncology patients articulated through AECC and GEPAC:
     - 248 cancer patients
c. **Study of the impact of technology on infusion times** of systemic treatments carried out by the Health Consultancy and Research Unit of the Francisco de Vitoria University.

3- Drafting of the document of recommendations of the participating entities.

The project has received support through an Educational grant from Becton Dickinson

1.2 ONCOLOGY DAY HOSPITAL

The day hospital is a care facility whose main distinguishing feature is **the assistance and care of patients in hospital for a few hours both for treatments**, that do not require hospital admission, **and for diagnostic studies, clinical research and/or multiple examinations**, including simple extractions, invasive procedures or observation of possible complications.[1-3]

The **results of the national survey**, in relation to the description of the oncology day hospital, are summarised in the following table.

Description of the ODH	
Accreditation, research and training	
Have an accreditation system for quality standards	**40%**
Have a separate clinical trials research area or unit	**20%**
Structure	
Average size	**142 m²**
Provision of an emergency response or crash cart	**95%**
Open from Monday to Friday	**89,5%**
Resources	
Have specific staff who provide information on consultations, treatments and side effects to patients	**69%**
Have procedures that are agreed upon and well-known by all staff for work related to healthcare processes	**73%**
Have patient volunteers	**49%**
Do not have a protocol in place to manage requests for new infusion devices for the administration of chemotherapy treatments	**41%**
Have the figure of a coordinator	**60%**
In most cases the figure of a coordinator is a Nurse, mainly dedicated to the running of the centre	**71%**
Pharmacist(s) responsible for validation, processing and dispensing of cytostatics have advanced specialized training	**47%**
Average number of treatments administered in the morning	**40**
Average number of treatments administered in the afternoon	**23**
Average number of infusion pumps per centreInfusion pumps:	**34**
Average number of patients per day attending the ODH	**75**
Approximate number of walk-in patients	**8**
Average number of chairs	**20**
Average number of beds	**5**

It is essential to ensure **early care and treatment for patients, reducing waiting lists**. Improved treatments and early detection have extended the life expectancy of cancer patients, and many patients are able to overcome the disease or reduce it to a chronic condition, with prolonged treatment over time.[8] In Oncology, lengthening the time to treatment **can significantly reduce patient survival**. In addition, the lengthening of patient waiting time for treatment leads to a significant reduction in patient satisfaction.[4-7]

1.3 THE PROBLEM IN DAY HOSPITALS IN SPAIN

The increase in demand for day hospital services, as a consequence of the increase in the number of cancer cases, has not been matched by a **proportional increase in human resources, material resources and technological resources**. This imbalance between demand and supply has led to **longer waiting times**[2] in the administration of oncology medication, **reducing survival expectancy and the satisfaction** of oncology patients.[4-7]

The **results of the national survey**, in relation to the processes of the oncology day hospital, are summarised in the following table.

Processes in the ODH	
Waiting lists for medication and waiting times	
Time from diagnosis or surgery to the start of oncology medication administration < 30 days	**85,8%**
Patient appointment for oncology treatment	
Electronic notification and appointment reminders via SMS, mobile app, email, etc.	**57%**
Electronic identification of patients on arrival, by means of a bar-coded wristband	**58%**
Blood collection and analysis	
Average waiting time from patient arrival at the ODH to blood collection	**1 h**
Average waiting time from blood collection to availability of lab results	**1,45 h**
Have a Point-of-Care system for blood collection	**46%**
Medical visit	
Average waiting time from the time the lab results are available to the consultation with the patient	**1,16 h**
Confirmation of the schedule	
Have a planning system in place for available chairs and for managing or prioritizing the patient treatment schedules (mainly: activity analysis)	**59%**
Preparation of medication	
Have a computerized or electronic system for prescribing cancer medication	**95%**
Includes information on, among other things, drug interactions, drug allergies, duplicate therapy, or dosage adjustments based on liver and kidney function	**70%**
Use an electronic/digital method to receive medication prescriptions and all have a pharmaceutical validation system for the prescription of oncology treatments	**80%**
Average number of preparations per week	**310**
Average number of delays per week in the preparation of cancer treatments in general	**11**
Are supported by standardized preparation software	**48%**
Have a gravimetric system to validate the preparation	**45%**
Have an automation system for all necessary calculations (size, number of vials, volume, etc.) for the preparation of medication	**92%**
Once ready to be administered the prepared treatment is delivered to the patient by an orderly	**75%**
Incidents occurring during clinical validation of the prescription (dosage, drug, other) are recorded	**70%**
This registration is mainly carried out in the Pharmacy Service	**76%**
Monitor and control incidents during the administration of treatment, mostly electronically/digitally)	**92%**

Processes in the ODH	
Administration of the treatment	
Do not have a bar code-based patient/medication/pump identification system	**71%**
Infusion pumps are programmed manually	**84%**
Average time from consultation to the start of administration of the medication	**1,59 h**
Average time to dispensing	**1 h**
Final check	
The activity of nurses is recorded electronically in the patient's electronic health record	**88%**
The clinical management of the patient is carried out electronically, which includes or integrates the patient's data, including lab results	**98%**
Percentage of the working day taken up by administrative work, as opposed to patient care	**35%**
Safety/hazardous drugs	
Average number of adverse events per month associated with the administration of oncology medication, mainly infusion-related reactions and extravasations	**9**
Closed Systems Transfer Devices (CSTD)	**62%**
Use safety syringes and needles	**12%**
Perform regular monitoring of surface contamination by cytostatic medication	**45%**
Perform this monitoring more than once a month	**74%**

The following table summarizes the inefficiencies and bottlenecks by care process in ODHs detected through the analysis of evidence and the results of the national survey.

Bottlenecks and inefficiencies	
Care process	**Problem**
Patient appointment for oncology treatment	**Bottleneck:** manual planning and management of appointments. **Inefficiencies:** in the available resources (availability of chairs and beds, of nursing staff).
Blood collection and analysis	**Bottleneck:** until the lab results are available, the patient cannot continue the care process in the ODH, resulting in a delay. **Inefficiencies:** lengthened hospital stays due to waiting time for results that reduce the capacity of the ODH and lengthen patients' stay in the facility.
Medical visit	**Bottleneck:** limited time for the consultation. **Inefficiencies:** • Delays due to waiting time for the medical visit reduce the capacity of the ODH and lengthen patients' stay in the facility. • Lack of electronic prescribing systems linked to the pharmacy service.
Confirmation of the schedule	**Bottleneck:** the number of existing chairs as well as human resources is the limiting factor when it comes to increasing the number of patients receiving medication. **Inefficiencies:** delays and lack of synchronization in the process up to the point of medication preparation are a major inefficiency, resulting in vacant, unoccupied chairs waiting for the patient to go through all the above processes and be ready to receive their medication.

	Bottlenecks and inefficiencies
Preparation of medication	**Bottleneck:** The capacity of the pharmacy service to prepare medication is limited. Until the medication is prepared, it cannot be sent to the administration area. **Inefficiencies:** • Lack of electronic prescribing systems linked to the pharmacy service. • Lack of a system that prioritizes the preparation of medication based on the patient's condition. • Lack of an electronic system for the preparation of medication. • Lack of an electronic system that displays the status of the preparation of medication by patient and that enables effective coordination between the pharmacy and the administration service, to avoid constant phone calls that reduce the efficiency of both services. • Delays due to waiting time in the preparation of medication reduce the capacity of the ODH and lengthen patients' stay in the facility. • If the synchronization between the pharmacy department and the medication administration department is not effective, it will result in inefficiencies in both departments, leading to delays and prolonged patient stays. • On top of this, if the Pharmacy and ODH are a significant distance apart there will be an added delay due to transport.
Administration of medication	**Bottleneck:** number of chairs as well as human resources as the limiting factor when it comes to increasing the number of patients receiving medication. **Inefficiencies:** • Delays and lack of synchronization in the process up to the point of assigning the medication are a major inefficiency, resulting in vacant, unoccupied chairs waiting for the patient to go through all the above processes and be ready to receive their medication. • Lack of protocols for selection of infusion systems and/or intravenous therapy teams in ODH treatment areas. • Lack of electronic systems that allow the identification of the patient/medication/pump by bar code. • Lack of smart pumps with safety and self-programming systems.
Final check	**Bottleneck:** availability of Nursing to document the administration of medication. **Inefficiencies:** • The time the Nursing service spends on manual documenting the administration is time that is not spent administering medication to other patients. • This manual process could be automated by means of electronic patient/medication/pump identification systems using bar codes and smart pumps.

It is crucial to understand that the **best way to prevent missed opportunities** in patients with cancer in **oncology day hospitals** is the **prioritization of time and mobilization of human and technological resources.**[9,10]

1.4 SOLUTIONS

The **introduction of new technologies is the most viable and cost-efficient solution to reduce waiting times** in Spanish oncology day hospitals, as well as to improve patient safety.[1,11]

Providing human and structural resources, along with the introduction of new technologies, especially electronic traceability systems **are the most immediate and cost-effective solution to reduce waiting lists and improve patient safety**.[1,11]

The results of the national survey and the Francisco de Vitoria University study, in relation to new technologies of the oncology day hospital, are summarised in the following table.

Technologies in the ODH	
Computerized Provider Order Entry (CPOE) and preparation systems	
Have a computerized provider order entry system	**95%**
Electronic medication preparation system	**48%**
Do not have a gravimetric preparation system	**55%**
Communication between Medical Oncology and the Pharmacy Service carried out using paper	**18%**
Electronic connection systems between departments	
Communication between Medical Oncology and the Pharmacy Service carried out electronically	**80%**
"Patient/medication/pump" bar code identification systems	**30%**
Smart pumps	
Average number of infusion pumps for the administration of treatment	**34**
Do not have dual-channel infusion pumps	**57%**
Infusion pumps are programmed manually	**84%**
Do not have sufficient infusion pumps available to care for unscheduled patients requiring unplanned care, ensuring their continuum of care	**84%**
Does not have a protocol in place to manage requests for new infusion devices for the administration of chemotherapy treatments	**41%**
Microbore* infusion systems	
Reduction in overall infusion times through the use of intravenous infusion devices with primary and secondary microbore systems such as those available in BD BodyGuard Duo	**9´11´´**
Point-of-care testing.	
Have a Point-of-Care system for blood collection	**46%**

* Francisco de Vitoria University Study

In short, the **degrees of implementation** of the **different systems** are as follows:

- Electronic prescription systems: 95%.
- Electronic medication preparation systems: 48%.
- Bar Code Medication Administration (BCMA): 30%.
- Microbore pumps: reduction of total infusion times by nine minutes and eleven seconds per session.
- Point-of-care testing: 46%.

The following table lists the **technologies available in ODHs and their impact on the efficiency and reduction of waiting lists** for the administration of oncology medication in Spain.

Solution	Efficiency generated	Penetration in the ODHs ONCOptimal	Average reduction in the number of waiting days
Electronic prescription systems	10 minutes	95%	Not significant due to high penetration
Gravimetric medication preparation systems (Hospital Pharmacy)	35%	26%	8 days
BCMA: Bar code medication administration	43%	30%	8 days
		TOTAL	8 days
Microbore system	9 minutes and 11 seconds	--	260 more patients per year per HDO of medium-sized*
Point-of-care blood sampling systems	No evidence available	46%	4,795 hours

*Estimated time reduction calculation for a Chemotherapy Unit type: 12 chairs, with a rotation of 1.5 patients per chair/day: 18 patients/day.

Furthermore, **patient safety in ODHs is also a top priority**. Adverse events in cancer patients are more prevalent than in other types of patients and have a high human, social and economic cost. The main adverse events that jeopardize patient safety in the administration of medication to oncology patients in ODHs are: **medication errors, catheter-related infections and those related to infusion therapy.**[1,12]

The following table summarizes the **adverse effects on cancer patients in ODHs, their economic impact and possible solutions.**

Adverse effects	Magnitude of the problem	Economic impact	Solutions
Medication errors	8.1 errors per 100 clinic visits	Spain: €2 billion	• **CPOE:** Computerized Provider Order Entry • Gravimetric medication preparation systems • **BCMA:** Bar code medication administration • **Smart pumps:** with DERS system (medication error reduction software) and infusion stations with centralization tablets, or pumps with self-programming capability.
Infections, phlebitis and extravasations	0.05 and 6.8/1000/day	Spain: €17,221,000/year	**Infusion therapy protocols** with algorithms for infusion system selection based on medication, patient's venous status and duration of treatment.
Bacteraemia			
Extravasations	3.454/año	España: 15.635.000 €	
Phlebitis	1.049/año	España: 1.257.400 €	
TOTAL		Spain: €2,034 million	

The **introduction of new technologies is the most viable and cost-efficient solution to reduce waiting times** in Spanish oncology day hospitals, as well as to improve patient safety.

Computerizing the processes, **from** prescription, preparation, and administration would:

- **Minimize adverse effects** throughout the process.
- **Reduce waiting time** by 8 days
- **Generate an estimated saving** for the Spanish health system of **€2.034 billion**.

1.5 RECOMMENDATIONS FROM ONCOPTIMAL SCIENTIFIC BODIES

HEALTHCARE MANAGEMENT

- Healthcare management is the cornerstone of the health system to function in terms of ensuring **health outcomes and efficiency**. Therefore, the **commitment of Health Managers and their professional approach** is necessary to understand the real needs, engage, and make decisions regarding the efficiency of the oncology day hospital.

DESCRIPTION OF THE ONCOLOGY DAY HOSPITAL

Accreditation

- The **quality of care** for cancer patients should entail the **accreditation of oncology day hospitals**, through objective and well-known criteria and recognized systems.
- Specialists working in these care areas must have **specific skills, training and experience** in caring for oncology patients.
- Progress is needed in creating **new professional roles, accreditation diplomas or the development of specialization in this field**.
- Pharmacy services should accredit/certify, through external entities, the **activities of the pharmacotherapeutic process** (validation, preparation and dispensing). These tools make it possible to incorporate continuous improvement systems, periodically analysing processes in order to evaluate their efficiency, establish prioritizations, etc.

Research and training

- Oncology day hospitals should have a **separate clinical trials research unit**.
- The services involved should actively participate in the establishment of **technological or process innovation programmes in the oncohaematological area** by promoting **ongoing training, accreditation**, as well as **specialization** in the area of specific professional training in oncohaematological pharmacotherapy.
- Nurses, in addition to having the necessary qualifications to perform their work, should be trained in **cardiopulmonary resuscitation**, be familiar with working in an environment of **good clinical practice, be trained in research, and trained in conducting pharmacokinetic studies, handling biological samples, hazardous drugs, and ensuring the biosafety** of patients and professionals. They should also have

extensive **care experience**, especially in the field of antineoplastic chemotherapy, with knowledge of adverse effects and precautions to be taken to maximize safety during administration.

STRUCTURE AND RESOURCES OF THE ONCOLOGY DAY HOSPITAL

Human resources: numbers, training and communication

- The oncology day hospital should be a unit where the patient is **received, cared for and discharged in the centre itself**, although sometimes it may require the support of other services to perform a specific procedure (diagnostic imaging, etc.).
- The functional design of an oncology day hospital should take into account the varying health conditions of patients, and facilitate patient movement between different areas. The recommendations establish a **minimum of one nurse per shift for every 6 treatment posts with specific training and expertise in oncology**. However, the staffing recommendations are made based on the increasing number of patients and treatments/procedures that are progressively occurring in healthcare centres due to both population growth and the growing prevalence of treatable neoplasms across multiple lines.

Beds/chairs

- The structure and resources of oncology day hospitals **must conform to the quality standards** established by scientific societies and competent bodies, and adapt to the increasing processes of meeting patient needs.
- The stations can take various forms (beds and/or chairs), depending on the specific characteristics of each treatment and the patient's condition. Given the wide range of possible therapeutic modalities, **flexible structures** are required that can easily adapt to the changing needs of the patient and accompanying persons in the centre.

PROCESSES IN THE ONCOLOGY DAY HOSPITAL

Bottlenecks to reduce waiting times and improve the different processes: appointments, blood sample collection, preparation of medication, etc.

- **Waiting times at the bottlenecks identified in this report should be reduced** by incorporating new technologies, bringing certain processes closer to the patient, through home hospitalization and telemedicine, by carrying out sample collections and analyses prior to the patient's stay in the oncology day hospital, by optimizing treatments, etc.
- **A periodic review of the pathways** should be carried out by a multidisciplinary team, with the aim of optimizing the activity.
- **A global view of the process** should be reflected in the review of the pathways to find solutions that improve the patient's experience while ensuring their safety.

Incorporation of new technologies to improve systems

- Procedures and actions should be **standardized, computerizing the process**, from prescription, preparation and administration, to avoid errors throughout. Computerizing the process could reduce the average medication administration time in Spain by up to 8 days and result in savings for the Spanish healthcare system through the prevention of medication errors.
- Oncology day hospitals should have a **comprehensive and integrated information**

system and across different levels of care for managing the pharmacotherapeutic process for oncohaematological patients.

- The **electronic prescription system** for medication should be integrated into the patient's health record and should include all the necessary elements to assist in decision-making, as well as to assist in the validation and traceability of the entire process of preparation, dispensing and administration.
- The continuum of care using **digital technologies can strengthen the system and ensure greater accessibility for health professionals**.
- Case manager nurses or oncology nurses can take on **these new roles by following up with patients prior to their visits or by addressing any queries that may arise after treatment**.
- Oncology day hospitals should have a **validated protocol for infusion system selection and algorithms for selecting the appropriate infusion set**, which should be of mandatory compliance. The creation of infusion therapy teams in oncology day hospitals is also recommended.

SAFETY

Healthcare professionals in the oncology day hospital

- Oncology day hospitals should have and use mandatory **closed systems for the preparation and administration of hazardous drugs(Closed Systems Transfer Devices, CSTD)**, airtight systems that prevent medication, when prepared and administered, from escaping to the outside.
- Oncology day hospitals should regularly **monitor the presence of hazardous drugs on work surfaces**, in both preparation and administration areas to determine the presence of hazardous drugs and evaluate the effectiveness of the safe drug handling programme, following the recommendations of the National Council of Nursing and the SEFH. The evaluation should include a study of the efficiency of engineering controls, work practices and cleaning and decontamination processes.

Patient

Preventing errors and improving safety

- Oncology day hospitals should have a **validated protocol for infusion system selection and algorithms for selecting the appropriate infusion set**, which should be of mandatory compliance. The creation of infusion therapy teams in oncology day hospitals is also recommended.
- Oncology day hospitals should undertake **improvement and prevention projects related to major patient safety issues**, such as medication errors, prevention of catheter-related infections, and therapy-related issues.
- The oncology day hospital should **actively participate in the development and maintenance of a risk management programme** applied to the prevention and resolution of health problems related to oncohaematological medication and participate actively in the establishment of processes for the safe management of antineoplastic therapy, taking into account not only patient risks, but also occupational risks, and covering all phases of the pharmacotherapeutic process.
- **Procedures and actions should be standardized**, with the computerization of gui-

delines, to prevent errors in reading and calculations. Electronic prescription is the safest method, and dual or multiple checks should be performed at each step of the process.

- **Pharmaceutical interventions**, carried out by all staff involved, **should be documented in the patient's health record** and should be evaluated in order to develop improvement measures.

Patient Experience

- Oncology day hospitals **should have procedures in place to assess the patient experience and incorporate their expectations and needs** into the improvement of their care process to ensure improved health outcomes.
- **Further research** is required on **satisfaction and quality of care received** from the point of view of the patient and family, to find areas for improvement.
- **A more humanized form of pharmaceutical care should be provided for the patient and caregiver** on an ongoing basis throughout their care process. This includes **offering information** about their treatment and adapting the pharmacotherapeutic plan to their health, considering individual needs, agreed-upon goals, and the necessary interventions to achieve them.
- **New technologies** should be incorporated to facilitate patient education, communication and active participation, as well as to allow the, access to information about their own process. This would include, for example, apps, mobile devices, telecare and platforms that open communication channels with patients.

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2 ONCOptimal PROJECT

2.1 ONCOptimal PROJECT

The **ONCOptimal project** (Optimizing the efficiency of oncology day hospitals) is a collaborative initiative between several entities related to the field of Oncology: **The Foundation for Excellence and Quality in Oncology** (ECO Foundatiopn), **the Spanish Society of Health Managers** (SEDISA), **the Spanish Society of Hospital Pharmacy** (SEFH) and **General Council of Nursing** (CGE). **The Spanish Association Against Cancer** (AECC) and the **Spanish Cancer Patients Group** (GEPAC) have also participated and support has been provided by the company **Becton Dickinson** (BD) through an Educational Grant.

The main goal was **to draw up a report of recommendations on optimizing efficiency in oncology day hospitals** (ODH) in Spain. The hope is that this report will help:

- **Reduce the waiting time for cancer treatment** for new patients once diagnosed and for those already on treatment on subsequent occasions.
- **Humanize healthcare** by optimizing waiting times, and therefore the patient's stay in the day hospital.
- **Prevent errors in the prescription, preparation and administration** of medication.

The ONCOptimal project consisted of several phases:

1. **Creation of a working group (Scientific Committee)** made up of 8 health professionals representing each participating entity: ECO Foundation, SEDISA, SEFH and CGE.
2. **Analysis of the situation** through:
    - Review of the available **clinical evidence**.
    - Conducting of a **national survey on the care situation** in oncology outpatient clinics in Spain. This survey was addressed to healthcare professionals from the ODHs (Health Managers, Medical Oncology, Nursing and Hospital Pharmacy) anonymously and led by the Scientific Committee.
    - Conducting of a **national survey of cancer patients** who receive or have received treatment in ODHs in the last year, anonymously and led by the AECC and the GEPAC.
    - Evaluation of the impact of technology on infusion times of systemic treatments carried out by the Health Consultancy and Research Unit of the Francisco de Vitoria University.
3. **Drafting of the document of recommendations of the participating entities.**

2.2 NATIONAL ONCOPTIMAL SURVEY ON THE CURRENT CARE SITUATION IN ODHs

Cancer, due to its major impact on health, generates in patients certain **complex needs that require personalized and multidisciplinary care**. The ODH offers an **alternative form of healthcare** to conventional hospitalization, promoting **a continuum of care and coordinated, agile and ambulatory care** without the inconvenience of hospitalization or a prolonged hospital stay.

