

Seminar PH2

CANCER THERAPY: REVIEW OF THE PRESENT AND A LOOK TO THE FUTURE



Back to the earth ...



CANCER THERAPY: REVIEW OF THE PRESENT

*The continuum of care
for the oncology
pharmacist*

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CONFLICT OF INTEREST

Nothing to disclose

QUESTIONS

- Do you think the role of OP is due to evolve in the next years?
 - Do you think OP role has any challenge in the new era of cancer medicine?
-

Why Add a Pharmacist in the cancer care team?

- Drug distribution and preparation?
- Safety?
- Control costs?



As an integral part of the cancer care team

- As an integral part of the cancer care team, oncology pharmacists represent a **broad range of expertise and levels of practice, skills, and responsibilities**



Oncology pharmacists are viewed as the **cancer drug therapy experts** in many countries, based on their training, expertise and function

...the role of the oncology pharmacist has **evolved**

As with other professions, the pharmacy profession experienced a change from traditional drug-oriented services, such as drug distribution and preparation toward patient-oriented services



...to address many aspects of direct patient care and to support overall cancer care

...and continues to evolve

Some historical definitions



ASHP → guidelines in 1990, 1993, 1996, and 2002

→ describe a pharmacist's role not only in safe handling, preparation, and dispensing of drugs but also in pharmaceutical care as the health professional who is

"... directly responsible for the provision outlined for medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life "



The pharmacist is responsible for **identifying, resolving, and preventing MRP** such as

- untreated indications
- improper drug selection
- inadequate dosing
- adverse drug reactions
- Interactions
- medication use without indication

Carolyn SJ Ma. Role of pharmacists in optimizing the use of anticancer drugs in the clinical setting. Integrated Pharmacy Research and Practice 2014;3 11-24

Some historical definitions



The Board of Pharmacy Specialties, an autonomous division of the American Pharmacists Association, is the premier post-licensure certification agency



Board certification through BPS is recognized as the **gold standard** for determining which pharmacists are **qualified** to contribute at advanced practice levels.

Oncology Pharmacy

*...provides **evidence-based, patient-centered** medication therapy management and **direct patient care** for individuals with cancer, including treatment assessment and monitoring for potential adverse drug reactions and interactions*

Carolyn SJ Ma. Role of pharmacists in optimizing the use of anticancer drugs in the clinical setting. Integrated Pharmacy Research and Practice 2014;3 11-24

Some historical definitions



Describes oncology pharmacists as

*“...having specialized knowledge of medications and their role in cancer is essential as interdisciplinary team members who **maximize the benefits** of drug therapy and **minimize toxicities**”*

Carolyn SJ Ma. Role of pharmacists in optimizing the use of anticancer drugs in the clinical setting. Integrated Pharmacy Research and Practice 2014;3 11-24

Knowledge and skills



Knowledge and skills



Training

- best **practices**
- appropriate **dosages**
- delivery **techniques**
- **Formulations**
- routes of **administration** of anti-cancer drugs



Understand

- acute and long-term drug **toxicities**
- management of cancer-related and drug related **complications**
- drug **interactions**
- safe handling of **hazardous** drugs



Ability

- participate in and manage **clinical trials**
- understanding and interpretation of **research** methodologies and outcomes



