Retinoblastoma Clinical Research in Egypt, A 5 Year Experience.

Ahmad Samir Alfaar*, Radwa Nour, Mohamed Kamal, Mohamed Sabry Bakry, Sameera Ezzat

* MD, MSc., Ophthalmology, Clinical Research Specialist Children’s Cancer Hospital – Egypt 57357
Anatomy (+ aim) of the presentation

• History before/at 2007
• Research plan/requirements we set.
  – Duties
• Results
  – Blueprint /timeline for activities
  – Projects
• Challenges
Public Centers Dealing with RB in Egypt 5 years ago

No real figures about the disease

No structured clinical research efforts

Scattered case series and reports

Physicians rather than centers
5 years ago, At Children's Cancer Hospital Egypt (CCHE) 57357, we started Retinoblastoma management through a Disease Strategy Team; a multidisciplinary approach for a multi-faceted disease.

So We planned a set of requirements for research future.
Our system requirements

I. Treatment Related Requirements

II. Research Related Requirements
Clinical requirements

• The major challenge hindering the treatment of Retinoblastoma in developing countries is the lack of an oncology center comprising different disciplines necessary for diagnosis, evaluation, treatment and follow up.

• **Experienced** team of multi disciplines; pediatric oncology, ophthalmology, Radiotherapy, radiology, clinical pharmacy

• Imaging: CT, MRI

• RetCam

• Surgery

• Moderate-high-dose chemotherapy

• Radiotherapy: Intensity-Modulated

• Focal therapy: LASER, Cryotherapy

• Hematopoietic stem cell rescue
Clinical Information Management

- The complexity of care and the interdependence of different disciplines required an implementation of a **Hospital Information System** that served only the clinical needs.

- Telepax (Imaging) 2008
- Laboratory Information System 2008
- Radiology Information System RIS 2008
- Electronic Medical Records EMR 2009
- Pathology Imaging 2011
Bringing them together
An essential role in retinoblastoma team; a disease coordinator
Research Team Duties

- Supporting the clinical team with recent evidence.
- Designing Research Protocols based on international guidelines and evidence.
- Ensuring proper regulatory procedures.
- Registering patients on protocols
- Ensuring adherence to protocols.
- Monitoring, reporting and reducing protocol violations.
- Real-time data validation and statistical analysis.
- Facilitating International collaboration.
<table>
<thead>
<tr>
<th>Year</th>
<th>Clinical Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>2007</td>
<td>RetCam</td>
</tr>
<tr>
<td></td>
<td>1 Ophthalmologists</td>
</tr>
<tr>
<td></td>
<td>Paper-based</td>
</tr>
<tr>
<td>2008</td>
<td>First enucleation</td>
</tr>
<tr>
<td></td>
<td>Telepax, RIS</td>
</tr>
<tr>
<td></td>
<td>2 ophthalmologists</td>
</tr>
<tr>
<td>2009</td>
<td>Hospital EMR</td>
</tr>
<tr>
<td></td>
<td>Brachytherapy</td>
</tr>
<tr>
<td></td>
<td>3 ophthalmologists</td>
</tr>
<tr>
<td>2010</td>
<td>COG extra-ocular</td>
</tr>
<tr>
<td></td>
<td>Testing Stereotactic RTh</td>
</tr>
<tr>
<td></td>
<td>1 dedicated PedOnc</td>
</tr>
<tr>
<td>2011</td>
<td>Biobanking design</td>
</tr>
<tr>
<td></td>
<td>Standardizing Documentation</td>
</tr>
<tr>
<td>2012</td>
<td>Inaugurating Biobank (+catissue)</td>
</tr>
<tr>
<td></td>
<td>Protocols Portal</td>
</tr>
<tr>
<td></td>
<td>RedCap Consortium</td>
</tr>
<tr>
<td></td>
<td>2 CRS</td>
</tr>
<tr>
<td>2013</td>
<td>Molecular Epidemiology</td>
</tr>
<tr>
<td></td>
<td>Publishing</td>
</tr>
</tbody>
</table>
Results

• Number of **protocols**
  – International : 1
  – Institutional: 4
• Two rounds of lectures for nursing **education** and one for pharmacists
• **Patients** on protocols: 320 /6 years (250 to July 2012)
• 10% of the patients are **Non-Egyptian** (Arab and SubSah African patients)
• **Central** and **accessible** research **data management**.
Results cont.

- Feeding national **Egyptian Cancer Registry** Regularly
- **No drop-outs** (during treatment and follow-up)
- **Samples**: 1/5 of patients had banked blood samples (June 2013)
- **Grants**
  - Biobanking 2
  - Molecular epidemiology 1
- **Software**: developed our own integrated package for real-time analytics e.g. survival.
- **Presentations** and Publications: 15 oral presentations / 2 years (+ ongoing papers)
- **Some numbers**
All cancers:
Estimated # of New Patients diagnosed/year in country
4600*

Av # of New Patients diagnosed/year in CCHE 1134 (~25%)

Based on Rb incidence of 1/20,000 live births and 2.6 million Eg New births

Estimated new cases (Sporadic) 130 new cases

We are recruiting 25-30%

* Estimated # of patients in country is calculated based on Gharbya Cancer Registry (ASR for children < 20 = 129/million).
Survival

[Graph showing survival rates over time for different categories: Intraocular, Initial, After management, Intraocular-censored, Initial-censored, After management-censored.]

Cum Survival

TimeToEvent

Extra-ocular Milestone
Challenges

• Clinical orientation of physicians
• Understaffing
• Staff resistance to structured documentation
• High (and increasing) number of patients
• Lack of patients’ compliance to treatment and follow-up
• Loss of clinical data.
• Lack of funding for research
Ongoing Projects

• Rb National Cancer Registry
• Training larger number of highly qualified pediatric oncologists / nurses / Research coordinators.
• Patient education protocols
• Rb testing and counseling
Rb Research Department Team
Rb Team

• Dr. Adel AliElDin, Ophthalmologist
• Dr. Hatem Qabtan, Ophthalmologist
• Dr. Hossam ElZomor, Pediatric oncologist
• Radwa Nour, Clinical Research Associate
• Dr. Hala Taha, Surgical Pathology
• Dr. M. Saad Zaghloul, Radiation oncology
• Dr. Nayera ElShaqanqeiry, Molecular Biology
• Dr. Sherine Salem, Cytogenetics
• Mohamed ElShami, Psychosocial department
• Rabab Hassan, Research Nurse
• Fairouz Ossama, Ophthalmology Resident
• Mohamed Kamal, Mohamed Sabry – Informatics Team
• Dr. Sherif AbouElNaga, VP academic affairs, research and outreach
• Dr. Sameera Ezzat, Director of research department.
• Dr. Shahenda ElNagar, Basic research coordinator.
• Dr. Alaa AlHaddad, Pediatric Oncology
Acknowledgement

- Dr. Brenda Gallie, SikKids, Toronto
- Dr. Helen Dimaras, SikKids, Toronto
- Dr. Carlos Rodriguez-Galindo, DFCI, Boston
- Dr. Guillermo Chantada, Hospital JP Garrahan, Buenos Aires
- Dr. Ibrahim Qaddoumi, St. Jude, Memphis
- Dr. Ira Dunkle, MSKCC, New York

Funding:
STDF (Science and Technology Development Fund, Egypt)
NBE (National Bank of Egypt)
Thanks to

For supporting the presentation of our efforts with travel grant
Remembering all innocent souls lost in their fight for freedom in Egypt

Scan this code or use link below to download the presentation

http://goo.gl/pwTdnr
ahmadsfar@gmail.com