SACT Protocols
The How and Why of Different Countries

Netty Cracknell, Ramsay Health Care UK, UK
Evelyn Handel, National Comprehensive Cancer Network, USA
Cristina Ibáñez, Catalan Institute of Oncology, Catalonia, Spain
Shaun O'Connor, St. Vincent's Public Hospital, Melbourne, Australia
Irene Weru, Kenyatta National Hospital, Kenya
Rukhsana Yusuf, University of California Irvine, Pakistan

Objectives of the session

1. Explore how SACT protocols are created and provided in six different countries around the world.
2. Learn the similarities and differences between the countries
3. Discuss the strengths and weakness of each model

Disclosures / Conflict of Interests

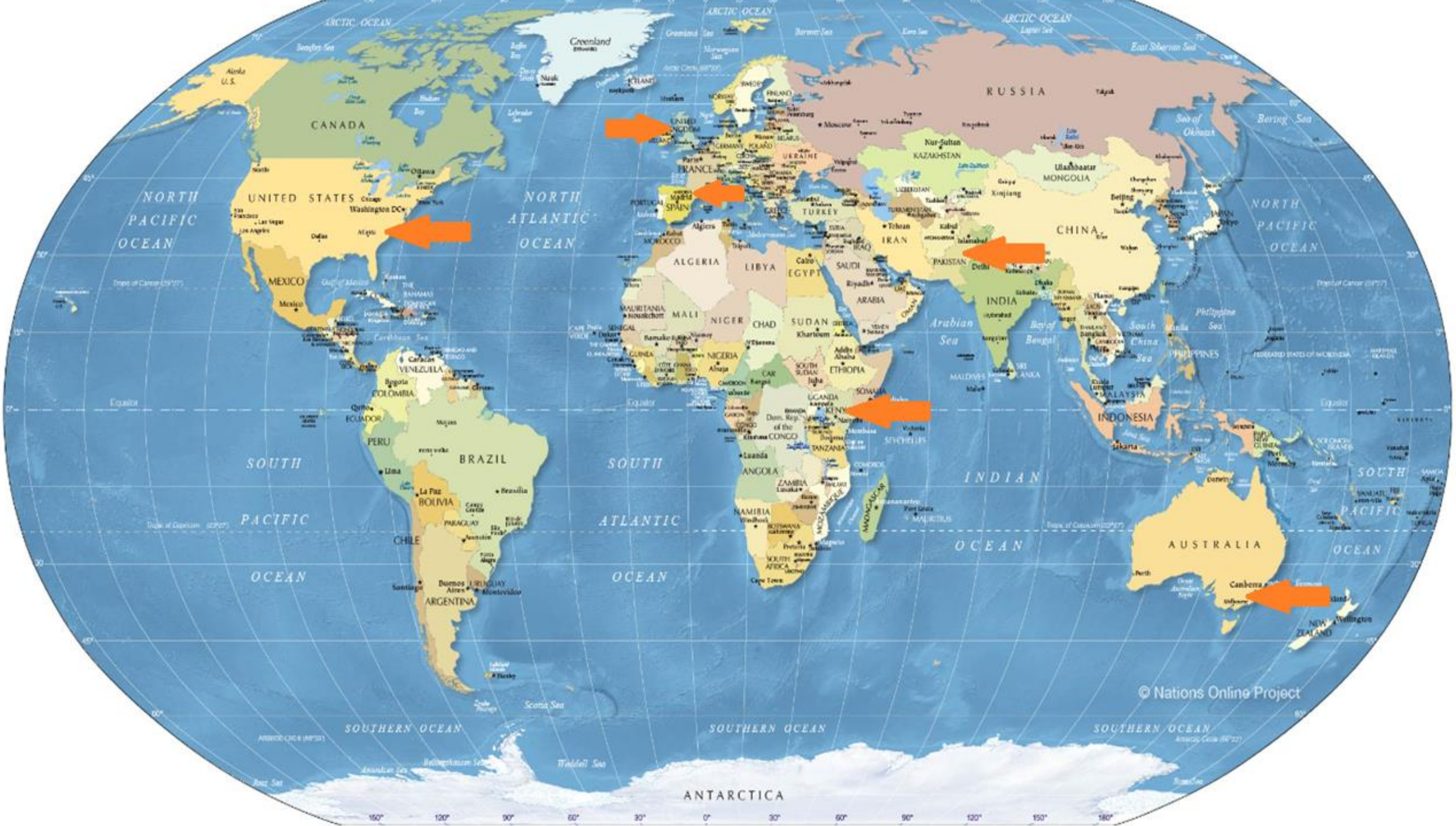
- Netty Cracknell, UK – *none*
- Evelyn Handel, USA
  - *NCCN Employee*
- Cristina Ibáñez, Spain
  - *formative activities sponsored by Organon, Janssen, Pfizer and Merck. honoraries by Seagen. no conflict of interests.*
- Shaun O'Connor, Australia
  - *EviQ Pharmacy Clinical Advisory Committee*
- Irene Weru, Kenya – *none*
- Rukhsana Yusuf, Pakistan – *none*

Introduction

- Session plan
- Includes
  - Introduction to countries healthcare system
  - SACT protocol information
- Excludes
  - Treatment decision trees / algorithms
  - Guidelines determining treatment choice

Definitions and terminology

- Regimen
  - Collection of medicines for a treatment (SACT and supportive)
  - Terminology used in UK, USA, Spain, Africa, Pakistan
- Protocol
  - More detailed medicines information resource
  - Terminology used in UK, USA, Spain, Africa, Australia, Pakistan
- Order Templates
  - USA, Spain - General guidance on SACT and doses needed. Also used as template for building on eP system.
  - Australia, Pakistan - proforma paper script
  - UK, Africa - not used
- Order Set / Final Prescription / Treatment Sheets / Chemo Sheet
  - Final order and doses of all medicines that is prescribed for a patient.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Presentations from Countries

- Pakistan
- Kenya
- Spain
- United Kingdom
- Australia
- United States of America

- Rukhsana Yusuf
- Irene Weru
- Cristina Ibáñez
- Netty Cracknell
- Shaun O'Connor
- Evelyn Handel

Pakistan

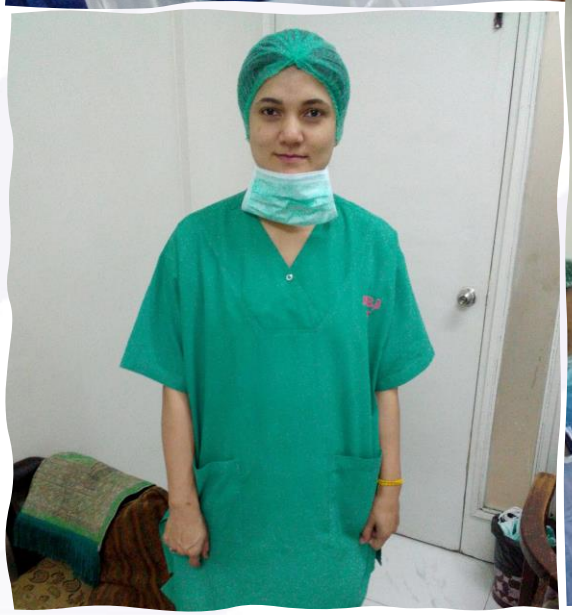
Rukhsana Yusuf

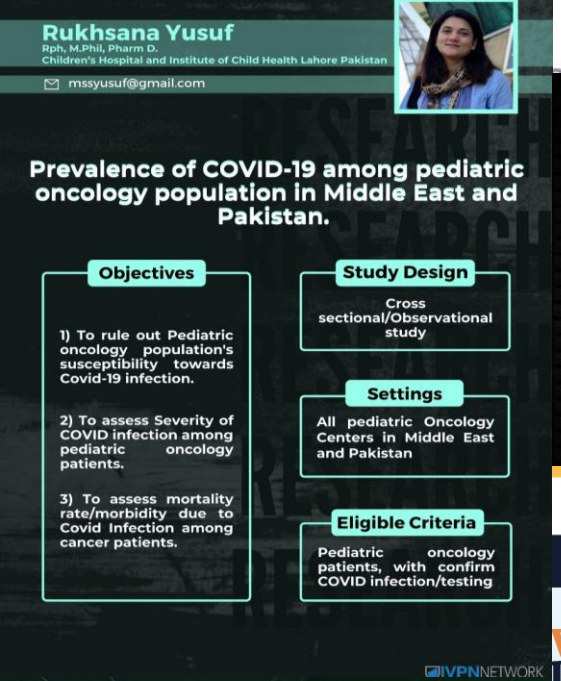
Clinical Pharmacist Pediatric Oncology/BMT
University of Child Health Lahore Pakistan
PhD Fulbright Scholar
School of Pharmacy & Pharmaceutical Sciences
University of California Irvine USA

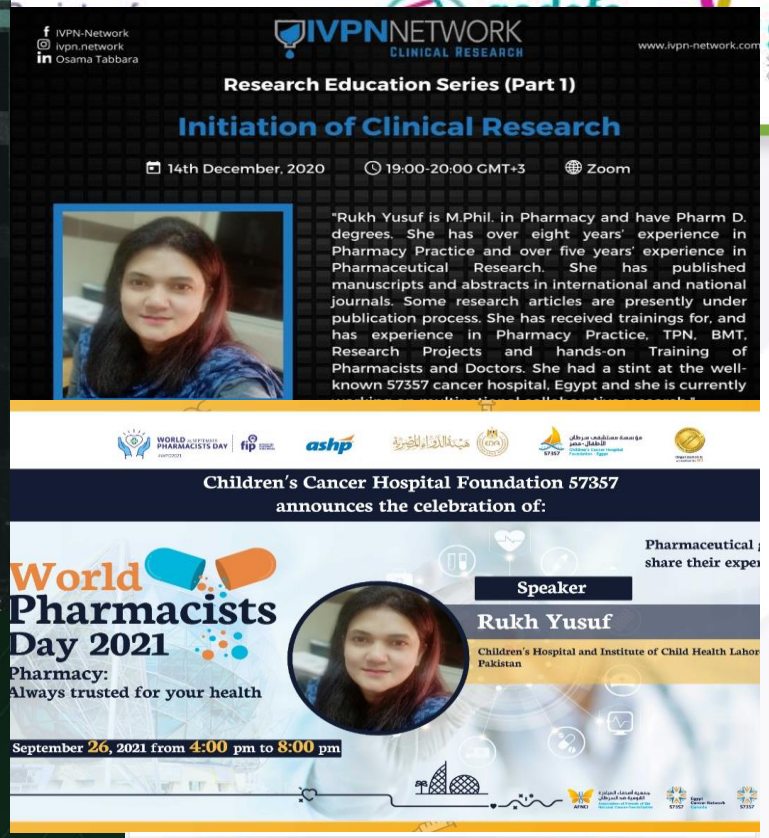
Rukh Yusuf

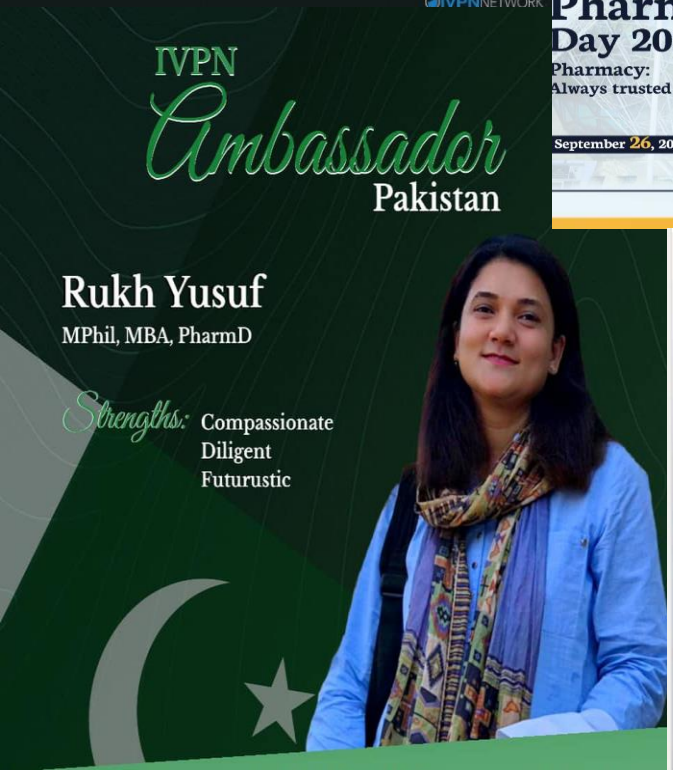
- Clinical Pharmacist pediatric Oncology/ BMT
- Total Parenteral Pharmacist Children Hospital Lahore