Key role

in supporting
oncology
health care
teams

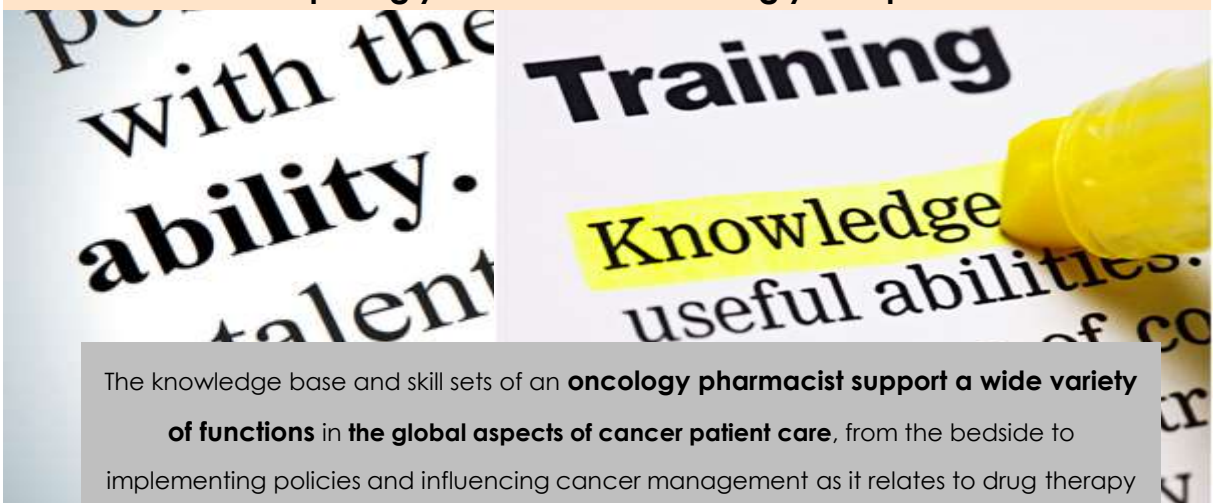
Placed in the team

What have placed them **in an optimal position** to collaboratively provide **medication management services across the care continuum**, from the time of assessment and diagnosis through cancer treatment decisions, supportive care, and management of cancer- or treatment-related symptoms as well as survivorship programs.



Knowledge and skills

The role of OP is surprisingly broad and increasingly complex



The knowledge base and skill sets of an **oncology pharmacist support a wide variety of functions** in the global aspects of cancer patient care, from the bedside to implementing policies and influencing cancer management as it relates to drug therapy



This in-depth knowledge and skill set provide the healthcare team with a **unique perspective on disease management** that encompasses not only individual patient care but also the institution and healthcare system

Why Add a Pharmacist in the cancer care team?

*Oncology pharmacists are viewed as the “**cancer medication experts**” who have the training and expertise that place them in an optimal position to collaboratively*

provide medication management services across the care continuum

from the time of assessment and diagnosis through supportive care, cancer treatment decisions, and management of cancer- or treatment-related symptoms





CORE FUNCTIONS OF TODAY'S WORK

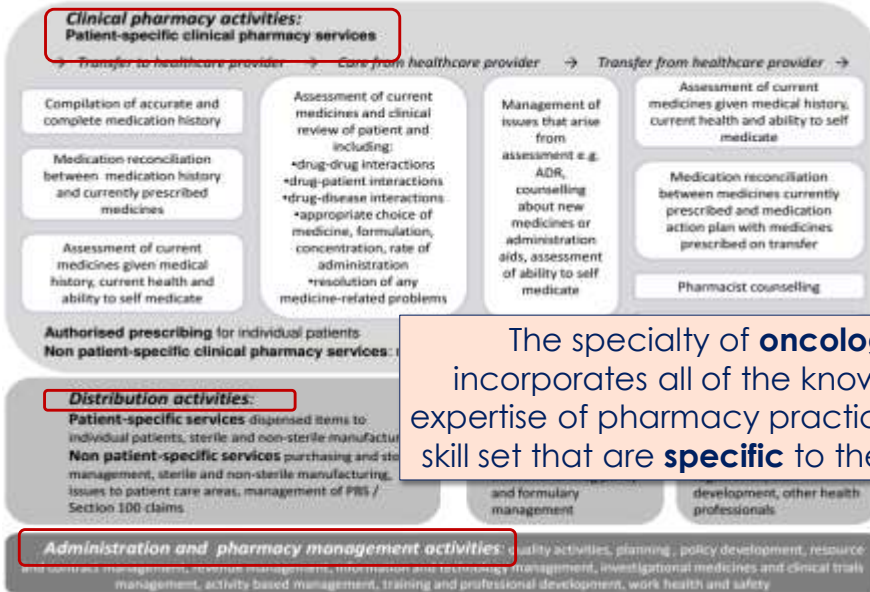
Classic responsibilities as oncology pharmacist



