NIH Clinical Center: Patient Safety, Clinical Quality, and Employee Safety Update

Report to the NIH Clinical Center Research Hospital Board
October 21, 2016
Agenda

• NIH CC Overview and Recent Accomplishments
  – John I. Gallin, MD

• Patient Safety and Quality Performance Metrics
  – Laura M. Lee, RN, MS

• Employee Safety Overview and Performance Metrics
  – Michele Evans, DrPH
  – James Schmitt, MD
Overview and Recent Accomplishments

John I. Gallin, MD
Director, NIH Clinical Center
NIH Associate Director for Clinical Research
Chief Scientific Officer, Clinical Center

New Position:

• Report directly to NIH Director
• Extensive interactions with ICs and Intramural Research Program
• Major role developing a systematic approach to distribute scarce CC resources
• Close partnership with CC CEO and NIH Deputy Director for Intramural Research (DDIR)
NIH Associate Director for Clinical Research
Chief Scientific Officer, Clinical Center

Duties:

1. Scientific review of clinical protocols
2. Setting priorities for use of scarce CC resources
3. Review IC Directors oversight of Clinical Directors
4. Scientific Director for independent research of CC investigators
5. Strategic planning for intramural clinical research (with DDIR)
6. Strategic partnerships
7. Clinical research training
Improving Clinical Studies in the IRP

NIH Associate Director for Clinical Research and Chief Scientific Officer, CC

Priority Setting for Scarce Resources
Scientific Review of Clinical Protocols

Idea
Write Protocol
Protocol Review
Funding
IRB Review
FDA Review
Product Manufacture
Enrollment and data collection
Results
Translation to Patient Care

Deputy Director for Intramural Research
OHSRP
ORSC

CC CEO

Patient Care
NIH CC Patient Activity
## Year End Activity

<table>
<thead>
<tr>
<th>Category</th>
<th>Year End 2015</th>
<th>Year-End 2016</th>
<th>% Change FY15-16</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient Admissions</td>
<td>5,448</td>
<td>5,275</td>
<td>-3%</td>
</tr>
<tr>
<td>Average Length of Stay</td>
<td>8.9</td>
<td>8.7</td>
<td>-2%</td>
</tr>
<tr>
<td>Inpatient Days</td>
<td>47,847</td>
<td>46,394</td>
<td>-3%</td>
</tr>
<tr>
<td>Average Daily Census (7-Day)</td>
<td>131.1</td>
<td>126.8</td>
<td>-3%</td>
</tr>
<tr>
<td>Outpatient Total Visits</td>
<td>100,507</td>
<td>100,141</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Clinic Visits</strong></td>
<td>81,471</td>
<td>81,210</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Day Hospital Visits</strong></td>
<td>19,036</td>
<td>18,931</td>
<td>-1%</td>
</tr>
<tr>
<td>New Patients</td>
<td>10,761</td>
<td>10,498</td>
<td>-2%</td>
</tr>
</tbody>
</table>
Average Daily Census (ADC) by Month

ADC Stats
- 3-Year Average (FY 2012-2014) = 141.0
- Year End FY 2015: 131.1
- Year End FY 2016: 126.8

Release of RED team report and press coverage (April 21, 2016 in WP)

FY16 May-Sep
- 13% FY15
- 16% 3-Yr Avg
Recent Accomplishments

Patient Safety and Clinical Quality
Patient Safety and Quality Initiatives

- New Patient Safety Event Reporting System (ORS)
- Anonymous Reporting System
- Morbidity and Mortality Rounds
- Institute-based Patient Safety/Quality Liaisons
- Cascading Patient Safety Element in Personnel Reviews (PMAPs)
- New Recruits
  - New Chief of Pediatric Anesthesia and Critical Care (recruiting)
  - Staff for New Pediatrics Observation Unit
  - New Chief of Pharmacy
- Physical Infrastructure Upgrades for Sterile Manufacturing
- Visits to Academic Medical Centers
Environmental Scan: Site Visits

Johns Hopkins Medicine – Peter Pronovost, MD

- Armstrong Institute infrastructure
- Approach to identifying and managing risk
- Data dashboard