- Fulbright PhD Scholar
  Clinical Pharmacy practice
  UCI California

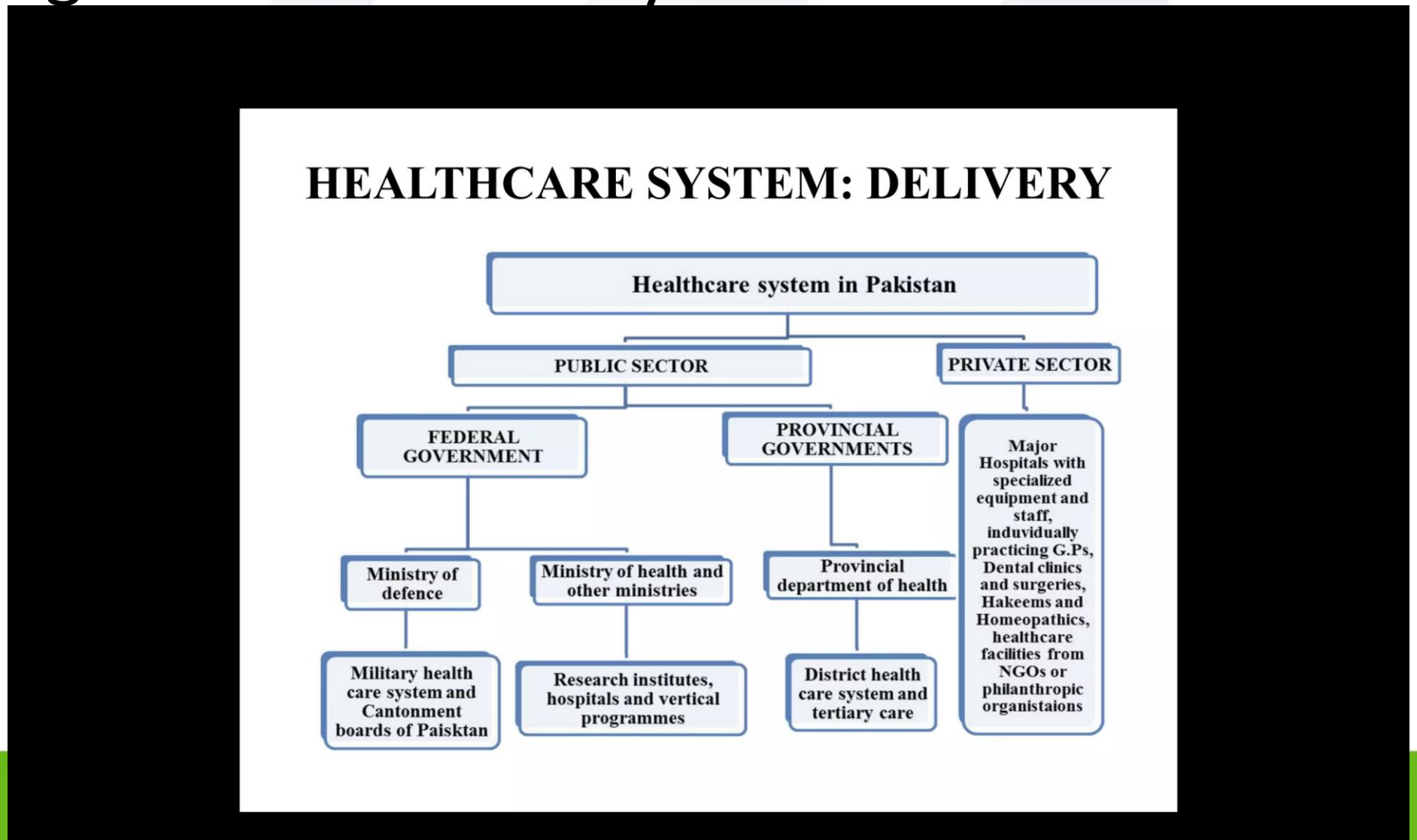
- IVPN Ambassador
- IVPN clinical Research
- 57357 Joint clinical research working
- SIOP –Working group
- PSOP-

Use

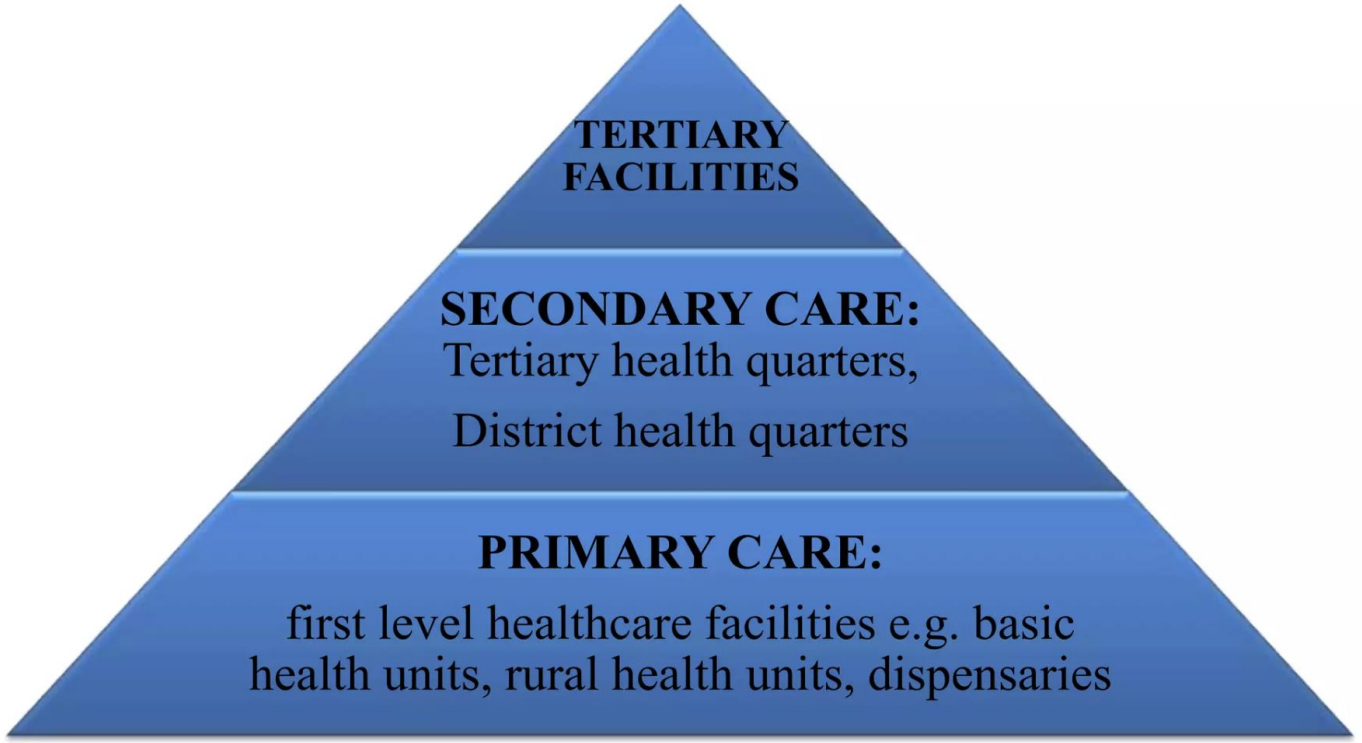
HEALTHCARE IN PAKISTAN

Sanaa Aslam
Msc. DPH Student
Kings' College London
Nov2012

Background of health system in Pakistan



HEALTHCARE SYSTEM: ORGANISATION



Background of health system in Pakistan

Health workforce per 10 000 population as of 2018

- Physicians - 9.8
- Nurses/midwives - 5.1
- Pharmacists - 1.6 --- in. 2023?

Few cancer centres across the country.

- Mostly private in each big city, Some public sector
- **231,954,224** population as of February 2023,
- 131 Pharmacy schools, 8102 pharmacists in Pakistan,
- App 3000 work in the public sector
- 5000 in private settings

Background of healthcare system in Pakistan

- Majority of healthcare is fully funded by the Govt (Federal/Provincial)
  - Free at the point of delivery for everyone
  - Working population taxed
- Health Card 'approved list' of SACT treatments with specific indications
  - Cancer was not included initially in Health card approved list
  - Later Cancer has been included with free treatment everywhere (pvt/pub)
- Private healthcare is available
  - Self pay
  - All licensed indications/ evidenced treatments available

Current Status of SACT protocols

National

- No national protocols
- Institutes decide their protocols
- Few National societies have started developing national protocols

Approval process

- Department head initiates, Physicians team
- Individual bodies/ societies realized need of uniform protocols
- Initiation of different Oncology Societies e.g. PSPO
- PSPO started developing national protocols for six cancer types initially
- ALL, Low grade GLIOMA, RB, Hodgkins, NHL, Wilms
- How widely used
- Initially large cancer centres, later nationally.

Example of what is used in Pakistan

A	B	C	D	E	F	G
	Baby Abdul Rehman	AGE	7 yrs	MR # 3850		Tx #
	Weight - 20 Kg	Height - 117cm		0.79m2		Diagnosis: BTM
Day	Date	REMARKS				
Day-16 TO Day -12	Wed 6 Jan to Sun 10 Jan 2016	IV hydration with 1/2st D/S 30ml/hour,				
		Fludarabine (20 mg/m2) 16 mg in 100mil 5% DW IV X OD FOR 5 days				
		Syp.Acyclovir 5ml 8hrly, Enziclor MW x QID				
		Syp. Notocan 50 mg x OD,Nilstat MW 2.5 ml x QID				
Day -12	Sun 10 Jan 2016	Syp Phenytoin mg 20 ml x BID (Loading)				
Day - 11 to Day - 8	Mon 11 Jan to Thur 14 Jan 2016	Tab Busulphan 3.5mg/kg/day (70mg) 9+9+9+8				
		Syp.Phenytoin 10 ml X BD				
Day - 7 to Day - 4	Fri 15 Jan to Mon 18 Jan 2016	IV hydration with 1/2st D/S 40ml/hour,				
		Inj.Endoxan 800 mg in 200 ml 5% D/W over 2 hour x OD for 4 days				
		Inj.Mesna 500 mg before endoxan x IV infusion over 4 hours				
		Inj.Mesna 100 mg x IV infusion over 1 hour x 6 hourly for 5 days				
		Inj. Onset 2 mg x 8hrly , Inj Gravinate 25 mg IV x 8 hrly				
Day -3 to Day - 1	Tue 19 Jan to Thur 21 Jan 2016	REST DAY (for plasmapharesis)				
Day - 2	Wed 20 Jan 2016	Inj Sandimumm 60 mg in 50 ml 5% DW over 10 hours				
		Tab Deltacortil 5mg 2+ 0+ 2, Syp Polypep 5ml OD				
0	Fri 22 Jan 2016	BMT DAY				
+1	Sat 23 Jan 2016					
+2	Sun 24 Jan 2016					

Dexamethasone	All patients should receive dexamethasone starting on day 1. Oral dexamethasone 6mg/m²/day (maximum dose 10mg/day in induction only) for **28 days** starting on day 1 and then tapered over the next 7 days. The steroid should be divided into two doses per day. **NB. For severely ill patients, it is permissible to use intravenous dexamethasone.**
Vincristine	1.5mg/m² (maximum single dose 2mg) intravenous weekly for five weeks starting on day 2 and continuing on days 9, 16, 23 and 30.
Pegaspargase (Oncaspar)	1000iu/m² **intramuscular** on day 4 and day 18
Intrathecal methotrexate	**On days 1, 8⁺ and 29.** Dose by age: <2yrs: 8mg 2yrs: 10mg ≥3yrs: 12mg. NB Patients who have CNS disease at presentation should receive weekly doses until two clear CSF samples are obtained (see section 7.4.1). **Do not schedule vincristine on the same day as the intrathecal methotrexate** **+ Regimen A patients can receive day 8 intrathecal methotrexate with a day 15 bone marrow, if appropriate**
Mercaptopurine	75mg/m²/day orally once a day starting on day 29 (beginning week 5) (if neutrophils >0.75x10⁹/L and platelets >75x10⁹/L) and continuing to day 21 of consolidation (4 weeks from the start in week 5 of induction). If necessary, give extra doses between induction and consolidation to ensure continuity of therapy. Dose adjustments are described in section 8.8.1.
Co-trimoxazole	This drug is given as PCP prophylaxis orally twice a day (bd) on 2

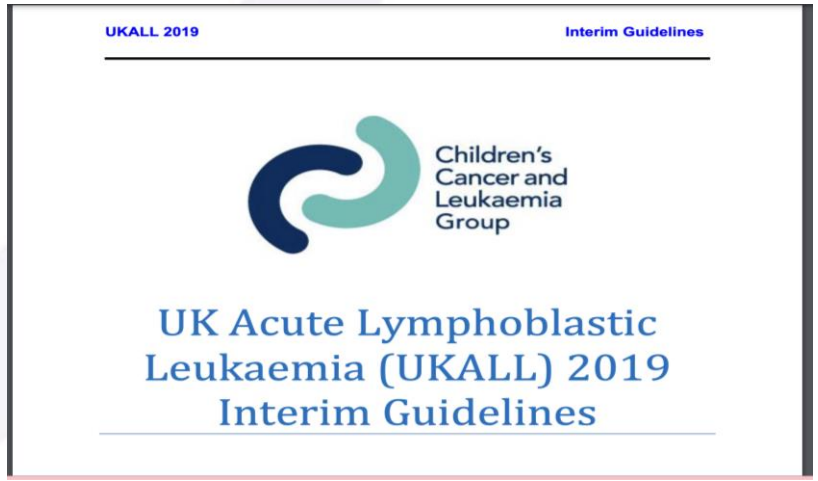
History

<u>How did Pakistan get to current status</u>

- Early 2000, few Cancer hospitals in major cities
- Both public and private cancer centres
- Philanthropists, Charity based centres, Private set ups
- Practitioners (Oncologists) brought protocols from their institutions they were trained from.
- St Jude, UK , Malaysia etc
- International guidelines like NCCN, CCLG, COG

Approval processes of a SACT protocol

- In the absence of National protocols, hard and fast approval process is missing.
- Some regional or institutional protocols
- Individual hospitals/Trusts or private groups
- Oncologist team
- Approved by consensus
- Pharmacist role is minimal
- Cost benefit analysis
- Availability / drug registration is an issue



Where is the Pakistan going?