For its optimal implementation, a multidisciplinary team is required which, **coordinated by the centre's directors**, includes **specialists in Medical Oncology, Hospital Pharmacy and Nursing**, as well as psychologists, experts in social sciences, rehabilitators, administrative staff, etc.; all of them **in close collaboration, forming a team of professionals who complement each other's efforts**.

Meanwhile, we should not forget that the most important components of the team are the **patient themselves and their family**. The opinion and perception of patients regarding the operation and conditions of ODHs are essential for improving the **healthcare provided to them**.

Through the participation of the collaborating organizations (ECO Foundation, SEDISA, SEFH, and CGE), the AECC and the GEPAC, information has been compiled with the aim of **understanding the care situation in oncology outpatient clinics in Spain by means of a descriptive analysis of the situation**.

Managers, Medical Oncologists, Hospital Pharmacists and Nurses were invited to participate, as were **patients**. The instruments used to collect the information were two questionnaires drawn up ad hoc for the project by the Scientific Committee. The survey was programmed to be answered online and disseminated through the collaborating scientific societies and bodies.

The questionnaire collected information on different aspects related to the **efficiency of oncology day hospitals**. A series of questions with closed answers were posed in order to collect the information that was considered to be of interest for the objectives set.

The survey addressed to healthcare professionals included aspects related to **the structure and resources of the ODH, patient management, oncology medication and perception of the patient's experience of the centre**. The patient survey included aspects such as **appointments and admissions management at the ODH, waiting times, medication administration, and their overall personal perception**.

The statistical processing of the data was carried out with the IBM SPSS software package (IBM Corp. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp.) showing results as absolute frequencies (number of cases) and percentages (%) for categorical variables and as mean ± standard deviation for continuous variables. For the crossover analysis, the Chi-Square test of independence was used to test the hypothesis that the variables are independent. When the significance level is greater than 0.05, the hypothesis of independence between variables is accepted, i.e. the hypothesis that the two populations are equal (no significant differences) is accepted. When the significance level is less than 0.05, the hypothesis of independence between variables is rejected, i.e. the hypothesis that the two populations are equal (there are significant differences) is rejected.

Both surveys were completed during **the last quarter of 2022 and the first quarter of 2023**.

The survey was answered by a total of **212 healthcare professionals (10 Managers, 47 Medical Oncologists, 97 Nurses, and 58 Hospital Pharmacists)** belonging to 116 Spanish public, private or subsidized centres, **and 248 patients**. 52% of the patients had breast cancer and 17% had haematological cancer. The average age of the participating patients was 47 years.

No statistically significant differences were found by Autonomous Community in the cross-tabulation of both health professional and patient variables. Annex 1 shows the results of the national health professional survey and Annex 2 shows the results for patients.

2.3 COMPARATIVE EVALUATION OF INFUSION TIMES WITH INTRAVENOUS INFUSION DEVICES FOR SYSTEMIC TREATMENTS

Health Consultancy and Research Unit of Francisco de Vitoria University. Faculty of Medicine Researchers. Francisco de Vitoria University (Madrid): Francisco J. Campos Lucas. Health Consultancy and Research Unit Director; Diana Monge Martín; Associate Dean for Medical Research and Education. Collaborating researchers: Mª Amparo Corral Rubio; Carlos García Manrique; José Miguel Pérez Sánchez.

Optimizing waiting times in ODHs includes the **use of elements that improve the daily operation** of the services offered in the centre, to help improve the management of the treated patients. These elements are in continuous development.

Thus, **certain infusion devices**, given the technical characteristics of their intravenous infusion systems, may lead to an improvement in the overall treatment administration times per patient, generating a **positive impact on the management of available chairs in an ODH**.

Therefore, in the context of the ONCOPTIMAL project, a comparative evaluation of infusion times was conducted with two intravenous infusion devices for chemotherapy treatments. The primary objective of this evaluation was to determine the impact of the BD BodyGuard™ Duo infusion pump on the infusion time and efficiency of the ODH as a performance indicator versus the BD Alaris™ GP Plus Guardrails infusion system.

To evaluate the infusion devices, a group of 3 Nursing Diploma experts in the use of intravenous infusion pumps used two types of infusion devices from the company BD: BD Alaris™ GP Plus Guardrails and BD BodyGuard™ Duo, both commonly used in some ODH Chemotherapy Delivery Units and with similar technical characteristics.

The corresponding intravenous infusion systems for each of these devices were: Alaris™ GP Series Oncology primary set 60950E + Secondary set DEHP Free 72947NE & Microset™ oncology non dehp 4x smartsite with 15µm filter with drip chamber ONC00008 + Microset™ Low Sorbing Oncology Extension set ONC00004.

They were used to simulate 12 infusions of chemotherapy treatments in a Chemotherapy Unit (12 chairs), performing 6 infusions with each of the devices and measuring the administration times of a standard chemotherapy protocol (infusion of 3 drugs with flushes between each of the drug infusions), the flushing times between drugs and the total infusion time from the beginning to the end of the protocol being infused.

Measurements were carried out on 2 consecutive days (6 per day) to avoid possible personal influences from the panel of researchers (fatigue, mood, etc.) that could affect the administration of the treatments.

The parameters measured were:

- **Set up drug infusion 1**
  - Enter the flow rate
  - Enter VTBI (volume to be infused)
  - Start the infusion
  - Stop the perfusion once completed
  - Rinse the line (26 ml)
  - Set up drug infusion 2
  - Enter the flow rate
  - Enter VTBI (volume to be infused)
  - Start the infusion
  - Stop the perfusion once completed
- **Rinse the line (26 ml)**
- **Set up drug infusion 3**
  - Enter the flow rate
  - Enter VTBI (volume to be infused)
  - Start the infusion
  - Stop the perfusion once completed
- **Rinse the line (26 ml)**
- **Remove the infusion set and switch off the pump.**
- **Total perfusion time required**

The results of the evaluation are set out in section 5.1. New technologies. It is observed that drug infusion times in both devices are very similar, but **the use of intravenous infusion devices with primary and secondary microbore systems such as those available in BD BodyGuard Duo, show a reduction in overall infusion times**.

3 ONCOLOGY DAY HOSPITAL

3.1 DESCRIPTION OF THE ONCOLOGY DAY HOSPITAL

INTRODUCTION

The ODH is a care facility whose main distinguishing feature is **the assistance and care of patients in hospital for a few hours both for treatments**, that do not require hospital admission, **and for diagnostic studies, clinical research and/or multiple examinations**, including simple extractions, invasive procedures or observation of possible complications.[1-3]

Certain minimum **requirements are necessary for the authorization to open and/or operate** these ODHs. These requirements are in place to ensure safety and quality conditions in various dimensions, including the **efficiency of service delivery, patient rights and safety assurance, organization and management, physical structure and material resources, human resources, and healthcare quality**.[2]

The document "Hospitales de Día en Oncología" (Oncology Day Hospitals), by the Spanish Society of Medical Oncology (SEOM), first set out the lines of work to improve the conditions of safety, quality and service provision in these units. Experts from the services most closely linked to the Oncology Day Hospital, such as Oncology Nursing, Hospital Pharmacy and Medical Oncology, took part. This document focused especially on key aspects such as **legislation and organization of the ODH, architectural structure, human and material resources, management and organization, quality, research and teaching**[1]. These aspects will be discussed throughout this report.

Although the ODH model **has opened up new approaches to care for cancer patients**, there are many barriers still to overcome (such as limitations of space and architectural structures or availability of human resources, both medical and nursing, among others). However, **the possibilities for the development of ODHs, technological advancements that facilitate the improvement of healthcare and administrative processes, and the inclusion of various activities** related to the care of outpatients with cancer provide **an opportunity to achieve comprehensive care**.[1]

The **Ministry of Health, Consumer Affairs and Social Welfare** (MSCBS) has published a document of standards and recommendations for these units which provides Public Health Administrations, managers (public and private) and professionals, with guidelines to promote the expansion of ODHs, contributing to an improvement in their day-to-day operational conditions of safety and quality.[2]

REGULATIONS

There are **few ODH-related regulations** and there have been no recent updates. There are no guidelines from international institutions. Neither the World Health Organization (WHO) nor the European Union has developed regulations in this regard.[1]

In Spain:

- Royal Decree 1277/2003[4] which establishes the general foundations for the authorization of healthcare centres, services, and establishments, defines day hospitals

identified by code U65 as *"care units where, under the supervision or prescription of a specialist physician, the treatment or care of patients who require diagnostic or treatment methods that necessitate continuous medical or nursing attention for a few hours is carried out, but not hospitalization"*. This definition includes both individual and multidisciplinary units of other medical or surgical specialties, in addition to the original onco-haematology unit.[1]

- **There is no specific legislation on the requirements that ODHs** must meet, and they are subject to the general regulations. Both the General State Administration and the Autonomous Communities have legislation concerning the authorization and registration of health centres.[1]
- The Spanish National Health System monitors **day hospitalization activity**, and considers the ratio of **outpatient hospital places per inhabitant** as a key indicator of resources.[5]

In the United States:

- There is no regulation by the Department of Health and Human Services, nor by the Medicare and Medicaid institutions. There are also no criteria or standards for accreditation of these care facilities by the official accreditation body, the Joint Commission.[6]

In the United Kingdom:

- The National Health Service (NHS) has a guide that lists the care processes and procedures that can be carried out, but focuses primarily on the architectural aspects and the distribution of spaces and equipment.[7]

ACCREDITATION

In Spain there is **no accreditation system specifically** aimed at ODHs. It is **voluntary and individual, and involves subjecting the ODH** to external verification by an authorized body, which assesses the level at which it stands in relation to a set of standards established by expert consensus.[1]

The **results of the survey** show that **60% of centres are not certified with any quality standards scheme**. This result is in line with a study published by the SEOM in which only 20% of the centres had quality standards certification, a figure which was even lower for smaller hospitals.[3]

This shows an area for improvement, since the **introduction of accreditation programmes**, preferably promoted by the SEOM in collaboration with other scientific societies, could be a **key step to ensure adequate care** for cancer patients.[3]

Examples of **accrediting bodies or standards that may apply to ODHs** include: ISO (International Organization for Standardization) certificationfor quality management, UNE (A Spanish Standard) certification for patient safety and for the charter of services, EFQM (European Foundation for Quality Management) model of excellence, Joint Commission international accreditation, Aenor (Spanish Association for Standardization and Certification) certification,QOPI (Quality Oncology Practice Initiative) international certification, etc.[8,9]

The European Commission has developed a **compliance standard** for future specialized cancer centres in the European Union, known as Comprehensive Cancer Centres. All of them will have to comply with the **accreditation scheme** to become part of the Comprehensive Cancer Centres Network (CCCN).[10]

RESEARCH AND TRAINING

Clinical research is the foundation of oncology practice, through the conduct of clinical trials (CT)). The ODH **provides** the flexible and coordinated organizational structure for the conduct of these trials. Medical Oncology services **encompass between 10% and 15% of the total number of patients seen in the CTs**.[1]

The ONCOptimal analysis of the situation in Spain indicates that **80% of centres do not have a separate clinical trials research area or unit**. It would be of interest to carry out more studies and scientific publications on this subject.

The **continuous training of ODH staff is seen as essential**. The ODHs in Spain are constantly working on **continuous training programmes** and refresher courses in order to continue to work towards quality and excellence.[11,12]

The **multidisciplinary team** exchanges information from the various areas of expertise and establishes the minimum requirements for training and updating of skills, as well as **periodic review** of procedures and action protocols through joint sessions, and accredited training programmes.[1]

3.2 STRUCTURE AND RESOURCES OF THE ONCOLOGY DAY HOSPITAL

STRUCTURE

Dimensions

Defining the basic dimensions of the ODH depends mainly on **demographic factors (population served)**.[1] The number of material resources usually increases according to the ODH catchment area (e.g. more beds/chairs or infusion pumps the larger the population assigned), **except in the case of the total physical space assigned**.[1]

The size (m^2) of an ODH facility is approximately 300 m^2, divided into three large groups according to the care population assigned to the hospital in which the ODH is located:1

- 200 m^2 for a population of less than 300,000 inhabitants.
- 375 m^2 for a population of between 300,000-500,000 inhabitants.
- 313 m^2 for a population of over 500,000.

The average size of the ODH participating in the survey is **142 m^2**, with **60% of the centres** assigned populations of less than 300,000 inhabitants. In terms of the size of the facility, this should account for an optimal design that makes the ODH as **safe, efficient and intelligent as possible**. The results of the ONCOptimal analysis and the data published so far on the **most efficient size** should be studied further.

Physical spaces

From an architectural point of view, an ODH is equipped with various physical spaces, including **the ODH entrance, the admission/reception area, the waiting area, the consultation area, and the day hospital area where diagnostic and therapeutic procedures are performed**. The functional design of an ODH should facilitate patient movement between different areas taking into account the patient's health conditions:[1,2]

- **Access to the ODH:** this should be signposted to avoid, as far as possible, loss of time in accessing the ODH. The design must comply with the disabled accessibility regulations and the DB-SUA (basic document on safety of use and accessibility).

- **Admission and reception area:** this should include the necessary space, with a certain degree of privacy, for attending to the patient and their companions during the admission process, which includes patient identification, appointment scheduling, patient communication, among other things. These areas should be sufficiently large to allow people to walk up to the desk, avoiding overcrowding that could hinder access and avoiding unnecessary loss of time.
- **Waiting area:** specific area for relatives and patients, with direct access from the entrance hall. Since waiting times can be long, it should be designed as much as possible with the maximum comfort and privacy in mind for patients and their companions, with toilets, screens, Wi-Fi connection, automatic water fountain and vending machines for refreshments/coffee, etc. The size of the area will depend on both the planned activity and the characteristics of the population (normally with a forecast of 1.5 seats per patient). This waiting room must provide access to the ODH area, especially to the consultation and treatment rooms. In order to facilitate and speed up waiting times, electronic notification devices on screens should be installed, managed through computer applications linked to the appointment manager.
- **Day hospital area:** this area should be provided with:
  - Sample collection room.
  - Doctor/nurse consulting room.
  - CT consulting room.
  - Psycho-oncology consulting room.
  - Oncology pharmacy consulting room.
  - Oncology pharmacy integrated in the ODH for the preparation, dispensing of oncology preparations, storage, etc.
  - Outpatient unit for the preparation/dispensing of supportive treatments or oral antineoplastic drugs.
  - Treatment area (with its corresponding monitoring by the Nursing area).
  - Support areas.
  - Administrative area.
  - Changing rooms and toilets.
  - Staff break room.

The **sample collection room** is used for collecting blood and other biological samples. **The treatment area** can take various forms, with treatment stations in the form **of recliners and/or beds**, set up in common or individual rooms, always ensuring the privacy of patients. In addition, the layout of treatment stations should allow visibility for healthcare staff to access the patient as easily and quickly as possible.[1]

Having a **drug preparation and dispensing area** near or in the ODH facilitates pathways and can reduce delivery times.

Resources

Organization

The ODH is its own entity within the organizational structure of the healthcare centre to which it belongs.[13]

The **organization of ODHs is not uniform** across all hospitals as the volume of treatments to be administered, the presence of a pharmacy in the ODH itself, the type of treatments to be administered and even the type of patients may require different types of organization.[1]

ODHs must be **connected to the outpatient clinics**, but with a distinct form of organization. They are usually monographic, serving oncology, haematology or oncohematology patients, although they are sometimes part of multi-specialty day hospitals in lower volume centres. Oncology patients account for 80% of the activity of multi-purpose day hospitals.[1,2]

ODH facilities must be connected to **oxygen and vacuum** systems. In addition, the **emergency care trolley or crash cart station should be universal** for all ODHs.[1] For ease of location, they should be placed in the same room, in an accessible area, close to the entrance door, near the oxygen tanks and near an electricity socket. All professionals who may need to use it should be aware of its location.

95% **of the Spanish ODHs surveyed in ONCOptimal have** this indispensable element.

Portfolio of services

The ODH is a hospital-based care facility in which patients do not need to be admitted to hospital, as it offers a **wide range of diagnostic and therapeutic procedures**. This type of care improves the quality of life of patients, reduces the pressure on conventional hospitalization resources and reduces healthcare spending. **Table 1** details the portfolio of ODH services.[1]

Table 1. ODH portfolio of Services[1]
Ambulatory care for oncology patients in ODH
Administration of chemotherapy and targeted therapies
Pre-treatment medical consultation and toxicity assessment for chemotherapy and targeted therapies
Patient consultation in CT
Hospital Pharmacy Consultation
Blood and urine collection for analytical purposes
Haemotherapy
Transfusion of red blood cell concentrates
Transfusion of platelets
Parenteral administration of drugs
Nursing care
Vascular catheter/reservoir treatment
Recovery after diagnostic or therapeutic radiological examination
Targeted biopsy
Percutaneous drainage
Cavity puncture
Diagnostic or therapeutic paracentesis
Diagnostic or therapeutic thoracentesis
Lumbar puncture
Nursing consultation with telephone hotline

Table adapted from SEOM. Oncology Day Hospitals. 2015. Available at: https://www.seom.org/seomcms/images/stories/recursos/Libro_Hospitales_Dia_en_Oncologia.pdf. Last accessed: July 2023.

The survey shows that the centres are open, **from Monday to Friday, in the mornings and afternoons . Some centres also have morning hours available at weekends**. It is possible that the extension of ODH opening hours could speed up waiting times.[1,13]

Table 2. National survey results. Days on which the ODH is open. Nursing	
M-F	89.5%
Morning	average
Opens	8.15 am
Closes	3.30 pm
Afternoon	average
Opens	2 pm
Closes	8.30 pm
Saturdays	5.7%
Morning	average
Opens	8 am
Closes	2 pm
Afternoon	average
Opens	3 pm
Closes	10.30 pm
Sundays and public holidays	4.8%
Morning	average
Opens	8 am
Closes	2.30 pm
Afternoon	average
Opens	2.30 pm
Closes	9 pm

As part of the services to patients in ODHs participating in ONCOptimal, **specific staff** provide information about consultations, treatments, and side effects to patients (69%); and there are **procedures are agreed upon and well-known** by all staff for work related to healthcare processes (73%). About half of the centres surveyed also have **patient volunteers**.

Table 3. National survey results. Number of ODH health professionals per shift. Health managers	
Professionals Morning shift	Average no.
Medical oncology	4.8
Nurses	4.9
Nursing auxiliary care technicians	2.6
Hospital Pharmacy	1.1
Psycho-oncology	1.3
Administration	1.0
Other (orderly)	1.0
Professionals Afternoon shift	Average no.
Medical oncology	1.5
Nurses	2.4

Nursing auxiliary care technicians	1.4
Hospital Pharmacy	1.3
Psycho-oncology	1.0
Administration	1.0
Other (orderly)	1.0

Protocols

The ODH usually has its own protocols, developed by the centre itself, which usually coincide with other ODHs in terms of the key or main points. Relevant clinical protocols include:[1]

- Protocol for the selection of infusion systems for the administration of chemotherapy.
- Action protocol for chemotherapy spills and extravasations.
- Protocol for managing infusion reactions.
- Protocol for safe administration agreed upon with Hospital Pharmacy.
- Therapeutic decision algorithms.

Approximately half of the ODHs surveyed in ONCOptimal have a protocol in place to manage **requests for new infusion devices** for the delivery of chemotherapy treatments.

Staff

The quantification, and also the qualification, of the assigned care and administrative staff will largely depend on three factors: **type of hospital, number of patients served, and the internal planning of the centre**.[1]

Staff should work in **multidisciplinary teams**, and address the different needs of patients. The ODH should have the following profiles:

- **Organizational manager:** their specific dedication, whether partial or full, will vary depending on the volume of activity and complexity. This role usually falls to the Medical Oncology specialist. In other ODHs the responsibility lies with someone in the Nursing department and in other cases it will be shared.[1,2,14]
- **Nursing Officer:** Nursing work is essential. ODH nursing staff should be required to have certain training, recognizing the specialization of **Oncology Nursing** and ensuring the stability of staffing levels.[14]
- **Clinical specialists:** doctors specializing in Medical Oncology.[1,2,14]
- **Nursing: Nurses:** Nursing graduates if possible with training and experience in Oncology.[1,2,14]
- **Pharmacy:** the presence of a satellite pharmacy is recommended in ODH units with an activity volume of more than 30 administrations/day, providing better coordination between the prescription, preparation and administration processes, contributing to reduce patient waiting times. In Spain at the end of 1995, the GEDEFO Group created a specific framework to facilitate training in the field of oncohaematology, and to increase collaboration and exchange of knowledge and experience in this field among hospital pharmacists.[15] Nevertheless, the training of pharmacists in the field of oncohaematology in Spain is high. Currently, Spain is the second country, after the US, with the most hospital pharmacists certified by the *Board of Pharmacy Specialties* in Oncology,specifically with 151.[16]

- **Other staff:** Nursing assistants, administrative staff, orderlies and, depending on the healthcare approach and size of the ODH, it may be appropriate to assign, part-time or full-time, other healthcare professionals such as psychologists, nutritionists, social workers and volunteer programmes.[1,2,14]

The ONCOptimal analysis indicates that 60% of the Spanish ODHs surveyed have the **figure of a coordinator, who most of the time (71%) is a Nurse, mainly dedicated to the running of the centre**. It is noteworthy that 40% of the centres indicate that they do not have this figure.

