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

Khawar Siddiqui, Viqaruddin K Mohammed, Asim Belgaumi

King Fahad National Centre for Children’s Cancer
King Faisal Specialist Hospital and Research Centre
Riyadh, Central Province
Kingdom of Saudi Arabia
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.
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*
Rationale

- The information available to physicians, researchers or health care providers is often huge making analysis difficult - Decision making.

- Often the information made available for analysis is in the form of customized spreadsheets.
  - Lack of common standard structure
  - Overlapping and inconsistently updated data
  - Less feasible for complex data

- Thus, sound decision making requires a solid multi-factorial statistical analytical support
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.
<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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<tbody>
<tr>
<td>U.S.A</td>
<td>High Income OECD</td>
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</table>
King Faisal Specialist Hospital and Research Centre (KFSHRC) is a multispeciality tertiary care hospital with a facility of 894 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.
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

Leukemia & Lymphoma
Solid Tumors
Non Malignant/Hematology
Stem Cell Transplantation

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
PIMS Development Model

Extended Data Set

Minimum Data Set

PHO Res Projects
Leukaemia
Lymphoma
Solid Tumors
B&PM Hem
Neuro-Onc
Stem Cell Transplantation
Other Res Studies
CORE COMPONENTS (PIMS)
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.
Welcome to Patients Information Management System.

This database management system is for Department of Pediatric Hematology / Oncology at King Fahad National Centre for Children’s Cancer and Research, Riyadh, Kingdom of Saudi Arabia.

Information in this database is related to Medical and Treatment history of patients and is Confidential. Access to this system is restricted and strictly on need-to-know basis, governed by the Confidentiality and Privacy Policy of The Central Data Unit.

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Ver. 2.0

Central Data Unit
Department of Pediatric Hematology / Oncology,
King Faisal Specialist Hospital and Research Centre,
Riyadh, Saudi Arabia. Fax: +966 (1)-2055265
Demographic and Patients' Status

Central Data Unit
Department of Pediatric Hematology/Oncology
King Faisal Specialist Hospital and Research Centre

Patients' Information Management System - Core Module: Demographics, Tx and Patients Status Data

MR No: [Redacted]   Name: [Redacted]   Accession No: 2005235

Gender:  Male  Female  Undetermined  Unknown

Primary Physician 1: HASSAN EL-SOLH   Assigned By: RAGHAD AL-SAAD   Assigned on: 07 May 2005
Primary Physician 2: [Redacted]   Assigned By: [Redacted]   Assigned on: [Redacted]
Primary Physician 3: [Redacted]   Assigned By: [Redacted]   Assigned on: [Redacted]
Primary Physician 4: [Redacted]   Assigned By: [Redacted]   Assigned on: [Redacted]
Primary Physician 5: [Redacted]   Assigned By: [Redacted]   Assigned on: [Redacted]
Primary Physician 6: [Redacted]   Assigned By: [Redacted]   Assigned on: [Redacted]

Provisional Dx Date: 15 May 2005   Date of Confirmed Dx at KFSHRC: 15 May 2005
Birth date: 03 October 2003   Date First seen at PHO: 02 May 2005
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<th>Field</th>
<th>Value</th>
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<tr>
<td>Tumor Category</td>
<td>LEUKEMIA: KFSHRC Riyadh</td>
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<tr>
<td>Disease Status at Last Contact</td>
<td>CR-2</td>
</tr>
<tr>
<td>Patient Status</td>
<td>Expired</td>
</tr>
<tr>
<td>Date Last Seen</td>
<td>10 September 2007</td>
</tr>
<tr>
<td>Status Date</td>
<td>10 September 2007</td>
</tr>
<tr>
<td>Abstracted by</td>
<td>SAADAH MANSOUR</td>
</tr>
<tr>
<td>Abstraction Date</td>
<td>17 September 2005</td>
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<tr>
<td>Coded by</td>
<td>AMAL AL-SHARIF</td>
</tr>
<tr>
<td>Date Coded on</td>
<td>18 January 2006</td>
</tr>
<tr>
<td>Entered by</td>
<td>CHRISTOPHER ALVIEDO</td>
</tr>
<tr>
<td>Entry Date</td>
<td>09 January 2006</td>
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PIMS-The Stem Cell
Transplantation Module
### SCT Registration Form

**Central Data Unit**
Department of Pediatric Hematology / Oncology, KFNCCCR
King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia

**Patients’ Information Management System Stem Cell Transplant Registration Module**

<table>
<thead>
<tr>
<th>MR No:</th>
<th>Name:</th>
<th>Accession No: 2005235</th>
</tr>
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</table>