With regards to SACT protocols

- Keen to have national SACT protocols for Pak
- Keen for medicines availability /registration
- Ensure clinical staff have access to high quality information to be able to safely treat patients
- In developing phase of building uniform protocols e.g PSPO
- Implementation is the next challenge

Kenya

Irene Weru

Senior Specialist Pharmacist, Kenyatta National Hospital, Nairobi

Background of health system in country

Level of Care	Scope of Services
Level 1 (Community)	Health promotion; Prevention
Level 2(Dispensaries)	Health Promotion; Screening; Early detection
Level 3 (Health Centres)	Health Promotion; Screening; Early detection
Level 4 (Primary Referral facilities)	Health Promotion; Screening; Early detection; Treatment (Surgical, Chemotherapy, Supportive); Palliative care
Level 5 (Secondary Referral facilities)	Health Promotion; Screening; Early detection; Treatment (Surgical, Chemotherapy, Radiotherapy, Supportive); Palliative care
Level 6 (Tertiary Referral facilities)	Centres of excellence

Chemotherapy Services:

Public sector

- 2 National referral hospitals
- 11 county referral hospitals (Mombasa, Meru, Nyeri, Embu, Garissa, Nakuru, Kisumu, Kakamega, Machakos, Makueni and Bomet)

Private Sector

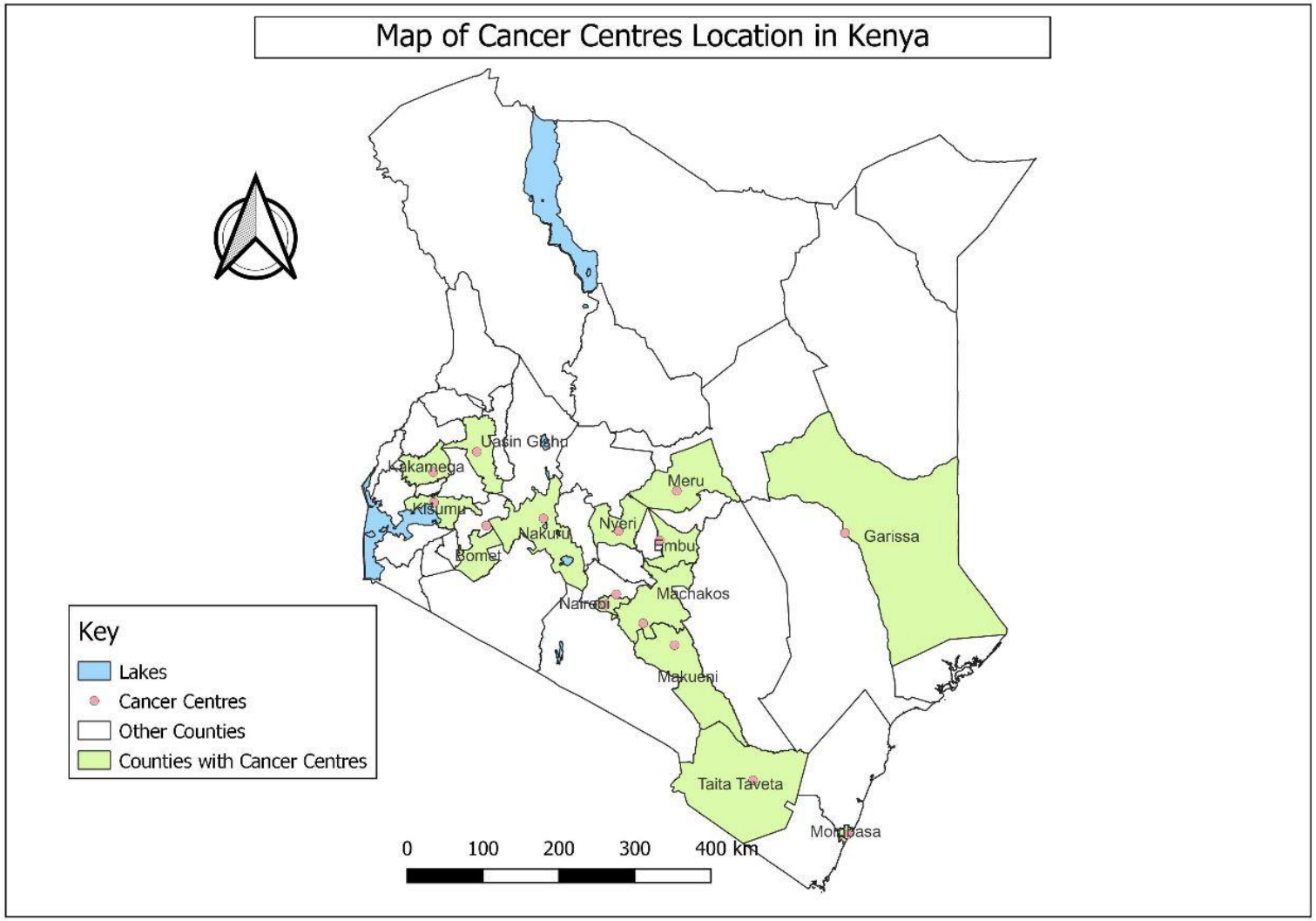
- Widely available in faith-based and private facilities

Financing:

NHIF is main financier with limits for first line/basic chemotherapy and complex/second line chemotherapy

Other Insurance

Out of pocket



13/47 counties with public cancer centres

Current Status of SACT Protocols

- *Institutional*
  - Available for some cancers
  - Shared across facilities
- *National*
  - Available but no details on doses; Process led by National Cancer Control Program
  - NCCN harmonized guidelines for sub-Saharan Africa - available
- *How widely used*
  - In Kenya National and Regional protocols - moderately used
  - Prescriber and institutional differences exist

History

National – TWGs formed first edition 2016,
review 2019

Regional

- Partnership between different organizations:
  - African Cancer Coalition (ACC)
  - American Cancer Society (ACS)
  - Clinton Health Access Initiative (CHAI)
  - IBM

JCO Global Oncology > List of Issues > Volume 6 >

SPECIAL ARTICLES | Cancer Prevention and Control

Toward Optimization of Cancer Care in Sub-Saharan Africa: Development of National Comprehensive Cancer Network Harmonized Guidelines for Sub-Saharan Africa

Miriam Mutebi, MBChB, MMed, MS[1]; Isaac Adewole, MBBS, DSc[2]; Jackson Orem, MD[3]; Kunuz Abdella, MD, MPH[4]; Olujimi Coker, MBBS[5]; Israel Kolawole, MBBS[6]; ...

Show More

- NCCN and members of ACC adapted the NCCN Guidelines and NCCN Framework for Resource Stratification of NCCN Guidelines (NCCN Framework) to create the NCCN Harmonized Guidelines for Sub-Saharan Africa
- ACC was formed in 2016
- Harmonization for each guideline completed by a group of 6-10 African cancer experts from a range of specialties with representation across resource levels. Each working group chaired by African oncologist and included a member of the appropriate NCCN guidelines panel.

Aim of SACT Protocols

To standardize care – improve access and outcomes (especially as cancer care is decentralized)

To streamline financing/reimbursement by NHIF

Example - Institutional

Table 13: INTERIM MAINTENANCE FOR STANDARD RISK ALL (Start 7-10 days after consolidation).

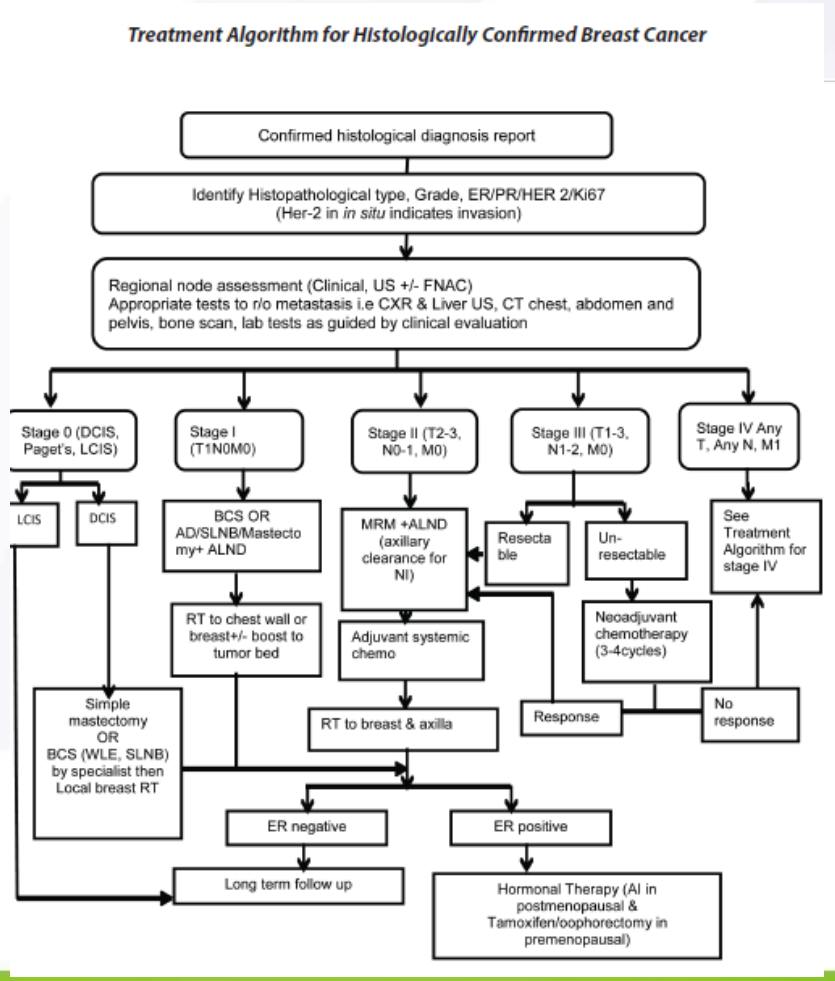
DRUG	ROUTE	DOSING	DAYS	COMMENTS	OBSERVATION
Vincristine	IV	1.5mg/m^2	1 & 29	Maximum 2mg with extravasation precautions	a. History and Physical b. CBC w/diff c. Liver & renal panel d. CSF Cytospin and
prednisolone	PO	40mg/m^2	1-5, 29-33	Don't taper	
6 mercaptopurine	PO	60mg/m^2	1-50	Reduce dose by 50% if ANC <750/ µL & plate Stop or pl Give even empt 1 hou drink	
Methotrexate	PO	20mg/m^2	1, 8, 15, 22, 29, 36, 43, 50	Hold meth	
Methotrexate	IT	Age / Dose: 1-1.99: 8 mg 2-2.99: 10 mg 3- 9: 12 mg >9: 15 mg	29	Reco befor (rem least be ad patie least	

STANDARD RISK ACUTE LYMPHOBLASTIC LEUKEMIA

Table 11:INDUCTION CHEMOTHERAPY FOR STANDARD RISK ALL.

DRUG	ROUTE	DOSAGE	DAYS	COMMENTS	OBSERVATIONS
Prednisolone	PO	40mg/m^2 per day (divided BD)	1-28	Taper from day 29 over 7 days.	a. History and Physical b. CBC w/diff c. Liver & renal panel d. Blood glucose e.. Bone marrow biopsy and aspirate f. CSF Cytospin and cell count g. Calcium and phosphates the above studies and other can be done as clinically indicated. Tapering prednisolone. Half dose for 1st two days, half again for the next 2 days, then half again to the 7th day.
Vincristine	IV	1.5mg/m^2	1,8,15,22	Maximum 2mg with extravasation precautions	
L-asparaginase	IM	6000I.U/m^2	D2, D4, D6 D9, D11, D13 D16, D18, D20 (total 9 doses)	Delay on days when vincristine is given.	
Methotrexate	IT	Age / Dose: 1-1.99: 8 mg 2-2.99: 10 mg 3- 9: 12 mg >9: 15 mg	1, 15, 29	Reconstitute to 5-10ml before administration (remove CSF volume at least half the volume to be administered. Let patient lie down for at least 30 minutes).	

Example of Protocol – National



HER2 negative disease

- o Doxorubicin/Cyclophosphamide x 4 cycles. Repeat cycle every 21 days.
- o Docetaxel/Cyclophosphamide x 4 cycles. Repeat every 21days.
- o Cyclophosphamide/Methotrexate/5-Fluorouracil x 6 cycles. Repeat every 28 days.
- o 5-Fluorouracil /Epirubicin /Cyclophosphamide. Repeat every 21 days x 6 cycles
- o Doxorubicin/Cyclophosphamide x 4 cycles every 21 days followed by Taxane x 4 cycles every 21 days.
- o Doxorubicin/Cyclophosphamide x 4 cycles followed by 12 weekly paclitaxel
- o Doxorubicin/Docetaxel/Cyclophosphamide for 6 cycles

HER 2 positive disease

- o Doxorubicin/Cyclophosphamide x 4 cycles followed by paclitaxel/trastuzumab ± pertuzumab x 4 cycles followed by trastuzumab ± pertuzumab x 18 cycles (9 cycles of trastuzumab ± pertuzumab can be used as an alternative)
- o Docetaxel/carboplatin/trastuzumab ± pertuzumab x 6 cycles followed by trastuzumab ± pertuzumab for 12 cycles
- o Paclitaxel and trastuzumab x 4 cycles followed by trastuzumab x 18 cycles

If using anthracycline and trastuzumab based chemotherapy, baseline echocardiograph will be required.