All staff involved in the prescription, preparation and administration of chemotherapy should undergo training with established controls to **ensure their qualification and ongoing training**, and the periodic review of compliance with the standards in question.1 The survey indicates that 47% of pharmacists responsible for validation, preparation and dispensing of cytostatics have advanced specialist training.

The SEOM carried out a recent study, published in 2021, with the aim of obtaining updated data on the workload and estimates on the future evolution of medical **oncologists in Spain. The study highlights the need for oncologists to allocate more time to basic, clinical, and translational research activities**, as well as increased time for associated healthcare activities. This is due to the growing complexity of personalized medicine and the need for multidisciplinary teamwork. Furthermore, the results show that by 2040, there will be a **significant increase in tasks associated with the interpretation of molecular and genetic data, in telemedicine consultations, and a proportional reduction in the time dedicated to hospitalized oncology patients. Additionally**, 51% of teaching activities and 50% of research activities will be conducted outside of regular working hours.[17]

In conclusion, **healthcare professionals** should have **sufficient time** within their working day to carry out **all necessary training, teaching, and research activities** and to take part in the **teaching and researc**h offered to professional in training at first-rate centres with the aim of training future leaders in oncology.[17] It is essential that administrative tasks do not occupy a significant portion of their time, to the detriment patient care.

Average number of patients/day

The expected number of treatments and/or procedures performed in a year can be established based on epidemiological data and the penetration of the facility's care in that population. It should be noted that chemotherapy treatment involves a **complex care process** and **is not always the same**, which translates into a **specific variability** of times for each treatment and patient. There are an estimated **30 30 treatments/procedures per thousand inhabitants/year**:[1]

- In a population of 250,000 inhabitants, the ODH should be equipped to respond to **7,500 treatments/procedures per year**, which would represent about **270 procedures/treatments per week, and between 50-55 per day**.
- The analysis of the situation in the Spanish ONCOptimal centres indicates that the average number of treatments administered per day is **40 in the morning and 23 in the afternoon (63 per day)**, with an average of 34 infusion pumps per centre.

Theoptimal utilization ratio for treatment rooms would be 2-3 patients treated/chair/day and 1-1.5 patients/bed/day. That is, the **average number of patients treated/day** (in an ODH with an average of 20 chairs and 4.5 boxes/beds) will be **60 patients per day**.[1] The Spanish ONCOptimal centres reveal that the average number of patients per day atten-

ding an ODH **is 75**, either for treatment or consultation (8 being the approximate number of patients seen at an ODH each day on a walk-in basis).

The data collected in the survey is consistent with the evidence: an **average of 20 chairs and 5 beds**, so we can deduce that there would not be a shortfall in resources. However, the **average number of patients attending an ODH is higher** (75 patients according to the 2023 national clinical practice analysis, versus 60 patients in the scientific evidence analysis) indicating a need for an increase in these resources.

The number of cancers diagnosed in Spain in 2022 was estimated at **280,100 cases** (number of cancer diagnoses according to calculations by the Spanish Network of Cancer Registries).18 If we assume, based on the scientific evidence, that every month some 70,000 patients receive oncological medication in Spanish ODHs, at an average of **2.5 treatments per day per chair/bed** (data taken from the national survey), we would obtain a figure of 28,000 treatments. Considering 20 working days per month for the administration of medication, **approximately 1,400 chairs/beds would be needed in Spain**.

Considering that the ONCOptimal analysis indicates an **average of 20 chairs and 5 beds and that 63 treatments are administered per day, an average of 2.5 treatments per chair/bed is obtained**. At an average of **2.5 treatments per day per chair/bed**, in the 212 centres participating in the study, **530 chairs/beds are being used in Spain, a low number compared to the number that would be needed (1,400), indicating a deficit in this regard**.

Table 4 summarizes the results of the national ONCOptimal survey in relation to **general information, structural data and resources of the ODH** with input from health managers, oncologists, nurses and hospital pharmacists.

Table 4. National survey results. General information and structural data of the ODH

HEALTH MANAGERS	%
Managerial position held in the hospital	
Medical Director	20.0
Managing Director	0.0
Other	80.0
TOTAL	100.0
Population assigned to the centre	
<300,000	60.0
300-500,000	10.0
>500,000	30.0
TOTAL	100.0
Type of Oncology Day Hospital	
Oncology	0.0
Oncohaematology	70.0
Multi-purpose	30.0
TOTAL	100.0
Does the ODH have a coordinator?	
Yes	60.0

NURSING	%
Indicate number of chairs at the ODH	19,9
Indicate number of beds at the ODH	5,2
Indicate the size of the ODH (m2)	142,3
Indicate the number of infusion pumps available in the ODH	33,9
Indicate the average number of treatments administered per shift.	
Morning	40.0
Afternoon	23.0
Does the ODH have a planning system in place for available chairs and for managing or prioritizing patient treatment schedules?	
Yes	59.4
Does the ODH have a crash cart?	
Sí	94,8
Are blood product transfusions performed?	
Yes	83.3
If so, estimate the number of blood product transfusions performed per week	12.2
Indicate whether the activity of nurses in the ODH is recorded electronically.	
Sí	87,5

HOSPITAL PHARMACY	%

Table 4. National survey results. General information and structural data of the ODH			
Does the ODH have quality standards certifications?		Does it have a cytostatic biosafety cabinet?	
	No 60.0		Yes 94.7
Does the ODH have a separate clinical trials research area or unit?		Does it have a dispensing system for oral chemotherapy and external drugs?	
	No 80.0		Yes 86.0
MEDICAL ONCOLOGY	%	Does it have an oral chemotherapy dispensing and supportive care clinic integrated into the ODH?	
Indicate the average number of patients per day attending the ODH.	74.9		Yes 47.4
Indicate the approximate number of walk-in patients seen at the ODH each day	8.0	Do the pharmacist(s) responsible for validation, processing and dispensing of cytostatics have advanced specialized training (e.g. BCOP)?	
			Yes 47.4

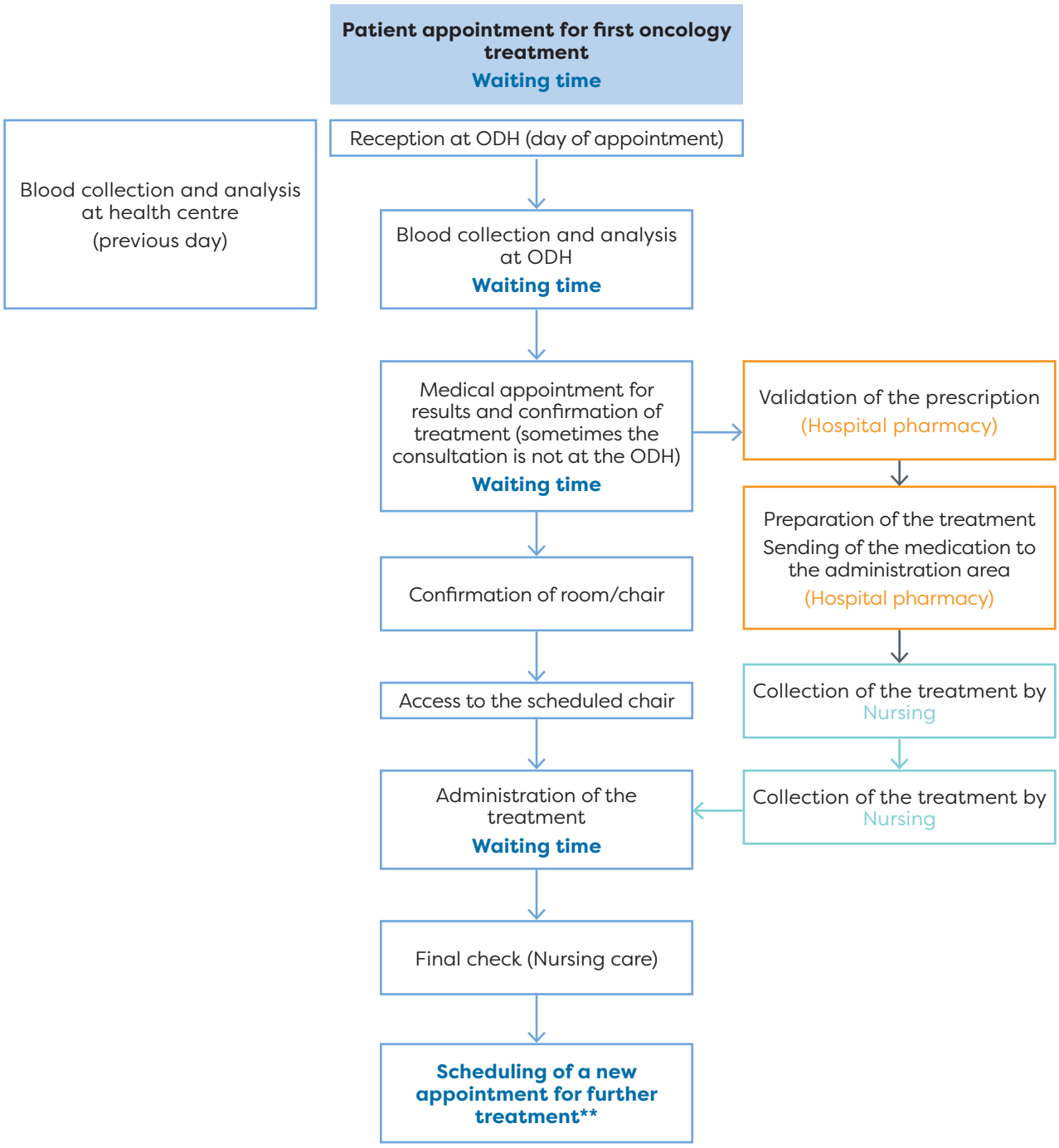
[o]quality and admission; director of nursing; block chief; deputy medical director; area supervisor.

3.3 PROCESSES IN THE ONCOLOGY DAY HOSPITAL

One aspect to take into account in ODHs is the **complexity in the care pathway** of patients receiving oncology treatment. **Defining processes in ODHs**, with adequate information and progressively improving care coordination among different services mitigate the impact of care fragmentation on patients, which should be a **priority for ODHs in the coming years**.[1]

The care pathway for treatment in ODHs in Spain is summarized in the following figure **(Figure 1)**.

Figure 1. Care pathway for treatment in ODHs in Spain*



Care process in the Oncology Day Hospital for workflows administered in ODH . Workflow based on the SEOM documents Oncology Day Hospitals,[1] White Paper on Medical Oncology in Spain[2] and Prevemed Report[3]. In black the patient pathway, in red the hospital pharmacy pathway and in green the Nursing pathway. *This pathway does not include possible treatments that are not administered in the ODH (e.g. oral drugs or granulocyte colony-stimulating factor (G-CSF) but are included in chemotherapy regimens and are dispensed in hospital pharmacies or satellite pharmacies. Not all treatments, due to the time required for administration, can be given on the same day. In which case the patient has to come another day, taking into account in this case that there is no waiting time for preparation, as the treatment is already available for administration. **Sometimes the appointment is scheduled at the same time as the confirmation or search for a chair for administration.

The following is a summary of the key steps a patient goes through during their stay at the ODH:

Patient appointment to start oncology treatment

Preferably the **appointment will be computerized**, and it can be either multiple appointments (appointments for several cycles) or consecutive appointments (the next one is scheduled after completing a chemotherapy cycle), depending on the type of cycles. The appointment for a medical consultation will be synchronized with the time when the pharmacy supplies the medication and with the reservation of a chair or bed for the administration of the treatment. After the patient arrives and is registered at reception, the consultation and treatment chair appointments are confirmed and those inside the ODH are notified of the patient's arrival.[1]

Blood collection and analysis

This is usually done at the ODH on the **same day as the treatment or at the Health Centre the day before**. It can also be carried out on a different day to the consultation (in the general sample collection unit of each centre). If done at the ODH the results should be available within 1 hour and the sample collection should be performed 1-1.5 hours before the consultation with the specialist.[1]

Consultation with the specialist

The oncologist will need to perform a **clinical assessment, evaluate the lab results**, and issue the final prescription of medication for the patient before the treatment is administered. If the patient is unable to receive the medication, a new appointment will be scheduled for another day.[1]

Based on the existing infusion protocol (if available), **the most appropriate infusion route** for the patient is defined and the IV is inserted. During the consultation it is decided whether the IV can be inserted by the Nursing staff. If the IV cannot be inserted by the nursing staff, because it involves central systems or ports, the patient will not continue with the administration process and will have to go to the hospital for the IV insertion.

Confirmation of the schedule

The treatment station must be confirmed prior to preparation by Pharmacy. If it is a very lengthy treatment, and there is no available chair, it is sometimes delayed until the next day, and the Pharmacy does not prepare it until the location and chair are confirmed. Furthermore, taking into account the administration time, it may be prepared later, depending on the stability of the drugs.

Nursing (or the centre's administrative staff) confirm **the treatment station and the duration of the treatment** (assigned at the time the appointment is made). The schedules for treatment stations, whether chairs or beds, are organized in time modules based on the treatment, with an additional 30-minute buffer to prepare the station for the patient. Appointments for consultation with the specialist and for treatment administration should be synchronized in such a way that the Hospital Pharmacy Service has the necessary time to validate and prepare the treatment.[1]

Preparation of medication by the pharmacy service

Once the treatment has been confirmed by Oncology, the hospital pharmacy starts the process of **validating the prescription and preparing the medicine** according to the dose and presentation appropriate to the patient's specific needs, taking into account the scheduled administration time, and it is sent to the **administration area**. The medication will normally be collected and transported by support staff/orderlies.

Administration of the treatment

To avoid delays in administration, treatments should be **scheduled and planned**. The patient proceeds **to the chair or bed in the administration room** which will have been previously scheduled upon arrival at the ODH. This reservation should be **synchronized with the doctor's appointment and with the pharmacy shift** supplying the medication, in order to avoid delays and waiting times during which the scheduled chair remains vacant.1.

In some hospitals the time is scheduled after confirmation of the treatment by the doctor. This avoids chair vacancies when treatments are cancelled because the correct analytical results are not available, for example, which prevent the treatment from being administered on that day. This allows for a greater optimization of the chairs by allocating them to patients who will receive treatment.

Nursing will verify the **correct identity of the patient and the medication**, and proceed to schedule the administration of medication via infusion pumps.1 Some systems already output the prescription and preparation information (with infusion times, rate, flushes, order of administration, waiting times, etc.). This reduces the workload for nurses and minimizes errors by eliminating the need for manual programming.

Final check

After the treatment has been administered, Nursing must confirm that the patient can leave ODH. Otherwise, the patient is referred to the oncologist for assessment.[1]

New appointment

Before leaving the ODH, the patient proceeds to the admission area to schedule the new appointment for consultation, sample collection and/or administration of treatment.1 However, this process is sometimes carried out while a chair is being found for the administration of medication. SMS appointment systems now exists so that the patient does not have to make an appointment in the admission area.

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4 THE PROBLEM IN DAY HOSPITALS IN SPAIN

4.1 WAITING LISTS FOR MEDICATION AND WAITING TIMES IN ODH

Cancer has become the second leading cause of death worldwide, with approximately 18 million new cases diagnosed and more than 9.6 million tumour-related deaths per year. The latest studies indicate that cancer is responsible for one in six deaths and suggest that in **the next two decades the number of new cases will increase by around 60%, reaching 29.5 million by 2040**.[1]

It is essential to ensure **early care and treatment for patients, reducing waiting lists**. Improved treatments and early detection have extended the life expectancy of cancer patients, and many patients are able to overcome the disease or reduce it to a chronic condition, with prolonged treatment over time.[2]

In Oncology, **lengthening the time to treatment** can significantly reduce **patient survival**. In addition, the lengthening of patient waiting time for treatment leads to a significant reduction in **patient satisfaction**.[3-6]

The **waiting time for treatment** is defined as **the time from diagnosis** to first treatment, and from **the time of first treatment to treatment for adjuvant indications**.[4]

A **four-week waiting time for treatment** is associated with **increased mortality** for all common forms of cancer treatment, and **longer delays** are increasingly harmful **(up to an 8% increased chance of death for every four weeks of treatment delay)**. These **waiting times are multifactorial in cause** depending on the demand for treatment (based on the type of cancer) and the existing resources (staff, number of chairs/beds, etc.).[4]

According to medical oncologists in the ONCOptimal survey, the approximate time from diagnosis or surgery to the start of oncology medication administration is **less than 30 days (Table 5)**. However, just over 14% receive medication after 30 days or more and almost 5% over 61 days. Every 4 weeks of delay in treatment results in a decrease in survival rates.[4]

Table 5. National survey results. Average waiting times from the indication of treatment to the start of oncological medication. Medical oncology		
	%	%
< 7 days	7.1	85.8
7-14 days	4.8	
15 days	14.3	
21 days	31.0	
28 days	11.9	
30 days	16.7	
31-45 days	7.1	14.3
46-60 days	2.4	
61-75 days	4.8	
76-90 days	0.0	0.0
91-120 days	0.0	
121-150 days	0.0	
> 151 days	0.0	

It is important to note that **depending on the treatment** (chemotherapy, surgery, oral treatment) different times which may not necessarily be considered **delays to the start of medication or delays in the ODH**. However, the participating oncologists agree that waiting times at ODHs could be improved especially by **decreasing the time between analysis, medical assessment, treatment approval and treatment administration**.

In a recent study published by Cone EB, et al., involving patients with breast cancer, prostate cancer, non-small cell lung cancer and colon cancer, the median time to the start of cancer treatment (interval between diagnosis and treatment) was **32 days for breast, 79 days for prostate, 41 days for lung cancer and 26 days for colon**. Across all cancers, an overall increase in predicted 5- and 10-year mortality was associated with an increase in time to cancer treatment initiation.[7]

In Spain, according to the data collected in the Resa 2017 study[8], published by the Institute for the Development and Integration of Healthcare Foundation (IDIS), for the sixth consecutive year, the time that elapses **between the diagnosis of three of the most common types of cancer and the start of treatment is less than 15 days on average (in private centres): 13.84 days in colorectal cancer, 14.84 days in lung cancer and 13.93 days in breast cancer**. Although these results refer to private centres, they differ significantly from those of ONCOptimal centres; this aspect must therefore be improved in order to reduce waiting times.

As already mentioned, another particular aspect of ODH care is the **complexity of the pathways faced by patients**, who often get lost in the multiple instances of multidisciplinary care and are obliged to manage and coordinate their own appointments and processes. The main problem detected in these ODH care pathways in Spain is the **limitation of resources, especially human resources, together with other inefficiencies that are detailed below**.[9] Future efforts should focus on **reducing these times by increasing human, material and technological resources** which s**hould be reviewed and adapted in each centre on a regular basis, at least annually**.[4,9]

Thus, it is crucial to understand that the **best way to prevent missed opportunities** in patients with cancer in ODHs is the **prioritization of time and mobilization of human and technological resources**.[7,10]

4.2 BOTTLENECKS AND INEFFICIENCIES

PATIENT APPOINTMENT FOR ONCOLOGY TREATMENT

Normally, when cancer patients visit the ODH, they are scheduled for three appointments on the same day. The first is for the blood sample collection (performed by Nursing) and takes place first thing in the morning. The second is the consultation with the oncologist and **occurs at least 1 hour after the blood collection** (based on the results of the blood samples, the oncologist adjusts the chemotherapy treatment for the patient; and this information is received by the pharmacy department, which will then prepare the drug). The third is for the administration of the treatment (carried out by Nursing) and **occurs at least 3 hours after the Oncology appointment**.[9-11] Sometimes, the analysis and consultation are carried out on one day and the appointment for the treatment is made for another day.

- **Bottleneck:** due to manual planning and management of appointments.
- **Inefficiencies:** in the available resources (availability of chairs and beds, of nursing staff).

The ONCOptimal survey results show that **only 57% of patients receive electronic notification and reminders of their appointment via SMS, mobile app, email, etc**. Once treatment has been prescribed and confirmed, treatment appointments **are usually scheduled for the same days** as the consultations with the specialist. The ODH does not carry out a **quality control of the punctuality of patient appointments** and **it does not have electronic systems to alert patients on the screen in the waiting room**.

Both Nursing and Hospital Pharmacy agree that waiting times for patients in the ODH could be improved by **scheduling appointments according to the availability of treatment slots**. These times should be planned one day prior to administration for confirmation and preparation of the treatment station.

The patient's appointment for treatment **should be computerized to be synchronized with other appointments** (sample collection, consultation, etc.) so that the patient can complete all actions in the shortest possible time. Once the treatment is finished, and if the next treatment is confirmed, the new appointment should preferably be computerized, and it can be either multiple appointments (appointments for several cycles) or consecutive appointments (the next one is scheduled after completing a chemotherapy cycle), depending on the type of cycles[9] although it should be borne in mind that this planning may be changed (due to toxicities, for example). Appointment management software is now available to help optimize scheduling.

One point **worth noting** is that, of the participating ODHs, only 58% use electronic identification of patients on arrival through **bar-coded wristbands**.

BLOOD COLLECTION AND ANALYSIS

The sample collection room and laboratory have a limited capacity to test ODH patients and other patients scheduled for other specialties:

- **Bottleneck:** until the lab results are available, the patient cannot continue the care process in the ODH, resulting in a delay.

- **Inefficiencies:** lengthened hospital stays due to waiting time for results that reduce the capacity of the ODH and lengthen patients' stay in the facility.

The survey shows that the **average waiting time**, from arrival at the ODH to **blood collection is 1 hour and from blood collection to obtaining lab results is 1.45 hours, and that only 46% of ODHs have a Point-of-Care system for blood collection. These systems allow the patient to remain in their chair and significantly reduce the time for blood sample collection and obtaining lab results**.[12-15] The shorter these times are, the shorter the patient's stay in the ODH.