Key areas of today's work

Overview of HP services

Hospital pharmacy services that support the medicines management pathway



The speciality of **oncology pharmacy** incorporates all of the knowledge, skills, and expertise of pharmacy practice, with a **focus** and skill set that are **specific** to the area of **oncology**

Core functions

- The **knowledge base and skills** sets of an oncology pharmacist **support a wide variety of functions** in the global aspects of cancer patient care,
- **Traditionally**, pharmacists have worked in the pharmacy to provide necessary **safety** checks and accurately **dispense** medication, but

The **traditional role of OP has shifted** from dispensing functions to provide **direct patient care** at the bedside or in the clinic where treatment decisions are being made due to:

- **Automation/ Robotics**
- **Technology** (computerized prescriber order entry, patient-assistance program software, hand-held electronic devices to assist with clinical activities, use of technicians, etc.)

Hematology/Oncology Pharmacy Association: Scope of Hematology/ OncologyPharmacy Practice.
www.hoparx.org/uploads/files/2013/HOPA13_ScopeofPracticeBk.pdf

Core functions → Direct Patient Care

OP typically work with other health care providers in



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www.hoparx.org/uploads/files/2013/HOPA13_ScopeofPracticeBk.pdf



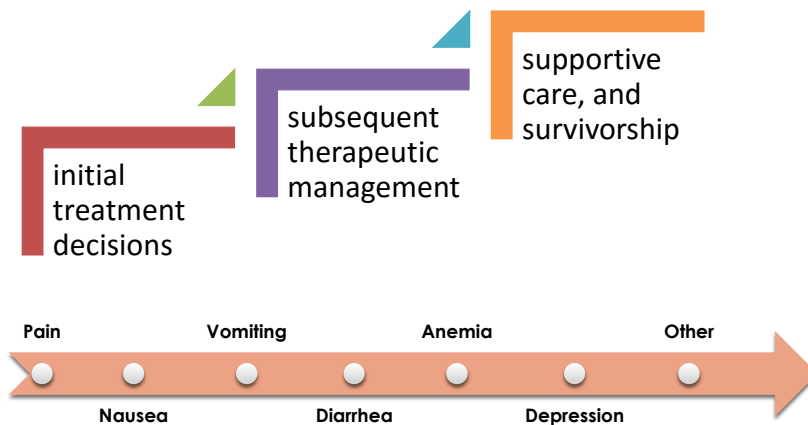
Pharmaceutical Care

"The responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient' quality of life"

(Hepler and Strand, 1990)

Core functions → Direct Patient Care

Oncology pharmacists have the training and expertise that places them in an optimal position to **provide evidence based care** to the patient with cancer, including



Involved in **acute and longitudinal support for management** of different symptoms

Core functions → Education

➤ Patient-directed education

- **Tools to improve medication adherence** with complicated regimens
- Develop **educational materials** for patients and caregivers
 - to **monitor and report treatment concerns**
 - **To make it easy to understand proper handling** and disposal of chemotherapy medications in the home and how to limit chemotherapy exposure
- **Development of educational tools**
- Implementation of **educational programs**

➤ Other healthcare providers



Hematology/Oncology Pharmacy Association: Scope of Hematology/ OncologyPharmacy Practice. www.hoparx.org/uploads/files/2013/HOPA13_ScopeofPracticeBk.pdf