Example - Regional

NCCN Harmonized Guidelines™

- Global Program +
- Global Clinical Resources -
  - Clinical Guidelines Translations
  - Guidelines for Patients Translations
  - Distress Thermometer Tool Translations
  - International Adaptations
  - Framework for Resource Stratification
  - Harmonized Guidelines
- Global Support

NCCN Guidelines are used by clinicians around the world as a standard resource for clinical decision-making. The NCCN Harmonized Guidelines™ are targeted regional resources created as part of a collaborative effort to combat the skyrocketing cancer rates and unique circumstances of cancer care. They represent both the optimal care that resource-constrained areas aspire to provide and pragmatic approaches that could be used to improve the availability of effective treatment options.

Using the Harmonized Guidelines

Recommendations within the NCCN Harmonized Guidelines™ are represented as follows:

- **Black Text:** Generally available standard of care
- **Gray Text:** Highly advanced/optimal care that may be costly, technically challenging, and/or have a lesser impact on oncologic outcome
- ***Italicized Blue Text:*** Regional options that may be considered when availability precludes general standard of care
- **Gray Text with ~~Strikethrough~~:** Indicates care options that are not feasible or available at this time

NCCN Harmonized Guidelines™ for Sub-Saharan Africa

As part of a joint project with the African Cancer Coalition (ACC), American Cancer Society (ACS), the Clinton Health Access Initiative (CHAI), and IBM, NCCN and members of ACC adapted the NCCN Guidelines® and NCCN Framework for Resource Stratification of NCCN Guidelines (NCCN Framework™) to create the NCCN Harmonized Guidelines™ for Sub-Saharan Africa.

NCCN Harmonized Guidelines™ (Sub-Saharan Africa) - Guidelines for Treatment of Cancer by Type

- Acute Lymphoblastic Leukemia Version 2.2019
- Acute Myeloid Leukemia Version 3.2020
- Anal Carcinoma Version 2.2020
- B-Cell Lymphomas Version 5.2022
- Bladder Cancer Version 5.2020
- Bone Cancer Version 2.2022
- Breast Cancer Version 4.2021
- Central Nervous System Cancers Version 1.2019
- Cervical Cancer Version 1.2021
- Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma Version 3.2022
- Chronic Myeloid Leukemia Version 3.2020
- Colon Cancer Version 4.2020
- Esophageal and Esophagogastric Junction Cancers Version 4.2020
- Gastric Cancer Version 3.2020
- Gestational Trophoblastic Neoplasia Version 3.2020
- Head and Neck Cancers Version 1.2021
- Hepatobiliary Cancers Version 5.2020

Approval Process for SACT Protocol

- Institutional
  - Protocol committee appointed by the Medicines and Therapeutics Committee Chair
  - Committee develops protocols
  - Internal review
  - External review
  - Ratification by MTC
  - Order sheets approval by hospital documentation committee
- National / Regional
  - TWGs for each cancer
  - Consensus amongst members of ACC
  - Countries not obligated to implement or adapt

Where is the Country going

- Special interest groups e.g. Paediatrics, Hemato-oncology, Breast Ca
- Working on specific SACT
- Working with NHIF to standardize protocols – will ease funding approvals

- The region continuous to work on harmonized guidelines for SSA

Catalonia (Spain)

Cristina Ibáñez Collado

PharmD, BPS-BCOP

Catalan Institute of Oncology

Salut/ ICO Institut Català d'Oncologia

Spain has 17 regions with decentralized healthcare competencies

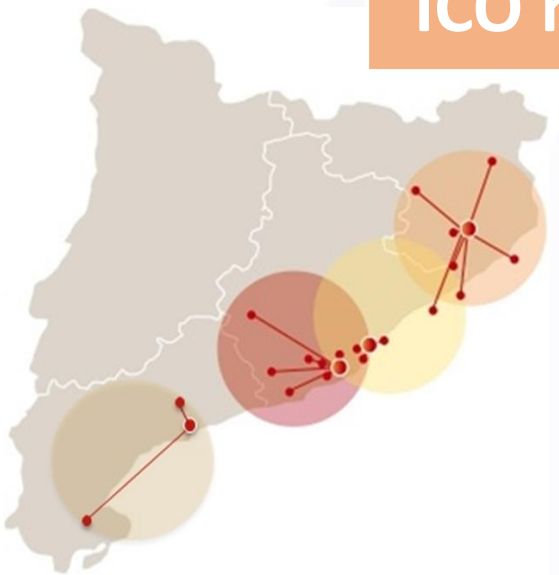
SPAIN
47.3 million people

7.6 million people

Salut/ ICO Institut Català d'Oncologia

Catalan Institute of Oncology created in 1995 by Catalan Health Service as a comprehensive multicenter cancer center.

ICO network



MISSION

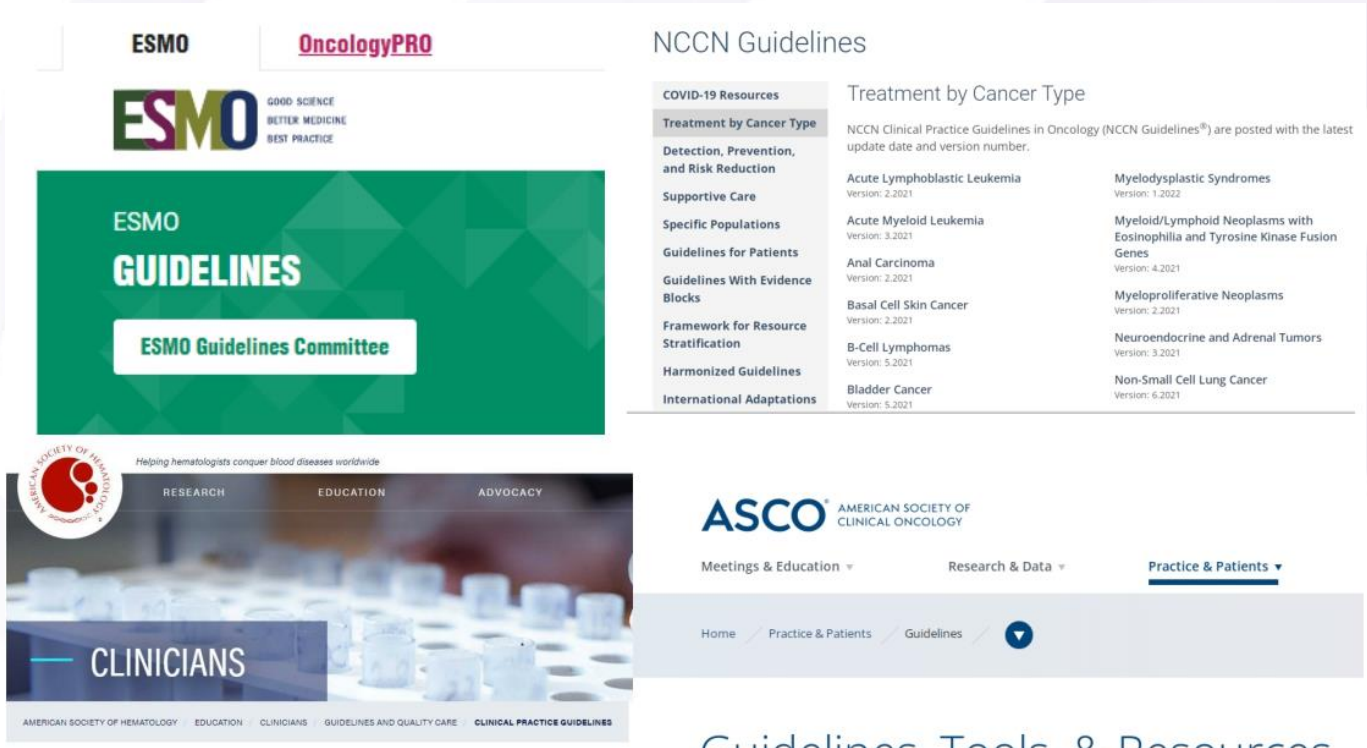
To work to reduce the impact of cancer in Catalonia.

Currently working as a multicentric network and serving over 4.5 million adult people living in Catalonia.

Salut/ ICO Institut Català d'Oncologia

Available from: https://ja.cat/ICO

Different CPG available, although applicability sometimes difficult



Salut/ ICO Institut Català d'Oncologia

Continued expansion of the ICO Guidelines

ICO Guidelines (2000)
Local guidelines

Oncoguies (2008)
Oncology Catalan Program (ICOnetwork)

ICO-ICS Praxis (2017)
Oncological Network of Catalonia

→ Adhesion of new catalan hospitals

Salut/ ICO Institut Català d'Oncologia

ICO-ICSPraxis

Guideline selection

UPDATE

Evaluation

Definition of indicators

Authors selection

-Multidisciplinary

-Multicentric

-Hospital Pharmacist leadership

Implementation

ESPOQ Eina de Suport al Procés Oncohematològic de Quimioteràpia

e-prescription

Methodology

-Evidence-based.

-Disclosures of conflicts of interest.

-National reimbursement criteria.

-Final recommendations according to level of evidence.

Edition and communication

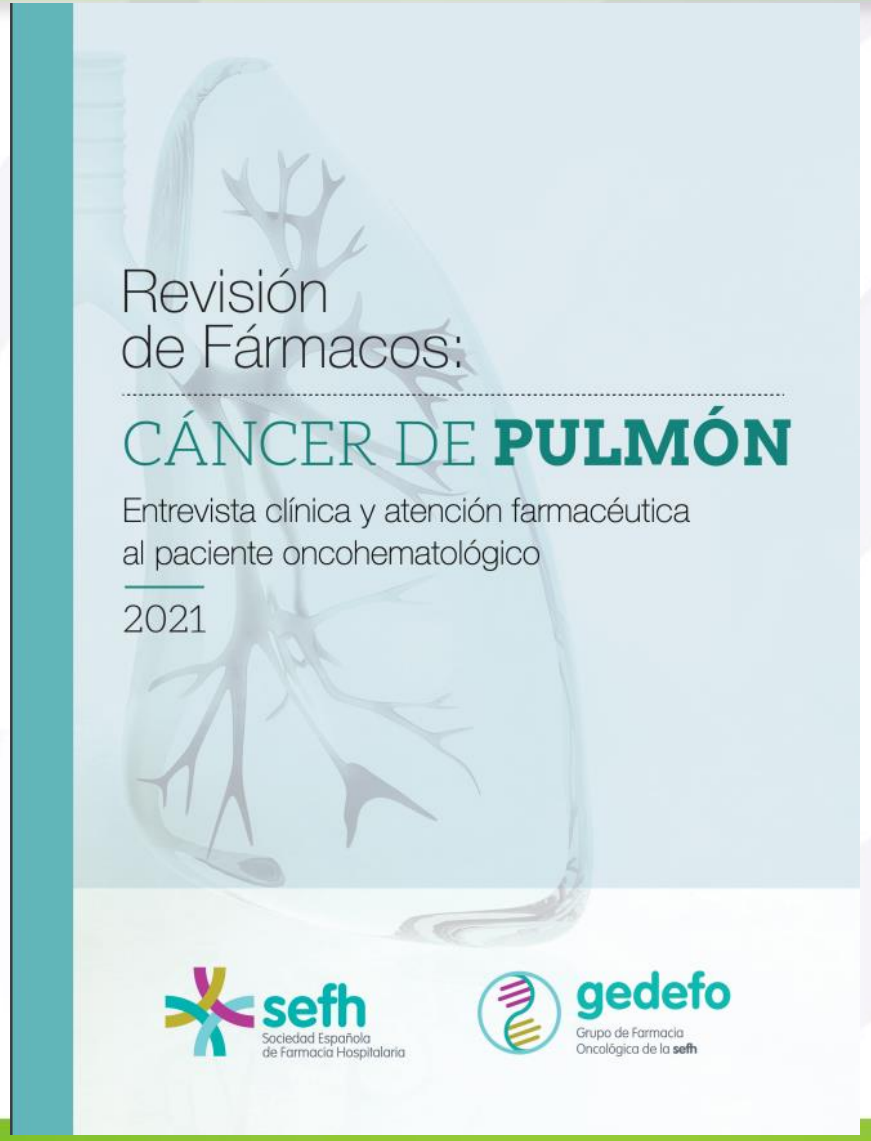
External review

P&T Committee approval

Salut/ ICO Institut Català d'Oncologia

@varelalaf

Available from:
https://gruposdetrabajo.sefh.es/gedefo/index.php/monografias



ÍNDICE

CÁNCER DE **PULMÓN** REVISIÓN DE FÁRMACOS

PACIENTE:

- Sexo.
- Edad.
- ECOG.
- Fumador.
- Indicación:
  - Cáncer de pulmón no microcítico estadio III o IV, en monoterapia o en combinación con carboplatino o cisplatino.