It should be noted that not all ODHs perform blood collection. At times, patients in the ODH are scheduled and managed through the hospital's general sample collection facility. Sometimes the patient even comes with the results of the analysis carried out at his or her health centre.

MEDICAL VISIT

Once the medical oncologist reviews the patient's clinical condition and lab results, they prescribe and confirm the treatment. This prescription is passed on to the pharmacy service for preparation. Electronic prescribing systems, linked to the hospital pharmacy service, greatly facilitate medical prescribing by the oncologist and communication with the pharmacy service; and avoid delays and errors.[9] The number of oncologists available for the medical visit is limited, which means:

- **Bottleneck:** limited time for the consultation.
- **Inefficiencies:**
  - Delays due to waiting time for the medical visit reduce the capacity of the ODH and lengthen patients' stay in the facility.
  - Lack of electronic prescribing systems linked to the pharmacy service.

The survey shows that the **average waiting time, from when the lab results are available to the consultation with the patient is 1.16 hours.** Nursing staff agree that waiting times for patients in the ODH could be improved by **scheduling appointments according to the availability of treatment slots**.

Conducting the medical visit and administration of treatment on different days could help to optimize day hospital places, especially in the early morning.

CONFIRMATION OF THE SCHEDULE

The patient is assigned a chair in the administration room that has been previously scheduled. This reservation should be synchronized with the doctor's appointment and with the pharmacy shift supplying the medication, in order to avoid delays and waiting times during which the scheduled chair remains vacant.[9] his would result in a bottleneck and inefficiencies in the ODH.

- **Bottleneck:** the number of existing chairs as well as human resources is the limiting factor when it comes to increasing the number of patients receiving medication.
- **Inefficiencies:**
  - Delays and lack of synchronization in the process up to the point of medication preparation are a major inefficiency, resulting in vacant, unoccupied chairs waiting for the patient to go through all the above processes and be ready to receive their medication.

In the survey, only 59% of **participants have a planning system in place for available chairs and for managing or prioritizing the patient treatment schedules** (mainly: activity analysis). This should be improved to avoid bottlenecks.

PREPARATION OF MEDICATION

Once the medical oncologist prescribes and confirms the treatment, the pharmacy service prepares the medication. Electronic prescribing systems, linked to the hospital pharmacy service, greatly facilitate communication with the pharmacy service; and avoid delays and errors.[9,10] All this means:

- **Bottleneck:** The capacity of the pharmacy service to prepare medication is limited. Until the medication is prepared, it cannot be sent to the administration area.
- **Inefficiencies:**
  - Lack of electronic prescribing systems linked to the pharmacy service.
  - Lack of a system that prioritizes the preparation of medication based on the patient's condition.
  - Lack of an electronic system for the preparation of medication.
  - Lack of an electronic system that displays the status of the preparation of medication by patient and that enables effective coordination between the pharmacy and the administration service, to avoid constant phone calls that reduce the efficiency of both services.
  - Delays due to waiting time in the preparation of medication reduce the capacity of the ODH and lengthen patients' stay in the facility.
  - If the synchronization between the pharmacy department and the medication administration department is not effective, it will result in inefficiencies in both departments, leading to delays and prolonged patient stays.
  - On top of this, if the Pharmacy and ODH are a significant distance apart there will be an added delay due to transport.

Ninety-five percent of ONCOptimal survey participants indicate that they have a **computerized or electronic oncology medication prescription system**, including information on, among other things, drug interactions, drug allergies, duplicate therapy, or dosage adjustments based on liver and kidney function (70%).

As a method of communication between the Oncology consultation, the laboratory and the Hospital Pharmacy Service, 80% use **an electronic/digital method to receive medication prescriptions and all have a pharmaceutical validation system for the prescription of oncology treatments**.

In the Hospital Pharmacy Service, an average of **310 preparations are produced per week. There is an average of 11 delays per week in the preparation of cancer treatments in general**, mainly due to staff shortages.

For the preparation process **only 48% of the respondents indicated that their centre is supported by standardized preparation software. Only 45% have a gravimetric system to validate the preparation. 92%** have an automation system for all necessary calculations (size, number of vials, volume, etc.) for the preparation of medication. Once ready to be administered, in **75% of centres, the prepared treatment is delivered to the patient by an orderly**.

According to the national survey, 70% of the incidents occurring during clinical validation of the prescription (dosage, drug, other) are recorded. This registration is mainly carried out in the **Pharmacy Service** (76%). 92% of participating centres **monitor and control incidents during the administration of treatment**, mostly electronically/digitally).

ADMINISTRATION OF THE TREATMENT

The patient then receives the oncological medication. The nurses must perform medication and patient check processes, as well as programme the medication infusion pumps for administration of the treatment (computer systems can assist in this programming).9

Depending on the treatment, they should also be responsible for monitoring the patients who are being administered medication. Depending on the number of nurses and the type of process, the time spent on this activity may vary.

According to the document of recommendations on cancer patient safety in intravenous therapy published by SEOM11 in day hospitals, an average of 7 cases of extravasation and 23 of phlebitis occur per year (98 Spanish hospitals). Extrapolated to the national level, the document estimates 3,454 cases of phlebitis and 1,049 extravasations per year.

71% of ONCOptimal survey participants indicate that they do not have a **bar code-based patient/medication/pump identification system, and the majority carry out a check verbally/visually**. These systems prevent errors associated with the administration of medication (right medication, right patient, right time) and improve the efficiency of the nursing staff since the checking and documentation process in the ODH computer system is done automatically, rather than manually.

In addition, 84% of the ODHs surveyed indicate that **pump programming is done manually**. Smart infusion pumps with safety systems that prevent programming errors already exist. Some new infusion pumps can be connected to the hospital's prescription system so that they can be programmed automatically, improving the efficiency of nursing staff and minimizing pump programming errors. Smart pumps allow the transfer of medication administration information automatically into the patient's electronic health record.

- **Bottleneck:** the number of existing chairs as well as human resources is the limiting factor when it comes to increasing the number of patients receiving medication.
- **Inefficiencies:**
  - Delays and lack of synchronization in the process up to the point of assigning the medication are a major inefficiency, resulting in vacant, unoccupied chairs waiting for the patient to go through all the above processes and be ready to receive their medication.
  - Lack of protocols for selection of infusion systems and/or intravenous therapy teams in ODH treatment areas.
  - Lack of electronic systems that allow the identification of the patient/medication/pump by bar code.
  - Lack of smart pumps with safety and self-programming systems.

Assessing the patient prior to initiating treatment allows the most appropriate infusion route to be selected and decrease delays. The survey shows that the **average time from the consultation to the start of administration of the medication is 1.59 hours**. For outpatients being dispensed medication, in the event they have a pharmaceutical consultation, the **average time to dispensing** is 1 hour. It should be noted that these outpatients

do not occupy a chair in the ODH. In this case, it must be taken into account that before the pharmacological dispensation, the patient has a pharmaceutical consultation and the validation of the treatment takes place, with an interview, in many cases with the patient.

Both Nursing and patients report that **delays in the administration of treatment occur from the patient's scheduled appointment time** (with no monitoring system in place).

All the professionals surveyed (Medical Oncology, Nursing and Hospital Pharmacy) agree that **errors related to the prescription, preparation and administration of medication** could be reduced especially by electronically standardizing administrative processes, using double-check procedures and providing specific training.

FINAL CHECK

Once the administration is completed, nurses must document the administration of the medication in the patient's health record in the ODH system.9 Depending on the prescribing system, the administration may be documented during the process, for example by scanning the bar code on the patient's wristband.

- **Bottleneck:** Nurses per patient seen available to document the administration of medication.
- **Inefficiencies:** the time the Nursing service spends on manual documenting the administration is time that is not spent administering medication to other patients.

The use of bar code systems for the administration of medication and smart pumps would allow this documentation to be done automatically, improving the efficiency of nurses in ODHs.

In this regard, it should be noted that in real clinical practice in **most ODHs (88%), Nursing activity is recorded electronically in the patient's electronic health record** and in **98% of them the clinical management of the patient is carried out electronically, which includes or integrates the patient's data, including lab results**.

Finally, it should be pointed out that the Nursing service, in the ODHs surveyed, considers that **the percentage of the working day spent on administrative work compared to patient care is 35%**. This percentage is high and should be reduced to avoid bottlenecks.

The following table summarizes the inefficiencies and bottlenecks by care process in ODHs **(Table 6)**.

Table 6. Inefficiencies and bottlenecks by care process in ODHs

Care process	Problem
Patient appointment for oncology treatment	**Bottleneck:** due to manual planning and management of appointments. **Inefficiencies:** in the available resources (availability of chairs and beds, of nursing staff).
Blood collection and analysis	**Bottleneck:** until the lab results are available, the patient cannot continue the care process in the ODH, resulting in a delay. **Inefficiencies:** lengthened hospital stays due to waiting time for results that reduce the capacity of the ODH and lengthen patients' stay in the facility.
Medical visit	**Bottleneck:** limited time for the consultation. **Inefficiencies:** • Delays due to waiting time for the medical visit reduce the capacity of the ODH and lengthen patients' stay in the facility. • Lack of electronic prescribing systems linked to the pharmacy service.

Table 6. Inefficiencies and bottlenecks by care process in ODHs	
Confirmation of the schedule	**Bottleneck:** the number of existing chairs as well as human resources is the limiting factor when it comes to increasing the number of patients receiving medication. **Inefficiencies:** delays and lack of synchronization in the process up to the point of medication preparation are a major inefficiency, resulting in vacant, unoccupied chairs waiting for the patient to go through all the above processes and be ready to receive their medication.
Preparation of medication	**Bottleneck:** The capacity of the pharmacy service to prepare medication is limited. Until the medication is prepared, it cannot be sent to the administration area. **Inefficiencies:** • Lack of electronic prescribing systems linked to the pharmacy service. • Lack of a system that prioritizes the preparation of medication based on the patient's condition. • Lack of an electronic system for the preparation of medication. • Lack of an electronic system that displays the status of the preparation of medication by patient and that enables effective coordination between the pharmacy and the administration service, to avoid constant phone calls that reduce the efficiency of both services. • Delays due to waiting time in the preparation of medication reduce the capacity of the ODH and lengthen patients' stay in the facility. • If the synchronization between the pharmacy department and the medication administration department is not effective, it will result in inefficiencies in both departments, leading to delays and prolonged patient stays. • On top of this, if the Pharmacy and ODH are a significant distance apart there will be an added delay due to transport.
Administration of medication	**Bottleneck:** the number of existing chairs as well as human resources is the limiting factor when it comes to increasing the number of patients receiving medication. **Inefficiencies:** • Delays and lack of synchronization in the process up to the point of assigning the medication are a major inefficiency, resulting in vacant, unoccupied chairs waiting for the patient to go through all the above processes and be ready to receive their medication. • Lack of protocols for selection of infusion systems and/or intravenous therapy teams in ODH treatment areas. • Lack of electronic systems that allow the identification of the patient/medication/pump by bar code. • Lack of smart pumps with safety and self-programming systems.
Final check	**Bottleneck:** availability of Nursing to document the administration of medication. **Inefficiencies:** • The time the Nursing service spends on manual documenting the administration is time that is not spent administering medication to other patients. • This manual process could be automated by means of electronic patient/medication/pump identification systems using bar codes and smart pumps.

Table prepared ad hoc by the authors.

Table 7 shows the results of the national ONCOptimal survey in relation to ODH waiting times as answered by Nursing.

Table 7. National survey results. Patient waiting times	
Indicate the average waiting time (in hours) at the ODH.	Average
From patient arrival to blood collection	1 h
From blood collection to availability of lab results	1.45 h
From the time the lab results are available to the consultation with the patient	1.16 h
From consultation to the start of administration of the medication	1.59 h
Estimated duration of treatment	3.06 h
Until dispensing to outpatients in the event they have a pharmaceutical consultation	0.82 h

Table 8 shows the results of the national ONCOptimal survey in relation to patient management as answered by Health Managers, Medical Oncology and Nursing.

Table 8. National survey results. Patient management	
Health Managers	%
Does the ODH have a procedure to assess the patient's experience?	
No	80.0
Medical oncology	
Indicate how patients are referred from other hospital services to the ODH.	
Telephone communication between the responsible practitioner and the ODH coordinator.	31.9
ODH referral report template filled in by the responsible practitioner	42.6
Other	25.5
Does the patient receive electronic notification and appointment reminders via SMS, mobile app, email, etc.?	
Yes	57.1
Does the ODH have a quality control system in place to monitor the punctuality of patient appointments (electronic tracking)?	
No	47.6
Does it have electronic systems to alert patients on the screen in the waiting room?	
Yes	64.3
Does it currently have a computerized or electronic system for prescribing cancer medication?	
Yes	95.2
Does it currently have an electronic health record management system?	
Yes	97.6
Nursing	
Are patients provided with electronic identification on arrival at the ODH by means of a bar-coded wristband?	
Yes	58.4
Does the ODH have a blood collection point (point of care) that allows the patient to remain in the scheduled chair?	
Yes	45.5

Tables 9 and 10 show the results of the national ONCOptimal survey in relation to medication answered by Nursing and Hospital Pharmacy.

Table 9. National survey results. Medication. Nursing	
	%
Does the ODH have a decision algorithm to choose the most appropriate catheter according to the diagnosed treatment and its duration?	
Yes	42.6
Indicate the type of venous access and percentage (%) used	
Peripherally inserted central catheter (PICC)	33.5
Subcutaneous reservoir	32.4
Peripheral catheter	34.0
Butterfly	9.6
With safety system	37.2
Short needle and cannula catheter	43.6
Medium length	7.4
Other	2.1
Indicate the method used and percentage (%) for the administration of chemotherapy treatments.	
Infusion pump	85.4
Volumetric	86.8
Syringe	13.2
Infusion by gravity	14.6
Does the ODH have dual-channel infusion pumps?	
Yes	42.6
Does the ODH use "patient/medication/pump" bar code identification systems?	
Yes	29.4
Are infusion pumps programmed manually or automatically?	
Manually	83.8
Automatically (choice of specific programme)	16.2
Select from the following options related to how the prescription is checked against the medicine received and the patient to whom it is to be administered	
Visual/verbal check by asking the patient their name	52.2
Visual/verbal check, though the patient has a wristband or other identifying element	32.2
Automatic check by scanning the bar code	13.9
Does the ODH have sufficient infusion pumps available to care for unscheduled patients requiring unplanned care, ensuring their continuum of care?	
Yes	83.8
Does the ODH have a protocol in place to manage requests for new infusion devices for the administration of chemotherapy treatments?	
Yes	30.9
Are cytostatic surface contamination controls carried out regularly in the ODH?	
No	67.6

Table 9. National survey results. Medication. Nursing	
Are there any delays in the administration of treatment from the patient's scheduled appointment time?	
Yes	76.9
Does the ODH have a system for monitoring the delay in the start of treatment?	
Yes	26.2
Are any incidents that may occur in the administration of the treatment monitored and controlled?	
Yes	92.3
How are such incidents recorded?	
Manual recording system	26.9
Electronic/digital system	70.5
Other	2.6
Indicate the average number of adverse events per month associated with the administration of oncology medication.	
Average	9.07
Estimate the type and percentage (%) per year of adverse events associated with the administration of oncology medication.	
Extravasation	29.4
Infusion-related reaction	31.6
Inflammation of the area of administration	21.5
Medication error (incorrect medication)	16.4
Other	1.1

Table 10. National survey results. Medication. Hospital Pharmacy	
Preparation of medication	%
What method of communication is used between the Oncology consultation and the Hospital Pharmacy Service to receive medication prescriptions?	
Electronic (digital)	80.0
On paper	18.2
Other	1.8
Does the ODH have a system of pharmaceutical validation for the prescription of oncology treatments?	
Yes	100.0
If so, please indicate the pharmaceutical validation system for the treatment	
Electronic validation	88.2
Manual validation	11.8
What method do the Hospital Pharmacy Service and the laboratory use to communicate with each other?	
Electronic (digital)	85.2
On paper	9.3
Another method	5.5
How many preparations are carried out weekly in the Hospital Pharmacy Service of your hospital?	
Average	309.9

Table 10. National survey results. Medication. Hospital Pharmacy	
Are there any delays in the preparation of cancer treatments that lead to delays in the administration of treatments?	
Yes	51.0
If so, please indicate the average number of weekly delays in the preparation of chemotherapy treatments resulting in a delay in the administration of this treatment.	10.64
Indicate the causes for delays in the preparation of medication.	
Lack of staff	36.9
Lack of IT or technological support	10.9
Lack of communication between the Hospital Pharmacy Service and the ODH	10.9
Laboratory delays	6.5
Medication/treatment supply problems	17.4
Other	17.4
Does the preparation process have any kind of support?	
Preparation robot	3.7
Standardized preparation software	48.1
Manual process without technical support	42.6
Other	5.6
Is there a system in place to manage the inventory of reusable drug vials based on their expiry date/stability once opened?	
Yes	70.6
If so, please indicate the type of record used	
Computer record	22.2
Manual record	75.0
Other	2.8
Once ready to be administered, indicate the way in which the treatment is dispensed until it reaches the patient.	
Orderly	74.5
What systems are used to avoid exposure of staff to cytostatics during preparation?	
Needles and syringes	11,6
Preparation systems with a filter	24,6
Closed system drug transfer (CSTD)	62,3
What systems are used to avoid exposure of staff to cytostatics during preparation?	
Needles and syringes	11.6
Preparation systems with a filter	24.6
Closed system drug transfer (CSTD)	62.3
What kind of dispensing systems are used for the delivery of medicines from the Hospital Pharmacy Service to the ODH?	
Stock or hospital floor medicine cabinet	45.7
Unit dose dispensing system for medicines without assisted electronic prescription	4.9
Unit dose dispensing system for medicines with assisted electronic prescription	32.1

Table 10. National survey results. Medication. Hospital Pharmacy	
Automated dispensing system without assisted electronic prescription	3.7
Automated dispensing system with assisted electronic prescription	12.3
Other	1.2
Are cytostatic surface contamination controls carried out regularly in the medication preparation area?	
No	51.0
Is there a system in place to prioritize certain preparations according to urgency or duration of treatment?	
Yes	74.5
Medication incidents and errors	
Are any incidents that may occur during the clinical validation of the prescription (dosage, drug, other) recorded in any way?	**51.0**
Yes	76.0
If so, where are they recorded?	
Internal register of the Pharmacy Service	60.0
Patient's health record	30.0
Other	10.0
Are any incidents that may occur during the preparation of the medication (dosage error, labelling error, spillage, etc.) recorded in any way?	
Yes	70.0
If so, please indicate the system for recording such incidents.	
Internal register of the Pharmacy Service	76.3
Patient's health record	5.3
Other	18.4

4.3 PATIENT SAFETY IN THE ODH AND ITS ECONOMIC IMPACT

Patient safety in the ODH is of utmost importance due to the human, social and economic cost of adverse events in cancer patients, as they are immunosuppressed individuals receiving high-risk medication.[9]

Due to the complexity of cancer diseases and treatments, oncology patients make up some of **the highest hospitalization rates**. Adverse events associated with cancer care, whether in outpatient or inpatient settings, are among **the main challenges to patient safety**.[16]

The main adverse events that jeopardize patient safety in the administration of medication to oncology patients in ODHs are:

- Medication errors.
- Catheter-related infections.
- Related to infusion therapy.

MEDICATION ERRORS

The **National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)** defines a medication error as: ***"any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer, Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing, order communication, product labelling, packaging, and nomenclature, compounding, dispensing, distribution, administration, education, monitoring, and use"***.[17]

Incidence

Medication errors are the **most common hospital adverse event and have very significant health and economic consequences**. Adverse events related to medication errors cause more deaths than road traffic accidents, breast cancer or HIV.[18]

According to a recent report by the Organisation for Economic Co-operation and Development (OECD) entitled "The economics of medication safety: Improving medication safety through collective, real-time learning", **as many as 1 in 10 hospitalizations in OECD countries may be caused by a medication-related event and as many one in five inpatients experience medication-related harms during hospitalization**.[19]

In Europe, according to the **European Medicines Agency** (EMA), the rate of medication errors in the hospital setting varies between **0.3% and 9.1% at prescription** and between **1.6% and 2.1% at the dispensing stage**.[20]

In the UK, a 2017 study in the NHS quantified 237 million medication errors in a year in its hospitals, **21.3% at prescription, 15.9% at dispensing and 54.4% at administration**. However, 72% of the errors have little or no potential for harm[21]

In Spain, the **National Study on Hospitalization-Related Adverse Events (ENEAS)** concluded that the incidence of adverse events in hospitalized patients was 8.4%, with the **most frequent adverse event being medication errors**, which accounted for **37.4% of the total**.[22] A study on the incidence of medication errors in medication use processes indicated that up to 17 medication incidents occur per day for every 100 hospitalized patients, **16% at prescription, 27% at transcription, 48% at dispensing and 9% at administration**. 85% did not reach the patient and only 0.35% caused harm. Omission was the most frequent error in all processes.[23] In Spain there are numerous multicentre studies on adverse events in healthcare, including medication errors **(Table 11)**.