Sibley Hospital – Chip Davis, PhD

- Innovation Center
- Similar scale/size as the NIH CC
Environmental Scan: Site Visits

Brigham & Women’s – Allen Kachalia, MD

- Public display of data and transparency
- Death reviews
- Team members had multiple roles

Future Visits

- New York Presbyterian
- University of Virginia
- Massachusetts General Hospital
Communicating Performance

Patient Safety and Clinical Quality Dashboard
Performance Metrics Dashboard

• What we measure:
  o Regulatory (Joint Commission, FDA, OSHA)
  o Protocol-related (SAEs, UPs)
  o High-Risk Processes (Medications, Infection Control, Blood Use)
  o Patient Perceptions
Performance Metrics Dashboard

Best options to present data?

How to capture centrally clinical research metrics?
Discussion
Patient Safety and Quality Performance Metrics

Laura M. Lee, RN MS
Director, Office of Patient Safety and Clinical Quality, NIH Clinical Center
Patient Safety and Quality Metrics

• Measurement Challenges/Opportunities
  • Operative Environment
  • Small ‘n’

• Anonymous Reporting Hotline

• New Patient Safety Event Reporting System
Metrics Challenges/Opportunities

The Operative Environment
Peri-Operative Antibiotic Delivery

Percent Compliance

- < 60 mins before incision
- > 60 mins before incision
- After incision
Post-Operative Antibiotics Discontinued within 24 Hours

Percent Compliance:

Q1 13: 90%
Q2 13: 90%
Q3 13: 90%
Q4 13: 90%
Q1 14: 90%
Q2 14: 90%
Q3 14: 90%
Q4 14: 90%
Q1 15: 90%
Q2 15: 90%
Q3 15: 80%
Q4 15: 90%
Q1 16: 90%
Q2 16: 90%
Days Between Count Discrepancies

# of days between discrepancies


# Days

CC Average
Other Operative Measures......

- Complications
- Duration of cases
- Returns to the OR
- Blood use
- Others?
The Conundrum of Small ‘n’........

Programs and Procedures
Programs
NIH Transplant Program

• Multi-Institute Consortium (NCI, NHLBI, NIAID)

• Malignant and Non-Malignant Disease

• High acuity population; novel therapies

• Focus on use of innovative therapies for reducing Graft Versus Host Disease, transplant mortality, and minimizing relapse
Relative Size of NIH CC Transplant Program: 2012-2013

- **52%** of the total number of transplant centers (207) are in the 0-50 category.
- **19%** are in the 51-100 category.
- **16%** are in the 101-200 category.
- **13%** are in the >200 category.

Total number of transplant centers = 207

*Data reported to Center for International Blood and Marrow Transplant Research (CIBMTR)*
Indications for Stem Cell Transplantation: 2010-2015

- Myeloma
- AML
- ALL
- CML
- NHL
- HD
- MDS/MPD
- CLL
- Aplastic Anemia
- Other non-malignant disease
- Other Cancer

Number of Transplants

- Allo N=396
- Auto N=20
## Acute myeloid leukemia (AML) - 1st Complete Remission

Transplants performed 2010-2014

<table>
<thead>
<tr>
<th>Source</th>
<th>Donor type</th>
<th>#</th>
<th>F/U</th>
<th>Day 100</th>
<th>1 year</th>
<th>3 year</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHLBI (7) NCI (2)</td>
<td>Sibs</td>
<td>9</td>
<td>31 mo (8-47)</td>
<td>100%</td>
<td>77.8%</td>
<td>66.7%</td>
<td>66.7%</td>
</tr>
<tr>
<td>National Benchmark¹</td>
<td>Sibs</td>
<td>2297</td>
<td></td>
<td>93.3% (92.1-94.2%)</td>
<td>72.5% (70.6-74.2%)</td>
<td>55.0% (52.7-57.3%)</td>
<td></td>
</tr>
</tbody>
</table>