DOSIS:

- **DOSIS RECOMENDADA:**
  - Primeras tres administraciones: 60 mg/m² de superficie corporal, administradas una vez por semana.
  - Siguientes administraciones: Se recomienda incrementar la dosis a 80 mg/m² una vez por semana, excepto en aquellos pacientes cuyo recuento de neutrófilos haya descendido una vez por debajo de 500/mm3 o se sitúe más de una vez entre 500 y 1000/mm3 durante las tres primeras administraciones de 60 mg/m².
- **AJUSTES DE DOSIS:** **DOSE MODIFICATION**
  - Para cualquier administración en que se ha previsto administrar 80 mg/m², si el recuento de neutrófilos desciende por debajo de 500/mm3 o se sitúa más de una vez entre 500 y 1000/mm3, la administración debería retrasarse hasta la recuperación y la dosis reducirse de 80 a 60 mg/m² por semana durante las siguientes 3 administraciones.
  - Es posible incrementar nuevamente la dosis de 60 a 80 mg/m² por semana, si el recuento de neutrófilos no ha descendido por debajo de 500/mm3, o no se ha situado más de una vez entre 500 y 1000/mm3 durante las 3 administraciones en dosis de 60 mg/m², según se ha especificado previamente respecto de las primeras 3 administraciones.
- **REVISAR:** **MUST BE CHECKED**
  - Superficie corporal ≥ 2 m² → Dosis total nunca debería exceder de 120 mg /semana a la dosis de 60 mg/m² y 160 mg por semana a 80 mg/m².
  - Insuficiencia hepática moderado (bilirrubina entre 1,5 y 3 x LSN, independientemente de los niveles de ALT y AST) → Administrar a una dosis de 50 mg/m²/semana.
  - Insuficiencia hepático grave → No administrarse.

EFECTOS ADVERSOS: ADVERSE REACTIONS

EFECTO ADVERSO	RECOMENDACIÓN
ALTERACIONES HEMATOLÓGICAS (ANEMIA, LEUCOPENIA, TROMBOCITOPENIA), NEUTROPENIA, RIESGO DE INFECCIONES	• Lavarse las manos frecuentemente, siempre tras usar el baño. • Cuidar la piel y la boca. • Evitar aglomeraciones de personas y el contacto con personas enfermas. • Acudir a urgencias si tiene fiebre mayor de 38ºC.
TRASTORNOS NEUROSENSORIALES, NEUROMOTORES	• Precaución si manipula cosas que están calientes o muy frías.
MUCOSITIS	• Utilizar un cepillo dental blando. • Cepillar los dientes tras cada comida. • Enjuagar la cavidad bucal con colutorio sin alcohol. • Evitar tomar bebidas o alimentos muy calientes, picantes o ácidos.
HIPERTENSIÓN, HIPOTENSIÓN	• Control de la tensión frecuente. • Dieta sin sal ni cafeína. • Consultar al médico.
NÁUSEAS, VÓMITOS	• Tomar la medicación prescrita para el manejo de las náuseas. • Tomar alimentos ligeros y de sabores suaves. • Hacer comidas frecuentes, pero de pequeña cantidad. • Beber suficientes líquidos, en pequeñas cantidades.
ESTREÑIMIENTO	• Beber líquido abundante durante el día. • Ejercicio suave diario (andar). • Tomar alimentos ricos en fibra (si no hay contraindicación).
DIARREA	• Hidratación adecuada. • Dieta blanda: arroz, carne y pescado a la plancha. • Evitar fibra (fruta y verdura, excepto manzana, zanahoria y plátano). • Utilizar antidiarreicos (por ejemplo, loperamida). • Si aparece dolor abdominal, presencia de moco o sangre en heces, acudir al médico.
ALOPECIA LEVE	• El pelo vuelve a crecer cuando se termine el tratamiento. • Usar un champú suave y un cepillo blando. • Evitar tintes o cualquier producto agresivo para el cabello.
ARTRALGIA, MIALGIA, DOLOR DE CABEZA	• Consultar al médico. Puede probar a tomar paracetamol cada 6/8 horas (máximo 4 gramos al día).
MALESTAR GENERAL, CANSANCIO, ASTENIA	• No conducir o manejar maquinaria. • Hacer ejercicio suave (Ej caminar 15 min/día).

PRECAUCIONES: WARNINGS & PRECAUTIONS

- Sobredosis → Hipoplasia de médula ósea a veces asociada con infección, fiebre, íleo paralítico y trastornos hepáticos.
- Conducir y utilizar máquinas, debido a sus efectos adversos.
- En caso de vómito a las pocas horas de la toma del fármaco, no repetir nunca la administración de esta dosis.

- No debe administrarse concomitantemente con radioterapia si el campo de tratamiento incluye el hígado.
- Debe tenerse especial cuidado al prescribir este fármaco a pacientes.
  - Con antecedentes de cardiopatía isquémica.
  - Con bajo estado funcional.
- Contraindicación: Recuento de neutrófilos < 1500/mm3 o infección grave actual o reciente (en periodo de 2 semanas). Recuento de plaquetas < 100000/mm³.

EDUCACIÓN AL PACIENTE: PATIENT EDUCATION

- Explicar cómo guardar y cómo eliminar el fármaco:
  - Conservar en nevera (entre 2ºC y 8ºC). Mantener el blíster perfectamente cerrado.
  - Para abrir el envase:
    - Cortar el blíster a lo largo de la línea punteada negra.
    - Quitar la lámina de plástico blando.
    - Empujar la cápsula a través de la lámina de aluminio.
- Las cápsulas alteradas no deben tragarse y deben devolverse a la farmacia o al médico para que sigan el procedimiento habitual de destrucción de la vinorelbina.
- Educación antitabáquica.
- Las mujeres en edad fértil deben utilizar un método anticonceptivo efectivo durante el tratamiento y hasta 3 meses después de finalizar el tratamiento.
- Interrumpir la lactancia antes de iniciar el tratamiento.
- En hombres: riesgo de infertilidad irreversible → Buscar asesoramiento para conservar esperma.
- Se aconseja a los hombres no que no conciban un hijo durante el tratamiento y hasta 3 meses como mínimo después de finalizar éste.

ADHERENCIA: TREATMENT ADHERENCE

- Valorar el grado de comprensión de cada punto (hacer repetir al paciente cómo debe tomar la medicación) ___.
- ¿Es necesario un refuerzo de la información en futuras visitas? Sí/No.
- Valorar el grado de adherencia al tratamiento:
  - Recuento de medicación sobrante (real) versus teórico.
  - Seguimiento de visitas.
  - Preguntar directamente al paciente.

Available from: https://gruposdetrabajo.sefh.es/gedefo/index.php/monografias


High quality decisions
Better health results
G4 O3 A2 L4
Reduced variability
Improved efficiency

Guidelines and protocols

ICOPraxis

The ICO, as a center of excellence and reference in cancer prevention, treatment, research and training, produces different documents, guides and clinical practice protocols.

Important changes are currently taking place in the world of oncology treatment, with the introduction of new drugs and new therapeutic targets. The great current challenge is the evaluation of these new therapeutic and technological strategies with efficiency criteria, together with a continuous effort to evaluate the results.

One of the aims of the ICO is to provide evidence-based care, using a fundamental tool such as clinical practice guidelines (CPGs). These guidelines help us maintain therapeutic equity between patients and are a fundamental tool for therapeutic discussion with the patient, allowing for shared decision-making. In our area we will call them ICO therapeutic guides (ICOPraxis).

The starting point for the ICO therapeutic guidelines work is obviously and naturally the OncoGuidelines, due to the great involvement of the ICO professionals in their development. Based on them, adaptation and concretization will be made to the reality of our institution, concentrating efforts on the part of the treatments, both pharmacological and radiotherapy.

Salut/ ICO Institut Català d'Oncologia

Available from: https://ico.gencat.cat/ca/professionals/guies_i_protocols/

gencat

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Catalan Institute of Oncology

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Home > professionals > Guide

Guidelines

Para cualquier comentario o sugerencia de las ICOpraxis puede ponerse en contacto a través del correo electrónico: *praxis@iconcologia.net*

- Atención al final de la vida
- Cabeza y cuello
- Colorrectal
- Dolor oncológico
- Esófago
- Factores estimulantes de colonias granulocíticas
- Gástrico y de unión esofagogástrica
- Leucemia linfática crónica

Languages:

Spanish & Catalan

ICOPraxis

The ICO, as a center of excel practice protocols.

Important changes are curre at current challenge is the evaluation of these ne

One of the aims of the ICO i s maintain therapeutic equity between rea we will call them ICO therapeutic guides (ICOI

The starting point for the IC onals in their development. Based on ther nts, both pharmacological and radioth

Salut/ ICO Institut Català d'Oncologia

Available from: https://ico.gencat.cat/ca/professionals/guies_i_protocols/

ICO-ICS PRAXIS

ICO-ICSPraxis para el tratamiento médico y con irradiación del cáncer de mama

Actualización marzo 2022

ÍNDICE

Available from: https://ico.gencat.cat/ca/professionals/guies_i_protocols/

Recomendación de tratamiento hormonal adyuvante en tumores luminales HER2

(nivel de evidencia V para el algoritmo, los esquemas tienen un nivel de evidencia IA)

Como primera opción hay que valorar incluir a la paciente en un ensayo clínico.

Para indicaciones de quimioterapia adyuvante de plataformas ver el capítulo correspondiente.

PACIENTE PREMENOPÁUSICA

- **Si pT1-2 y pN0-N1mi:** tamoxifeno 20 mg/d x 5 años
  -Si menopausia a los 2-3 años*: cambiar a IA hasta completar 5 años *(nivel de evidencia IA)*.
- **Si > 45 años y pT3-4 o ≥ pN1a:** tamoxifeno 20 mg/d x 5 años y después:
  -Si premenopausia después de 5 años: completar 10 años de tamoxifeno 20 mg/d.
  -Si menopausia después de 2-3 años* o 5 años de tamoxifeno 20 mg/d, continuar IA 3-5 años *(nivel de evidencia IA)*.
- **Si ≤ 45 años y pT3-4 o ≥ pN1a:** tamoxifeno 20 mg/d x 5-10 años + análogos GnRH x 5 años o bien IA + análogos GnRH x 5 años *(nivel de evidencia IA)*. Valorar de forma individualizada prolongar el tratamiento con tamoxifeno o IA x 2-5 años más, en función del riesgo y estado menopáusico.

PACIENTE POSMENOPÁUSICA

- IA x 5-10 años** (letrozol 2,5 mg/d o anastrozol 1 mg/d) *(nivel de evidencia IA)*.
- En tumores de bajo riesgo: tamoxifeno 20 mg/d x 2 años seguido de IA hasta completar 5 años *(nivel de evidencia IA)*.
- En caso de carcinoma lobelar: letrozol 2,5 mg/d x 5-10* años *(nivel de evidencia IA)*.

* Hay que tener especial precaución cuando se inicia un IA en pacientes con amenorrea inducida por quimioterapia. No hay que iniciar IA en mujeres con amenorrea inducida por quimioterapia si tienen < 50 años (es preferible prolongar el uso de tamoxifeno el tiempo necesario). Se recomienda evaluar en conjunto los niveles de estradiol, FSH, edad y tiempo de amenorrea, así como el recuento de folículos antrales mediante una ecografía transvaginal antes de realizar el cambio a IA.

