Ann & Robert H. Lurie
Children's Hospital of Chicago®

Diving into Research -

A bedside nurse's journey through the Carroll Scholarship Program

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BEST CHILDREN'S HOSPITALS U.S.News & WORLD REPORT RANKED IN 10 SPECIALTIES 2019-20

MAGNET RECOGNIZED AMERICAN NURSES CREDENTIALING CENTER

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OBJECTIVES

- Review history of and current status of nurse-led research project - "Timing of Pegfilgrastim"
- Describe project development planning
- Identify barriers to nurse-led research
- Recommend strategies for success

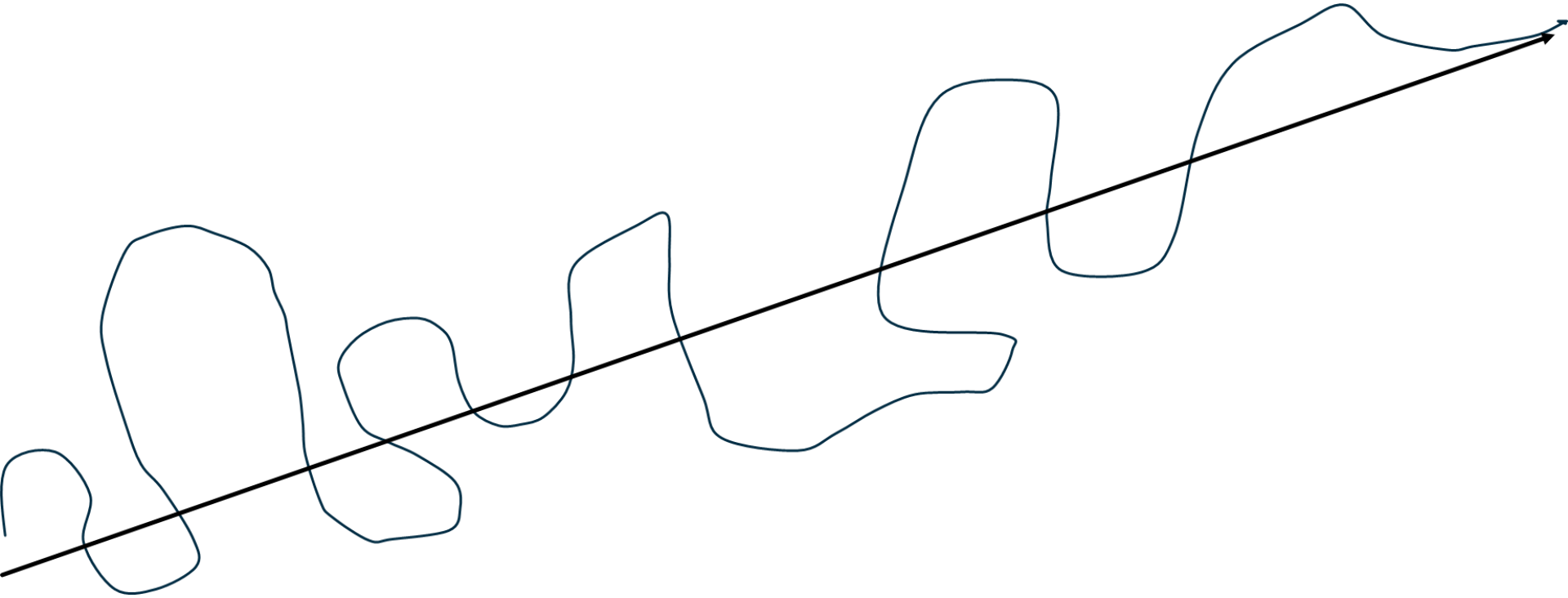
I HAVE NO FINANCIAL CONFLICT OF INTEREST OR DISCLOSURES

RESEARCH DESCRIBED IN THIS PRESENTATION WAS GENEROUSLY FUNDED BY THE EMILY AND ROBERT CARROLL NURSING INNOVATION SCHOLARSHIP

IT STARTED WITH A QUESTION

- September 2016 – Why 24 hours?
- Why does knowing the answer matter?
- How will the answer impact patients and practice?
- Do we already know the answer?

NOVICE ≠ LINEAR PROCESS



EARLY PROJECT DEVELOPMENT

- September – November 2016 Literature review and proposal development
- Adult outcome data, mixed populations, no pediatric data
- Feasibility check with DAR – numbers help estimate time required
- Statistician request submitted to BRC
- November 2016 - Prince proposal submission
- January 2017 – Carroll Scholar Award

DEVELOPMENT TO APPROVAL – 8 MONTHS

- March – May 2017
  - Departmental feedback
  - NRC study approval
  - Scientific review Lurie Cancer Center
  - Cayuse IRB submission
  - NOTIS submission
  - DAR data request after IRB approval

TIME TO COLLECT THE DATA…

DATA COLLECTION – 6 MONTHS

- June 2017 – Chart pulls requested – offsite storage
- July 2017 - Data collection begins weekly, 4-8 hours per week
- December 2017 – Last data collected (961 data points)

Data collected – time to analyze!