Table 11. Frequency of adverse drug events in national multicentre studies[23]

Study	Total AE (% patients)	Most frequent AE	Drug-related AE	
			Percentage of total	Preventable (%)
ENEAS	9.3%	**Medication (37.4%),** HCAI (25.3%) Procedures (25%)	37.4	34.8
APEAS	10.11%	**Medication (47.8%)** Worst course of the underlying disease (19.9%) Procedures (10.6%)	47.8	59.1
EARCAS	Qualitative study	Care, **Medication** HCAI	-	-
SYREC	33.1%	Care (26%) HCAI (24%) **Medication (12%)**	11.6%	58.9%
EVADUR	7.2%	Care process (46.2%), **Medication (24.1%)** Procedures (11.7%)	24.1%	-

APEAS: Study of Adverse Events in Primary Care; AE: Adverse event; EARCAS: Adverse Events in Nursing Homes and Residential Care Facilities; ENEAS: National Study on Hospitalization-Related Adverse Events; EVADUR: Adverse Events in the Emergency Department; HCAI: Healthcare-associated infections; SYREC: Safety and Risk in the Critically Ill . Table modified from the Patient Safety Strategy for the National Health System. 2015.[23]

In the ENEAS and APEAS (Study on Adverse Events in Primary Care) studies, medication errors are the leading adverse event in hospital and primary care.[24]

To record adverse events related to healthcare, reporting systems such as the Patient Safety Incident Reporting and Learning System (PSIRLS) exist.[25]

PSIRLS is the incident and event reporting and recording system developed (for hospitals and primary care centres) by the Ministry of Health, Consumer Affairs and Social Welfare as part of the Patient Safety Strategy for the National Health System.[25]

In the latest report published by PSIRLS (2019), medication-related incidents were the most reported type of incident (20.4%) **(Figure 2).**[25]

Figure 2. Type of incidents reported to the PSIRLS[25]

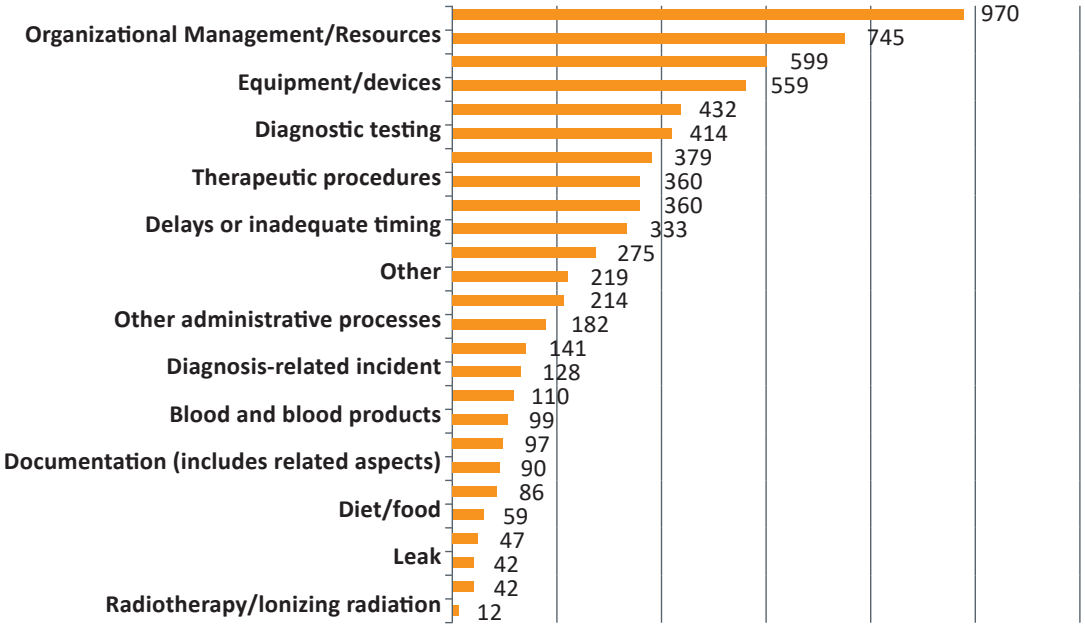

Figure modified from the Patient Safety Incident Reporting and Learning System (PSIRLS). 2019[25]

Fewer incidents were reported to PSIRLS in 2020 than in previous years, undoubtedly due to the high pressure on care during the pandemic. Nonetheless, healthcare professionals have continued to voluntarily report incidents, demonstrating their interest in sharing this information and ensuring that it is used to learn and to prevent similar incidents from recurring, ultimately benefiting patient safety.[26]

Type of medication errors in healthcare facilities

Medication errors can occur at each stage of medication management in the healthcare facility: **prescription, transcription/validation, preparation, dispensing, administration** and **clinical follow-up**.

In the **2018 PSIRLS report**, at the SAC1 (extreme risk) level, **5 incidents related to medication errors** were reported. A case of allergy in which the suspicion was present in the documentation provided by the patient but had not been included in the hospital records The other four incidents were errors in administering an excessive dose, in two of the cases involving paediatric patients.[25]

The **Institute for the Safe Medication Practices** (ISMP) has published a report on the most frequent medication errors in 2020 with serious consequences for patients. According to this report, the **10 most common errors** are shown in **Table 12**.[26]

Table 12. 10 types of medication errors with the most serious consequences detected in 2020. ISMP[26]
1. Errors due to omission or delay of medication
2. Administration of medication to the wrong patient
3. Errors associated with known allergies or adverse drug events
4. Dose calculation errors in paediatric patients
5. Errors due to similarity in labelling or packaging of commercially available medications
6. Errors associated with the non-use of smart infusion pumps
7. Errors due to accidental administration of neuromuscular blockers
8. Wrong intravenous administration of oral liquid medicines
9. Errors in medication reconciliation at admission and discharge from hospital
10. Errors due to patients' misunderstanding of how to use medicines

Modified table from the Institute for safe medication practices.[26]

Medication errors in the administration of oncology medication in ODHs

In the **ASHP *(American Society of Hospital Pharmacists)* Guidelines on the prevention of medication errors with chemotherapy and biotherapy**, the overall rate of chemotherapy errors was 8.1 errors per 100 clinic visits. In adults, errors were associated with 7.1% of clinic visits and 18.8% of paediatric clinic visits.[27]

In oncology medication, errors occur at a rate of between 1 and 4 per 1,000 prescriptions, affecting at least 1-3% of adult and paediatric oncology patients, and occur at all stages of the medication use process.[28]

In 2001 **GEDEFO** drafted a document that provides an in-depth analysis of the problem of medication errors in the oncohaematology. This paper also details measures specific to each phase of the pathway (prescription/validation/preparation/administration) aimed at preventing these errors. The **majority of these errors are almost always dose-related** (66% of the total).[29]

Hodkinson A, et al.[30] documented a **error rate of 9.9% for oral chemotherapy** administered to paediatric patients with acute lymphoblastic leukaemia. In this study, errors occurred at the prescription and administration steps.

Medication errors in chemotherapy can have serious consequences for patients due to the narrow therapeutic margin of antineoplastic drugs. In fact, the therapeutic dose is often set at the limit of acceptable toxicity for the patient, so that even small increases in the dose can have serious toxic consequences.[31]

These errors are made more likely by numerous factors such as: **individualized dosing based on body surface area, dose variability of the same drug** when used against different tumours, and **co-existence of dose-escalating research protocols** or intensification chemotherapy protocols.[31].

When discussing errors in oncology medication, we must also consider the social impact and the alarm they generate among the population since they often lead to serious consequences.[31]

A chemotherapy medication error is **any potential or actual error**, in which chemotherapy or adjuvant medication is prescribed, transcribed, prepared, dispensed or administered at a dose different from what is appropriate for that patient, on an incorrect date, by an incorrect route and/or with an incorrect administration technique. This includes the wrong vehicle, du-

ration, speed, concentration, compatibility and stability in solution, order of administration, or the actual administration technique. It also includes the inadvertent omission of a medicine from the prescription or transcription. **In the case of excess doses**, the consequences can involve severe toxicity or the death of the patient.[32]

In the case of **default doses**, the therapeutic response of many cytostatics is linked to the intensity of the administered dose, depriving the patient of the opportunity for potential improvement or cure of their disease. Furthermore, in the absence of a response, the clinician may choose to discontinue further cycles or move to a subsequent line of treatment, which may be more toxic, less effective or more expensive. Another form of default dosing is to either skip a dose of a cytostatic during the cycle or to omit it altogether. This error is becoming increasingly common due to the greater complexity of chemotherapy treatment regimens, and it requires increased vigilance from all healthcare staff, including doctors, pharmacists, and nurses.[31]

The **factors that make medication errors** in chemotherapy more likely are:[32]

a. **Lack of knowledge and/or experience of staff.**
b. **Human errors.** Given the rapid development of oncohaematology units in our country, there is often a shortage of human resources in a context of a growing volume of activity. Both circumstances create an environmental situation that is conducive to human error.
c. **Complexity of the prescription, transcription, preparation, dispensing and administration pathway.**
d. **Factors related to the characteristics of the treatment.** These include the following: narrow therapeutic margin, need to individualize dosage based on body surface area calculation or pharmacokinetic parameters, variability of the dose of a cytostatic when it becomes part of different chemotherapy regimens, management of high doses with salvage therapy, proliferation of new cytostatics, increased complexity of chemotherapy regimens, coexistence of investigational protocols or intensification chemotherapy protocols with standard chemotherapy regimens, lack of consistency between dosage forms of some cytostatics and therapeutic doses, which requires the handling of a large number of vials.
e. **Limited implementation of a culture of process control in the hospital environment.**

The average number of adverse events per month associated with the administration of oncology medication, as recorded in the survey, is 9, mainly infusion-related reactions and extravasations.

Economic impact

Up to 1 in 10 hospitalizations in OECD countries may be caused by a medication-related event and 1 in 5 inpatients experience medication-related harm during hospitalization. Together, the costs of preventable hospitalizations and/or consultations due to drug-related events and the additional length of stay due to hospital-acquired medication-related harm add up to more than **54 billion USD in OECD countries**. This report includes four components; 1) It assesses the human impact and economic costs of drug safety events in OECD countries, 2) explores opportunities to improve prescribing practices, 3) examines the current state of systems and policies to improve drug safety, and 4) provides recommendations for improving drug safety at the national level.[19]

According to the European Health Management Association (EHMA), in its report on "Digital medication management in healthcare settings", the annual cost of medication errors in the **European Union amounts to approximately €43 billion**.[33].

In the UK, more than 5% of all hospitalizations result from adverse events in primary care. The annual cost of treating adverse events considered "definitely and probably preventable" across all sectors of healthcare in England is estimated **to be £840 million (approximately $924 million) or 0.7% of healthcare expenditure**.[34]

The estimated cost to the UK NHS of preventable medication-related adverse events in hospital inpatients, combined with those occurring in hospital admissions and emergency consultations, is approximately **£98.5 million (representing 2.9% of NHS health expenditure)**.[30,35]

In Spain, the "Patient Safety Strategy for the National Health System 2015-2020" **estimates the cost of medication errors at around €2 billion (which represents 3% of the total expenditure of the National Health System)**.[24]

CATHETER-RELATED INFECTIONS

Incidence

Infections are one of the most serious complications to consider among cancer patients, both due to treatment conditions and the malignancy of the disease and because of conditions related to the venous access itself.[36] **The incidence of catheter-related infections ranges from 0.05 to 6.8 infections per 1000 catheter days**.[37,38]

Some studies[11] in cancer patients showed significantly lower rates with peripherally inserted central catheters (PICC) versus centrally inserted central catheters (CICC) (1.23 vs. 5.3/100 days of catheter use) or a lower incidence with PICC in outpatients, **while other data suggests that in the short term the incidence of infection is similar**.

According to information provided by ECO, SEOM and the Spanish Oncology Nursing Society (SEEO), there are approximately **150 centres in Spain that administer intravenous oncology therapy**.[39]

To reduce the negative impact of venous punctures, it is beneficial to have a stable venous access that can be reused, **facilitating both drug administration and adequate monitoring of the patient's condition, and reducing the anxiety associated with this procedure**.[40] To achieve this, many devices exist for both central and peripheral venous access.[41,42] It is an essential requirement for all of them to be **reliable and safe to use, as there are intrinsic complications related to both the medication and the procedure, which must be performed properly to achieve the best clinical outcomes**. It is essential to analyse the different vascular access options available and establish adequate criteria to select the most appropriate device in each case. This should take into consideration key factors such as the physicochemical characteristics of the therapy and its duration, the patient's physical condition and health record, the resources and devices available and the integrity of the patient's vascular system and personal preferences.[43] It is also important to **consider the experience and level of training of the professionals** responsible the insertion and care. It has been established that with greater specific professional preparation, there are fewer associated problems.[44]

In the analysis of the current situation regarding the **safety of oncology patients receiving intravenous therapy in Spanish hospitals** (IniciatIVas project involving 98 Spanish public,

private or subsidized hospital centres), it was observed that these **centres** have intravenous therapy teams for oncology patients in their hospital centre, but a considerable percentage of them (60.1%) report that they do not keep records of adverse events associated with this type of therapy in their unit. In the case of those that do keep such records, safety data is primarily collected through the Oncohematology Day Hospital, **with an average incidence of 7 cases of bacteraemia per year**. The incidence is even higher in the case of **phlebitis, with an average of 23 cases per year**.[45]

Extrapolating this data to the total number **of centres in Spain that administer intravenous oncology therapy**, we calculate an **average incidence of 11 cases of bacteraemia per year for every 150 centres**.

Economic impact

Taking into account the incidence of each of the main complications related to the administration of oncology treatments, there is no doubt that these events represent a significant burden, both clinically for professionals and patients, and economically for the healthcare system. Extrapolating the costs involved in the management of these events reported in US hospitals, **each episode of catheter-related infection is associated with a cost of €16,400, plus a substantial increase in morbidity and length of hospital stay, resulting in an annual burden of €17,221,000 for the healthcare system due to bacteraemias**.[45]

RELATED TO INFUSION THERAPY

Incidence

With more than 100,000 doses of chemotherapy and more than 1,000,000 intravenous infusions administered every day worldwide, **minimizing adverse events related to infusion therapy is another essential aspect** for both the patients receiving them and healthcare systems.

Infusion reactions manifest as allergic reactions and can involve a wide range of symptoms, affecting body systems such as the cardiovascular, central nervous, dermatological, endocrine, gastrointestinal, genitourinary and respiratory systems; they vary in severity from mild to life-threatening. Such reactions must be managed by a multidisciplinary team including nurses, pharmacists, physicians and various other healthcare providers. Healthcare facilities should provide staff with appropriate **training to ensure** prompt recognition and appropriate management of infusion-related reactions. Special emergency kits for infusion therapy reactions should be readily available, and particular attention should be given to appropriate premedication. This can be tailored to each patient's specific conditions while following the manufacturer's recommendations. Comprehensive protocols should be in place to guide the medical team in managing infusion reactions.

In the cancer patient population, the risk of complications related to infusion therapy is potentially higher, due to the presence of immunosuppression, thrombocytopenia and coagulopathy from both the disease and its treatment, which increases the incidence of infections and thrombosis. Furthermore, most of the treatments used are potentially harmful to tissues, with the consequent risk of extravasation and complications.[45]

Extravasation is a potential accidental complication associated with chemotherapy administration with serious consequences for the patient. It may result in tissue necrosis as-

sociated with several factors, such as the characteristics of the chemotherapy agent (e.g. vesicant potential, volume and concentration administered, rate and duration of infusion) or the patient (e.g. access to small or fragile veins, presence of lymphoedema or obesity, or history of multiple venous punctures). **Its prevalence varies between about 0.1-6% when administered through a peripheral catheter and between 0.26-4.7% if a central catheter is used**.[45]

In the analysis of the current situation in the IniciatIVas project, the incidence of **extravasations was 7 cases each year**.[45] Extrapolating this data to the total number **of centres in Spain that administer intravenous oncology therapy**, we calculate an **average incidence of 11 cases of bacteraemia per year for every 150 centres**.

The **GEDEFO-SEFH Extravasation Group recently published the results of a national survey on the management of extravasations**. This survey highlights the involvement of Spanish pharmacists in extravasation management, the use of physical and/or pharmacological measures as the method of choice in extravasation management, as well as discrepancies in the classification of the risk of tissue damage and management recommendations.[46]

Economic impact

A survey conducted in Spain among outpatient oncology services revealed an average of 7 extravasations per year, with an average of 3% resulting in serious consequences for patients. Extrapolating the costs associated with managing these events reported in US hospitals, **the approximate annual costs amount to €1,257,400 for resolving phlebitis and €15,635,000 for managing moderate extravasations. These costs increase almost tenfold in the case of severe extravasations, which undoubtedly imply a significant burden on the healthcare system**.[45]

4.4 SAFETY OF THE HEALTH PROFESSIONAL IN THE ODH: HAZARDOUS DRUGS

HAZARDOUS DRUGS

So-called **hazardous drugs (HD)** represent an important health risk factor for health professionals and especially for nurses who come into contact with and handle these drugs on a daily basis. The highest number of adverse events in hospitals, not only in terms of quantity but also in terms of morbidity and mortality, affects over 20 million European workers who are exposed to dangerous carcinogenic, mutagenic, and reproductive toxic drugs.[47]

The document *'Safer and Healthier Work for All',* published by the European Commission, states that **in 2012 there were more than 106,500 deaths from cancer attributed to exposure to carcinogenic substances in the workplace, making occupational cancer the "the first cause of work-related deaths in the EU" and, according to the ILO, "worldwide"**. It is estimated that there are more than 12.7 million health professionals in Europe potentially exposed to dangerous carcinogenic, mutagenic and reproductive toxic drugs, **of whom 7.3 million are nurses**. Furthermore, exposure in the workplace to these drugs has resulted in the deaths of 1,467 deaths professionals.[47]

According to this data, nursing staff are among the most exposed, with 316,094 registered nurses and midwives in Spain in 2019, but it is no less true that other healthcare workers, such as storage and reception staff, orderlies, pharmacists, doctors, cleaning staff, nursing assistants, among others, are also exposed to dangerous medicines. According to the **European Agency for Safety**

and Health at Work, hazardous drugs represent the most important chemical risk factor in healthcare. While the majority of occupational risks are covered by European and national legislation, there are gaps regarding the exposure of healthcare workers to hazardous drugs.[47]

The European Commission has recognized, in the case of anti-tumour medication that the risk to the health of health workers **depends on the level and frequency of exposure, the toxicity of the medication handled and the existence of inappropriate working practices, among other factors**.[47]

The studies carried out, especially regarding Nursing staff who prepare and administer them, have linked workplace exposure to **anti-tumour drugs with acute and/or chronic health effects**. In fact, an increase in genetic alterations in Nursing staff has been proven, **especially in outpatient hospital nurses**, who are the most vulnerable group because they **handle the largest quantities of drugs during the administering process, due to their heavy patient load of hemato-oncological or rheumatological patients receiving anti-tumour, antineoplastic, immunosuppressive and other drugs**.[47]

It is highly significant that the effects of exposure may be sub-clinical, not manifesting themselves over years or generations of permanent exposure. This is the case of occupational cancer, which is generated by exposure in the workplace and often takes several decades to appear. For example, a case of leukaemia diagnosed in a nurse today could be the product of repeated and frequent workplace exposures during the 1970s or 1980s. Unfortunately, in many cases, a link between work and disease has never been established, although numerous allegations of risk exposure are reported on a daily basis by professionals and representatives. The risk of exposure to a hazardous drug depends on multiple factors and the protection of staff must be adapted to each activity, as the precautions to be taken are different in each case.[47]

The European Commission has just published recommendations for the **prevention of risks associated with exposure to hazardous drugs for healthcare workers**.[48]

The guide provides an **outline of existing good practices and practical advice aimed at reducing workers' exposure to hazardous drugs**.[48]

LEGISLATION IN FORCE

HDs include cytostatic drugs that are prepared and administered to **oncology patients in ODHs**. Cytostatics are substances that kill cells, such as cancer cells. These drugs can stop cancer cells from dividing and growing and can shrink tumours.

The risk to healthcare professionals can come from a variety of routes, including:

- **Inhalation of aerosols and/or microdroplets** that are released during handling, preparation and/or administration due to ampoule breakage, system flushing, etc.
- **Direct contact through the skin and/or mucous membranes** which includes both contact with contaminated surfaces during handling, preparation and/or administration, and during collection and disposal of the waste generated.
- **Orally, through the ingestion of contaminated food or drink.**
- **Parenteral route**, by direct incorporation of the medication into the bloodstream (punctures or cuts caused by broken ampoules).

The protection of workers against this type of risk is regulated in **Spain by RD 665/1997 and its subsequent amendment RD 1124/2000**. Each autonomous community has its own regulations on healthcare waste management, which should be consulted.[47]

RECOMMENDATIONS

Given that the long-term toxic effects of exposure to these drugs have not been clearly established due to the occupational hazards involved in their handling and their consequences, **it is essential to adopt measures that help reduce this exposure and to ensure optimal working conditions as far as possible**.

Scientific societies have established **recommendations to minimize the risk** for healthcare professionals in the area of cytotoxics. The SEFH recommends:

- **The use of closed systems** (Closed Systems Transfer Devices (CSTD), airtight systems that prevent medication, when prepared and administered, from escaping to the outside.[49]
- **The monitoring of surfaces** to determine the presence of hazardous drugs and to evaluate the effectiveness of the safe drug handling programme in Pharmacy Services. The evaluation should include a study of the efficiency of engineering controls, work practices and cleaning and decontamination processes.[50]

The **National Council of Nursing** has also published guidance on regular monitoring of work surfaces in Nursing areas, in particular medication administration areas in ODHs.[47]

The ONCOptimal survey result shows that only **62% of OHDs use CSTD** systems. **12% still use syringes and needles**, which is the system that poses the greatest risk to health workers.

Regarding the monitoring of surfaces, only **45% of the facilities perform regular monitoring of surface contamination by cytostatic medication, and of these**, 74% conduct these checks with a **frequency of more than one month**.