¹ Center for International Blood and Marrow Transplant Research (CIBMTR)
<table>
<thead>
<tr>
<th>Source</th>
<th>Cell source</th>
<th># pts</th>
<th>F/U</th>
<th>Day 100</th>
<th>1 year</th>
<th>3 year</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>08-H-0046</td>
<td>cord + haplo CD34</td>
<td>14</td>
<td>35 mo (3-59)</td>
<td>100%</td>
<td>92.9%</td>
<td>85.7%</td>
<td>85.7%</td>
</tr>
<tr>
<td>National Benchmark¹</td>
<td>cord</td>
<td>62</td>
<td></td>
<td>75.8%</td>
<td>59.7%</td>
<td>52.4%</td>
<td>59.7%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(63.1-84.6%)</td>
<td>(46.4-70.7%)</td>
<td>(39.1-64.1)</td>
<td>(39.1-64.1)</td>
<td></td>
</tr>
<tr>
<td>European Benchmark²</td>
<td>cord</td>
<td>71</td>
<td>35 mo (8-83)</td>
<td></td>
<td>38%</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(32-44%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹ Center for International Blood and Marrow Transplant Research (CIBMTR)
² European Society for Blood and Marrow Transplantation (EBMT)
## Sickle Cell Anemia

### Transplants performed 2010-2014

<table>
<thead>
<tr>
<th>Source</th>
<th>Donor type</th>
<th># pts</th>
<th>F/U</th>
<th>Day 100 Survival</th>
<th>1 year Survival</th>
<th>3 year Survival</th>
<th>Overall Survival</th>
<th>Reject</th>
</tr>
</thead>
<tbody>
<tr>
<td>03-H-0170</td>
<td>Matched related</td>
<td>27</td>
<td>31mo (5-62)</td>
<td>100%</td>
<td>96.3%</td>
<td>96.3%</td>
<td>96.3%</td>
<td>11.1%</td>
</tr>
<tr>
<td>14-H-0077</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>09-H-0225</td>
<td>Haplo PBSC</td>
<td>18</td>
<td>32mo (6-60)</td>
<td>94.4%</td>
<td>94.4%</td>
<td>94.4%</td>
<td>94.4%</td>
<td>50%</td>
</tr>
<tr>
<td>National Benchmark¹</td>
<td>Matched related</td>
<td>228</td>
<td></td>
<td>98.7% (96.0-99.6%)</td>
<td>96.9% (93.6-98.5%)</td>
<td>95.0% (90.9-97.3%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hopkins²</td>
<td>Haplo marrow</td>
<td>14</td>
<td>21mo (13-35)</td>
<td>100%</td>
<td>100%</td>
<td></td>
<td>100%</td>
<td>43%</td>
</tr>
</tbody>
</table>

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¹ Center for International Blood and Marrow Transplant Research (CIBMTR)

Procedures
The Conundrum of Small ‘n’....

- Protocol-driven (and dependent)
  - Phase I/II
  - Rare diseases
- Consultative cases
- Incidental cases

*Complex cases ("redux"; court of last resort)*
Operative Procedures: Small ‘n’....

- Number of surgical procedures
- Appendectomy
- Cholecystectomy
Operative Procedures: Small ‘n’....

• How do you measure competence?
  o Volume
  o Complications
  o Other?

• How do you maintain competence?
  o Simulation
  o Outside cases (legal issues; competition)
  o Other?
Operative Procedures: Small ‘n’.....

• What is the trigger for changing privileges?

• How do you sustain clinical investigators participation in clinical care?
Anonymous Reporting Hotline
### Summary of Anonymous Reports