**Según riesgo clínico y tolerancia.

Adjuvant hormonal treatment in luminal HER2 breast cancer

-> **First option, try to include patient in a clinical trial.**

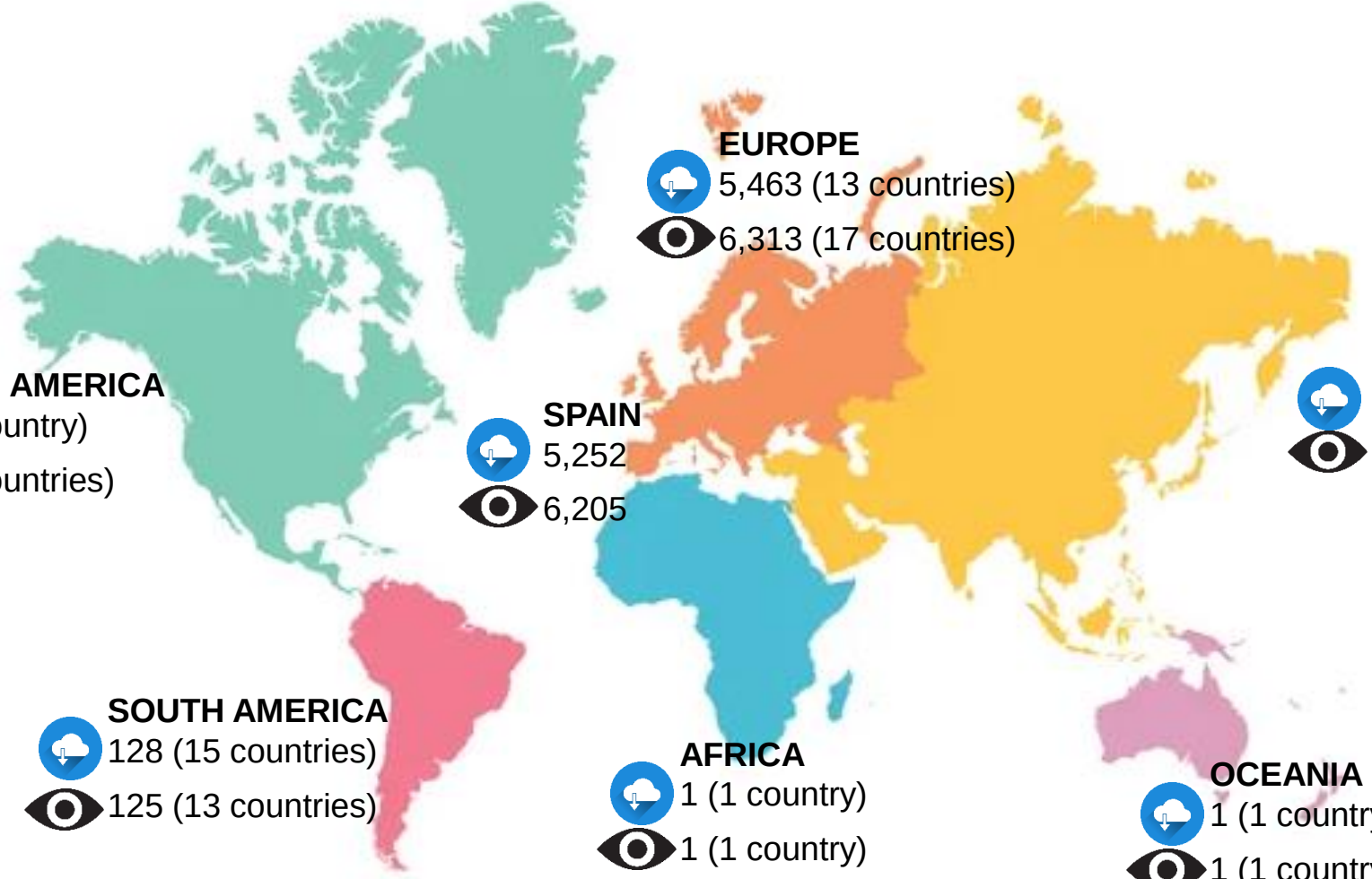
Available from: https://ico.gencat.cat/ca/professionals/guies_i_protocols/

Salut/ ICO Institut Català d'Oncologia

ICO-ICSPraxis downloads and visits in 2022

5,608 (32 countries)

6,480 (38 countries)



NORTH AMERICA
12 (1 country)
24 (2 countries)

EUROPE
5,463 (13 countries)
6,313 (17 countries)

SPAIN
5,252
6,205

ASIA
3 (1 country)
16 (4 countries)

SOUTH AMERICA
128 (15 countries)
125 (13 countries)

AFRICA
1 (1 country)
1 (1 country)

OCEANIA
1 (1 country)
1 (1 country)

Facilitating elements

- ✓Institutional project.
- ✓Multidisciplinary and multicentric project.
- ✓Evidence-based guidelines.
- ✓Commitment and leadership of professionals.
- ✓Real and practical implementation.

Barrier elements

- ✓Invested time (updates and elaboration).
- ✓Need for resources.

Cristina Ibáñez Collado

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United Kingdom

Netty Cracknell *MPharm, PGDip, MSc, FRPharmS (IP)*
Lead Cancer Pharmacist, Ramsay Health Care UK
ISOPP Secretariat Member
ISOPP Engagement and Communications Committee Chair
BOPA Digital Subcommittee Chair
UK SACT Board Member


United Kingdom
Physical
Orkney Islands
Shetland Islands
National Capital (2.765.000 in 2007)
over 1.000.000
over 500.000
over 200.000
over 50.000
other main city
other city
Capital of country
ATLANTIC
OCEAN
SCOTLAND
Aberdeen
Dundee
Edinburgh
Glasgow
Motherwell
Kilmarnock
Londonderry
NORTHERN IRELAND
Belfast
Dundalk
IRISH SEA
Isle of Man
Tynemouth
Newcastle upon Tyne
Sunderland
Hartlepool
Middlesbrough
Blackpool
Bradford
Leeds
Preston
Manchester
Liverpool
Sheffield
Kingston upon Hull
Dublin
IRELAND
Waterford
Stoke-on-Trent
Nottingham
Leicester
Birmingham
Coventry
Norwich
Peterborough
WALES
Northampton
Bedford
Cambridge
Ipswich
Swansea
Cardiff
Newport
Oxford
Swindon
Bristol
LONDON
Southend-on-Sea
Exeter
Southampton
Portsmouth
Brighton
Eastbourne
Plymouth
ENGLISH CHANNEL
CELTIC SEA
NORTH SEA
Calais
FRANCE
Lille
BELGIUM

Back ground of healthcare system - UK

- Majority of healthcare is fully funded by the NHS (4 separate)
  - Free at the point of delivery for everyone
  - Working population taxed
- NHS have 'approved list' of SACT treatments with specific indications
  - Assessed on cost effectiveness using Qaly (Quality Adjusted life year) - NICE
  - May restrict treatments to a narrower cohort of patients than license dictates
  - CDF (cancer drugs fund) access to SACT prior to NICE/ Qaly review – gain data on effectiveness in larger cohort of real patients
- Private healthcare is available
  - Insurance or self pay
  - All licensed indications/ evidenced treatments available

Current Status of SACT protocols

- *No National SACT Protocols*
- *Some regional protocols*
- *Individual hospital Trusts or private groups*

UK SACT Board (formally UK Chemotherapy Board)

- *Options appraisal published January 2022*
  - *Why, How, Costs, Next steps*
- *Currently working a proposal to develop National SACT Protocols with a UK wide 'not for profit' company already in the pharmacy field.*
  - *https://www.uksactboard.org/publications*

Aim - National SACT protocols

To improve patient outcomes, increase patient safety and reduce treatment variation by providing nationally consistent evidence-based best practice treatment protocols for information to support health professionals in the delivery of cancer treatments at the point of care

Local UK Example

(1 page of 5)

Dose dense EC-Paclitaxel (Epirubicin and Cyclophosphamide and Paclitaxel)

Indication
Adjuvant or neo-adjuvant treatment for high risk early stage and locally advanced breast cancer.

ICD-10 codes
Codes with a prefix C50

Regimen details
Cycles 1-4 EC

Day	Drug	Dose	Route
1	Epirubicin	90mg/m^2	IV bolus
1	Cyclophosphamide	600mg/m^2	IV bolus

Cycles 5-8 Paclitaxel

Day	Drug	Dose	Route
1	Paclitaxel*	175mg/m^2	IV infusion

*Paclitaxel may also be administered weekly at 80mg/m^2 for 8-12 weeks

Cycle frequency
14 days with GCSF support.

Number of cycles
Maximum of 8 cycles (4 x EC followed by 4 x paclitaxel)

Administration
Epirubicin and cyclophosphamide are administered by slow IV bolus into the arm of a fast running drip of sodium chloride 0.9%. Cyclophosphamide may also be given as an IV infusion in 250-500mL sodium chloride 0.9% over 30 minutes.

Paclitaxel is administered as an IV infusion in 500mL PVC free sodium chloride 0.9% via a 0.22 in line filter over 3 hours.

Patients should be observed closely for hypersensitivity reactions, particularly during the first and second infusions.

Hypersensitivity reactions may occur within a few minutes following the initiation of the infusion of paclitaxel and therefore facilities for the treatment of hypotension and bronchospasm must be available.

If hypersensitivity reactions occur, minor symptoms such as flushing or localised cutaneous reactions do not require discontinuation of therapy. The infusion may be temporarily interrupted and when symptoms improve re-started at a slower infusion rate. Severe reactions, such as hypotension, bronchospasm or generalised rash/erythema require immediate discontinuation of paclitaxel and appropriate therapy.

History

- *Lack of standardisation*
  - Lead to substandard care, inconsistency in practice and increased risk regarding patient safety
- *Significant duplication of work*
  - Inefficient resource use
  - Workforce issues in pharmacy, medical and nursing
- *No government money to fund a new programme*
- *Need to reduce access delays*

More than 100 Sydney cancer patients given wrong chemotherapy doses, report confirms

Dr John Grygiel under-prescribed doses to 129 cancer patients at St Vincent's hospital between 2012 and 2014

A damning report handed down by NSW Health has slammed St Vincent's hospital in Sydney for responding too slowly to cancer patient mistreatment concerns. Photograph: Dean Lewins/AAP

More than 100 cancer patients were given incorrect doses of chemotherapy by a senior doctor at St Vincent's hospital in Sydney, a report has found.

New South Wales Health handed down a damning final report into the dosing scandal on Tuesday, revealing that senior oncologist Dr John Grygiel had under-prescribed doses of cancer treatment drug carboplatin to 129 people, 103 of whom were head and neck cancer patients between 2012 and 2014.

Tayside

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NHS Tayside criticised for low chemotherapy doses

1 April 2019

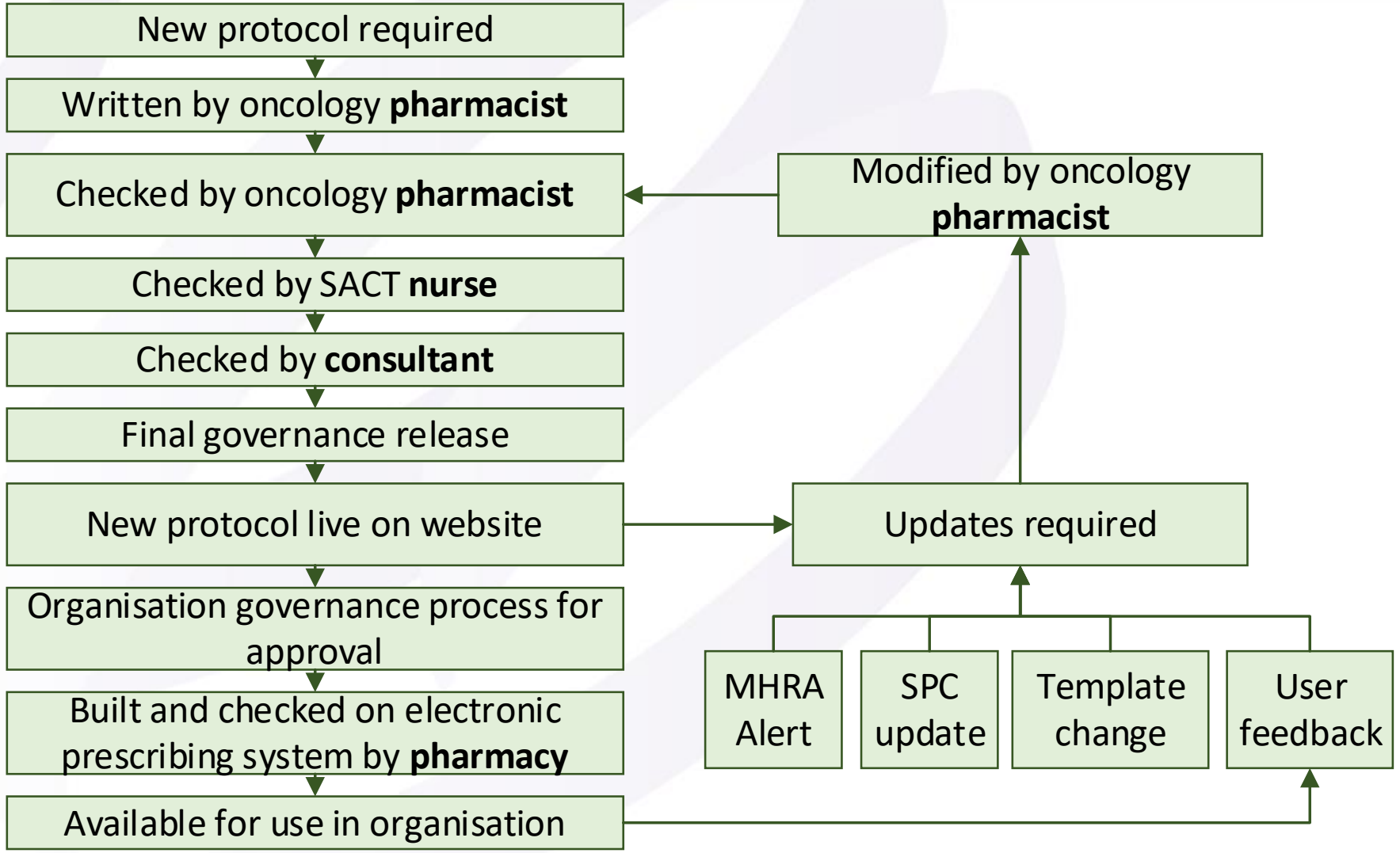
A health watchdog has criticised NHS Tayside after breast cancer patients were given lower doses of chemotherapy than patients elsewhere in Scotland.

A Healthcare Improvement Scotland (HIS) report also found Tayside patients were not told their treatment was different.

NHS Tayside said dosages were lowered in an attempt to reduce side-effects, and that the risks to the 304 patients involved were very small.

It will now bring treatment into line with the rest of the country.

Approval process of a SACT protocol



Where are the UK going?