Core functions → Guidelines, Policies, and Standards

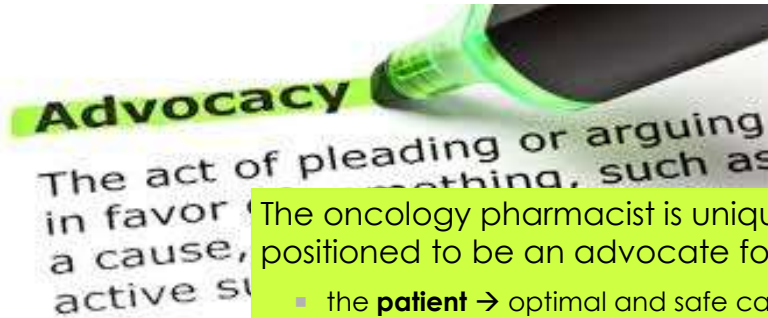
The more **global aspects** of oncology pharmacy functions include pharmacists' → to provide essential insight and practicality regarding the **development of guidelines, policies, and standards**



Implementation of these **guidelines and standards** is essential to maintain **compliance with regulations, improve safety and patient outcomes, improve** medication reimbursement and **access** to care, and **efficiently use medications**

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Core functions → Advocacy



The oncology pharmacist is uniquely suited and positioned to be an advocate for

- the **patient** → optimal and safe care
- the **institution** → safety, financial responsibility
- **health care colleagues** → education and standards
- the **community**

Hematology/Oncology Pharmacy Association: Scope of Hematology/ OncologyPharmacy Practice. www.hoparx.org/uploads/files/2013/HOPA13_ScopeofPracticeBk.pdf

Other Functions → Technology

Depending on the practice setting, oncology pharmacists may also be involved in other **indirect patient care** responsibilities related to product and service offerings, which also have important implications in the care of individuals affected by cancer.

Technology → increasingly used in routine function



pharmacists → **additional** opportunities to prepare for a more global clinical role

- contribute to develop **automation** for the traditional tasks

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Other Functions → Information Technology

Depending on the practice setting, oncology pharmacists may also be involved in other **indirect patient care** responsibilities related to product and service offerings, which also have important implications in the care of individuals affected by cancer.

High-risk nature of the drugs used in cancer care



OP play an instrumental role in

- medication **safety** initiatives
- **oncology clinical decision support** (informatics)
- **electronic health record** and **CPOE** development



Hematology/Oncology Pharmacy Association: Scope of Hematology/ OncologyPharmacy Practice. www.hoparx.org/uploads/files/2013/HOPA13_ScopeofPracticeBk.pdf

Other Functions → Research

Depending on the practice setting, oncology pharmacists may also be involved in other **indirect patient care** responsibilities related to product and service offerings, which also have important implications in the care of individuals affected by cancer.

Research → carrying out basic, clinical, or translational science in academic or pharmaceutical industry-related setting



to improve **access** to and **development** of cancer medications

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Why Add a Pharmacist in the cancer care team?

An OP recommends, designs, implements, monitors, and modifies **pharmacotherapeutic plans** to optimize **outcomes** in patients with malignant diseases



...in more detail,
traditional role
related to
pharmaceutical
care



MEDICATION
MANAGEMENT

Medication Management



The Joint Commission

The accreditation body for health care facilities in the US and for international institutions

Medication Management → a process of seven critical steps that constitute to safe and complete medication manage (2013)



1. Selection
2. Procurement
3. Prescribing, dosing
4. Storage
5. Preparing and dispensing (includes delivery)
6. Administering
7. Monitoring, evaluation, and education

Ma, Carolyn SJ. "Role of pharmacists in optimizing the use of anticancer drugs in the clinical setting." *Integr Pharm Res Pract* 3 (2014): 11-24.

