

More Research in Pediatric Patients in the Clinical Center

October 21, 2022

**James K. Gilman, MD
NIH CC CEO**

Early CCRHB Pediatrics Discussions

JULY 14, 2017, 5th Meeting of CCRHB

- **“NIH Clinical Center CEO: Update:** Dr. Gilman described changes in the works to improve care of pediatric patients. Planning for the new pediatrics observation unit is underway. The Clinical Center is hiring its first pediatrics hospitalist. Also, pediatrics expertise is being added to the Code Blue Team. “
- **“Recommendation #2.1 from 2017 Engagement Project Report (S. Simonson):** The CC CEO should seek funding to enhance services provided by Institutes, such as hospitalists with categorical expertise in the areas they would be covering. Such hospitalists might include those with expertise in general pediatrics, pediatric anesthesia, pediatric critical care, or multi-institute clinical programs such as that for stem cell transplantation. The objective of this funding should be to ensure the quality of inpatient, outpatient, and consultative services at the CC”

APRIL 20, 2018, 8th Meeting of CCRHB Agenda Topic: Pediatrics at the NIH Clinical Center

- **Presenters:**
 - Deborah Merke, M.D., M.S., Senior Investigator & Chief, Pediatric Service, CC
 - Krista Cato, M.H.A., RN, Nurse Manager, Pediatric Program of Care, CCND
 - Zenaide Quezado, M.D., Chief, Pediatric Anesthesiology & Critical Care, CC
- **Areas of Focus:**
 - Pediatric Consult Service, Pediatric Care Committee, Creating High-Reliability Systems, Enhanced Preadmissions Process, Pediatric CLABSI Prevention Bundle, Monitored Pediatric Care Unit in 1 Northwest, Care Details

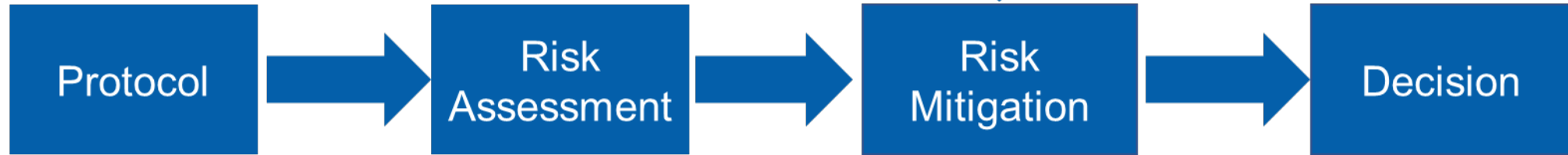
People, Places, & Capabilities (Research in Pediatric Patients)

- **Historically limited**
- **For the past several years – only children older than 3 and larger than 15 kg**
- **Only can be done if it is done safely**
- **Has been studied by one intramural working group assessing the near-term requirements**
- **Further evaluation (strategic perspective) by separate intramural work group**

Selective Engagement

MEC / CCGB
OHSRP/IRBO
FMEA, FMEA, FMEA, FMEA

Didactic
Simulation



Go / No go decision

CCND
Pediatric Care Committee



Capstone Exercise (Live Fire)

- Summer 2021 – two infants with GM 1 Gangliosidosis – partnered with Children’s National Hospital
- NHGRI Investigator – Gene Therapy protocol
- 6 months of preparation – CCND, CCMD, Pediatrics, Nutrition, Radiology, Lab, Transfusion Medicine, Pharmacy
- Extensive FMEA – Office of Patient Safety & Clinical Quality
- Extensive training – didactic and simulation
- Experienced almost every contingency imaginable but they were all covered

Became apparent early that we could not exert this much effort for every protocol.

Pediatric Care at the NIH Clinical Center Pediatric Planning Group (PPG)