YEAR 2 – POSTER OR BUST

- Jan 2018 – Conference application for poster presentation
- Jan-Feb 2018 – Coding data and submission to statistician
- Feb 2018 – September 2018 – Roadblocks

OVERCOMING BARRIERS

- Knowledge gaps
  - Working effectively with a statistician
  - Keeping up with IRB requirements
  - New knowledge changes ideas about data interpretation
  - APA formatting
  - Effective data presentation in graphs, tables

- Process issues
  - Computer failures
  - Space considerations
  - Offsite or lost research charts
  - New literature

WHEN YOU FEEL LIKE YOU'RE CLIMBING A MOUNTAIN…

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WHEN REAL LIFE INTERFERES…

- Competing interests
  - Patient care
  - Departmental office move to John Hancock Building
  - Chemotherapy electronic ordering implementation
  - Staffing
  - Family
  - Health
  - Role changes

- Poster presented at 2018 APHON conference

Timing of Pegfilgrastim: Association with F&N Admits and Chemotherapy Delays in a Pediatric Solid/CNS Tumor Population

Laura Schlenker, BSN, RN, CPHON, and Alfred Rademaker, Ph.D.

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Background/Significance

Pegfilgrastim was approved and labeled by the FDA to be administered 24 hours or more after chemotherapy.

Barriers to administration of pegfilgrastim after 24 hours in pediatrics include:

- Limitations in availability of home health services
- Missed work and school days for appointments for next day administration
- Lack of caregiver/patient comfort with self-administration
- Difficulty with measurement of pediatric dosages from prefilled Pegfilgrastim adult dosing syringes

Limited adult literature exists regarding timing of Pegfilgrastim in various populations, and some authors have concluded it may be acceptable to administer Pegfilgrastim less than 24 hours after chemotherapy in certain circumstances.

Objectives

In a pediatric solid tumor and CNS tumor population, how does administration of Pegfilgrastim greater than or less than 24 hours after end of chemotherapy correlate with:

- admissions for febrile neutropenia?
- delays of 7 days or more to next cycle of chemotherapy?

Methodology

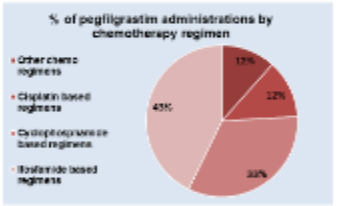
- Retrospective chart review
- Single institution
- Home health queried for home administration data
- Dates of Pegfilgrastim administration: 6/1/2007 – 12/31/2017
- IRB approval obtained

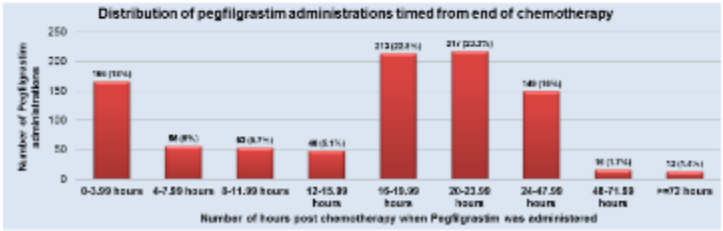
Inclusion Criteria	Exclusion Criteria
• Solid or CNS tumor • Primary or recurrent disease • Age under 30 (to reflect typical "pediatric" solid tumor population)	• Age over 30 • Bone marrow involvement • Hematologic malignancy or lymphoma • Frequent delays in heavily pre treated patients • Patients in radiation with delays were excluded until transfusion independent hematologic function recovered

Results

Population Characteristics for all Pegfilgrastim Administrations	
Age mean (median)	10.4 (11)
Age range (in years)	0.3 - 29
Sex	
Male n (%)	552 (59.6%)
Female n (%)	375 (40.4%)

- 927 administrations examined in 185 patients
- Data not received from home health; all data was from administration at the institution, lending skew towards earlier administrations
- Mean time of Pegfilgrastim administration post chemotherapy: 18.8 hours
- 19% of Pegfilgrastim administrations occurred 24 hours or more after end of chemotherapy





Chi square analysis results, including mixed modeling to account for multiple administrations per patient

	Less than 24 hours	Greater than 24 hours	All patients	p-value (chi-square test)	p-value (mixed model)
Delay of 7 days or more to next chemo cycle	153/642 (23.8%)	28/156 (18.0%)	181/798 (22.7%)	0.095	0.38
Admission for febrile neutropenia	155/733 (21.1%)	28/169 (16.6%)	183/902 (20.3%)	0.15	0.93

Conclusion

- Trend towards fewer delays and admissions for febrile neutropenia in patients who received Pegfilgrastim greater than 24 hours after chemotherapy, but it was not statistically significant.
- High number of administrations in the period 16-24 hours after chemotherapy.
- Further data analysis will examine relationships among the variables when different timing cut points are used (such as administration less than or greater than 18 hours).

Future Research

Prospective multicenter trials examining expanded outcomes, along with selection of patients based on chemotherapy regimens received, may help lend additional clarity to the clinical implications of the timing of Pegfilgrastim in different populations.

Acknowledgement

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YEAR 3 – MANUSCRIPT OR MOVE ON???

- October 2018 – first manuscript draft circulated internally for feedback
- Revisions needed
  - What happens when you want to correct your data?
  - What happens when your statistician retires?
  - What happens when you exhaust your funding?
- March 2019 – presentation of data to Oncology Team
- Magnet renewal


Don't lose heart when
things fall apart.
It just means they're
about to be put back
together in a new and
better way.
— Mandy Hale

STILL MOVING FORWARD

- Manuscript submission or bust
- More thoughtful personal review of data points
- Reviews from those in the oncology field will be insightful

TAKEAWAYS

DO	DON'T
Assemble a team	Go in alone
Clearly delineate roles up front	Leave room for role ambiguity
Listen to advice of those more experienced	Let that advice stop you from pursuing an idea
Learn from the process	Quit because it's hard
Accept feedback	Make changes you don't agree with
Take breaks if needed	Compromise your health or family
Be kind to yourself	Beat yourself up
Stay true to your goal	Forget why you started

STAY INSPIRED

KEEP CALM AND RESEARCH ON !!!