4.5 PATIENT EXPERIENCE IN THE ONCOLOGY DAY HOSPITAL

The patient and their **experience must be the centre around which ODH is organized**, with the **best safety standards and maximum comfort** for patients.[9]

The health services of the Autonomous Communities must provide ODHs with sufficient **human, technological and organizational resources** to improve efficiency and reduce bottlenecks. This would both shorten the **waiting times for receiving oncological medication and humanize the process, reducing patients' stay times in the day hospital**.[51-53]

In the analysis of the situation in Spain, **248 patients** (82% women) were interviewed, with an average age of 47 years. They had breast cancer (52%) and were on sick leave (27%).

Table 13 shows the results of the national ONCOptimal survey in relation ODH appointment scheduling and admission management.

Table 13. National survey results. Patients. ODH appointment scheduling and admission management

	%
Available appointment days for the administration of oncology medication at the ODH are Monday to Friday.	93.1
Available appointment hours for the administration of oncology medication at the ODH are morning and afternoon	73.2
Receives electronic notification and appointment reminders via SMS, mobile app, email, phone, etc.	57.7

Does not receive electronic notification and appointment reminders via SMS, mobile app, email, etc.	51.2
Appointments for treatment are usually scheduled on the same days as their appointments with the specialist	73.4
Has not received notification of appointment cancellation or change of appointment day or time from the ODH.	78.6
Has not had to cancel or change the day and time of the scheduled appointment	80.2
Is not given a bar-coded identification bracelet at admission	56.6
Does not receive information during the stay in the ODH.	59.3

The majority of participants indicate that the waiting time from their arrival at the ODH:

- Until entry or admission to the ODH: less than 15 minutes (55%).
- From admission to clinical analysis when performed on the same day: 15-30 minutes (39%).
- Until receipt of the results of the analysis and consultation with the specialist: more than 1 hour (76%) .
- From consultation to the start of administration of the medication: more than 1 hour (52%).
- Until administration of oral treatments and supportive care: more than 1 hour (40%).

The majority of participants (30%) say that, several times, the administration of medication has been delayed with regard to the scheduled time

According to the patients in the ONCOptimal survey, the approximate time from diagnosis or surgery to the start of oncology medication administration is **less than 30 days (Table 14). Table 15** shows **the waiting times in the ODH** as answered by the patients. A considerable percentage (27%) of patients indicate a waiting time of **over 30 days**, with 2% indicating a waiting time of over 90 days.

Table 14. National survey results. Patients. Waiting times

	%	%
< 7 days	20.6	
7-14 days	10.7	
15 days	9.1	67.5
21 days	9.1	
28 days	5.8	
30 days	12.3	
31-45 days	12.8	
46-60 days	6.2	
61-75 days	3.3	
76-90 days	2.5	26.7
91-120 days	0.8	
121-150 days	0.4	
> 151 days	0.8	
I don't remember	5.8	5.8

Table 15. National survey results. Patients. Waiting times within the ODH					
	Until entry or admission to the ODH	From admission to clinical analysis when performed on the same day	Until receipt of the results of the analysis and consultation with the specialist	From consultation to the start of administration of the medication	Until administration of oral treatments and supportive care
15 to 30 minutes	18.8	39.2	7.7	14.3	15.1
30 minutes to 1 hour	15.8	17.5	14.1	23.8	20.5
More than 1 hour	9.9	9.3	76.1	52.4	39.7
Less than 15 minutes	55.4	34.0	2.1	9.5	24.7
TOTAL	100.0	100.0	100.0	100.0	100.0

Patients indicate that they have **psychological support** at the ODH (41%), and **tend to be accompanied (58%)** throughout the working day, and the costs involved are:

- Transport: less than €5 (35%).
- Parking: between €5 and €10 (48%).
- Meals: more than €10 (37%).

With regard to how the patients perceive communication and empathy, they indicate that the health professionals who attend to them introduce themselves by name, smile at them when they speak and when they see them, explain the procedures to them while they are taking place, resolve their doubts during their stay, listen to them and take their opinions into account when making decisions. They also ask them how they are feeling and reassure them. In general, **they are completely satisfied**, every time they go to the ODH for treatment.

However, in most of the ODHs surveyed (80%), **there is no procedure in place to assess the patient's experience**. Healthcare professionals indicate that key points that would improve the patient's experience include discussing expectations regarding waiting times (Medical Oncology and Hospital Pharmacy) or requesting information regarding the well-being of the patients (Nursing).

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5 SOLUTIONS

5.1 NEW TECHNOLOGIES

The **introduction of new technologies is the most viable and cost-efficient solution to reduce waiting times** in Spanish ODHs, as well as to improve patient safety. Of the possible new technologies that could be adopted, the most cost-effective would be the implementation of electronic drug traceability systems in ODHs. The **traceability of drugs in ODHs includes the following systems** which vary by health area:[1,2]

- **Electronic prescribing systems** with clinical decision support systems and protocols.
- **Electronic preparation system**, connected to electronic prescription and administration systems, with dose calculation aids, volumetric and gravimetric control systems, and product identification using codes or image recognition, for example.
- **Bar code medication administration** (BCMA) systems for patient drug/dose verification prior to medication administration, connected to the patient's health record.
- **Smart pumps** with safety systems and microbore infusion systems to reduce overall administration times, connected to the electronic administration system.
- **Comprehensive and integrated systems** to enable registration and traceability throughout the process.

The **GEDEFO-SEFH strategic plan 21/25** aims to provide the best pharmaceutical care to all oncology and haematology patients, regardless of whether they receive oral or parenteral antineoplastic treatment, whether in care or research protocols, and in any care setting (inpatient, day hospital or outpatient). Regarding organization, processes, and technological resources, the following aspects are considered[3]:

- **Comprehensive system** that includes the sub-processes of prescription, validation, preparation, day hospital scheduling, administration and outpatient dispensing of medicines. Understood as an information system based on information and communication technologies.
- **Integrated system** that is properly interconnected with other hospital information system tools (such as the electronic health record or the pharmacy logistics system, among others) and the different levels of care.

The **European Commission** has developed a compliance standard for future specialized cancer centres in the European Union, known as Comprehensive Cancer Centres. All of them will have to comply with the accreditation system in order to join the CCCN. The standard states that future CCCs should have available **"An electronic medication prescription and administration system that controls the entire medication process and that is linked to the patient's health record system**.[4]

This is essential for the implementation of actions aimed at **improving the safety** of the system of medication use in the patient.[3]

AREA: MEDICAL ONCOLOGY

Computerized Provider Order Entry (CPOE)

The available clinical evidence[5-7] highlights the **highly promising effectiveness of CPOE** in minimizing errors, not only in prescriptions, but also in the preparation and administration of medication.[2]

It is estimated that at least a quarter of all medication-related harm could be prevented through the use of CPOE. The **electronic entry of drug prescriptions and protocols** via CPOE prevents errors resulting from incorrect manual transcriptions.[2,8]

The ultimate goal of CPOE is to improve the safety, quality and value of patient care. CPOE systems often include features such as **dose proposal according to patient weight, clinical decision support information (need for dose adjustment in case of renal and/or hepatic insufficiency) and alerts on allergies, interactions, duplications, maximum doses, etc., which can further reduce errors**.[1,2,8]

Likewise, **CPOE provides a significant improvement in prescribing and dispensing efficiency** in ODHs versus manual procedures **saving an average time per prescription of 10 minutes**.[9]

According to the results of the survey, the degree of implementation of these **computerized or electronic oncology medication prescription systems is 95%**.

AREA: HOSPITAL PHARMACY

Electronic medication preparation systems

The incorporation of new technologies by Hospital Pharmacy Services in the treatment preparation process aims to **maximize the quality, safety and traceability of the antineoplastic drug preparation process**.[10]

Electronic systems that control the processing of medication are classified as:[2,10-13]

- **Volumetric systems:** these systems are connected to the prescription system by scanning the bar code of the medication to be used in the preparation, allowing for quantitative verification that it is correct. Some of these systems are connected to a camera that records and displays the volume in the syringe that is added to the IV solution. In more sophisticated systems, doses can be validated.
- **Gravimetric systems:** gravimetry is a quantitative method of determining the amount of substance required by measuring the weight of the substance on a scale. These systems, which are also connected to the prescription system, make it possible to verify, as in the previous case, that the medication to be used in the preparation is the correct one, the one prescribed, but they also ensure that the dose prepared is the correct one.

Qualitative identification, by scanning the bar code, can be performed with both volumetric and gravimetric systems. Qualitative identification ensures that the correct vial or solution is used. There are also qualitative methods that use vial imaging[11-13].

The operation of a gravimetric system for the preparation of medication is as follows:[2,10]

- **Entry to the system** to perform the preparation of the medication.
- **Validation of the active substance, excipient or vehicle** by means of the bar code reader. This validation completely eliminates the possibility of error in the selection of the active substance, excipient or vehicle to be added.

- **Weighing of the components of the preparation**, including the primary packaging material to be used. The system allows the densities of the liquids to be included as well as the acceptable tolerance range of the weighed product and informs the healthcare professional, step by step, of the processes to be carried out with the preparation in mind at each stage.
- **Generation of an identification label**. A label is generated before the medication is prepared. Reprinting the label with the exact final dose is not mandatory; the decision not to print it may be taken if it falls within the previously defined ranges to avoid confusion in the event it doesn't exactly match the prescription made by the doctor.

The system does not allow the preparation process to continue if, at any point in the preparation, the exact dose has not been processed (within the internally agreed-upon deviation percentage).[10]

Gravimetric control systems have a **great potential for reducing errors in the identification of the medication used and for reducing dosing errors**. They are also highly efficient.[2,10]

According to some studies on the efficiency of these gravimetric electronic preparation systems, the efficiency of the Pharmacy service in the preparation of medication increases by **35%. In other words, with the same available human and structural resources, up to 35% more preparations of oncological medication could be performed in ODHs**.[14,15]

According to the results of the survey, the degree of implementation of these **electronic medication preparation systems in** Spain is only 48%, and of these 55% do not have a gravimetric preparation system.

Moreover, **communication between Medical Oncology and the Pharmacy Service is done using paper in 18% of cases**, even though 95% of the centres have an electronic prescription system.

AREA: MEDICATION ADMINISTRATION AND COMMUNICATION WITH PHARMACY SERVICE

Electronic connection systems between the ODH and the pharmacy service

Existing electronic systems **allow the pharmacy service that prepares the medication to be integrated with the day hospital administration area**.[10] The Pharmacy service has full visibility of the treatments planned for the day, treatments confirmed for other days, cancellations for any reason, etc., and can plan its activities efficiently. Likewise, the medication administration department has visibility of the status of the preparation and dispensing of medication. This avoids continuous calls to the pharmacy department for updates on the status of preparations, which causes stress and reduces the efficiency of both departments: pharmacy and medication administration. However, there are currently no studies quantifying the efficiency in number of additional treatments delivered derived from such systems. Some systems allow the ODH to inform the pharmacy that the patient has arrived at the ODH, so they can prepare the treatment, especially for treatments with very short stability.

The results of the survey show that the method of communication used between the **Oncology consultation and the Hospital Pharmacy Service** to receive medication prescriptions is **electronic in 80% of cases**.

Electronic systems for resource planning

Technological changes have occurred simultaneously with significant healthcare changes. For several years now, the **new healthcare models and new healthcare formulas** (telemedicine, monitoring systems, hospitalization at home, etc.) in developed countries are constantly being reviewed in an attempt to meet the demands for increased healthcare services, improved quality, and doing so within the existing resource constraints.[16]

ODHs already use electronic systems that allow for resource planning for chairs or beds. Through these systems, it is possible to reserve and assign chairs or beds to patients for the administration of their treatment. This resource planning is carried out automatically, but can also be done manually for special requirements. These systems **greatly improve the efficiency of chair and bed use in the ODH and significantly reduce the number of empty chairs or beds due to resource planning errors**.[10] However, there are currently no studies quantifying the efficiency in number of additional treatments delivered resulting from such systems.

According to Medical Oncology, the **areas for improvement in communication between the staff of the different services** of the ODH are related to interactions and treatment after-effects. According to Nursing, they are related to changes in treatment. According to Hospital Pharmacy, they are related to treatment after-effects.

Bar code medication administration - BCMA

These **identification systems** use bar code scanning of the patient's wristband and of the medication. The system then verifies that the medication, patient, timing, and route of administration are correct.[17-19] it can also connect to smart pumps, the nurse's handheld PC (PDA), etc.

The administration of medication using the bar code identification and scanning system **has proven to be an effective solution in preventing medication errors associated with errors in identifying the correct patient, correct medication, correct timing, correct administration time and correct route**, as well as efficiently controlling patient information and improving the documentation process.[17-19]

It has also been shown to improve the efficiency of Nursing staff. In a European study,14 the average verification time taken by nursing staff in the ODH before administering medication to the patient amounted to 6 minutes. After the implementation of a bar code identification and scanning system, it amounted to 41 seconds. **This represents a reduction of more than 6 times the average verification time per patient, the equivalent of a time saving per nurse of 42.5% per year. For an ODH with 55 treatments per day, the Nursing time saved time equates to almost 5 hours per day of Nursing staff efficiency**.

According to the national survey, the degree of implementation of "patient/ medication / pump" bar code identification systems in Spain is only 30%.

Smart pumps

Traditionally, mechanical forms of drug infusion devices have been used to infuse drugs intravenously. The advent of smart infusion pumps has allowed clinical decision support tools to be integrated into the medication administration process.[20]

Clinical decision support provided by medication error reduction software (dose error reduction software, DERS) connected to infusion pumps includes **alerts of minimum and maximum levels for dosage, concentration, infusion times, pressure, etc**. This support

can prevent incorrect programming of the pumps or keystroke errors such as programming 55 mg instead of 5 mg.[20]

Furthermore, the availability of complementary software enables both remote drug library updates and continuous monitoring of infusions, allowing nursing staff to anticipate alarms and the end of infusions. All of this results in an improvement in the efficiency of the ODH. The emergence of devices with **self-programming capability** is an element of improved efficiency and safety in the administration of medication, although their availability and uses remain limited at present.

Numerous studies have demonstrated the **benefits of smart pumps** in preventing programming errors.[21-23] In a study conducted at the Gregorio Marañón hospital in Madrid with smart pumps over 17 months, 92 pump programming errors were intercepted, of which 49% would have been moderate, serious or catastrophic for patients.[22]

The **software for these pumps** provides bi-directional feedback and allows monitoring of usage to identify critical points and opportunities for improvement to strengthen the system. Pump infusion data can be recorded on the prescription and downloaded to a computer for compliance auditing, including details of deviations from standard procedures.24 This enables the traceability of the entire pathway, including information on what has been prescribed, what has been prepared and the administration details, such as start and end times, who administered it, and any incidents.

Most of the administration of medication to oncology patients in ODHs is done by intravenous infusion. Nursing staff in ODH administration units must ensure that all infusions are administered correctly, while also performing many other clinical tasks.[25]

The increase in the number of chairs and beds makes it difficult for Nursing staff to control and monitor medication infusions. **Infusion hubs are already available (installed in the Nursing control areas of the ODH) that connect all infusion pumps on a unit or floor to a personal computer or tablet**. These systems allow a review of the history of infusion activities, including events, alerts, and alarms, which encompass issues like blockages, air in the line, pressure alarms, boluses, and notifications for when the infusion is nearing its end. They also enable the calculation of the patient's fluid balance, continuously incorporating the infusion volumes from the pumps and monitoring the pressures in the lines.[25]

Smart **infusion pumps** allow for **self-documentation**. The pumps automatically send all pump activity information to the unit's clinical system, which significantly improves the productivity of Nursing staff, especially in critical patient units. Manually documenting multiple infusions administered to critically ill patients requires a considerable amount of work and poses a high risk of errors. This would also improve the efficiency of ODH nursing staff. The administration systems connected to the pumps also facilitate this capability.

The new smart infusion pumps **allow for self-programming of the pump**. The infusion pumps are connected to the electronic prescription system, so they receive infusion instructions directly from the system, eliminating the need for nursing staff to manually programme them. These smart pumps improve the efficiency of nursing staff and eliminate pump programming errors.

In the analysis of the situation at the national level, the majority of ODHs surveyed **use infusion pumps for the administration of chemotherapy treatments** (average of 34 infusion pumps per centre) but **do not have dual-channel infusion pumps (57%)**. The programming of infusion pumps is done manually (84%), they have sufficient infusion pumps to deal with unscheduled patients requiring unplanned care to ensure continuum of care

(84%), and there is no protocol in place to manage requests for new infusion devices for the administration of chemotherapy treatments (41%).

Microbore infusion systems

Microbore infusion systems would allow for optimizing the flush times between medications administered in a chemotherapy treatment, potentially reducing the total administration times.[26]

In the comparative evaluation of infusion times for two infusion devices in the ONCOPTIMAL project, the formulated hypothesis considered that **the use of the BD BodyGuard™ Duo infusion pump and the use of microbore primary and secondary infusion systems (1 mm) can reduce the total infusion time for chemotherapy protocols compared to using standard-calibre systems (3 mm)**. This reduction is attributed to **a shorter flush time between medications, thus reducing the total infusion time**. This improvement in time and efficiency **could be translated into a surplus of time that allows for optimizing the use of treatment chairs in ODHs where there is a constant and increasing demand for patients to be treated**.

Overall, drug infusion times for both devices (**Table 16**. ALA – BD Alaris™ GP Plus Guardrails & DUO – BD BodyGuard™ Duo) are very similar while **the flushing times, given the smaller purge volume of the microbore systems (for BD BodyGuard™ Duo), result in a significant time reduction, sometimes up to 50% of the time required for BD Alaris™ GP Plus Guardrails**.

Table 16. Results. Francisco de Vitoria University Study

equipo	FAR1	LAV1	FAR2	LAV2	FAR3	LAV3	Retirada	Total
ALA1-E1	00:30:46	00:04:10	0:30:56	00:04:07	0:25:00	00:03:53	0:00:29	01:39:21
ALA1-E2	00:29:08	00:03:51	0:29:44	00:03:00	0:24:53	00:03:49	0:00:00	01:26:04
ALA1-E3	00:29:40	00:02:02	0:30:02	00:03:19	0:24:00	00:04:17	0:00:12	01:33:32
ALA2-E1	00:30:00	00:04:02	0:30:50	00:03:49	0:24:41	00:03:47	0:00:12	01:37:21
ALA2-E2	00:30:26	00:34:55	0:30:14	0:04:40	0:24:18	0:03:41	0:00:00	02:05:54
ALA2-E3	00:30:11	00:03:51	0:30:20	00:03:43	0:24:29	00:04:09	0:00:19	01:37:02
DUO1-E1	00:30:38	00:02:48	0:29:44	00:02:33	0:24:23	00:02:10	0:00:16	01:32:32
DUO1-E2	00:30:43	00:03:07	0:31:30	00:02:13	0:23:40	00:02:10	0:00:00	01:28:56
DUO1-E3	00:29:20	00:01:58	0:29:57	00:01:58	0:24:03	00:02:00	0:00:13	01:29:29
DUO2-E1	00:30:13	00:02:19	0:30:13	00:02:08	0:24:20	00:02:16	0:00:09	01:31:38
DUO2-E2	00:30:20	00:02:00	0:30:10	0:02:10	0:24:12	0:02:13	0:00:00	01:29:40
DUO2-E3	00:30:19	00:02:18	0:30:17	00:02:14	0:24:12	00:02:14	0:00:20	01:31:54

Measuring statistically and calculating the mean times to infuse the entire standard chemotherapy treatment, **a reduction of nine minutes and eleven seconds per chemotherapy protocol administered (00:09:11 or 551 seconds)** is observed, as shown in table 17.

Table 17. Results. Francisco de Vitoria University Study

BD Alaris GP Plus Guardrails	BD BodyGuard Duo
Average in hours	**Average in hours**
01:39:52	01:30:41

In conclusion, based on the times collected, **the use of intravenous infusion devices with primary and secondary microbore systems such as those available in BD BodyGuard**

Duo, show a reduction in overall infusion times of nine minutes and eleven seconds per session (09:11). If we were to calculate the time reduction for a typical chemotherapy unit: **12 chairs, with a turnover of 1.5 patients per chair/day: 18 patients/day = 02:45:30 time saved**.

This would mean being able to accommodate at least one more patient per day, receiving a treatment such as the one tested (with a total duration of around 01:30:00), resulting in an additional **5 patients per week and approximately 260 more patients per year (52 weeks)**. This would significantly contribute to addressing the growing pressure on these units due to the continuous diagnosis of new cases and the increasing number of cancer patients requiring intravenous chemotherapy treatments. These units are facing challenges with reduced resources in terms of both numbers and their capacity to accommodate this increasing demand.

Infusion systems

There are numerous types of **vascular catheters with different characteristics** depending on the method of insertion, indication, material, calibre, length, location, tip termination, number of lumens they contain or associated risk of complications. These various infusion access points are designed to **prevent issues related to infusion therapy**. In general, based on their location, catheters can be classified as either **peripheral or central**, and their selection is determined by various factors such as the duration of use, the pharmacological nature of the infusion, the specific characteristics of the patient, or the assessment of potential risks associated with their use.[27]

Peripheral venous catheters

Currently, there are two fundamental types of peripheral venous access catheters: short catheters **(3 to 6 cm in length) and midline catheters (MVC), Midline ((8 and 25 cm)**, which **offer the possibility of extending the duration of infusion therapy**.[28-30] Midline catheters allow for the administration of fluids with low irritant capacity for a maximum period of 7 days and have been associated with **lower rates of phlebitis** compared to short catheters.[28,30]

According to available studies, complications associated with the use of peripheral catheters occur in **35-50%** of cases before the end of the expected time of use, so it is routinely recommended that they be replaced **after 72-96 hours**.[31-33]

Central venous catheters

Central venous catheters (CVCs) are used for a variety of purposes, such as infusion of drugs and blood derivatives, haemodialysis, blood sampling and haemodynamic monitoring, **and can remain in place for weeks or even years**. Depending on the method of insertion, they are classified into **peripherally inserted central catheters (PICC) and centrally inserted central catheters (CICC)**. In oncology, the most commonly used are PICCs, tunnelled central catheters like Hickman or Broviac (with cuff) or non-tunnelled (without cuff), **and reservoir-type devices**.[28,34]

PICCs are considered an effective alternative to traditional central catheters for numerous indications **(Table 18)**, both short- and long-term, so their use in routine clinical practice has been growing due to their safety, ease of insertion and low number of complications.[1,27,28,35]

A study conducted in Spain showed that nurse-guided ultrasound cannulation of PICC lines in oncology and haematology patients is associated with a **high insertion success rate (89.7%), with a mean catheter dwell time of 92 days and very low complication rates**.[36]

Table 18. Main indications for PICCs according to the MAGIC guide (Michigan Appropriateness Guide for Intravenous Catheters)[29]	
1	Administration of chemotherapy in cycles of ≥ 3 months.
2	Infusion of agents compatible with peripheral administration that require administration for ≥ 6 days.
3	Infusion of agents requiring central venous access for any period of time.
4	Central venous monitoring in critically ill patients for ≥ 15 days.
5	Frequent venous punctures for ≥ 6 days.
6	Intermittent infusions or infrequent phlebotomy in patients with difficult venous access for ≥ 6 days.
7	Infusions or palliative treatment in terminally ill patients.