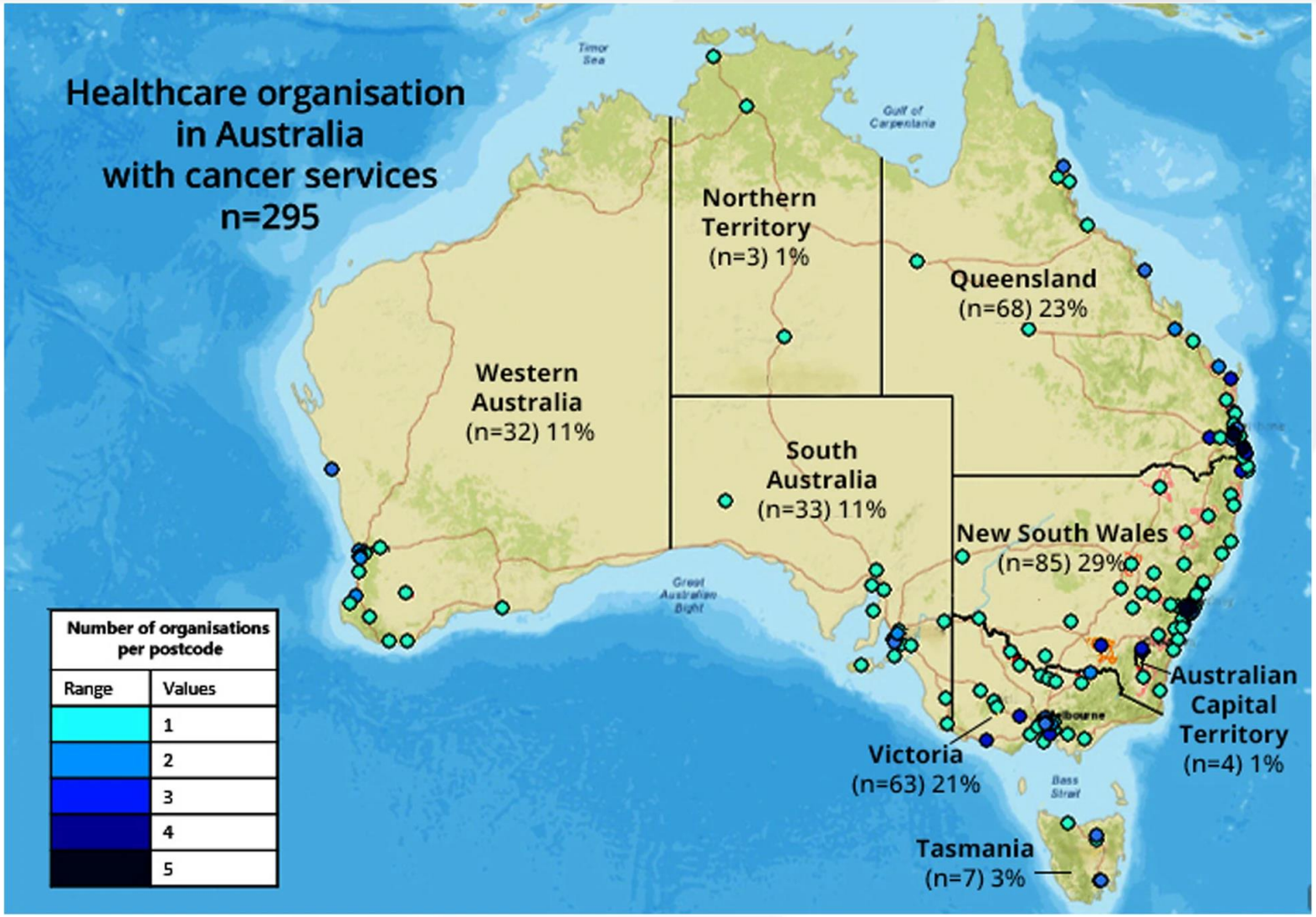
- High engagement to have national SACT protocols for UK
- Ensure clinical staff have access to high quality information to be able to safely treat patients
  - health products increase in complexity and become more personalised
- *UK SACT Board working with a UK wide 'not for profit' company in the pharmacy field to develop a proposal to take forward*
  - *For licensed indications or established standard of care – within the UK*
  - *Integration with ePMA systems*
  - *Potential to integrate with consent forms*

Australia

Shaun O'Connor

Senior Cancer Services Pharmacist, St Vincent's Public Hospital Melbourne

ISOPP Past President



Hunter, J., Smith, C., Delaney, G.P. et al. Coverage of cancer services in Australia and providers' views on service gaps: findings from a national cross-sectional survey. BMC Cancer 19, 570 (2019). https://doi.org/10.1186/s12885-019-5649-6

Information is 2016

Back ground of health system in Australia

- Significant private and public systems
  - However Prescription Benefits Scheme (PBS) single biggest funder of treatment in both private and public – federal government funded
  - Issues with inpatient care – state funded and can't access PBS - sometimes treatment given on discharge
- SACT treatments – progress to funding
  - Therapeutic Goods Administration (FDA equivalent) – safety and efficacy
  - Prescription Benefits Advisory Committee – recommendations on funding to **Health Minister – Cost Benefit Analysis, Quality Adjusted Life Year (QALY)**
    - **2017 – AUD$50k per QALY (US$35.6k early Feb)**

History

- EviQ timeline
  - 2004 - Adopted from South Eastern Sydney Area Health Service Intranet
  - 2005 – Made available as website, called Cancer Institute's Standard Cancer Treatments Program (CI-SCatT)
  - 2009 - rebranded as EviQ
  - 2012 – National model developed in conjunction with other state and territory governments via MoU – increase pool of clinical expertise

History

- Significant incidents – 2015, 2016
- Carboplatin underdosing – 100mg fixed dose rather than AUC 2 for CRTx
- Cytarabine dosing – protocol on OMIS/EPS as once daily when should have been twice daily
- Major audits of chemotherapy provision across state jurisdictions
- Health services began much more rigid adherence
- EviQ was beginning to be resource it is today

Current Status of SACT protocols

- EviQ – part of Cancer Institute NSW (State Government)
  - MoU with each state and territory since 2012 endorsing EviQ as preferred source of cancer treatment information.
- Most health services have elected to use EviQ as the major component, with individual processes examining protocols outside of the EviQ range
  - Element of reduced burden of collecting and evaluating information

eviQ – what is it?

- Free, online Australian government resource of cancer treatment protocols and treatment information
- Evidence based and peer reviewed
- Editorially independent = highly trusted
- Used in every cancer centre across Australia

- **Primary audience:** health professionals
- **Secondary audience:** patients and carers

NSW GOVERNMENT | eviQ

Cancer Institute NSW

eviQ's place in the clinical landscape

eviQ is a safe place to start and is intended to provide guidance.

eviQ + clinical judgement + individual patient factors and hospital policies to guide your practice

Other evidence-based, cancer treatment resources may be used e.g. NCCN or BCCA

- Guidance not a guideline
- Not mandated
- Editorially independent
- Complies with TGA/PBS
- Variation may be appropriate

NSW GOVERNMENT | eviQ

Cancer Institute NSW

EviQ

Breast adjuvant/neoadjuvant AC (DOXOrubicin and CYCLOPHOSPHamide) dose dense

Treatment schedule

Overview | Detail

Cycle 1 to 4

Drug	Dose	Route	Day
DOXOrubicin	60 mg/m^2	IV	1
CYCLOPHOSPHamide	600 mg/m^2	IV infusion	1
Pegfilgrastim	6 mg	Subcut	2

Frequency: 14 days

Cycles: 4

Notes:
- This is a potentially toxic regimen and should only be used in patients with a good ECOG performance status. Strategies to minimise toxicity include dose attenuation, thorough patient education and vigilant monitoring for any potential septic episodes.
  - Link to eviQ patient information sheet - Infection during cancer treatment

Drug status: Doxorubicin and cyclophosphamide are on the PBS general schedule

Pegfilgrastim is PBS authority

Cost: ~ $170 per cycle

- Indications and patient population +
- Clinical information +
- Dose modifications +

Breast adjuvant/neoadjuvant AC (DOXOrubicin and CYCLOPHOSPHamide) dose dense

- Indications and patient population +
- Clinical information +
- Dose modifications +
- Interactions +
- Administration +
- Side effects +
- Evidence - Adjuvant +
- Evidence - Neoadjuvant +
- References +
- Literature search +
- History +

The information contained in this protocol is based on the highest level of available evidence and consensus of the eviQ reference committee regarding their views of currently accepted approaches to treatment. Any clinician (medical oncologist, haematologist, radiation oncologist, medical physicist, radiation therapist, pharmacist or nurse) seeking to apply or consult this protocol is expected to use independent clinical judgement in the context of individual clinical circumstances to determine any patient's care or treatment. While eviQ endeavours to link to reliable sources that provide accurate information, eviQ and the Cancer Institute NSW do not endorse or accept responsibility for the accuracy, currency, reliability or correctness of the content of linked external information sources. Use is subject to eviQ's disclaimer available at www.eviQ.org.au

Send feedback for this page

EviQ

Breast adjuvant/neoadjuvant AC (DOXOrubicin and CYCLOPHOSPHamide) dose dense

Overview | Detail

The supportive therapies (e.g. antiemetics, premedications, etc.), infusion times, diluents, volumes and routes of administration, if included, are listed as defaults. They may vary between institutions and can be substituted to reflect individual institutional policy.

*Antiemetics if included in the treatment schedule are based upon recommendations from national and international guidelines. These are **defaults only** and may be substituted to reflect individual institutional policy. Select here for recommended doses of alternative antiemetics.*

Cycle 1 to 4

Day 1		
Netupitant	300 mg (PO)	60 minutes before chemotherapy (fixed dose preparation with palonosetron)
Palonosetron	0.5 mg (PO)	60 minutes before chemotherapy (fixed dose preparation with netupitant)
Dexamethasone	12 mg (PO)	60 minutes before chemotherapy. Note: the full dose of dexamethasone on Day 1 may not be required and may be reduced to 8mg at the clinicians discretion.
DOXOrubicin	60 mg/m^2 (IV)	over 5 to 15 minutes
CYCLOPHOSPHamide	600 mg/m^2 (IV infusion)	in 500 mL sodium chloride 0.9% over 30 to 60 minutes
Day 2		
Dexamethasone	8 mg (PO)	ONCE a day (or in divided doses) with or after food. Note: dexamethasone doses on Day 2, 3 and 4 may not be required and may be reduced or omitted at the clinicians discretion.*
Pegfilgrastim	6 mg (Subcut)	inject subcutaneously on day 2 at least 24 hours after chemotherapy
Day 3 and 4		
Dexamethasone	8 mg (PO)	ONCE a day (or in divided doses) with or after food. Note: dexamethasone doses on Day 2, 3 and 4 may not be required and may be reduced or omitted at the clinicians discretion.*

Breast adjuvant/neoadjuvant AC (DOXOrubicin and CYCLOPHOSPHamide) dose dense

Evidence - Adjuvant

The evidence for this protocol comes from the trial CALGB 9741 by Citron et al, 2003. The study used a 2 X 2 factorial experimental design to assess the 2 factors of dose density (administering the drug every 2 weeks versus 3 weeks) and treatment sequence (concurrent vs sequential) and the possible interaction between them.[1]

A total of 2005 women were randomly assigned to receive one of the following 4 arms:

1. Sequential doxorubicin x 4 -> paclitaxel x 4 -> cyclophosphamide x 4 with every 3 weeks
2. Sequential doxorubicin x 4 -> paclitaxel x 4 -> cyclophosphamide x 4 every 2 weeks with filgrastim
3. Concurrent doxorubicin and cyclophosphamide x 4 -> paclitaxel x 4 every 3 weeks
4. Concurrent doxorubicin and cyclophosphamide x 4 -> paclitaxel x 4 every 2 weeks with filgrastim

The primary end point was disease-free survival (DFS) and overall survival (OS) was a secondary endpoint.

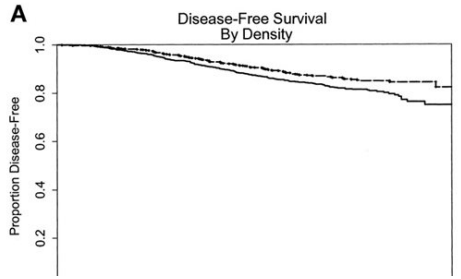
Efficacy

CALGB 9741 trial

After a median follow-up of 36 months, the dose dense treatment improved DFS (risk ratio (RR) =0.74; p=0.01) and OS (RR=0.69; p=0.013).

4 year DFS was 82% for the dose dense regimens and 75% for the others.

There was no difference in DFS or OS between concurrent and sequential regimens.[1]



Approval processes of a SACT protocol

- EviQ responds to advances in treatment and once TGA (+/- PBS) approved creates protocols
  - Volunteer committees of multidisciplinary teams recommend/review/produce protocols
    - Committees determine order of work
    - Specific Pharmacy reference committee that helps review and develop resources with pharmacy focus
- State or individual health services
  - Decide independently whether to adopt protocols
  - For EviQ protocols, most health services adopt as correct and adapt to hospital processes
  - Outside EviQ protocols, much sterner approval process

Where is the country going?

