Development of a distributed research data management system for a computerized Pediatric Hematology/Oncology Hematopoietic Stem Cell Transplant Registry - A cost effective modular approach

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Rationale

- In addition to well established risk factors the outcome of treatment is also influenced by the following factors:-
  1. Geographic and genetic makeup of the population being treated.
  2. Monitoring the toxicity of the therapy to determine the risk benefits of protocol outcomes.
  3. Update on advances in diagnostic tools and identification of new risk factors.
- Identifying Cancer Incidence and defining the level of success of the treatment strategies used

Research Data Management System

- Significance of a reliable data management and information system in oncology services is well recognized pertaining to its specialized nature of practice.
- The complexity of cancer care and high toxic cost of therapy desires collection and availability of locally relevant information on patient characteristics.

Commercial Data Management System

- Expensive
- Not customized
- Limited ability to incorporate changes
- Expensive license renewals

Cancer Registries

- Cancer Registry is a population based register which collects information on all primary malignant disease’s
- The data collected by a cancer registry can be used for cancer incidence
- Data collected by an integrated and comprehensive data management system allows an insight into treatment related toxicity (outcome) and identification of new risk factors.
- There is a large discrepancy between the number of cancer registries and the population they are serving, specially in the developing and resource poor countries.
### World Bank List of Economies

<table>
<thead>
<tr>
<th>Economy</th>
<th>Income Group</th>
<th>Population</th>
<th>No. of Registries</th>
<th>Proportion</th>
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### Center Information

- King Faisal Specialist Hospital and Research Centre (KFSHRC) is a multispecialty tertiary care hospital with a facility of 884 beds located in the Kingdom of Saudi Arabia (K.S.A).
- The mission of the hospital is to provide specialized medical care, promote medical research and educational programs.

### King Fahad National Centre for Children’s Cancer

- The King Fahad National Centre for Children’s Cancer is the only children’s cancer centre in Saudi Arabia & the Middle East tracking around 600 newly diagnosed cases every year.
- The Centre is an integrated part of the King Faisal Specialist Hospital and Research Centre and provides both inpatient and outpatient services to Pediatric Hematology /Oncology patients.

### Pediatric Hematology/Oncology Department

- **Central Data Unit**
  - Front-End Design (PIMS)
  - CRF Design
  - Data Abstraction
  - Data Entry
  - Data Management
  - Data preliminary analysis
  - Coordination with Statistician

### Section of Pediatric Stem Cell Transplantation

- Responsible for providing care to children in need of stem cell transplantation.
- The section performs Allogenic and Autologous transplantation.
- The program performs more than 100 stem cell transplants per year with a 12 bed facility.

### Patient Information Management System

- In-House developed: Independent of Commercial programs
- End User Input: Databases were designed with close consultation with the end-users
- Phased Development: Information retrieval from the core
- Robust and Scalable: New variables could be added or removed
- User Friendly
- Data safety and security
The core module was developed after selecting more than 20 variables after a careful examination of Minimum Essential Data Set (MEDS) recommended by World Health Organization (W.H.O).

The International Classification of Diseases (ICD-O Ver.3.0) was used as a primary system of disease classification along with ICD-9CM.

The core module is capable of handling multiple primaries, relapse information and cause of death.
PIMS-The Stem Cell Transplantation Module
We described the development of a data management system where the data collection of a HSCT patient is prospective in nature. Information of any HSCT patient could be retrieved from the database. We described the development of a data management system that allows retrieval of information for HSCT patients.
Conclusion

- We described the development of a fully customized data management system independent of commercial programs.
- By creating the database in-house, with close consultation with the end-users, a dataset relevant to the subject population was available.
- The three-tier designing of the system allowed it to be scalable and robust accounting for its dynamism.
- Provision of integrated data retrieval with the touch of the button for a given disease entity and enabling the physicians, researchers, or healthcare providers to download datasets for further statistical analysis accounts for the simple and user-friendly feature of the System.