Table adapted from Chopra V, et al. "The Michigan Appropriateness Guide For Intravenous Catheters (MAGIC): Results From A Multispecialty Panel Using The RAND/UCLA Appropriateness Method". Ann Intern Med. 2015 Sep 15;163(6 Suppl):S1-40.

CICCs are catheters that are inserted from a central vein such as the subclavian, jugular or femoral vein and whose distal end is placed in the superior or inferior vena cava, near the junction with the right atrium. Catheter replacement should be done on clinical indication and preferably at a new venous puncture site, as planned replacement strategies have shown no difference in infection rates, but an increased risk of mechanical complications.[36]

Implanted venous access devices **consist of a reservoir** from which a central catheter is threaded into a central vein near the heart. It is inserted subcutaneously, usually in the chest or upper arm, through a surgical procedure. **The reservoir is accessed through a needle, which is removed at the end of treatment and thus remains completely isolated from the outside of the body**.[28,34] This type of device is particularly indicated in **patients who require long-term intermittent venous access, such as oncology patients undergoing chemotherapy on a weekly ormonthly basis where peripheral venous access is highly inadequate**.[36]

The choice of **type of central catheter** for each situation should be based on criteria such as **treatment duration, patient characteristics, type of infusion** and **device characteristics**, with dwell time as one of the most determining factors.[32]

The **ECO-SEOM-SEEO** has recently published recommendations aimed at addressing the needs that arise in clinical practice in this field. These recommendations are designed to become a **tool that can be integrated** into electronic systems to provide **consistent guidelines for the management** of oncology patients who require venous access, optimizing the use of available healthcare resources while ensuring the highest levels of safety and quality of life for the patient.[28]

The document notes that, in some centres, **intravenous therapy teams** are available for oncology patients, but a considerable percentage of these centres do not have said teams (though teams are available for other, non-oncology patients), nor do they have a **record of adverse events associated with this type of therapy**.[28].

In the case of those oncology centres that do have these records, safety data are primarily collected through the **Oncohaematology Day Hospital (92.9%)** and, to a lesser extent, by the inpatient units (39.4%).[28]

Point-of-care testing.

Various technological advances and the integration of microtechnology into compact instruments have made it possible to bring certain laboratory tests closer to the patient **(Point-of-care testing)**.[37-39]

Performing these tests at the patient's point of care is an option that allows for the determination of specific biological parameters where and when they are needed. At the same time, it offers a new perspective on the role of the clinical laboratory and the potential for enhancing its range of services. Sometimes, **obtaining a reliable result immediately can be of enormous importance for sound clinical decision making**.[37]

In the case of **chemotherapy treatments**, to reduce the risk of renal toxicity, certain parameters must be met before administering them and a blood test must be performed beforehand. Because **laboratory tests may take longer than Point-of-care** methods to obtain results, physicians need to collaborate with the clinical laboratory to ensure that an accelerated process is implemented to avoid delays in chemotherapy administration.[40]

The use of these systems would reduce the average length of stay of patients in the ODH by approximately 2-3 hours, improving efficiency and increasing patient satisfaction. **According to the survey only 46% of ODHs have point-of-care systems**.

Tables 19, 20 and 21 show the results of the national ONCOptimal survey in relation to new technologies in patient management, oncology medication and medication errors.

Table 19. National survey results. New technologies in patient management

Medical oncology		%
Does it have electronic systems to alert patients on the screen in the waiting room?		
	Yes	64.3
Does it currently have a computerized or electronic system for prescribing cancer medication?		
	Yes	95.2
If so, does the system include information on, among other things, drug interactions, drug allergies, duplicate therapy, or dosage adjustments based on liver and kidney function?		
	Yes	70.0
Does it currently have an electronic health record management system?		
	Yes	97.6
If so, does this system include or integrate the patient's analytical data?		
	Yes	90.2
If so, is the ODH activity reflected in the patient's electronic health record?		
	Yes	80.5
Nursing		**%**
Are patients provided with electronic identification on arrival at the ODH by means of a bar-coded wristband?		
	Yes	58.4
Does the ODH have a blood collection point (point of care) that allows the patient to remain in the scheduled chair?		
	Yes	45.5

Table 20. National survey results. Healthcare professionals. New technologies. Oncology medication	
Nursing	%
Does the ODH have a decision algorithm to choose the most appropriate catheter according to the diagnosed treatment and its duration?	
Yes	42.6
Indicate the type of venous access and percentage (%) used	
Peripherally inserted central catheter (PICC)	33.5
Subcutaneous reservoir	32.4
Peripheral catheter	34.0
Butterfly	9.6
With safety system	37.2
Short needle and cannula catheter	43.6
Medium length	7.4
Other	2.1
Indicate the method used and percentage (%) for the administration of chemotherapy treatments.	
Infusion pump	85.4
Volumetric	86.8
Syringe	13.2
Infusion by gravity	14.6
Does the ODH have dual-channel infusion pumps?	
Yes	42.6
Does the ODH use "patient/medication/pump" bar code identification systems?	
Yes	29.4
Are infusion pumps programmed manually or automatically?	
Manually	83.8
Automatically (choice of specific programme)	16.2
Select from the following options related to how the prescription is checked against the medicine received and the patient to whom it is to be administered	
Visual/verbal check by asking the patient their name	52.2
Visual/verbal check, though the patient has a wristband or other identifying element	32.2
Automatic check by scanning the bar code	13.9
Other	1.7
Does the ODH have sufficient infusion pumps available to care for unscheduled patients requiring unplanned care, ensuring their continuum of care?	
Yes	83.8
Does the ODH have a protocol in place to manage requests for new infusion devices for the administration of chemotherapy treatments?	
Yes	30.9
Are cytostatic surface contamination controls carried out regularly in the ODH?	
No	67.6
Hospital Pharmacy	%
What method of communication is used between the Oncology consultation and the Hospital Pharmacy Service to receive medication prescriptions?	
Electronic (digital)	80.0
On paper	18.2

Table 20. National survey results. Healthcare professionals. New technologies. Oncology medication	
Does the ODH have a system of pharmaceutical validation for the prescription of oncology treatments?	
Yes	100.0
What method do the Hospital Pharmacy Service and the laboratory use to communicate with each other?	
Electronic (digital)	85.2
On paper	9.3
Does the preparation process have any kind of support?	
Preparation robot	3.7
Standardized preparation software	48.1
Manual process without technical support	42.6
Other	5.6
Does it have an automation system for all necessary calculations (size, number of vials, volume, etc.) for the preparation of medication?	
Yes	92.2
What systems are used to avoid exposure of staff to cytostatics during preparation?	
Needles and syringes	11.6
Preparation systems with a filter	24.6
Closed system drug transfer (CSTD)	62.3
Other	1.4
What kind of dispensing systems are used for the delivery of medicines from the Hospital Pharmacy Service to the ODH?	
Stock or hospital floor medicine cabinet	45.7
Unit dose dispensing system for medicines without assisted electronic prescription	4.9
Unit dose dispensing system for medicines with assisted electronic prescription	32.1
Automated dispensing system without assisted electronic prescription	3.7
Automated dispensing system with assisted electronic prescription	12.3
Other	1.2
Are cytostatic surface contamination controls carried out regularly in the medication preparation area?	
Yes	45.1
Weekly	13.0
Fortnightly	13.0
Monthly	39.1
Quarterly	13.0
Six-monthly	13.0
Annually	8.7

Table 20. National survey results. Healthcare professionals. New technologies. Oncology medication	
Is there a system in place to prioritize certain preparations according to urgency or duration of treatment?	
Yes	74.5
Is there a system in place to manage the inventory of reusable drug vials based on their expiry date/stability once opened?	
Yes	70.6
Once ready to be administered, indicate the way in which the treatment is dispensed until it reaches the patient.	
Internal or automated delivery system	3.9
Orderly	74.5
ODH staff	15.7

Table 21. National survey results. Healthcare professionals. Medication errors	
Nursing	%
Are there any delays in the administration of treatment from the patient's scheduled appointment time?	
Yes	76.9
Does the ODH have a system for monitoring the delay in the start of treatment?	
Yes	26.2
Are any incidents that may occur in the administration of the treatment monitored and controlled?	
Yes	92.3
How are such incidents recorded?	
Manual recording system	26.9
Electronic/digital system	70.5
Other	2.6
Indicate the average number of adverse events per month associated with the administration of oncology medication.	
Average	9.07
Estimate the type and percentage (%) per year of adverse events associated with the administration of oncology medication.	
Extravasation	29.4
Infusion-related reaction	31.6
Inflammation of the area of administration	21.5
Medication error (incorrect medication)	16.4
Other	1.1
Hospital Pharmacy	%
Are any incidents that may occur during the clinical validation of the prescription (dosage, drug, other) recorded in any way?	
Yes	76.0
Are any incidents that may occur during the preparation of the medication (dosage error, labelling error, spillage, etc.) recorded in any way?	
Yes	70.0

5.2 PROCESS IMPROVEMENT

RECORDING AND MONITORING OF MEDICATION ERRORS

There are **multiple plans and strategies** aimed at **preventing medication errors**, with varying levels of complexity, which constitute a **key strategy** for learning from errors and preventing their recurrence.[41-44]

To implement these strategies on essential elements is to have **multidisciplinary teams, with specific training in the case of nurses and electronic or computerized tools** to assess errors and implement changes if deficiencies are detected.[45,46]

In Spain, there are different **initiatives for recording and reporting events and medication errors** at national, regional and local level, such as ISMP-Spain, or the Spanish Pharmacovigilance system.[41]

There are multiple **error analysis methodologies** (Failure Mode and Effects analysis, Ishikawa diagram or cause and effect or fishbone diagram, London protocol, or root cause analysis) that help **identify vulnerable points** and, through strategies and recommendations, enable proactive management in the prevention of system failures.[41,47,48]

A report by the *Institute of Medicine* (IOM) stated that reporting systems are a key strategy for learning from mistakes and preventing their recurrence. This report states that reporting systems can serve two functions: they can be geared towards **ensuring social accountability** (where providers are held accountable for the safety of their practice) or, **alternatively or complementarily**, for providers to provide useful information on improving safety.[49]

The first approach is embodied in **mandatory and public reporting systems**. It focuses on adverse events that result in serious injury or death and focuses on providing a minimum level of protection to the public, serving as an incentive for institutions to avoid safety issues that could lead to fines and, ultimately, requiring organizations to invest in patient safety resources.[49]

The second approach is through **voluntary systems**. They focus on incidents (where no damage has occurred) or on errors that have resulted in minimal damage. Their aim is to identify vulnerable areas or elements of the system before harm occurs to patients and to train professionals on what has been learned through the analysis of multiple cases.[9] Both systems can play a positive role in improving the understanding of safety issues.[49]

In conclusion, **medication error recording and reporting systems** aim to be a **valuable tool** for **gathering information** to **learn from errors and prevent their recurrence**.[49]

RECORDING OF ADVERSE EVENTS RELATED TO INFUSION THERAPY

Patients with cancer require the **implantation of venous access devices** to meet their personalized therapeutic needs, which can be complex due to the nature of the medication and the state of the disease. Therefore, it is essential to have **standardization protocols and records** in place to ensure the best health outcomes and patient safety.[28]

Safety issues related to infusion therapy, such as **preventing extravasation, phlebitis and thrombosis** are a priority for healthcare professionals. The role of the various clinical areas involved in the prevention of such events **(Nursing and Medical Oncology Services) is fundamental**.[28]

PROTOCOLS AND ALGORITHMS FOR VENOUS ACCESS CATHETER SELECTION IN THE ONCOLOGY PATIENT

ODHs typically do not **have a validated protocol for infusion or algorithms for selecting the appropriate infusion set**, and those **centres that do have these procedures**, do not always comply with them.[28,36]

The lack of specific protocols and algorithms may be due to validation issues in the unit or hospital (64.9%) followed by other factors such as the lack of training of Nursing staff to manage PICCs (50.0%), insufficient information and awareness (41.9%) or even the lack of guidelines endorsed by scientific societies (29.7%).[28,36]

A **proposed algorithm for catheter selection** based on infusion characteristics, required duration of treatment and the patient's clinical condition is presented in the figure below **(Figure 3).**[28]

Figure 3. ECO-SEOM-SEEO algorithm for venous access catheter selection in the oncology patient[28]

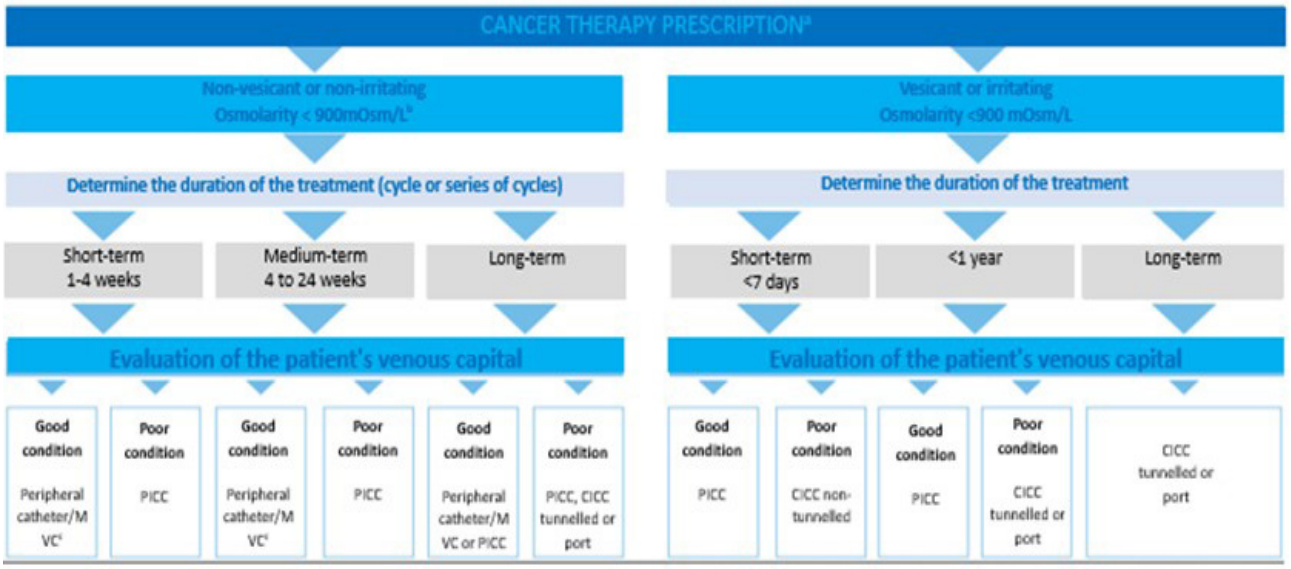

Figure adapted from Magallón-Pedrera I, et al. 2020.[28]

aOther criteria to consider include the number of lumens required, the required flow rate, the need for blood extractions, patient preferences, in-hospital availability, and the ability for self-care and continuation of treatment after discharge.bThe available literature varies with respect to recommendations on the osmolarity limit for solutions suitable for peripheral infusion. cThe maximum expected dwell time for the short-term peripheral catheters is 4 days and for MVCs, 28 days. The use of longer-dwelling devices should be considered based on the need to administer concurrent medications or perform blood extractions that require vascular access between treatment cycles.

IMPROVEMENT PROCESSES IN HEALTHCARE INNOVATION

Process improvement strategies in an ODH should be based on international recommendations for effectiveness and safety, institutional protocols and continuous improvement. Also crucial is ODHs is an **improved patient experience and quality of life, and increased professional satisfaction**.[50]

An example of this is the **project "HOPE, HOspital de Día PErsonalizado" of the Jiménez Díaz Foundation in Madrid**. Through the implementation of improvements in the care process, interdisciplinary work, and the utilization of technological innovation, they have managed to reduce **waiting times or "idle times"** and to do so incorporate key aspects, including **point-of-care systems to obtain blood test results in less than 5 minutes**.[50]

Patients have reported a **significant improvement in their cancer care experience**, with an increase in the NPS *(Net Promoter Score)* (a tool that indicates patient satisfaction by measuring their willingness to recommend a service they have used) of the Day Hospital from 75% to 95% between 2018 and 2021, The changes that patients appreciate most positively are the reduction in waiting times and travel times, instant access to their care team through the Patient Portal –the hospital's own application– and, in general, **more patient-centred care**. With this project, not only has the objective of **reducing waiting times by 97%** been achieved, but it is hoped, as the project becomes more established, that this figure could reach 100%.[50]

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6 CONCLUSIONS

The ODH is a **care facility** of growing importance in healthcare systems due to the **increasing number of cancer cases in Spain**.[1]

The increase in demand for ODH services, as a consequence of the increase in the number of cancer cases, has not been matched by a **proportional increase in human resources (number of pharmacists, nurses, oncologists, etc.), material resources (e.g. beds, chairs, etc.) and technological resources (electronic medication tracking systems, smart pumps, point-of-care blood testing systems, etc.)**. This imbalance between demand and supply has led to **longer waiting times**[2] in the administration of oncology medication, reducing survival expectancy and the satisfaction of oncology patients.[2-6]

Healthcare administrators should be able to improve the provision of care in ODHs by increasing human and material resources. Ensuring that these professionals have training and knowledge in oncology and that nurses have specific qualifications or recognition in this field. However, said **improvement in resources is not without its difficulties**, primarily due to the shortage of human resources in the healthcare system and the financial challenges faced by healthcare administrators.

The safety of the health professional is crucial. HDs include cytostatic drugs that are prepared and administered to **oncology patients in ODHs**. The long-term toxic effects of exposure to these drugs have not been clearly established due to the occupational hazards involved in their handling and their consequences, **but it is essential to adopt measures that help reduce this exposure and to ensure optimal working conditions as far as possible**.[7-10]

Scientific societies have established **recommendations to minimize risk** for healthcare professionals in the area of cytotoxics such as the **use of closed systems** *(Closed Systems Transfer Devices (CSTD)*, or the **monitoring of surfaces** to determine the presence of hazardous drugs and to evaluate the effectiveness of the safe drug handling programme in Pharmacy Services.[7-10]

Furthermore, **patient safety in ODHs is also a top priority**. Adverse events in cancer patients are more prevalent than in other types of patients and have a high human, social and economic cost. The main adverse events that jeopardize patient safety in the administration of medication to oncology patients in ODHs are: **medication errors, catheter-related infections and those related to infusion therapy**.[1,11]

The **introduction of new technologies and new healthcare organization methods is the most viable and cost-efficient** solution to **reduce waiting times** in Spanish ODHs, as well as to improve patient safety. Of the possible new technologies that could be adopted, **the most cost-effective would be the implementation of electronic drug traceability systems** in ODHs.[1,12]

Table 23 lists the **technologies available in ODHs and their impact on the efficiency and reduction of waiting lists** for the administration of oncology medication in Spain. Table 24 summarizes the **adverse effects on cancer patients in ODHs, their economic impact and possible solutions**.

The degrees of implementation of the different systems are as follows:

- **Electronic prescription systems: 95%.**
- **Electronic medication preparation systems: 48%.**
- **Bar Code Medication Administration (BCMA): 30%.**
- **Microbore pumps: reduction of total infusion times by nine minutes and eleven seconds per session.**
- **Point-of-care testing: 46%.**

The degree of implementation of the prescription systems is approximately 100%. **However**, the degree of implementation of **standardized preparation systems is only 48% and bar code identification and scanning systems-BCMA only 30%**.

As the evidence indicates:

- Electronic preparation systems can improve the efficiency of pharmacy staff by 35%. The implementation of such systems would mean a reduction of 8 days in the average waiting period for medication in Spain.
- **Bar code identification and scanning systems-BCMA** can **improve nursing staff efficiency in medication administration by 43%**. The implementation of such systems would mean a **reduction of 8 days** in the average waiting period for medication in Spain.

Meanwhile, the survey shows that **the average waiting time**, from arrival at the ODH to blood collection is 1 hour and from **blood collection to obtaining lab results is 1.45 hours, and that only 46% of ODHs have a Point-of-Care system for blood collection. These systems allow the patient to remain in their chair and significantly reduce the time for blood sample collection and the obtaining of the lab results in less than 5 minutes**.

If around 280,000 cases of cancer are diagnosed each year in Spain, **around 70,000 patients would receive oncological medication in Spanish ODHs every month**. Out of 3,500 patients per day (estimated for 20 working days per month), 5,075 hours would be used to obtain lab results using traditional methods (3,500 patients x 1.45 hours). **If *point-of-care systems* were used, only 280 hours would be needed (3,500 patients x 0.08 hours), i.e. 4,795 hours would be saved**.