<table>
<thead>
<tr>
<th>HSCT - A</th>
<th>Pre-HSCT Serology</th>
<th>Donor Information</th>
<th>Conditioning Regimen</th>
<th>Status D-100</th>
<th>Annual Follow-up</th>
<th>Case History</th>
<th>Multiple Primaries</th>
<th>CRF Status</th>
</tr>
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<tbody>
<tr>
<td>UPN: 1883</td>
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</table>

**CIBMTR No.:** 1883

<table>
<thead>
<tr>
<th>SCT Numbers:</th>
<th>1st Transplant</th>
<th>Bone Marrow Infusion Date: 14 May 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disease Status at SCT:</td>
<td>CR-2</td>
<td>Discharge Date: 12 June 2007</td>
</tr>
<tr>
<td>Core SCT Status:</td>
<td>Positive for HSCT</td>
<td>Pri Disease Response (Latest): CR-2</td>
</tr>
<tr>
<td>Sex:</td>
<td>Male</td>
<td>Nationality: SAUDI ARABIAN</td>
</tr>
</tbody>
</table>

**GVHD Prophylaxis:**
- Positive

**CSA:**
- Positive

**ATG:**
- Negative

**Other(s):**
- ”Not Applicable”

**Regimen:**
- Myeloblastic

**MTX:**
- Positive

**Steroids:**
- Negative

**Other(s):**
- ”Not Applicable”

**N-MYC:**
- Copies: 0

**N-MYC Date:**
- 2007

**Growth Factor:**
- GCSF

**Starting Date:**
- 22 May 2007

**Date ANC Recovered:**
- 28 May 2007

**Date PLT Recovered:**
- 07 June 2007

**Short Tendon Repeat:**
- %Myeloid: 100
- %Lymphoid: 100
- STR Date: 23 June 2007

**Graft Type:**
- Allogeneic

**HSCT Source:**
- BM

**BM Harvest Date:**
- 14 May 2007
### Pre-HSCT Serology

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
<th>Test Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hep A</td>
<td>Positive</td>
<td>03 April 2007</td>
</tr>
<tr>
<td>Hep B Ag</td>
<td>Negative</td>
<td>03 April 2007</td>
</tr>
<tr>
<td>Hep B Ab</td>
<td>Negative</td>
<td>03 April 2007</td>
</tr>
<tr>
<td>Hep B C Ag</td>
<td>Not Done/No Info</td>
<td>03 April 2007</td>
</tr>
<tr>
<td>Hep B C Ab</td>
<td>Negative</td>
<td>03 April 2007</td>
</tr>
<tr>
<td>EBV</td>
<td>Negative</td>
<td>03 April 2007</td>
</tr>
<tr>
<td>CMV</td>
<td>Positive</td>
<td>03 April 2007</td>
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<tr>
<td>Hep C</td>
<td>Negative</td>
<td>03 April 2007</td>
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<td>Donor's Med Rec No:</td>
<td>923662</td>
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<tr>
<td>---------------------</td>
<td>--------</td>
<td></td>
</tr>
<tr>
<td>Donor's Gender:</td>
<td>Male</td>
<td></td>
</tr>
<tr>
<td>Donor's Birthdate:</td>
<td>01 March 1987</td>
<td></td>
</tr>
<tr>
<td>HLA Typing:</td>
<td>HLA Identical - Siblings</td>
<td></td>
</tr>
<tr>
<td>Allele/Antigen Degree of Mismatch:</td>
<td>10 Matches out of: 10</td>
<td></td>
</tr>
</tbody>
</table>
### SCT Registration Form

#### Central Data Unit
Department of Pediatric Hematology / Oncology, KFNCCCR
King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia

#### Patients' Information Management System Stem Cell Transplant Registration Module

<table>
<thead>
<tr>
<th>MR No:</th>
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| Accession No: | 2005235 |

<table>
<thead>
<tr>
<th>HSCT - A</th>
<th>Pre-HSCT Serology</th>
<th>Donor Information</th>
<th>Conditioning Regimen</th>
<th>Status D-106</th>
</tr>
</thead>
</table>

| Acute GVHD: | Positive |

| Skin: | Grade I |

| Liver: | Not Applicable |

| Gut: | Not Applicable |

| Overall: | Grade I |

**Other Complications:**

- Hypertension: Positive
- Seizures: Negative
- Interstitial Pneumonia: Negative
- Gonadal: Negative
- Mucositis: Negative
- Mucositis Grade: None Experienced

