Pediatric Initiative Network: Past…Present…Future

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Chair, PIN
Oncofertility Consortium

- 2-way exchange of ideas, methods, technologies, and issues
- Multi-disciplinary
- Promulgate best practices and strong referrals to local centers
The Pediatric Initiative Network (PIN) is an international group of providers dedicated to preserving and protecting the fertility of children and adolescents at risk for infertility due to medical conditions or treatments.
Structure

- Chair: Leena Nahata, MD
- Vice-Chair: Molly Moravek, MD, MPH
- Past-chair: Leslie Appiah, MD

- Committees:
  - Best Practices - to develop strategies to optimize fertility related care for at-risk youth
    - Navigator subcommittee - dedicated to improving access to fertility related care for at-risk youth
  - Research - to design and implement collaborative multi-site research studies to advance fertility related care for at-risk youth
Committees

• Best practices
  – Chair: Lillian Meacham, MD
  – Vice-Chair: Holly Hoefgen, MD
  – Navigators lead: Stacy Whiteside, CPNP-AC

• Research
  – Chair: Veronica Gomez-Lobo, MD
  – Vice-Chair: Krista Childress, MD
  – Vice-Chair: Maggie Dwiggins, MD
2018-2019 membership

• 102 members
• 62 institutions
• Physicians, researchers, advanced practitioners, nurses, psychologists/SW, trainees…
• Quarterly PIN calls
• Ad hoc committee/working group calls
• PIN list-serv
INITIATIVES
PROGRAM DEVELOPMENT: EXISTING AND FUTURE
“I am trying to set up a FP program… and I need help.”

Where do I start?
How can I advocate for time and resources?
How can I identify/engage stakeholders?
Project

- *Led by Molly Moravek, MD, MPH*

- Online survey – completed by PIN members from 12 institutions

- Current practices and common barriers to FP program implementation/expansion
Development of a Pediatric Fertility Preservation Program: A Report From the Pediatric Initiative Network of the Oncofertility Consortium

Navigators Subcommittee

- Established after Oncofertility Consortium meeting in November 2018 (*led by Stacy Whiteside, CPNP*)
- First conference call December 14th 2018 with 7 participants
- Current membership up to 25 participants from 23 institutions across U.S. & Australia, both pediatric & adult representation
- Conference calls every other month
- Goals:
  - Provide forum to address unique needs of fertility navigators
  - Network of cooperative programs in all stages of development
  - Develop navigator specific projects & contributions to the Oncofertility Consortium
Navigators Subcommittee

• 2019 Accomplishments
  – Tripled membership in 9 months
  – Active member participation in bimonthly conference calls
  – Pilot program survey completed with 19 respondents
  – Legislative Working Lunch 11/13/19
    – Address real time insurance issues faced by providers on the front lines featuring actual cases provided by committee members
    – Discuss practical approaches for advocacy
  – Oncofertility Navigation publication in progress
“We need some consensus on infertility risk counseling.”

We need a consistent message when counseling patients and families about infertility risk, based on planned oncologic therapies.
Project

- *RSWG - led by Lillian Meacham, MD*
- 27 PIN members
- 200 emails
- 3 Conference calls
- 7 versions of the stratification grid
- Everyone submitted risk stratification systems they use
- Literature search
### Female Level of Risk for Gonadal Failure / Infertility above that for the general population

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Prepubertal</th>
<th>Pubertal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkylators* CED gm/m2</td>
<td>CED</td>
<td>CED</td>
</tr>
<tr>
<td>Heavy Metal</td>
<td>Cisplatin Carboplatin</td>
<td></td>
</tr>
<tr>
<td>HSCT</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Procarbazine is particularly gonadotoxic. In central deficiency, the ovaries are not harmed. The testes are not harmed. Treatment with gonadotropin can overcome this late effect.*

### Male Level of Risk for Infertility above that for the general population

<table>
<thead>
<tr>
<th>Treatment</th>
<th>CED &lt; 4*9,10</th>
<th>CED ≥ 4*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alkylators gm/m2</td>
<td>CED</td>
<td>Alkylator based and/or TBI Myeloablative and Reduced intensity</td>
</tr>
<tr>
<td>HSCT</td>
<td>Minimally Increased Risk</td>
<td>Significantly Increased Risk</td>
</tr>
</tbody>
</table>

*Procarbazine is particularly gonadotoxic. In central deficiency, the testes are not harmed. Treatment with gonadotropin can overcome this late effect.*

<table>
<thead>
<tr>
<th>Radiation Exposure</th>
<th>Testicular</th>
<th>Hypothalamus#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radiation Exposure</td>
<td>0.2-0.6 Gy</td>
<td>&gt; 30-39.9 Gy</td>
</tr>
<tr>
<td>Hypothalamus #</td>
<td>&gt; 40 Gy</td>
<td></td>
</tr>
</tbody>
</table>

