Creating a Learning Health System: Translating Research into the Standard of Care

William E. Smoyer, M.D.
C. Robert Kidder Chair,
Vice President and Director,
Center for Clinical and Translational Research
The Research Institute at Nationwide Children's Hospital
Professor of Pediatrics, The Ohio State University

Department of Learning Health Sciences
LHS Collaboratory
University of Michigan

December 15, 2017

NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

THE OHIO STATE UNIVERSITY
COLLEGE OF MEDICINE

Overview

- Summarize major trends and barriers to integrating clinical care and research
- Suggest a Learning Health System paradigm shift
- Describe the “Learn from Every Patient” (LFEP) program model and structure
- Share NCH experience with a LFEP Pilot Program
- Share lessons learned and opportunities!

Introduction

- Convergence of three major trends in medicine
  - Conversion to electronic medical records
  - Prioritization of translational research (in part via CTSA)
  - Increasing need to control healthcare expenditures
- Unprecedented interest and opportunities to develop systems that improve care while reducing costs
- "Learning Healthcare System" has been specifically called for by the IOM and others
- Hastings Center Report presented integration of clinical care and research as a <u>moral obligation</u> to patients

Introduction

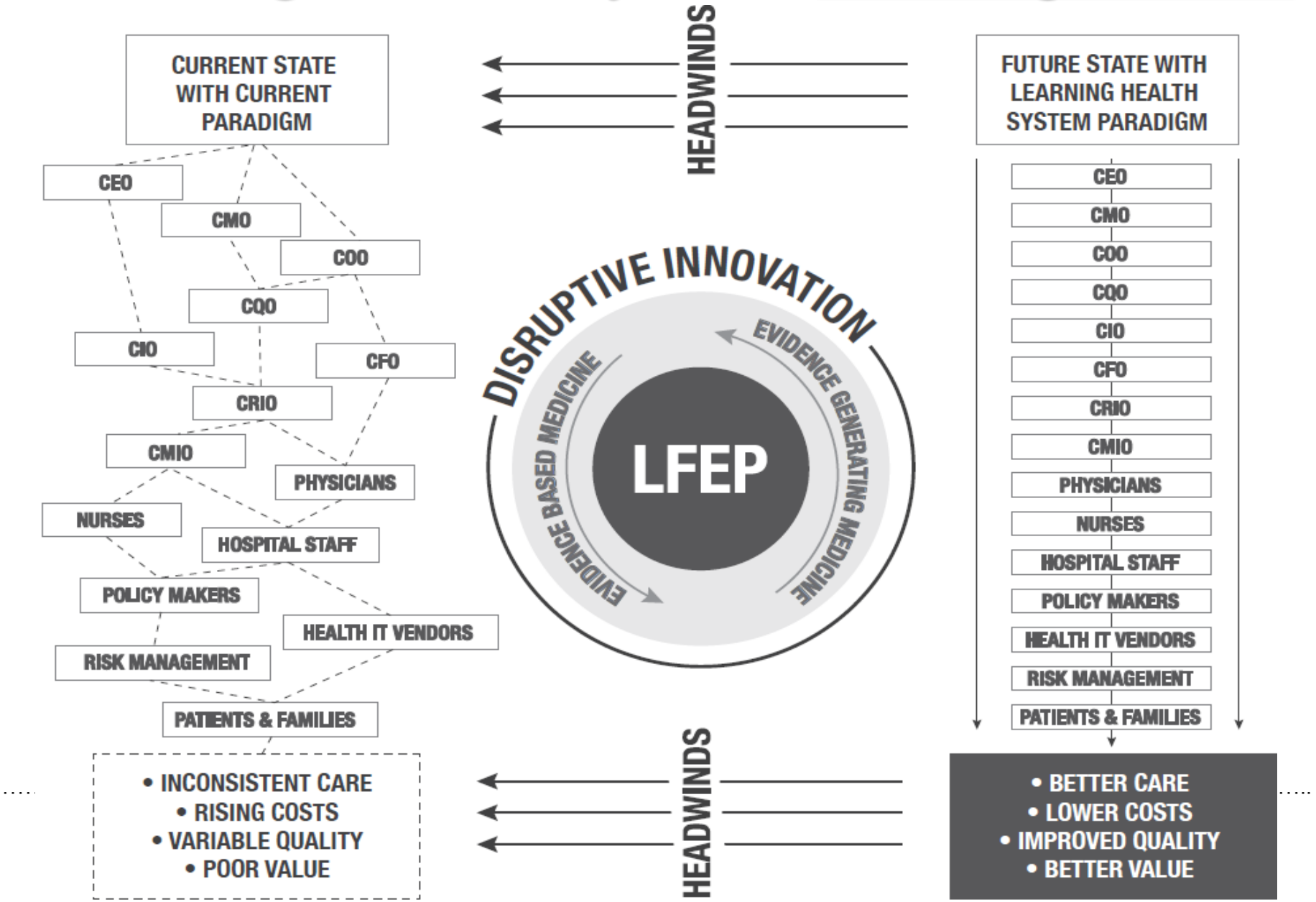
- Significant Barriers to Development of "Learning Health Systems"
  - Inadequate organizational readiness
    - Infrastructure-related / Financial / Political
  - Inadequate information standards
    - Differing terminologies, data models, data architectures
  - Inadequate technology integration
    - Differing IT systems
  - Inadequate workflow integration
    - Differing clinical care and research processes and cultures

