Interview Guide

Guiding questions:

1. **What is your role/your organization's role in the procurement of (childhood) cancer drugs?**
2. **What do you see as the major barriers to (childhood) cancer drug access in your country? How could access be improved?**

Part I. Policy and Economic Issues

A. Policy and Legal Framework

i. National medicine policy

- Is there a national medicine policy in your country, or written document specifying national goals for the pharmaceutical sector and/or a framework for coordinating this sector?
    - PROBE: For example, components of a national medicine policy might include legislative and regulatory frameworks, choice of essential medicines, and/or financial strategies
- What is the role of national regulatory authorities in ensuring patient access to pediatric cancer medicines? PROBES:
    - What is the purview of these authorities? How do they relate to international regulatory bodies and/or recommendations from regulatory authorities internationally?
    - How are regulatory authorities involved in decision-making regarding local pharmaceutical production?
    - What are the regulations and incentives for quality insurance of local pharmaceutical production?

ii. Intellectual Property and Access to Medicines

- How do national and international intellectual property regulations influence access to childhood cancer medicines in your country?
- Are there regulatory barriers to introducing generic competition for childhood cancer medicines?

B. Financing and Sustainability

i. Affordability (from system, institutional, and patient perspectives)

- What are the implications of the current financing mix/model for:
    - Drug purchasing and prices?
    - Drug affordability at the institutional and patient levels?
    - Resource sustainability for the procurement of childhood cancer care drugs?

  - Priority setting and resource allocation for childhood cancer programs and services?
  - Equity of access to childhood cancer medicines?
- How does the financing for childhood cancer care (including drugs) differ from that for cancer care and control in adults?
- What factors contribute to intra- and inter-national differences in the pricing of childhood cancer medicines?
  - PROBE: How do manufacturer pricing schemes and taxes along the pharmaceutical supply chain contribute to this?
- Health Insurance
  - Please describe the scope of health insurance coverage for cancer care and childhood cancer care. PROBES:
    - Are all childhood cancers covered by public funding or is coverage limited to only specific childhood cancers, certain populations or certain age groups of children/adolescents with cancer?
    - If funding is limited to specific cancers or populations, which ones and why were those ones selected (cost effectivesness, level of supportive care necessary, achievable cure rates, etc.)?
    - Is public coverage limited to specific sites of care (i.e. only government hospitals) or is there also partial payment of private care facilities)?
    - In general, do patients have access to public or employer-based health insurance?
- Patient Perspective
  - What are the cost-related barriers for patients to access childhood cancer medications in your institution and country?
    - PROBE: Are these medications available in generic formulations? How are off-patent cytotoxic drugs financed?
    - PROBE: Is there any form of regionally pooled purchasing for childhood cancer medications?

The following questions should be answered through **desk review** if possible:

i. Resource Distribution

- Please describe the existing systems of governance/organization for pooling and distributing funds for:
  - The health system
  - Cancer care
  - National Cancer Control Plan (NCCP) directed programs, if a NCCP exists
  - Childhood cancer care
  - PROBE: What, if anything, could be improved in terms of pooling and distributing of funds?
- How are resources allocated within the national health system? PROBES:

  - General health priorities? Disease priorities? Target groups? Target regions? Level of care (primary/secondary/tertiary)? Types of care (preventive/early diagnosis/curative treatment/palliative care)?
  - Is there a formula used for resource allocation?
  - How are cancer program budgets used, if at all, at the national, regional, district and/or community levels?
  - *If there is a National Cancer Control Programme (NCCP):* How has the NCCP influenced: the structures/systems for pooling and distributing of funds?
  - What, if anything, would you change about how resources are allocated for the national health system?
- What is the budget allocation for childhood cancer in your country? How much is actually spent on childhood cancer care? PROBES:
  - Absolute amount per year and the proportion from total health expenditure indicating the currency and year of estimation
  - If a national cancer center exists, its annual operating budget and proportion spent on childhood cancer
- Please describe the main modalities and streams of funding for the childhood cancer care continuum in relation to health system components (primary care, diagnosis and referral, tertiary care, palliative care, survivorship care). PROBES:
  - Are designated bundles of resources allotted to specific childhood cancer diagnoses? Or are system components (e.g. hospital services, physician services, medicines, etc) funded through distinct mechanisms? Or is it a mix of the above? Please describe.
  - Is there funding in your country to cover non-treatment related costs for cancer such as travel, food, and/or accommodation for families?
  - What components of medical care are patients/families required to self-fund? What out of pocket costs are typically incurred by patients/families?
  - If so, specify who provides these funds and the proportion of cost/amounts.
  - How do government subsidies, national health insurance, private foundations, public-private relationships, and user charges influence funding?
  - What roles do international organizations, such as the United Nations, pharmaceutical donations, and donor funding play in financing medications?