<table>
<thead>
<tr>
<th>Week</th>
<th>Occurrence Reporting System</th>
<th>Anonymous Reporting</th>
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<tbody>
<tr>
<td>June 12</td>
<td>90</td>
<td>2</td>
</tr>
<tr>
<td>June 19</td>
<td>96</td>
<td>0</td>
</tr>
<tr>
<td>June 26</td>
<td>132</td>
<td>3</td>
</tr>
<tr>
<td>July 3</td>
<td>62</td>
<td>1</td>
</tr>
<tr>
<td>July 10</td>
<td>81</td>
<td>3</td>
</tr>
<tr>
<td>July 17</td>
<td>101</td>
<td>3</td>
</tr>
<tr>
<td>July 24</td>
<td>118</td>
<td>3</td>
</tr>
<tr>
<td>August 7</td>
<td>91</td>
<td>2</td>
</tr>
<tr>
<td>August 14</td>
<td>73</td>
<td>0</td>
</tr>
<tr>
<td>August 21</td>
<td>124</td>
<td>1</td>
</tr>
<tr>
<td>August 28</td>
<td>57</td>
<td>0</td>
</tr>
<tr>
<td>Sept 4</td>
<td>56</td>
<td>0</td>
</tr>
<tr>
<td>Sept 11</td>
<td>62</td>
<td>2</td>
</tr>
<tr>
<td>Sept 18</td>
<td>70</td>
<td>0</td>
</tr>
<tr>
<td>Sept 25</td>
<td>52</td>
<td>2</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>1,265</strong></td>
<td><strong>22</strong></td>
</tr>
</tbody>
</table>

### Summary of Anonymous Reports

- **Total Reports**: 22
- **Reports with Identifiers**: 5
- **Mean Follow-Up Time**: 6 days
- **Median Follow-Up Time**: 6.5 days
- **Range of Follow-up Time**: 1-23 days
- **Direct Follow-Up Possible**: 20
- **No Direct Follow-Up Possible**: 2
Anonymous Reporting Hotline

**Clinical Care**
- Practitioner competence/technique
- Obtaining consultative services
- Staff fatigue
- Capacity to provide pediatric cardiac monitoring
- Staffing
- Orders in CRIS after practitioners have departed NIH

**Communication**
- Contacting appropriate practitioners with test results
- Information re: MRI safety training

**Leadership/Culture**
- Supervisor response to event reporting

**Ethics/Human Subjects Protection**
- Capacity to give informed consent
- Treatment of research participants
- Clinical research data collection practices

**Facilities/Security**
- Leaking tiles
- Room temperature
- Use of security cameras in pediatric areas
- Handicap accessibility of NIH hotel shuttles
- Pedestrian safety

**Other**
- Policies related to specimen transport
- Lag time in electronic health record changes
- Co-worker "etiquette"
Patient Safety Event Reporting
Patient Safety Event Reporting Framework

- Just Culture
- Patient Safety Event Reporting System
- Organizational Learning and Feedback
Existing Occurrence Reporting System

- “Custom-built” web-based system since mid 1980’s
- 4000 reports submitted per year
  - Errors
  - Near misses
  - Process issues
  - Kudos
- Exceedingly limited data analytics capacity
- Data analytics and reporting is time consuming and limited
Future State?

What does the ideal state look like?

What are the significant challenges to use/success?

What are the significant drivers to use/success?
Discussion
Occupational Illness and Injury

Michele Evans, DrPH
Environmental Safety Officer, NIH Clinical Center

James Schmitt, MD
Medical Director, Occupational Medical Service, NIH Division of Safety
NIH Occupation Medicine Service (OMS)

• Occupational exposures to blood and body fluids and management of post-exposure prophylaxis for blood-borne pathogens
• Emergency services
• Routine occupational health issues
• Health education and promotion
• Preplacement examinations
• Management of occupational injuries
• Workers’ compensation filing
• Return to work/”fitness for duty” exams
• Immunization, physical therapy, acupuncture
• Fit testing for respirators
• Targeted medical surveillance program
OSHA Criteria For Recordable Occupational Illness or Injury

• An occupational illness or injury is recordable if it results in:
  • death,
  • days away from work,
  • restricted work or transfer to another job,
  • medical treatment beyond first aid, or
  • loss of consciousness.

Also, an employer must consider a case to meet the general recording criteria if it involves a significant injury or illness diagnosed by a licensed health professional, even if it does not result in any of the above events.
OSHA Reportable Occupational Illness or Injury?