Misalignment of Health System Interests

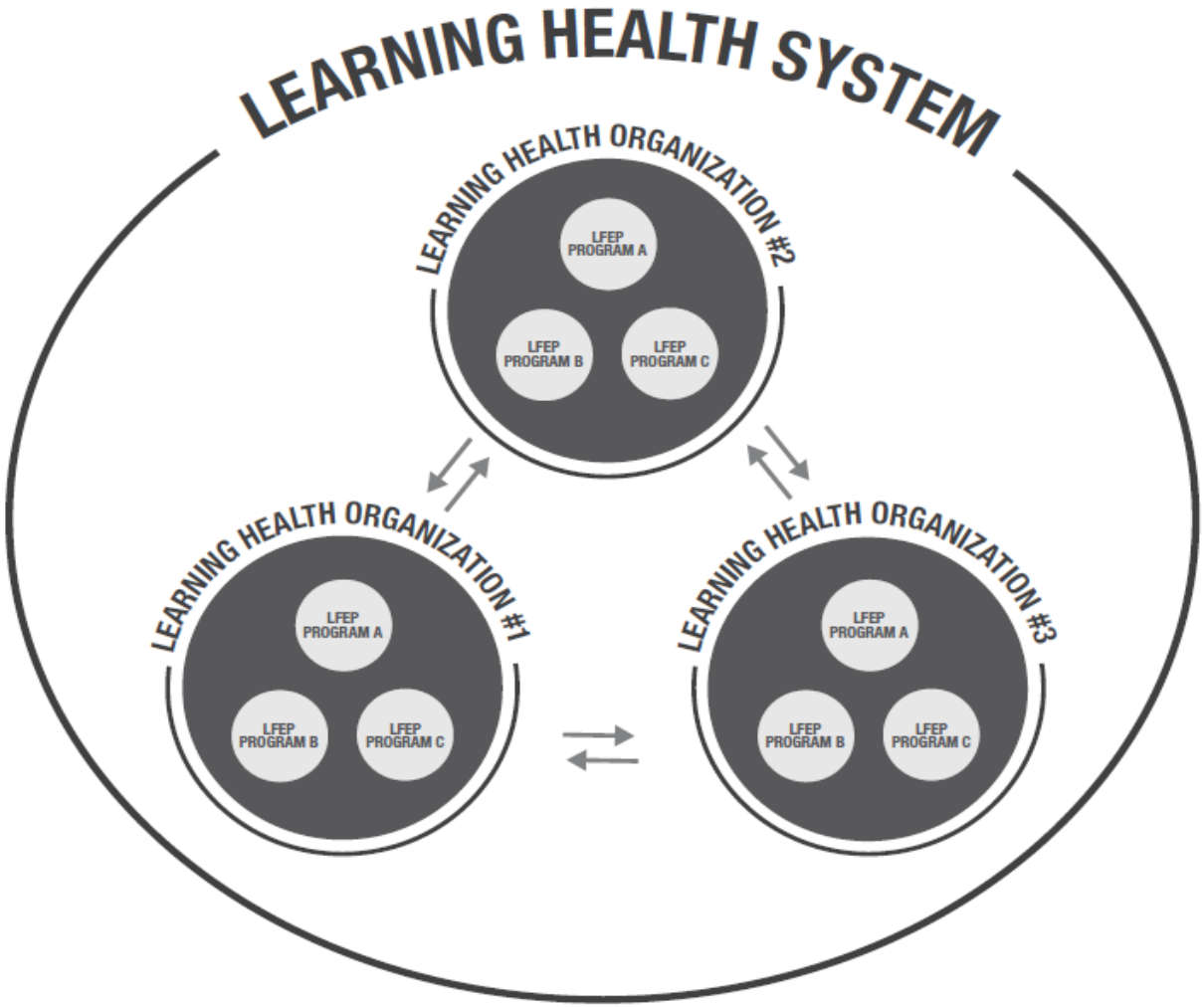
Varying Interests of Key Stakeholders	
Stakeholder	**Primary Interests**
CEO (Chief Executive Officer)	Reputation / Quality Care / Efficiency
CMO (Chief Medical Officer)	Medical Staff Administration / Peer Review
COO (Chief Operating Officer)	Efficiency / Improved Value
CQO (Chief Quality Officer)	Quality Improvement / Patient Safety
CIO (Chief Information Officer)	Efficiency / Data Governance
CFO (Chief Financial Officer)	Lower Care Costs / Increased Patient Volume
CRIO (Chief Research Information Officer)	Discrete Data Points / Data Interfaces / Data Accessibility
CMIO (Chief Medical Information Officer)	Usability of Medical Record / Quality of Care
Physicians	Best Care / Opportunity to Improve Care
Nurses	Ease of Documentation / Clear Care Guidelines
Hospital Staff	Standardized Care / Ease of Documentation
Policy Makers	Cost Containment / Improved Value
Health IT Vendors	Profitability / Data Accessibility
Risk Management	HIPAA Privacy / Data Integrity
Patients and Families	Quality of Care / Patient Satisfaction