- Please describe how the following receive payment:
  - Health care institutions in general?
  - NCCP supported programs?
  - Cancer treatment centers?
  - PROBE:
    - Does the payment mechanism for programs and institutions encourage or discourage productivity in any way? Honesty and quality assurance? Improved patient outcomes?

Part II. Pharmaceutical Management

A. Selection

- Is there a national drug formulary? Please provide.
    - PROBE: Who manages the national formulary? What governance and oversight mechanisms exist for the national formulary? Who sets priorities for pharmaceutical policy? What is the process for adding/removing products from the formulary?
    - PROBE: What factors influence the selection of this list? – e.g., prevalence of diseases, cost-benefit ratio, scientific data
    - PROBE: What, if any, barriers exist to national formulary compliance with World Health Organization (WHO) essential medicines list (EML) recommendations?
- Do you have a National Drug Price Reference Index? Please provide.

B. Procurement

i. Managing procurement

- Who is responsible for obtaining childhood cancer medicines – e.g., the patient, physicians/providers, the treating institution
    - PROBE: Through what channels are these medicines obtained – public/central medical stores, private outlets, private foundations?
- How are cancer medicines procured at the national level? – e.g., open or closed tender, direct procurement, competitive negotiation, purchasing from international procurement agencies?
    - PROBE: What principles or strategies dictate this procurement? – e.g., Procurement of generic medicines, pharmaceutical quality standards, limitation of procurement to essential medicines, competitive procurement?
    - PROBE: What purchasing models are followed? – e.g., annual purchasing, scheduled purchasing, perpetual purchasing?
- What is the role of global health initiatives (e.g., Pan American Health Organization (PAHO) Strategic Fund) in procurement?
- What is the role of civil society actors such as non-governmental organizations (NGOs) in procurement?
- Is procurement of childhood cancer medicines distinct than for other classes of medicines?
    - PROBE: How, if at all, do the procurement structures in the health system, disease programs, adult cancer programs, and pediatric cancer care programs interact? Do they use the same supply chain management systems?
- Are there national procurement laws which govern this process?

ii. Quality assurance

- What quality assurance programs exist for essential cancer medicines (national, institutional)? Are they put to routine use? – e.g., selection of suppliers with acceptable

quality standards; quality assurance for packing, storage, delivery, and recording; appropriate management of quality concerns

- Are there issues of drug safety and efficacy for EML medications, such as counterfeiting, improper production, and inadequate quality surveillance?

iii. Quantification

- What processes exist to determine the amount of medication required for procurement? – e.g.
    - Consumption method (based on past use) - what data and supply systems does this come from?
    - Morbidity method (predicts theoretical quantities needed for specific diseases) – requires data on morbidity and patient visits to quantify
    - Proxy consumption method – based on data from other facilities, regions, and countries
    - PROBE (if applicable): Given that procurement is at a national level, please describe how medications are coordinated and shared across institutions?
    - PROBE: How is the quantification process performed? Manually or computer-based? Centralized (government) or decentralized (peripheral warehouses, health facilities)?
- How does procurement relate to national drug formulary provisions?

C. Distribution

i. Managing Distribution

- How are medicines supplied to government and non-governmental health services?
- Please describe the process by which essential cancer medicines are distributed? – e.g.,
    - System type: Geographic or population coverage? Push or pull system?
    - Information system: What systems exist for inventory control, records and forms, consumption reports?
    - Storage: How are sites selected, what materials-handling systems exist?
    - Delivery: Are medicines collected or delivered? Is this done in-house or via a third party?

ii. Inventory Management

- How accurate and current are stock records for medicines? Are there regular reports on inventory, operating costs, and consumption patterns?
    - PROBE: What criteria are used to determine which medicines are held in stock all the time? (e.g. – VEN classification of vital, essential, nonessential)
- Are there significant or frequent problems with the supply (e.g. shortages) and/or availability of essential childhood cancer drugs in public sector health facilities? Are there identifiable (perceived) reasons for these shortages or excesses? What is the evidence for this? PROBES:
    - Is there a process in place to identify, prevent, and/or address medication stock outs in the country or public sector facilities?

  - How is the amount of safety stock held in storage facilities determined?
  - Is there a process to ensure stock for rapid availability of antibiotics for childhood cancer patients presenting with fever and neutropenia?
  - When was the most recent stockout? For what medicine? How was the issue solved?
  - How do people obtain chemotherapeutics, antimicrobials, and pain medications when they are not available? E.g. purchasing from the private sector, outside pharmacies, importing/black market?
  - How would you describe the turnaround time, or the time taken to deliver and fill an order after it is received?
- Please describe any systems in place for monitoring the supply and usage of medications and other therapeutics for the treatment of childhood cancer? PROBES:
  - Please describe which individuals and/or departments are responsible for this task. Is this a separate job within each department? Is the same system used within departments?
  - Are there routine access problems with supplies important to childhood cancer care, such as blood culture bottles, contrast agent, pathology stains?
  - Is expiry of drugs / consumables perceived to be an important challenge with drugs and logistics supply management?
  - How are pediatric pharmacists involved in supply chain management for antineoplastic drugs?
  - Are there intra-institutional and inter-institutional policies to minimize waste of essential cancer medicines?

iii. Local manufacturing & Importation

- Please describe the importation and/or port-clearing process for childhood cancer medicines? Are these processes managed in-house or privately?
- What are the types of pharmaceutical manufacturers that operate in your country (multinational companies, hospital-based firms, etc.)?

iv. Transportation

- Which authority manages the transportation of childhood cancer medicines? Is the contracted out? What quality assurance programs exist?

D. Use

i. Provider Perspective

- What strategies exist to encourage rational use of childhood cancer medicines? – e.g.,
  - Educational – Training of prescribers, distributing printed materials, using standardized international protocols
  - Managerial – Supervision, feedback, structured approaches like forms or guidelines
  - Economic – Financial incentives, reimbursement
  - Regulatory – Pharmaceutical registration, restrictions, limited medicine lists

  - PROBE: What factors contribute to irrational use? – e.g., polypharmacy, use of ineffective medicines, incorrect use of effective medicines
  - PROBE: What types of medicine-use data is collected, including both quantitative or qualitative? (e.g., pharmaceutical supply orders, patient registry data, patient interviews)
- What supports exist for ideal medicine dispensing practices? – e.g., prepackaging, labelling, record keeping, etc.
- What systems exist to ensure pharmacovigilance – product quality, monitoring of adverse drug reactions, and monitoring of medication errors?
  - PROBE: Do these differ for childhood cancer medicines in particular?

ii. Patient Experience

- How do socioeconomic and geographical factors, such as poverty and rurality, affect patient patients' abilities to access essential cancer medicines?
- What challenges arise for patients and providers due to unique characteristics of childhood cancer medicines – e.g., sterile injectable formulations, dosing by weight or body surface area
  - PROBE: Does the availability of formulations and/or their preparation influence childrens' abilities to take these medicines? – e.g., Are liquid formations available? Who is responsible for compounding medications (pharmacists, physicians, patients)?
- How would you describe the overall patient and provider experience with pediatric cancer treatment in your institution and country overall?

Part III. Management Support Systems

A. Planning and Administration

- What management support exists for the pharmaceutical supply system (processes of selection, procurement, distribution, and use)?
- What measures exist to control excess costs in the pharmaceutical supply system? – e.g., price comparison analyses, expiry data analyses, hidden cost analyses
- Who is responsible for financial planning and managing accounting systems related to childhood cancer medicines, locally and nationally?

B. Organization and Management

- What measures exist to protect against security breaches such as theft, bribery, and fraud for childhood cancer medicines?
- How is the supply of pharmaceuticals managed at the facility or hospital level?
- Please describe any processes to procure and manage medical and laboratory supplies required in the treatment of childhood cancer.

- PROBE: Is there national coordination of purchasing for these supplies? Is there data on the consumption and use of these supplies? Is there appropriate collaboration with front line staff in making these decisions? Do donations play a role in supplying these materials?

C. Information Management

- Please describe any systems that exist for monitoring and evaluating access to childhood cancer medicines in your institution and/or country – e.g., supervisory visits, routine data reporting, special studies to answer targeted questions when needed, needs assessments
- Is there a centralized or distributed pharmaceutical management information system? – e.g., record-keeping documents, feedback reports, performance indicators
    - PROBE: To what degree is this process computerized vs. manually recorded?

D. Human Resources Management

- Are there human resources issues that adversely impact patients' abilities to access childhood cancer medicines? – e.g., adequacy of training, salaries, and staff
    - PROBE: Is there specialized training for pharmacists or others who prepare and administer pediatric cancer medications?