1. Selection



Information → pharmacology, dosing adjustments, and adverse-effect profiles

Evaluate evidence-based guidelines

Availability of an investigational anticancer drug

Information of an anticancer drug for **off-label** use

Appropriate choice of a medication for a
specific indication



Carolyn SJ Ma. Role of pharmacists in optimizing the use of anticancer drugs in the clinical setting. *Integrated Pharmacy Research and Practice* 2014;3 11-24

2. Prescribing, dosing

Medication error

- **General** medication errors in hospitals generally range from 2% to 5%.
- **Chemotherapy** error rates have been reported at 3%–16%.
- Errors in **ordering** are most common, followed by administration and then dispensing



OPs are key players in helping to create **standardized electronic order (CPOE)** sets that are **linked to clinical laboratory** tests and program for medication **alerts for interactions** and doses that exceed maximum allowable limits

Carolyn SJ Ma. Role of pharmacists in optimizing the use of anticancer drugs in the clinical setting. Integrated Pharmacy Research and Practice 2014;3 11–24

3. Procurement



Shortages

- Increased **cost**
- Additional costs were also related to increased labor hours
 - These additional hours spent by pharmacists could be better spent in other areas
- **Changes in drug therapy** due to drug shortages also caused a **medication error** rate of 6%

There's a drug shortage. I'm thinking of replacing your meds with eight hugs a day before & after meals!

4. Storage



- Robotics
- Lookalike/soundalike
- Light
- Temperature

5. Preparation and dispensing

- Standardized
- Preparation areas
- Compounding
 - brand used, serial numbers (traceability)
- Dispensing
- Occupational Safety → closed-system transfer devices



6. Administration



- **Compatibility**
- **Schedule and sequency**
- **Infusion rates**
- **Extravasation**
- **Supportive care**

7. Monitoring, evaluation and education



Monitoring

- Clinical rounds
- During chemotherapy administration
- Continuum of care



Evaluating

- Drug Use Evaluation
- Outcomes



Education

- Empower the patient in their own care
- Counsel new chemotherapy patients
 - interactions
 - duplicate therapy
 - potential side effects.
- Counseling → adverse effects, compliance
- Adverse effects
- Administration issues

Why Add a Pharmacist in the cancer care team?

OP are vital members of the interdisciplinary team

OPs contribute heavily to improve **management** of supportive care, enhancing patient **education**, improve **efficiency**, ensure the **safety** of **antineoplastic medications** in order for them to **be utilized to their fullest therapeutic potential**



LOOKING TO THE FUTURE....

Challenges

Changing landscape of health care and approach to cancer care



Precision
oncology



Survivorship
Illness that is
becoming
chronic



New
therapeutic
options (non
cytotoxic)



New ways of
diagnosis



Sustainability

How to support tomorrow options?

How to support tomorrow options?

8 ways to create value in cancer care

1. **Evaluation** new therapeutic options. **Added value.**
2. **Compliance. Traceability. Adherence.**
3. **Research.** Provide **early access.** CT
4. **Clinical Information. Information technology projects. Real-Life Data.**
5. **Continuity of care. Survivorship care. Reconciliation.** Information for patients (**pharmaceutical care**).
6. **Toxicity** evaluation.
7. **Patient selection** for best results. **Pharmacogenomics**
8. **Evaluation** of health **outcomes. Pharmacoeconomics.**



How to support tomorrow options?

Create value in cancer care



1. Evaluation new therapeutic options. Added value.

- Evaluation through validated
- Biomarkers
- Added value of new therapies in different populations
- Treatment of cancer patients.
- New therapeutic options (non cytotoxic) measures to new therapy

New therapeutic options (non cytotoxic)



How to support tomorrow options?

Create value in cancer care

2. Compliance. Traceability. Adherence

- Monitoring adherence to therapy
- Implementing programs to enhance adherence
- New technologies → Developing tools to improve adherence
- Optimization of access to drug therapy and management of drug-drug interactions



Survivorship
Illness that is becoming chronic

How to support tomorrow options?

Create value in cancer care

3. Research. Provide early access. CT

▪ Evaluate

▪ alternative

▪ additional

▪ Provide

options to



New therapeutic options (non cytotoxic)

novel therapeutic protocols



How to support tomorrow options?