(Smoyer WE, Embi PJ, Moffatt-Bruce S, ***J Am Med Assoc***, 2016)

Learning Health System Paradigm Shift



"Bottom Up" Approach to Create a Learning Health System



***Hypothesis**:* A "Learning Health System" can be cost-effectively developed and implemented to systematically drive both clinical quality improvement and reduced healthcare costs

Aim: To develop and implement a pilot program based on full integration of research and clinical care.

Learn From Every Patient ® Program

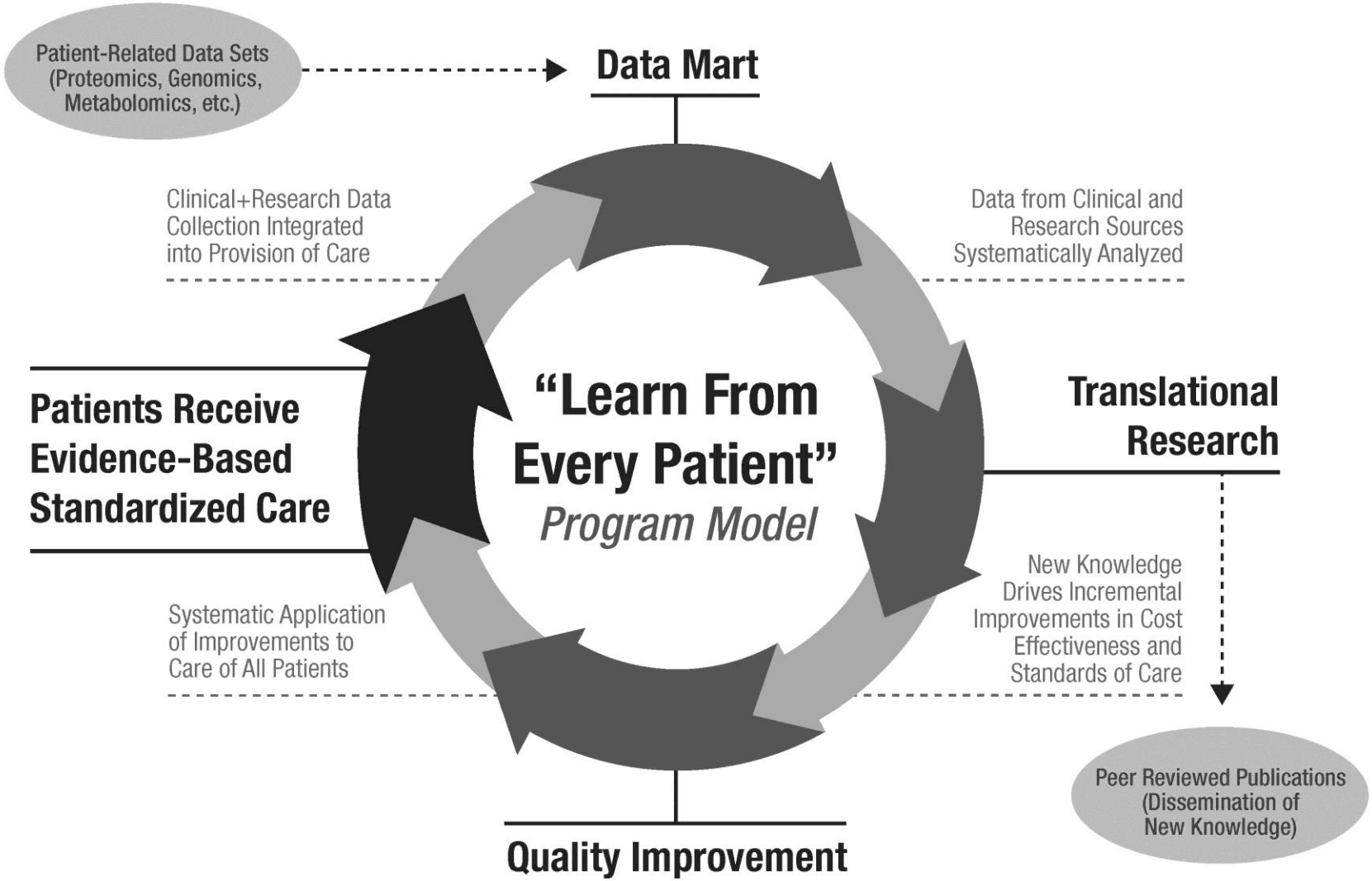
Learn From Every Patient ®
Program Mission

To fully integrate knowledge gained from clinical care with research to systematically advance the care of children

In other words…

"We will learn from every patient at every visit and use that knowledge to improve the care of the children that follow."

Learn From Every Patient® Program Model



NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

THE OHIO STATE UNIVERSITY
COLLEGE OF MEDICINE

Perspective on LFEP Program…

"… inspiration is easy. Implementation is the hard part."

Bob Taylor (Taylor Guitars)

Building the Team

- Pilot Program Identified
  - Cerebral Palsy Program
    - Small / Charged with “improving clinical care”
- Key Stakeholders for Pilot Program Identified
    - Physicians / Nurses / Clinical staff
    - Program administrators
    - Hospital EHR (EPIC) team
    - Enterprise Data Warehouse (EDW) team
    - Research informatics systems (RIS) team
    - Hospital informatics systems (HIS) team
    - Patient / Parent input (through MPOC survey)
- Project Manager Recruited

Setting Expectations

- Biweekly meetings convened
- Scope of LFEP program detailed for CP Program
  - Advantage: EHR had not yet been rolled out in program
- Benefits to organization and patients emphasized
- Individual expectations for roles in program clarified
  - Altered clinical practices required for physicians
  - Altered clinical practices required for nurses / staff
  - Altered interactions between hospital and research informatics teams
  - Altered rollout of EHR ("We've never done this…")

- **"This is a lot of change !!!"**

More Perspective on LFEP Program…

"Change is hard because people overestimate the value of what they have - and underestimate the value of what they may gain by giving that up."

James Belasco and Ralph Stayer

"Flight of the Buffalo"

IRB / HIPAA Compliance

- Working group developed to address issues
  - Legal Services / IRB Chair
  - Research Institute Administration
  - Research Informatics / CP Program Director
- Reviewed similar processes at other research institutions
- IRB Database Protocol Created
  - