ChemoSafe: Strengthening the safe handling and use of chemotherapy in Uganda

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Abstract

ChemoSafe is a comprehensive approach to promote the safe handling and administration of chemotherapy and quality service provision to patients in Sub-Saharan Africa. The program encompasses the lifecycle of chemotherapy delivery, including logistics, compounding, administration (including diagnostics and side effect management), and disposal. It engages all healthcare and facility workers with the potential for interaction with chemotherapy, such as physicians, pharmacists, nurses, students and trainees, cleaners, and laundry workers. Early establishment of these systems is a key precondition to creating context-appropriate cancer treatment programs that can be scaled up and decentralized to meet the needs of cancer patients in Sub-Saharan Africa.

The program has two objectives: 1) establish a safety culture for handling and administration of chemotherapy; and 2) improve access to appropriate personal protective equipment.

Main Collaborators

Technical experts: American Society of Clinical Oncology (ASCO) and Oncology Nursing Society (ONS) will lead the development and/or adaptation of technical content (curricula, standards, etc.) for ChemoSafe, in consultation with in-country experts, and will conduct the initial trainings in Sub-Saharan Africa.

Country partners: Ministry of Health and Uganda Cancer Institute leadership will provide logistical and in-kind support, provide overall oversight of chemotherapy provision, and manage the supply chain.

Market partner: Clinton Health Access Initiative (CHAI) will develop partnerships with manufacturers and distributors to expand access to quality, affordable health products, with a focus on diagnostics and personal protective equipment.

Logistical coordination: American Cancer Society will lead coordination, logistics, and planning, and will collect and oversee the funding contributed to ChemoSafe.

► Main Section of the Proposal

Overall Goal and Objectives

ChemoSafe is a comprehensive approach to promote the safe handling and administration of chemotherapy and quality service provision to patients in Sub-Saharan Africa. The program in Uganda has two objectives:

1) Establish a safety culture for handling and administration of chemotherapy

2) Improve access to appropriate personal protective equipment.

Current assessment of need

Sub-Saharan Africa's cancer burden is significant and growing. In 2012, there were an estimated 626,400 new cases of cancer and 447,700 deaths from cancer in Sub-Saharan Africa (1). Based on population aging alone, annual cancer deaths in Sub-Saharan Africa are projected to almost double by 2030 to 983,000 people (2). Access to chemotherapy is limited by a number of challenges, including a poorly functioning market, lack of diagnostic and pathology services, and a small oncology workforce.

The state of cancer treatment in Africa today looks similar to that of HIV in the early 2000s. There are effective tools to diagnose and treat cancer, but access to these tools is largely limited to developed countries. The American Cancer Society (ACS) is working to improve access to cancer treatment by building on the lessons learned in the successful scale-up of HIV treatment. In partnership with Ministries of Health, ACS is building key infrastructure needed to deliver effective, high-quality cancer treatment and to establish a robust culture of safety through a new program called ChemoSafe.

For cancer treatment programs to successfully scale, they must be 1) safe for providers, 2) safe for patients, and 3) widely accessible.

Safe for providers: Chemotherapy can pose occupational hazards for the healthcare workers who handle, prepare, and administer them. As use of chemotherapy increases, so will the risk of occupational exposure, and several African health ministries have requested assistance with improving the safety of chemotherapy management. Many African hospitals face challenges not seen in other regions. For instance, hot work environments make it challenging for staff to work for long periods in gowns, gloves, and masks. Large cancer centers that are spread over several buildings may require staff to carry supplies over long distances, often out of doors. And resources available for safe waste disposal vary.

Safe for patients: Chemotherapy treatments are cytotoxic, or toxic to living cells. Thus, in the process of combatting cancer cells, they can also cause harm to the patient. In order to ensure patient safety, strong diagnostic systems are needed, both prior to treatment initiation and on an ongoing basis for monitoring. In addition, health workers must be empowered to identify and manage adverse side effects. And strong referral systems are needed for cases that require advanced care.

Widely accessible: Currently, it is estimated that less than 10% of cancer patients in Sub-Saharan Africa access the treatment they need. Chemotherapy expansion will require expanding access to high-quality pathology and a well trained and equipped health workforce, across multiple cadres, that is empowered to deliver safe, effective chemotherapy.

Establishing a culture of safety, robust training and mentorship, and quality, affordable equipment and supplies will provide a foundation for the necessary expansion of chemotherapy.

ChemoSafe seeks to help countries ensure that the provision of chemotherapy can meet each of these goals. The program encompasses the lifecycle of chemotherapy delivery, including

logistics, compounding, administration (including diagnostics and side effect management), and disposal.

Target audience

Uganda, with a population of 37 million people, has 29,000 new cancer cases and 22,000 deaths from cancer each year (2012), translating into a mortality-to- incidence ratio of 0.76. The Uganda Cancer Institute is the only comprehensive cancer center in the country and has been designated the regional oncology center of excellence for the East Africa Community.

ChemoSafe engages all healthcare and facility workers at the Uganda Cancer Institute with the potential for interaction with chemotherapy, such as physicians, pharmacists, nurses, students and trainees, cleaners, and laundry workers.

Project Design and Methods

Objective 1: Establish a safety culture for handling and administration of chemotherapy

The first objective is to establish a safety culture for handling and administration of chemotherapy. The Oncology Nursing Society (ONS), US National Institute for Occupational Safety and Health (NIOSH), World Health Organization (WHO) and Pan-American Health Organization (PAHO) have all developed or published guidance for safe handling of chemotherapy, including training recommendations, checklists, and equipment recommendations. These efforts will serve as the foundation for ChemoSafe and ACS is collaborating with ONS to adapt and deliver these resources, including:

1. Development of training standards, curricula, and e-learning modules appropriate to the local context, leveraging international best practices
2. Development of standard operating procedures, job aids, checklists, and other supporting materials, leveraging international best practices
3. Development of surveillance, monitoring, incident reporting, and referral systems
4. Deployment of technical experts to launch the program and train local experts in Sub-Saharan Africa

In Uganda, ACS will work closely with the Ministry of Health and Uganda Cancer Institute to create a program that is reflective of their priorities and is shaped with input by their experts. Key steps in the plan include:

1. Establishment of a **ChemoSafe technical working group** led by the Ministry of Health and the Uganda Cancer Institute. and comprising cancer care experts, particularly from pharmacy and nursing departments
2. Development of a **hospital-level risk assessment**, using a tool adapted from ONS materials. The assessment considers every potential contact point, from receiving a delivery of chemotherapy, to patient discharge and including laundry, waste disposal, mixing, administration, and patient and caregiver exposure. It provides a blueprint for developing process interventions, such as spill kits, standard operating procedures,

specialized training, patient and caregiver education, and personal protective equipment standards.

3. **Develop or adapt standard operating procedures** identified by the technical working group. Initial scoping by a small group of experts at Uganda Cancer Institute indicates the need for the following standard operating procedures:

   a. Requesting/order for pharmacy to reconstitute cytotoxic drugs
   b. Storage of cytotoxic drugs in pharmacy
   c. Cleaning before chemotherapy reconstitution
   d. Putting on protective gear for pharmacists
   e. Reconstitution of cytotoxic drugs in pharmacy
   f. Waste disposal in pharmacy during and after reconstitution (in the pharmacy)
   g. Checking patient's details/prescription with prepared drugs (in pharmacy)
   h. Packing of cytotoxic drugs for transport (in pharmacy)
   i. Handing over procedure to the nurses
   j. Transport of cytotoxic drugs from pharmacy to place of administration (within institution)
   k. Checking patient's details/prescription with prepared drugs (on the ward)
   l. Checking patient's condition (performance score, vital signs, weight, labs etc.) before chemotherapy administration
   m. Step of action when patient's condition is questionable to receive chemotherapy
   n. Preparation of IV lines/cannula before chemo administration
   o. How to inform patients/caregivers about chemotherapy and safety
   p. Administration of pre-drugs
   q. Administration of chemotherapy IV/IM/IT/Central line/Port-a-Cath
   r. Administration of chemotherapy Oral
   s. How to protect yourself during administration
   t. How to handle in case of vomiting/diarrhea/urinating of patient
   u. Discharge procedure
   v. Waste disposal after chemotherapy administration (on the ward)
   w. What to do in case of extravasation
   x. What to do in case of adverse reaction (including anaphylactic shock)
   y. What to do in case of spill (direct spill of chemotherapy or through vomit, stool, urine, blood)
   z. How to clean possible contaminated surfaces
   aa. How to dispose of contaminated waste from the wards/pharmacy/labs
   bb. How to manage chemo contaminated lab samples

4. **Adaptation and adoption of the ONS curricula** for training of nurses, pharmacists, and ancillary staff in safe handling and administration of chemotherapy and creation of a training plan.
5. **Establish a list of essential personal protective equipment** and secure supplies in the Uganda Cancer Institute.
6. **Establish a cadre of nurse-trainers** with a Training of Trainers led by ONS experts.
7. **Train all staff with the potential to come into contact with chemotherapy**

Objective 2: Improve access to appropriate personal protective equipment

The second objective is to secure access to appropriate personal protective equipment, including laminar flow hoods, gloves, gowns, masks, and chemotherapy pumps. ACS will be partnering with CHAI to implement this objective, which will include:

1. Development of a minimum required health product list, including infrastructure, medicines, diagnostics, and consumables, leveraging the WHO's Essential Medicines List and Essential Equipment List
2. Provision of the required health products, though a combination of domestic and international funding, as well as supply chain strengthening
3. Commodity market-shaping to improve the availability, affordability, and quality of the required health products, through improved forecasting and stock management and engagement with manufacturers and in-country distributors.

Evaluation Design

The following process and outcome indicators will be used to monitor and evaluate the program.

1. Technical working group formed and meets at least three times
2. Development of training standards, curricula, standard operating procedures, and job aids: list of materials developed and in use at the Uganda Cancer Institute
3. Provision of the minimum required personal protective equipment/supplies in Uganda Cancer Institute: quarterly inventory list
4. Number (percent) of staff trained: proportion of staff who have completed training
5. Percentage increase in staff knowledge, via pre- and post- tests: proportion with 70% of questions answered correctly on post-test

Workplan and Deliverables

1. **ChemoSafe Pilot Launch**
    a. Preparation (October-December)
        i. Adaptation of key tools (curricula, standard operating procedures, job aides, etc.)
        ii. MOH and Uganda Cancer Institute leadership consultation and planning
        iii. Finalization of tools
    b. Program Launch at Uganda Cancer Institute (January)
        i. Hospital preparation (January)
        ii. Personal protective equipment/supplies provision (February-April)
        iii. Trainings and implementation of systems (March-ongoing)
        iv. M&E and development of lessons learned for expansion

Table 1. Schedule of deliverables

	2017								2018						
Task	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Technical working group meeting		X			X		X		X						
Adaptation of ONS curricula				X											
Finalize list of administrative controls (SOPs, job aids, etc)						X									
Complete adaptation of administrative controls (SOPs, job aids, etc)									X						
Finalize list of minimum PPE			X												
Complete procurement of minimum PPE							X								
ONS-led training of trainers					X										
Complete training of all staff with potential contact with chemotherapy													X		
Complete hospital needs assessment						X									
Implementation of surveillance and incident reporting system							X								

► References

1. International Agency for Research on Cancer. GLOBOCAN 2012: Estimated Cancer Incidence, Mortality and Prevalence Worldwide in 2012 [Internet]. 2014 [cited 2014 May 12]. Available from: http://globocan.iarc.fr/Default.aspx

2. World Health Organization. Global health estimates summary tables: Projection of deaths by cause, age and sex, by World Bank regions [Internet]. Geneva, World Health Organization; 2013 [cited 2017 Apr 28]. Available from: http://www.who.int/healthinfo/global_burden_disease/projections/en/

► Conclusion

As the burden of cancer grows rapidly in Sub-Saharan Africa, more health workers and more hospitals will be engaged in cancer care. It is imperative that a strong and safe foundation for chemotherapy provision is established in each country, so that treatment expansion can occur in a quality and timely manner. Investment from Pfizer in the launch of ChemoSafe in Uganda will lead to tangible outcomes in a short time and significant expansion of access to chemotherapy in the long term.