Create value in cancer care

4. Clinical Information

Information technology projects. Real-Life Data.



Precision oncology



New ways of diagnosis

System for biology to

the most patient from real



How to support tomorrow options?

Create value in cancer care

5. **Continuity of care. Survivorship care. Reconciliation.** Information for patients (pharmaceutical care).



- In primary care providers, to ensure continuity of care
- Role in survivorship care
- Reconciliation of medication through CPOE integrating levels of care.

Survivorship
Illness that
is becoming
chronic

“...information (update medication list)
...information technology is
...plemented integrating
...ent levels of care”



How to support tomorrow options?

Create value in cancer care

6. **Toxicity** evaluation



Survivorship
Illness that
is becoming
chronic



New
therapeutic
options
(non
cytotoxic)



How to support tomorrow options?



Create value in cancer care

7. Patient **selection** for best results.



New
ways of
diagnosis



Precision
oncology

Pharmacogenomics

Pharmacogenomics allows oncologists to **individualise therapy on the basis of a genetic test result**

Pharmacogenomics

- **Determine which patients** will have the best chance of receiving **benefit** from certain drugs and which patients will not realize any clinical benefit from the same drug

How to support tomorrow options?

Create value in cancer care

8. Evaluation of health **outcomes.**



Sustainability



Pharmacoeconomics.

- **Cost of care and patient access** → cost-effectiveness ratio
- **Accessible, affordable cancer care** → new payment models

Cost-effectiveness data should be integrated into the decision making process.

Why Add a Pharmacist in the cancer care team?

As the care of patients with cancer continues to be challenged with **high-cost** therapies, medication **shortages**, **regulatory** requirements, and decreasing **reimbursement**, the **oncology pharmacist** is heavily relied on to provide **support** for the clinical team to **improve** overall **cancer care and patient quality of life**

*The oncology pharmacist is often a clinician who understands both the **clinical** and **financial** components related to the care of a cancer patient*



Are OP prepared to take these challenges?

Published Ahead of Print on February 4, 2016 as 10.1200/JCO.2015.65.8427
The latest version is at <http://jco.ascopubs.org/cgi/doi/10.1200/JCO.2015.65.8427>

JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

Clinical Cancer Advances 2016: Annual Report on Progress Against Cancer From the American Society of Clinical Oncology

Don S. Dizon,* Lada Krilov, Ezra Cohen,† Tara Gangadhar,‡ Patricia A. Ganz,‡ Thomas A. Hensing,‡ Stephen Hunsberger,‡ Smitha S. Krishnamurthi,‡ Andrew B. Lassman,‡ Merry Jennifer Markham,‡ Erica Mayer,‡ Michael Neuss,‡ Sumanta Kumar Pal,‡ Liu C. Richardson,‡ Richard Schilsky,† Gary K. Schwartz,‡ David R. Spriggs,‡ Miguel Angel Villalona-Calero,‡ Gina Villani,‡ and Gregory Masters*

This report reviews the **recent top advances** and **emerging trends** in clinical cancer research. These advances are based on discoveries in cancer biology that are leading to improved cancer treatments for patients

Clinical Cancer Advances 2016: Annual Report on Progress Against Cancer From the American Society of Clinical Oncology
Don S. Dizon, Lada Krilov, Ezra Cohen et al. JCO JCO658427; published online on February 4, 2016

Clinical Cancer Advances 2016

Advance of the Year: Cancer Immunotherapy

- Immune Checkpoint Inhibitors: Enhancing the Immune Response to Cancer
- Melanoma Immunotherapy Moves Ahead: Comparing and Combining Treatments
- New Treatment Paradigm for Lung Cancer
- Broadening the Possibilities for Checkpoint Inhibitors
- Novel Immunotherapy Approaches Boost the Immune System
- Continuing Immunotherapy Research