**CMV Infection:** Negative

**Encephalopathy:** Negative

**Other Complication(s):** Negative

**Other Complication(s):** Negative

**Other Infecions:**

- Bacterial: Staphylococcus (coag. Neg): Negative
- Viral: Negative
- Fungal: Negative

| Graft Evaluation: | Engrafted |

| Graft Evaluation Date: | 23 June 2007 |

| New Malignancy: | Negative |

| Confirmation Date: | |

| Due Date on D-100 CRF F/Up: | 21 August 2007 |

| Bone Marrow Infusion Date: | 14 May 2007 |

| Post SCT Disease Response: | CR-2 |

| Response Evaluation/Release Date: | 10 September 2007 |
### SCT Registration Form

**Central Data Unit**
Department of Pediatric Hematology / Oncology, KFNCCCR
King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia

**Patients’ Information Management System Stem Cell Transplant Registration Module**

<table>
<thead>
<tr>
<th>MR No.</th>
<th>Name</th>
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</tr>
</thead>
<tbody>
<tr>
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<td>2005235</td>
</tr>
</tbody>
</table>

#### HSCT - A | Pre-HSCT Serology | Donor Information | Conditioning Regimen | Status D-100 | Annual Follow-up |
--- | --- | --- | --- | --- | --- |
Chronic GVHD: | No Information | Extent of GVHD: | Not Applicable |
Skin: | Not Applicable | Liver: | Not Applicable |
Gut: | Not Applicable | Other(s): | "Not Applicable" |

#### Other Complications:
- Hypertension: No Information
- Seizures: No Information
- Gonadal: No Information
- Mucositis: No Information
- Mucositis Grade: None Experience
- Other Complication(s): "Not Applicable/Not Done"
- Other Complication(s): "Not Applicable/Not Done"

#### Other Infections:
- Bacterial: "Not Applicable/Not Done"
- Viral: "Not Applicable/Not Done"
- Fungal: "Not Applicable/Not Done"

#### Graft Evaluation:
- Graft Evaluation: Not Done Due to Early Death
- Graft Evaluation Date: 
- New Malignancy: Negative
- Confirmation Date: 

#### Post SCT Disease Response:
- Post SCT Disease Response: Not Evaluated
- Response Evaluation/Relapse Date: 

**Due Date on D-365 CRF F/up:** 12 May 2008
**Bone Marrow Infusion Date:** 14 May 2007
### Case History

**First Primary**
- **PIMS Core Tumor Category:** ALL
- **Case Category:** NEOPLASM/ICD-O CASE (See Topography, Histology)
- **Topography:** Bone marrow
- **Histology:** Acute lymphoblastic leukemia, NOS
- **Comments:**

<table>
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<tbody>
<tr>
<td>Initial Dx Date:</td>
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<td>Date First seen at PHC:</td>
<td>02 May 2005</td>
</tr>
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<td>15 May 2005</td>
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<td>Date Last Seen:</td>
<td>10 September 2007</td>
</tr>
<tr>
<td>Above Status Date Recorded:</td>
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**BMT-Dis Class:** A.L.L
**BMT-Dis Sub Class:** B-CELL
**BMT-Dis Stage:** No information
**BMT-Tumor Category:** Malignant

**Patient Status (Latest):** Expired
**Disease Status at Last Contact:** CR-2

**Primary Physician 1:** HASSAN EL-SOLH
**Primary Physician 2:**
**Primary Physician 3:** **NO INFORMATION AVAILABLE**
**Primary Physician 4:**
**Primary Physician 5:**
**Primary Physician 6:**
<table>
<thead>
<tr>
<th>CRF Status</th>
<th>Case Closed for This HSCT. No More F/up ns</th>
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</thead>
<tbody>
<tr>
<td>Due Date for Regular Annual CRF Follow-Up:</td>
<td>12-May</td>
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<tr>
<td>Last Annual Follow-up on CRF Update done on:</td>
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<tr>
<td>D-100 Follow-up on CRF Update done on:</td>
<td>2 August 2007</td>
</tr>
<tr>
<td>Due Date on D-100 CRF Follow-Up:</td>
<td>21 August 2007</td>
</tr>
<tr>
<td>Bone Marrow Infusion Date:</td>
<td>14 May 2007</td>
</tr>
</tbody>
</table>
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

Diagnosis → Treatment → Treatment outcome → Transplant → Transplant outcome
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 to its dynamism.

- Provision of integrated data retrieval with the touch of the button for a given disease entity and enabling the physician, researchers or health care providers to download dataset for further statistical analysis accounts to the simple and user-friendly feature of the System.
Central Data Unit  - Our Strength

Dr. Asim Belgaumi M.D
Director - CDU

Khawar Saeed Siddiqui M.Sc, MBA
Head - CDU
Central Data Unit - Our Strength

Saada Mansour Suboh - CRC
Grace Barria – CRC
Central Data Unit - Our Strength

Viqaruddin Mohd Khaja, M.Sc -- CRC

John Paul Sahibbil – Asst CRC
Thank You!