Table 23. Summary of technological innovations and their impact on the average reduction in the number of waiting days

SOLUTION	EFFICIENCY GENERATED	PENETRATION IN ONCOPTIMAL ODHs	AVERAGE REDUCTION IN THE NUMBER OF WAITING DAYS
Electronic prescription systems	10 minutes	95%	Not significant due to high penetration
Gravimetric medication preparation systems (Hospital Pharmacy)	35%	26%	8 days
BCMA: Bar code medication administration	43%	30%	8 days
		TOTAL	8 days
Microbore system	9 minutes and 11 seconds	--	260 more patients per year per HDO of medium-sized*
Point-of-care blood sampling systems	No evidence available	46%	4,795 hours

*Estimated time reduction calculation for a Chemotherapy Unit type: 12 chairs, with a rotation of 1.5 patients per chair/day: 18 patients/day.
Table prepared ad hoc by the authors.

Table 24. Adverse effects, economic impact and solutions

ADVERSE EFFECTS	MAGNITUDE OF THE PROBLEM	ECONOMIC IMPACT	SOLUTIONS
Medication errors	8.1 errors per 100 clinic visits	Spain: €2 billion	• CPOE: Computerized Provider Order Entry • Gravimetric medication preparation systems • BCMA: Bar code medication administration • Smart pumps: with DERS system (medication error reduction software) and infusion stations with centralization tablets, or pumps with self-programming capability
Infections, phlebitis and extravasations			Infusion therapy protocols with algorithms for infusion system selection based on medication, patient's venous status and duration of treatment.
Bacteraemia	0.05 and 6.8/1000/day	Spain: €17,221,000/year	
Extravasations	3,454/year	Spain: €15,635,000	
Phlebitis	1,049/year	Spain: €1,257,400	
TOTAL		Spain: €2,034 million	

Table prepared ad hoc by the authors.

In conclusion, **reducing the average waiting time** for the administration of oncological medication and **reducing the adverse effects** that may appear in this process **should be a priority for the healthcare administration in our country. Providing human and structural resources**, along with the introduction of **new technologies**, especially electronic traceability systems **are the most immediate and cost-effective solution to reduce waiting lists and improve patient safety**.[1,12] This report estimates that **the average waiting time in Spain for oncological medication could be reduced by 8 days**. Additionally, this technology **would also minimize the adverse effects of this process**, with an estimated saving for the Spanish health system of **€2.034 billion**.

The **introduction of new technologies is the most viable and cost-efficient solution to reduce waiting times** in Spanish oncology day hospitals, as well as to improve patient safety.

Computerizing the processes, **from** prescription, preparation, and administration would:

- Minimize adverse effects throughout the process.
- Reduce waiting time by 8 days
- Generate an estimated saving for the Spanish health system of €2.034 billion.

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7 RECOMMENDATIONS ONCOptimal SCIENTIFIC BODIES

HEALTHCARE MANAGEMENT

- Healthcare management is the cornerstone of the health system to function in terms of ensuring **health outcomes and efficiency**. Therefore, the **commitment of Health Managers and their professional approach** is necessary to understand the real needs, engage, and make decisions regarding the efficiency of the ODH.

DESCRIPTION OF THE ONCOLOGY DAY HOSPITAL

ACCREDITATION

- The **quality of care** for cancer patients should entail the **accreditation of ODHs**, through objective and well-known criteria and recognized systems.
- Specialists working in these care areas must have **specific skills, training and experience** in caring for oncology patients.
- Progress is needed in creating **new professional roles, accreditation diplomas or the development of specialization in this field**.
- Pharmacy services should accredit/certify, through external entities, the **activities of the pharmacotherapeutic process** (validation, preparation and dispensing). These tools make it possible to incorporate continuous improvement systems, periodically analysing processes in order to evaluate their efficiency, establish prioritizations, etc.

RESEARCH AND TRAINING

- ODHs should have a **separate clinical trials research unit**.
- The services involved should actively participate in the establishment of **technological or process innovation programmes in the oncohaematological area** by promoting **ongoing training, accreditation, as well as specialization in the area of specific professional training in oncohaematological pharmacotherapy**.
- Nurses, in addition to having the necessary qualifications to perform their work, should be trained in **cardiopulmonary resuscitation**, be familiar with working in an environment of **good clinical practice**, be **trained** in research, and trained in conducting pharmacokinetic studies, handling biological samples, hazardous drugs, and ensuring the biosafety of patients and professionals. They should also have extensive **care experience**, especially in the field of antineoplastic chemotherapy, with knowledge of adverse effects and precautions to be taken to maximize safety during administration.

STRUCTURE AND RESOURCES OF THE ONCOLOGY DAY HOSPITAL

HUMAN RESOURCES: NUMBERS, TRAINING AND COMMUNICATION

- The ODH should be a unit where the patient is **received, cared for and discharged in the centre itself**, although sometimes it may require the support of other services to perform a specific procedure (diagnostic imaging, etc.).
- The functional design of an ODH DO should take into account the varying health conditions of patients, and facilitate patient movement between different areas. The recommendations establish a minimum of **one nurse per shift for every 6 treatment posts with specific training and expertise in oncology**. However, the staffing recommendations are made based on the increasing number of patients and treatments/procedures that are progressively occurring in healthcare centres due to both population growth and the growing prevalence of treatable neoplasms across multiple lines.

BEDS/CHAIRS

- The structure and resources of ODHs **must conform to the quality standards** established by scientific societies and competent bodies, and adapt to the increasing processes of meeting patient needs.
- The stations can take various forms (beds and/or chairs), depending on the specific characteristics of each treatment and the patient's condition. Given the wide range of possible therapeutic modalities, **flexible structures** are required that can easily adapt to the changing needs of the patient and accompanying persons in the centre.

PROCESSES IN THE ONCOLOGY DAY HOSPITAL

BOTTLENECKS IDENTIFIED TO REDUCE WAITING TIMES AND IMPROVE THE DIFFERENT PROCESSES: APPOINTMENTS, BLOOD SAMPLE COLLECTION, PREPARATION OF MEDICATION, ETC.

- **Waiting times at the bottlenecks identified in this report** should be reduced by incorporating new technologies, bringing certain processes closer to the patient, through home hospitalization and telemedicine, by carrying out sample collections and analyses prior to the patient's stay in the ODH, by optimizing treatments, etc.
- A **periodic review of the pathways** should be carried out by a multidisciplinary team, with the aim of optimizing the activity.
- An global **view of the process should be reflected** in the review of the pathways to find solutions that improve the patient's experience while ensuring their safety.

INCORPORATION OF NEW TECHNOLOGIES TO IMPROVE SYSTEMS

- Procedures and actions should be **standardized, computerizing the process**, from prescription, preparation and administration, to avoid errors throughout. Computerizing the process could reduce the average medication administration time in Spain by up to 8 days and result in savings for the Spanish healthcare system through the prevention of medication errors.
- ODHs should have a **comprehensive and integrated information system** and across different levels of care for managing the pharmacotherapeutic process for oncohaematological patients.

- The **electronic prescription system** for medication should be integrated into the patient's health record and should include all the necessary elements to assist in decision-making, as well as to assist in the validation and traceability of the entire process of preparation, dispensing and administration.
- The continuum of care using **digital technologies can strengthen the system and ensure greater accessibility for health professionals**.
- Case manager nurses or oncology nurses can take on **these new roles by following up** with patients prior to their visits or by addressing any queries that may arise after treatment.
- ODHs should have a validated **protocol for infusion system selection and algorithms for selecting the appropriate infusion set**, which should be of mandatory compliance. The creation of infusion therapy teams in ODHs is also recommended.

SAFETY OF THE HEALTH PROFESSIONAL IN THE ODH

- ODHs should have and use mandatory **closed systems for the preparation and administration of hazardous drugs** *(Closed Systems Transfer Devices*, CSTD), airtight systems that prevent medication, when prepared and administered, from escaping to the outside.
- ODHs should regularly **monitor the presence of hazardous drugs on work surfaces**, in both preparation and administration areas to determine the presence of hazardous drugs and evaluate the effectiveness of the safe drug handling programme, following the recommendations of the National Council of Nursing and the SEFH. The evaluation should include a study of the efficiency of engineering controls, work practices and cleaning and decontamination processes.

PATIENT SAFETY

PREVENTING ERRORS AND IMPROVING SAFETY

- ODHs should have a validated **protocol for infusion system selection and algorithms for selecting the appropriate infusion set** , which should be of mandatory compliance. The creation of **infusion therapy teams in ODHs is also recommended**.
- ODHs should undertake **improvement and prevention projects related to major patient safety issues**, such as medication errors, prevention of catheter-related infections, and therapy-related issues.
- The ODH should actively participate in the **development and maintenance of a risk management programme** applied to the prevention and resolution of health problems related to oncohaematological medication and participate **actively in the establishment of processes** for the safe management of antineoplastic therapy, taking into account not only patient risks, but also occupational risks, and covering all phases of the pharmacotherapeutic process.
- **Procedures and actions should be standardized, with the computerization of guidelines**, to prevent errors in reading and calculations. Electronic prescription is the safest method, and dual or multiple checks should be performed at each step of the process.
- Pharmaceutical interventions, carried out by all staff involved, **should be documented in the patient's health record and should be evaluated** in order to develop improvement measures.

PATIENT EXPERIENCE

- ODHs should have **procedures in place to assess the patient experience** and incorporate their expectations and needs into the improvement of their care process to ensure improved health outcomes.
- Further **research is required on satisfaction and quality of care received** from the point of view of the patient and family, to find areas for improvement.
- A more **humanized form of pharmaceutical care should be provided for the patient and caregiver on an ongoing basis throughout their care process**. This includes offering information about their treatment and adapting the pharmacotherapeutic plan to their health, considering individual needs, agreed-upon goals, and the necessary interventions to achieve them.
- **New technologies** should be incorporated to facilitate patient education, communication and active participation, as well as to allow the, access to information about their own process. This would include, for example, apps, mobile devices, telecare and platforms that open communication channels with patients.

8 ANNEXES

8.1 ANNEX 1: RESULTS OF THE NATIONAL SURVEY. HEALTH PROFESSIONAL

BLOCK 1. STRUCTURE AND RESOURCES OF THE ODH

Health managers

- The ODH has the figure of a coordinator (60%) (in 71% cases it is a nurse, mainly dedicated to operational management).
- It does not have an accreditation system for quality standards (60%)
- It does not have a separate clinical trials research area or unit (80%)

Medical Oncology

- The average number of patients per day attending ODH is 75
- The approximate number of walk-in patients seen at the ODH each day is 8

Nursing

- The average figures for the ODH are:
  - Chairs: 20
  - Beds: 5
  - Size (m2): 142
  - Infusion pumps: 34
  - Treatments administered: 40 in the morning and 23 in the afternoon
- The ODH:
  - Is normally open from Monday to Friday
  - Has specific staff providing information on consultations, treatments and side effects to patients (69%)
  - Does not have patient volunteers (49%)
  - Has procedures that are agreed upon and well-known by all staff for work related to healthcare processes (73%)
  - Has a planning system in place for available chairs and for managing or prioritizing the patient treatment schedules (59%) (mainly: activity analysis)
  - Has a crash cart (95%)
  - Blood product are transfusions performed (83%) (an average of 12 per week)
  - The activity of nurses is recorded electronically (88%).
  - The method of communication between the ODH and the laboratory (sample collection and delivery) is electronic (47%)
  - Administrative work, as opposed to patient care, accounts for 35% of the working day

Hospital Pharmacy

- Has a cytostatic biosafety cabinet (95%)
- Has a dispensing system for oral chemotherapy and external drugs (86%)
- Does not have an oral chemotherapy dispensing and supportive care clinic integrated into the ODH (51%)
- Pharmacist(s) responsible for validation, processing and dispensing of cytostatics have advanced specialized training (47%).

BLOCK 2. PATIENT MANAGEMENT

Health managers

- The ODH does not have a procedure to assess the patient experience (80%)

Medical Oncology

- The process of referring patients from other hospital services to the ODH is done by means of a referral report filled in by the responsible physician (43%)

Appointment management:

- The patient is notified (57%) and reminded (57%) of their appointment electronically via SMS, mobile app, email, etc.
- Once medication is prescribed, appointments for treatment are usually scheduled on the same days as appointments with the specialist (69%)
- The ODH does not have a quality control system in place to monitor the punctuality of patient appointments (48%)
- Has an electronic systems to alert patients on a screen in the waiting room (64%).
- Has a computerized or electronic oncology medication prescription system (95%), including information on, among other things, drug interactions, drug allergies, duplicate therapy, or dosage adjustments based on liver and kidney function (70%)
- Currently has an electronic health record management system (98%) which:
  - Includes or integrates the patient's analytical data (90%)
  - Reflects the ODH activity in the patient's electronic health record (81%)

Patient waiting times:

- The average time from diagnosis or surgery to the start of oncology medication administration is approximately 30 days (86%)

Nursing

- The ODH is equipped with:
  - Electronic identification of patients on arrival, by means of a bar-coded wristband (58%)
- Does not have a blood collection point (point of care) that allows the patient to remain in the scheduled chair (55%)
- The average waiting time (in hours) for the following processes is:
  - From patient arrival to blood collection: 1.00 hours

- From blood collection to availability of lab results: 1.45 hours
- From the time the lab results are available to the consultation with the patient: 1.16 hours
- From consultation to the start of administration of the medication: 1.59 hours
- Estimated duration of treatment: 3.06 hours
- Until dispensing to outpatients in the event they have a pharmaceutical consultation: 0.82 hour

BLOCK 3. ONCOLOGY MEDICATION

Nursing

- The ODH:
  - Does not have a decision algorithm to choose the most appropriate catheter according to the diagnosed treatment and its duration (50%)
  - Typically uses infusion pumps for the administration of chemotherapy treatments (85%) but does not have dual-channel infusion pumps (57%)
  - Does not use "patient/medication/pump" bar code identification systems (71%)
  - Infusion pumps are programmed manually (84%)
  - Checking of the prescription against the medicine received and the patient to whom it is to be administered is done visually/verbally by asking the patient their name (52%)
  - Does not have sufficient infusion pumps available to care for unscheduled patients requiring unplanned care, ensuring their continuum of care (84%)
  - Does not have a protocol in place to manage requests for new infusion devices for the administration of chemotherapy treatments (41%)
  - Cytostatic surface contamination controls are not carried out regularly (68%)
- Medication errors:
  - Delays occur in the administration of treatment from the patient's scheduled appointment time (77%)
  - Does not have a system for monitoring the delay in the start of treatment (66%)
  - Any incidents that may occur in the administration of the treatment are monitored and controlled (92%) (mainly electronically/digitally)
  - The average number of adverse events per month associated with the administration of oncology medication is 9, mainly infusion-related reactions and extravasations

Hospital Pharmacy

- An electronic/digital method is used as a method of communication between the Oncology consultation and the Hospital Pharmacy Service to receive medication prescriptions (80%)
- Has a system of pharmaceutical validation of the prescription of oncology treatments (100%) (computerized)
- The method of communication between the Hospital Pharmacy Service and the laboratory is electronic (85%)
- An average of 310 preparations are carried out weekly in the Hospital Pharmacy Service of the hospital

- Delays occur n the preparation of oncological treatments leading to delays in the administration of these treatments (51%) (average of 11 delays per week), mainly due to lack of staff.
- The preparation process is supported by standardized preparation software (48%).
- Has an automation system for all necessary calculations (size, number of vials, volume, etc.) for the preparation of medication (92%) (no gravimetric system for dose calculation (55%).
- The system used to avoid exposure of staff to cytostatics during preparation is the closed system drug transfer device (CSTD) (62%)
- The type of dispensing systems used for the delivery of medicines from the Hospital Pharmacy Service to the ODH is through stock or hospital floor medicine cabinet (46%)
- No regular cytostatic surface contamination controls are carried out in the medication preparation area (51%)
- It has a system in place to prioritize certain preparations according to urgency or duration of treatment (75%)
- Has a system in place to manage the inventory of reusable drug vials based on their expiry date/stability once opened (71%) (mostly manual record keeping)
- Once ready to be administered, the way of dispensing the treatment until it reaches the patient is through an orderly (75%)
- Any incidents that may occur during the clinical validation of the prescription (dosage, drug, other) are recorded (76%) in the internal records of the Pharmacy Service (60%)
- Any incidents that may occur during the preparation of the medication (dosage error, labelling error, spillage, etc.) are recorded (70%) in the internal records of the Pharmacy Service (76%)

BLOCK 4. PERCEPTION AND EXPERIENCE IN THE ODH

Health managers

- The most relevant areas for improvement are:
  - Coordination between professionals (33%)
  - Care process (33%)

Medical Oncology

- The areas for improvement in communication between the staff of the different services of the ODH are:
  - Regarding interactions with other treatments (24%)
  - Regarding successive appointments (20%)
  - Regarding treatment after-effects (20%)
- The key points that would improve the patient experience are:
  - Discussing my expectations regarding waiting times (43%)
- Above all, waiting times for patients at the ODH could be improved:
  - By decreasing the time between analysis, medical assessment, treatment approval and treatment administration (21%)

- Waiting times from diagnosis/surgery/radiotherapy to the start of oncology medication could be improved above all:
  - With process-based planning (surgery, renewal, decision, indication, etc.) (42%)
- Errors related to prescription, preparation and administration of medication could be reduced above all:
  - By double checking patient data (22%) or double checking the type and characteristics of the medication (22%)

Nursing

- The areas for improvement in communication between the staff of the different services of the ODH are:
  - Regarding changes in treatment (22%)
- The key points that would improve the patient experience are:
  - Asking for my opinion on patient well-being (46%)
- Above all, waiting times for patients at the ODH could be improved:
  - By scheduling appointments according to the availability of treatment slots (23%)
- Errors related to prescription, preparation and administration of medication could be reduced above all:
  - By training healthcare professionals on medication errors (20%)

Hospital Pharmacy

- The areas for improvement in communication between the Hospital Pharmacy staff and the staff of the different services of the ODH are:
  - Regarding treatment after-effects (29%)
- The key points that would improve the patient experience are:
  - Discussing my expectations regarding waiting times (37%)
- Above all, waiting times for patients at the ODH could be improved:
  - By scheduling appointments according to the availability of treatment slots (27%)
- Errors related to prescription, preparation and administration of medication could be reduced above all:
  - By standardizing administrative processes electronically (20%)

8.2 ANNEX 2: RESULTS OF THE NATIONAL SURVEY. PATIENTS

General information

Most of the participants:

- Are women (82%). From the Community of Madrid (33%). Have an average age of 47
- Have breast cancer (52%)
- Are on sick leave (27%)

Oncology Day Hospital appointment scheduling and admission management

The majority of participants indicate that:

- Available appointment days for the administration of oncology medication at the ODH are Monday to Friday (93.1%)
- Available appointment hours for the administration of oncology medication at the ODH are morning and afternoon (73.2%)
- They receive electronic notification and appointment reminders via SMS, mobile app, email, phone, etc. (57.7%)
- They do not receive electronic notification and appointment reminders via SMS, mobile app, email, etc. (51.2%)
- Appointments for treatment are usually scheduled on the same days as their appointments with the specialist (73.4%)
- They have not received notification of appointment cancellation or change of appointment day or time from the ODH (78.6%). In the case of participants who have answered that they have received a notification, this mainly due to a change of appointment date and time. This notification is normally by telephone
- They have not had to cancel or change the day and time of the scheduled appointment (80.2%). In the case of participants who answered yes, this is mainly due to a change of appointment date and time and they say that it was easy for them to cancel or change their appointment and that they did it by telephone.
- They are not given a bar-coded identification bracelet at admission (56.6%)
- They do not receive information during the stay in the ODH (59,3%)

Average waiting times at the ODH

The majority of participants indicate that:

- The average time from diagnosis, surgery or radiotherapy to receiving cancer medication is less than 30 days.
- The waiting time from arrival at the ODH:
  - Until entry or admission to the ODH: less than 15 minutes
  - From admission to clinical analysis when performed on the same day: 15-30 minutes
  - Until receipt of the results of the analysis and consultation with the specialist: more than 1 hour
  - From consultation to the start of administration of the medication: more than 1 hour
  - Until administration of oral treatments and supportive care: more than 1 hour

- Several times, the administration of medication has been delayed with regard to the scheduled time

Administration of medication

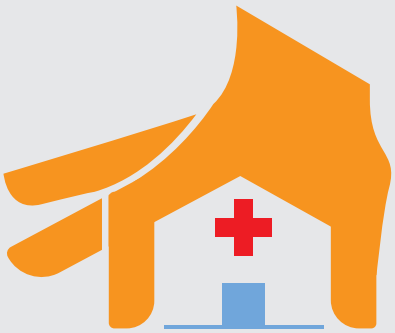
The majority of participants indicate that:

- The Nursing staff identifies that the medication to be administered is the right one, asking the patient's name (54.5%)
- They are not allowed to be accompanied by a family member/carer during the administration of medication (36.8%)
- They have not suffered any adverse effects related to the administration of oncological medication during their stay in the ODH (66.3%)

Personal perception

The majority of participants indicate that:

- A psychological support unit is available at the ODH (40.7%).
- They come to the ODH accompanied, for a whole working day, and the costs involved are less than €5 for transport, between €5 and €10 for parking, and more than €10 for food.
- With regard to how the patients perceive communication and empathy, they indicate that the health professionals who attend to them introduce themselves by name, smile at them when they speak and when they see them, explain the procedures to them while they are taking place, resolve their doubts during their stay, listen to them and take their opinions into account when making decision, they them how they are feeling and reassure them (60.9%)
- In general, they are completely satisfied, every time they go to the ODH for treatment (score of 7-10: 87.6%)



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