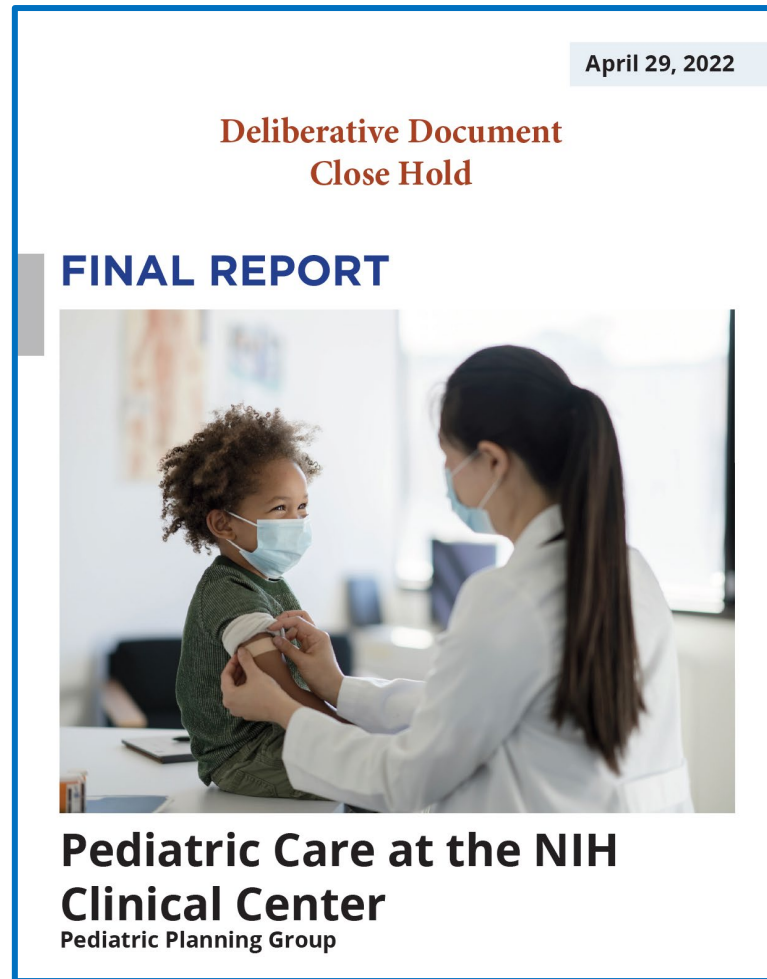
- **Spring 2021: Evaluation of CC pediatric care and assessment of feasibility of**
 - expanding patient volume,
 - increasing the ability to manage higher acuity patients, and
 - reducing the lower age limit for admissions from 3 years to 6 months
- **Response: 12-member Pediatric Planning Group (PPG; also called Operations Work Group) convened and reported to the Medical Executive Committee (MEC) and CC administration**
- **PPG: met 12 times between August 2021 and February 2022**
 - Subgroups were created that provided detailed recommendations in 3 areas:
 1. Pediatric Emergency Management
 2. Pediatric Critical Care, and
 3. Pediatric Subspecialty Coverage

**Clinical Center Governing Board
Requested External Review**

Specific Needs:

(PPG Report; pages 20-21)

- Personnel (NIH FTE)
- Personnel (Contract for on-call services and rotations)
- In-house Training
- Equipment/Medications
- Space



Financial Considerations:

(PPG Report; pages 22)

- Personnel (NIH FTE) – \$5.8M
- Personnel (Contract for on-call services and rotations) – \$2.0M
- One-time costs - \$5M

The estimated total cost for these proposals would be **~\$7.8 M** per year with initial additional costs in the **\$5M** range.

Conclusion: (PPG Report; page 23)

“In the United States, 6% of the population is under age 4. The cost of the proposed pediatric improvements, i.e., approximately 1.5% of the current Clinical Center budget, does not appear excessive to allow for inclusion of such a significant portion of our citizens and, at the same time, satisfy a moral imperative.”

Question to Be Answered



Can the NIH Clinical Center can provide more opportunities for early Phase 1 clinical trials in diseases of infancy and childhood?

Considerations:

- **Advisability**
- **Feasibility**
- **Safety**
- **Resources:**
 - **Adding modest number of organic capabilities**
 - **Partnering with a hospital or health system with a full complement of pediatric capabilities – specialties and subspecialties, services, etc.**

CCRHB Pediatrics Working Group

Chair: Dr. Sherin Devaskar, UCLA

Members:

- **Clifford W. Bogue, MD**, Professor & Chair of Pediatrics, Yale School of Medicine and Chief of Pediatrics and Chief Medical Officer, Yale New Haven Children's Hospital
- **Tina L. Cheng, MD, MPH**, Professor & Chair of Pediatrics, University of Cincinnati, Director, Cincinnati Children's Research Foundation, Chief Medical Officer, Cincinnati Children's Hospital Medical Center
- **Terence S. Dermody, M.D.**, Professor & Chair of Pediatrics, Professor of Microbiology & Molecular Genetics, University of Pittsburgh School of Medicine, Physician-in-Chief and Scientific Director, UPMC Children's Hospital of Pittsburgh
- **Donna Martin, M.D., Ph.D.**, Chair, Department of Pediatrics, Professor of Pediatrics and Communicable Diseases, Professor of Human Genetics, University of Michigan
- **D. Wade Clapp, MD**, Professor & Chair, Department of Pediatrics & Distinguished Professor at Indiana University, Physician-in-Chief, Riley Hospital for Children and a Professor; Microbiology & Immunology/Biochemistry & Molecular Biology.
- **Jordan S. Orange MD, PhD**, Professor & Chair, Department of Pediatrics, Vagelos College of Physicians and Surgeons, Columbia University, Physician In-Chief, Morgan Stanley Children's Hospital, New-York Presbyterian
- **Gary A. Silverman, M.D., Ph.D.**, Professor and Chairman, Department of Pediatrics, Washington University School of Medicine, Pediatrician-in-Chief, St. Louis Children's Hospital, Executive Director, Children's Discovery Institute

Timeline: *(pending CCRHB endorsement)*

CCRHB

Goals:

- **Series of virtual Working Group meetings led by Dr. Devaskar**
- **Deliverable to CCRHB at February Meeting: Review Report / Deliberate Recommendations**
- **CCRHB consensus with recommendation to NIH Director and CC CEO**