*Surgery | RPLND |

*CED < 4 gm/m2 89% were normospermic (Green Lancet Oncol 2014). Risk increase with cumulative alkylator dose. In central deficiency, the testes are not harmed. Treatment with gonadotropin can overcome this late effect RPLND - retroperitoneal lymph node dissection*
“We need more guidance for reproductive health in survivorship.”
Pediatric Blood and Cancer
Special Edition

• **Led by Leslie Appiah, MD and Antoinette Anazodo, MD**
  – Pediatric Reproductive Tumors
  – Male Pediatric and AYA Reproductive Survivorship
  – Female Pediatric and AYA Reproductive Survivorship
  – Reproductive Late Effects after BMT
  – Fertility Considerations in AYA Survivorship
  – Psychosexual Function in Survivorship
  – Reproductive Health Literacy
  – Reproductive Care Navigation in Survivorship

• All first drafts completed
• Open access (supported by Appiah, Anazodo, Woodruff)
“We need to assess long term outcomes after OTC.”

Creating a database...
OTC database

- 2016 PIN leadership reviewed data collection information, authorship guidelines

- 2017 Database created at MedStar Health Research Institute *(led by Veronica Gomez-Lobo, MD)*

- To date 2 sites entered retrospective data and 6-7 sites at different stages of obtaining IRB approval/entering prospective data
  - Some IRB’s did not think OTC could be considered research
  - Data collection and database allow for the argument that the protocol entails “research”

- 2019 applied for ASRM grant to support the database
  - October 2019 informed that we did not receive it

- 2020: Plan to relocate database to Norton Children’s
2019 PIN meeting

- 11/11/19 8am-3:30pm

- ~100 participants
  - Multi-disciplinary
  - Numerous institutions in various phases of FP program development
  - Several states
  - International presence
Formal Fertility Preservation Program?

- Nationwide
- Michigan
- Pittsburgh
- Lurie
- Cook Children’s Fort Worth
- Children’s National DC
- NIH
- Minnesota
- Duke
- Ohio State
- Iowa
- Johns Hopkins
- Utah
- Cornell
- USC
- Louisville
- Colorado
- Seattle
- Kansas City
- Connecticut
- Cincinnati
- Wash U St Louis
- Oregon
- CHOA
- Saudi Arabia
- Japan (>30)
- Australia
Key roles

- Dedicated navigator/coordinator: 13
- REI involved (egg freezing): 20
- Reproductive Urology involved (TESE/TESA): 19
Strategies to Maximize Access

- Opt-out (instead of opt-in) - 4
- Hard stop in EMR – 2
- Patient lists of upcoming patients – 7
  - Tumor board, State reporting
- Dedicated email address that includes entire team
- Outpatient/Inpatient order sets
- Floor nurse-based ordering for FP consult
- Education of providers
  - House officer didactics/orientation
- Nurse practitioner network within institution
- “Wish it was better?” – 30 (almost everyone)
OTC/TTC

• Who is offering it
• Which non-onc populations
  – BMT, Rheumatology, Nephrology, DSD/Turner, Transgender
• IRB issues
• Financial considerations for surgery, processing
  – Insurance coverage
  – Negotiating discounted payments (self-pay)
  – Philanthropy
Programmatic barriers

- Funding/resources for program development (navigator)
  - Developing a business plan
- Funding for procedures
- IRBs
- Access to slow freezers
- Engaging stakeholders
  - Procedures
  - Referrals
PLANS FOR UPCOMING YEAR
Best Practices - Plans

- AMH Clinical Practice Survey
  - When to check
  - How to interpret
  - How to use for clinical decisions

- Key Performance Indicators
  - Receiving and documenting FP consult
  - Providing written resources for families on FP
  - Clinical ethics checklist
  - Reporting on safety data (minor/major)
  - Documented f/u with patients on tissue ‘success/quality’
## Research - Plans

### Databases
- **OTC/TTC database**
  - OTC/TTC database transferring to Louisville
  - Working group to review OTC and TTC databases to finalize content
- **Overall Fertility Preservation Consultation Database**
  - Dedicated sites to organizing/finalizing all inclusive database for programs to use
  - Structure for future EMR database

### Tissue collection
- Mary Zelinski collecting sites interested in receiving tissue for research
- Mary Zelinski and Francesca Duncan
  - Protocols and grants for management of stored NPC tissue

### Decision making surrounding fertility preservation
- 3 project ideas lead by James Klosky and Brooke Cherven
Thank you!

- PIN executive committee
- PIN members
- Dr. Woodruff and conference organizers
- My family