Treatment-Resistant Cancers: Precision Medicine Pushes Ahead

Improving Quality of Life

Patients Gain Access to New Cancer Therapies

Federal Funds Support Critical Research

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AVANCES EN CANCER, ASCO 2016



ADVANCES IN CANCER PREVENTION

- Global Opportunity and Challenge
- Promise of **HPV Vaccines**
- Remaining Questions



ADVANCES IN CANCER TREATMENT

- Novel Treatment Device for Brain Cancer
- Avoiding Breast Cancer Recurrence
- Targeted Therapy
- Adjuvant Chemotherapy Extends Survival for Patients
- New Treatments for Soft Tissue Sarcoma
- Advances in Surgery
- Advances in Radiation Therapy for Early-Stage Breast Cancer
- Recent Clinical Practice Guidelines



ADVANCES IN PATIENT CARE

- Advances in **Childhood** Cancer Care
- **Reducing Disparities** in the Care of Minorities
- **Selecting** Care to Preserve Quality of Life
- **Palliative Care** Benefits Extend Beyond the Patient

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LOOKING TO THE FUTURE

Are OP prepared to take these challenges?



Cancer: A Growing Challenge

Focus on Prevention

Information

Changing Cancer Landscape

Evaluation

Precision Oncology and Immunoth

Patient selection.
Pharmacogenomics

Learning From Big Data

Information. **Real-Life Data**
Evaluation of health **outcomes**

Improving Care for Patients, Survivors, and Caregivers

Toxicity evaluation
Compliance
Provide early **access**

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IN CONCLUSION

OP...from the beginning



- **Safety → Centralized compounding areas**
 - safer handling systems, with the focus on patient safety and quality of the preparations
 - "good manufacturing standards"
- **Communication → workgroup units**
 - Spanish for the development of the Oncology Pharmacy (GEDEFO)
- **Knowledge**
 - Pharmaceutical care
 - Value in "control spending."

.... nowadays....

- **Crisis**
 - **Financial** → expenditure control
 - **Knowledge** → "Crisis of evidence-based medicine"
 - EBM, coming from Randomized Clinical Trials, only gives us answer rigorously to a small number of patients. Real world patients:
 - Comorbidities
 - Clinical Trials don't classify patients according to the molecular characteristics, which determine de effectiveness

The only solution to overcome this uncertainty in decision-making is to determine the **effectiveness** of treatments in clinical practice

...to the future**CHALLENGES**

Access to full patient information (EMR integrated care levels) to **select patients** who will benefit most → effectiveness

Big Data

Contribute to develop clinical decision systems considering different characteristics of each patient.

Personalized Medicine

- **Select patients for Pharmaceutical Care**
- **Robotics**
- **Mobile devices** → educational tools and support, monitoring and communication

Information Technology**Why Add a Pharmacist in the cancer care team?**

Including an oncology pharmacist in the treatment team for cancer patients is an **added value** and might improve outcome for patients



Take home message



To generate interest in oncology pharmacy as a **valued** and **sustainable** profession...

Documenting **outcomes** related to individual care and the healthcare system in the medical literature as a result of our **intervention**

QUESTIONS

- Do you think the role of OP is due to evolve in the next years?
 - Yes, to meet the expectations coming with the new era of cancer medicine, in terms of
 - Sustainability → pharmacoeconomics
 - Patient oriented → select patients (treatment selection, pharmaceutical care)
 - IT → as a tool to integrate all the information of the patients, including in all levels of care
-

QUESTIONS

- Do you think OP role has any challenge in the new era of cancer medicine?
 - Yes, in terms of
 - Knowledge → new drugs with different mechanisms of action, different toxicity profile → education
 - Pharmaceutical care in survivors
-



Thank you

**“...A world where
cancer is prevented
or cured, and every
survivor is healthy”**

Clinical Cancer Advances
ASCO 2016