As of January 1, 2015, all employers must report:

- All work-related fatalities within 8 hours.
- All work-related inpatient hospitalizations, all amputations and all losses of an eye within 24 hours.
Since 2011, the total number of recordable OI in the NIH CC fell by 31.4% compared to a decline of 8.8% for hospitals nationwide.
Comparison of Other Recordable Case (ORC) Incidence for the NIH CC to that of U.S. Hospitals

The dramatic reduction in TRC at the NIH CC is attributed to a significant drop in the number of OI that required more than first aid but did not require significant accommodations or lost time, i.e., ORC.
Comparison of the NIH CC’s Days Away From Work (DAFW) incidence to that of U.S. Hospitals

![Graph showing the comparison of NIH CC's and U.S. Hospitals' DAFW incidence rates per 100 FTEs from 2011 to 2015. The graph indicates a lower incidence rate for NIH CC throughout the years compared to U.S. Hospitals.]
Comparison of the NIH CC’s Days of Job Transfer or Restriction (DJTR) incidence to that of U.S. Hospitals
Nationally, the incidence of DART cases in hospitals averaged 2.6 cases per 100 FTE/year. The NIH CC’s DART incidence was 2.8 cases per 100 FTE/year with a range of 3.1 to 2.6.
Comparison of Incidence of Nonfatal Occupational Illness and Injuries

The NIHCC averaged 5.4 Total Recordable Cases per 100 FTE/year over the past five years. The national average for hospitals was 6.4 per 100 FTE/year.
Caveats and Summary

• Total Recordable Case (TRC) incidence for the CC declined by 31.4% from 2011 to 2015.

• This reduction resulted from a significant drop in ‘Other Recordable Cases’
  ▪ Our ORC incidence was 2.5 cases per 100 FTE/year versus the national average of 3.9 cases per 100 FTE/year.

• No work-related fatalities occurred at the CC in decades. Nationwide, approximately 25 fatalities occur among health care personnel in hospitals.
How Do We Use These Data to Reduce Occupational Illness and Injuries (OI) in the Hospital?
Comparison of the number and types of all OI reported by CC employees (2010 – 2015)

Number of OI Recordable Cases

- M/S Trauma
- Wounds
- Splashes
- Ergonomic
- Allergy
- Other*
- Burns

∞ M/S Trauma: Musculoskeletal Trauma
* Other cases includes inhalation, infectious exposures, and mental health concerns
Musculoskeletal Trauma Events In Clinical Areas in 2015 (N=49)

Activity at Time of Event
- No Patient Contact: 65%
- Near Patient w/o interaction: 33%
- Patient Transfer: 2%

Location at Time of Event
- Inpatient/Clinic: 63%
- Radiology: 16%
- Other Clinic Depts.: 21%
Musculoskeletal Trauma
Examples of Interventions and Control Measures

- Individualized consultations with an occupational therapist
- Improvements to the Grounds and Walkways
- Availability and use of powered and manual lifts and transfer devices for patients
- Standards of practice to safely manage patients at risk of falls
- Orientation and retraining on ergonomically safe techniques and practices
- Specially designed devices to reduce repetitive motion disorders
- Workplace assessments for ergonomic friendly furnishings
Human Blood & Body Fluid Wounds Among Health Care Personnel in 2015
N=19

• Includes all HBBF in the hospital regardless of IC affiliation.

• Majority (13) classified as mild risk with remaining (6) as moderate risk. No high risk exposures.

• Factors associated with wounds reported by physicians discussed with the Medical Executive Committee & the Hospital Epidemiologist.

• Two injuries involved recapping a needle during medical procedure.
Factors associated with HBBF wounds reported in 2012-2015
Targeted interventions including Universal Precautions training, engineering controls and personal protective equipment have resulted in sustainable, acceptable and stable performance. Diligence remains a priority to minimize these high risk injuries.
Human Blood & Body Fluid Wounds Reported by Health Care Personnel
2012-2015

Number of Wounds

2012 2013 2014 2015
Influenza Immunization Rates Among Staff with Patient Contact

Percent Compliance

- 2008-09 (Seasonal)
- 2009-10 (H1N1)
- 2010-11
- 2011-12
- 2012-13
- 2013-14
- 2014-15
- 2015-16
Discussion