- EviQ to keep developing range of protocols and tools to support use
- “Integration” into major electronic prescribing systems
- Big data – but what can we do with it?

- Thanks to Julia Shingleton, EviQ for information and slides!

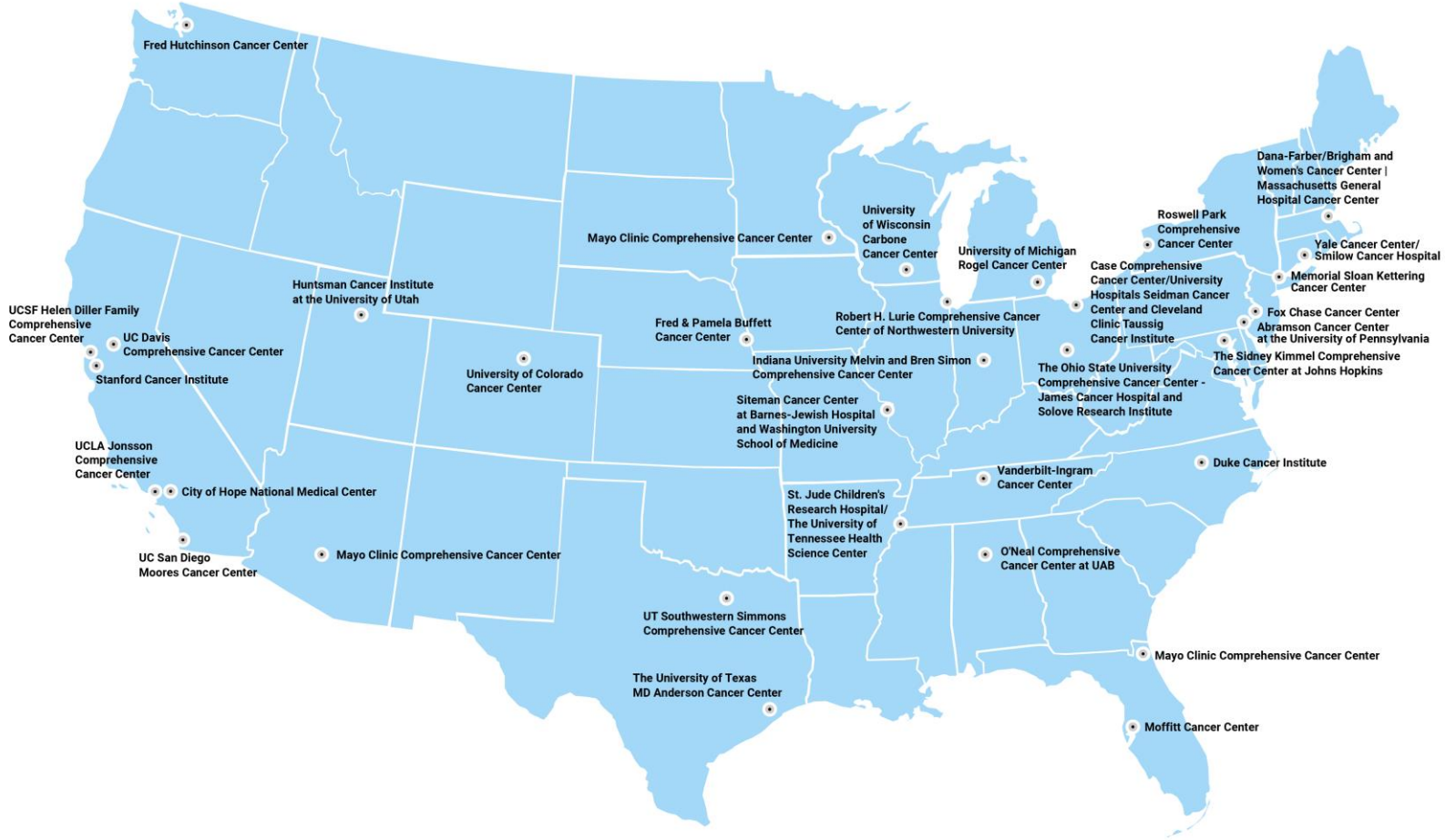
United States

Evelyn Handel Zapata, PharmD, BCPS, BCOP
Director, Drugs & Biologics Programs, NCCN
President, ISOPP (2022-2024)

Back ground of health system in US

- Access is largely dependent on insurance coverage
- Private and public payers in the US
  - Centers for Medicare & Medicaid Services (CMS) – government/taxpayer funded
    - Medicare – coverage for those age 65 and older
    - Medicaid – coverage for those with limited income
  - Private payers – employer-based or individual plans
    - Examples: Aetna/CVS, Anthem, Blue Cross Blue Shield, Cigna, Humana, Kaiser Permanente, UnitedHealth Group
- SACT treatment coverage determination
  - U.S. Food & Drug Administration (FDA) – approval based on safety and efficacy
  - Compendium listing – especially for off-label indications
    - NCCN Drugs & Biologics Compendium recognized by CMS and private payers as a reference for oncology coverage policy

NCCN: not-for-profit alliance of 32 leading academic cancer centers in the United States



Current Status of SACT protocols

- Institution-specific order set libraries
- NCCN Chemotherapy Order Templates are commonly referenced
  - Purpose: help clinicians safely and effectively administer SACT recommended in the NCCN Guidelines and NCCN Drugs & Biologics Compendium
  - Clinicians use them as a template for building institution-specific order sets
    - General guidance is intended to be adapted based on institutional standards
  - Licensed by 17 different EHR, prior authorization, and clinical pathway companies for integration into their systems
    - NCCN provides quality assurance (QA) of licensed content
  - Subscription required to access; NCCN is a not-for-profit organization
    - Over 1.7 million downloads in 2022
    - 10,319 unique users across 44 different countries in 2022

Example

National Comprehensive Cancer Network®

Chemotherapy Order Template

Breast Cancer

AC (DOXOrubicin/Cyclophosphamide) Every 21 Days

INDICATION:

HER2 negative: Neoadjuvant, Adjuvant, Recurrent unresectable (local or regional), or Metastatic

REFERENCES:

1. NCCN Guidelines® for Breast Cancer V.2.2022.
2. Nabholtz JM, et al. *J Clin Oncol.* 2003;21(6):968-75.[a]
3. Fisher B, et al. *J Clin Oncol.* 1990;8(9):1483-96.[a]

NCCN SUPPORTIVE CARE:

1. *Emetic risk:* Day 1 High
2. *Febrile Neutropenia Risk:* Refer to Myeloid Growth Factor algorithms in the NCCN Guidelines for Hematopoietic Growth Factors

CHEMOTHERAPY REGIMEN

*21-day cycle for 4 cycles (neoadjuvant or adjuvant) **or** until disease progression or unacceptable toxicity including reaching a lifetime cumulative anthracycline dose (Recurrent unresectable (local or regional) or metastatic)*

- **DOXOrubicin** 60 mg/m² IV push on Day 1
  - See *Safety Parameters and Special Instructions* for information on slow IV Push administration.
- **Cyclophosphamide** 600 mg/m² IV over 30 minutes on Day 1
  - Oral hydration is strongly encouraged with cyclophosphamide; poorly hydrated patients may need supplemental IV hydration. Patients should attain combined oral and IV hydration of 2,000 – 3,000 mL/day on day of chemotherapy.
    See *Other Supportive Therapy* for example of IV hydration.

SUPPORTIVE CARE

Antiemetic Therapy

Scheduled prophylactic antiemetic therapy should be given for prevention of acute and delayed nausea and vomiting based on the emetic risk of the chemotherapy regimen. This may include antiemetic therapy given on the days following chemotherapy. For more information on emetic prophylaxis, refer to the NCCN Guidelines for Antiemesis and Appendix D to the NCCN Chemotherapy Order Templates.

PRN for breakthrough: All patients should be provided with at least one medication for breakthrough emesis. Please consult the NCCN Guidelines for Antiemesis for appropriate antiemetic therapy.

Other Supportive Therapy

- For cyclophosphamide: *Example of recommended hydration*: Sodium chloride 0.9% infused IV at a rate of 1.5 – 3 mL/kg/hour for a total of 500 mL on day of chemotherapy.

MONITORING AND HOLD PARAMETERS

- CBC with differential should be monitored as clinically indicated for potential dose modification.
- For DOXOrubicin:
  - This agent is an anthracycline. Cumulative anthracycline dosage should be monitored.
  - Ejection fraction should be monitored prior to initiation of treatment and as clinically indicated.
  - Liver function should be monitored prior to each cycle and as clinically indicated for potential dose modification or discontinuation.
- For cyclophosphamide: Renal function should be monitored as clinically indicated for potential dose modification or discontinuation.

SAFETY PARAMETERS AND SPECIAL INSTRUCTIONS

- For DOXOrubicin:
  - **This agent is a vesicant OR an irritant with vesicant properties.**
  - This agent is administered IV push. The preferred IV push method for a vesicant is administration through the side port of a freely flowing IV.
  - Central venous access is recommended for administration of this agent.
  - Secondary malignancies have been associated with this drug. Review drug package insert for additional information.
- For cyclophosphamide: Secondary malignancies have been associated with this drug. Review drug package insert for additional information.

General Information:
- Disease
- Title, template ID
- Indications
- References
- Emetic risk & febrile neutropenia risk

Chemotherapy Regimen:
- Cycle information
- Chemotherapy dosing

Style Guide Notes:
- Supportive care
- Monitoring & hold parameters
- Safety parameters & special instructions

Templates link to Compendium/GL recommendation

NCCN Drugs & Biologics Compendium entry:

Guideline - Disease	Agent	Brand	Pharmacologic Class	Histology	Route(s)	ICD-10 Codes	NCCN Recommended Use	NCCN Category	Order Template	Billing Code
Breast Cancer - Invasive Breast Cancer Guideline Panel Disclosure	Cyclophosphamide	None	Alkylating Agent	Adenoid cystic and other salivary carcinomas, Ductal/NST, Encapsulated or solid papillary carcinoma, Lobular, Metaplastic, Micropapillary, Mixed, Other rare forms, Pure cribriform, Pure Mucinous, Pure Tubular, Rare low-grade forms of metaplastic carcinoma, Secretory carcinoma	PO, IV	C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929	Single-agent therapy or as a component of AC (doxorubicin and cyclophosphamide) regimen (useful in certain circumstances, in select patients with high tumor burden, rapidly progressing disease, and visceral crisis), EC (epirubicin and cyclophosphamide) regimen (useful in certain circumstances, in select patients with high tumor burden, rapidly progressing disease, and visceral crisis), or CMF (cyclophosphamide, methotrexate, and fluorouracil) regimen (useful in certain circumstances, in select patients with high tumor burden, rapidly progressing disease, and visceral crisis) for recurrent unresectable (local or regional) or stage IV (M1) human epidermal growth factor receptor 2 (HER2)-negative disease that is • hormone receptor-negative • hormone receptor-positive with visceral crisis or endocrine therapy refractory	2A	BRS4 BRS7 BRS12 BRS73	J8530, J9070, J9071

History

- Launched in June 2008 as a medication safety initiative
  - Initially available for 4 cancer types and published in a PDF format
  - Developed and maintained by external consultants
  - Updated every 2 – 3 years

- Currently 2,356 published templates as of February 2023
  - Covers 55 NCCN Guidelines, represents 104 unique cancer types
  - Published in PDF format as well as a FHIR-based XML available via API

Current Process

- Template libraries are updated annually by disease state in parallel with annual and interim version updates of the NCCN Guidelines and NCCN Drugs & Biologics Compendium

- NCCN Templates are developed and maintained by the NCCN Drugs & Biologics team of 13 nurses, APPs (NP/PA), and pharmacists

- Multi-step review and approval before publication
  - Templates built by RN → internal NCCN pharmacist review → external review by Chemotherapy Order Templates Committee → Guidelines panel physician
  - NCCN pharmacist publishes Compendium update with links to new templates

Future Directions

- Expansion into pediatric disease states underway
  - ALL, B-Cell Lymphoma, CNS, Hodgkin, Histiocytosis, Neuroblastoma, Wilms
- Ongoing improvements to the existing API and XML/FHIR format based on evolution of the HL7/FHIR and mCODE standards
- Grow existing and develop new licensed content relationships with heath information technology (HIT) companies to improve and facilitate quality, effective, equitable, and accessible cancer care

Summary

Similarities

- Started as medicines safety initiatives
- Cost and payments of treatments

- Tweaks to protocols at local sites

- Future and eP and integrations

Differences

- Availability of SACT in different countries
  - Licensed
  - Unlicensed
  - Government funded
- Different reimbursements on different SACT in different ways
- Level of engagement from pharmacists in writing/approving/leading

Pharmacists (per 10,000)

https://www.who.int/data/gho/data/themes/topics/health-workforce

The National health Workforce Accounts database, World Health Organization, Geneva (https://apps.who.int/nhwaportal, https://www.who.int/activities/improving-health-workforce-data-and-evidence).

Ask the Panel

The future of SACT Protocols

- National SACT Protocols needed in all countries?
- Re-inventing the wheel
  - Availability of SACT
  - Government funding of certain treatments
  - Facilities to prepare/administer different
- Sharing good practice
- Global sharing and language for EHR and eP/ePMA
  - FHIR based XML via API / mCODE / HL7
  - Ensure established National SACT protocols use WW common language

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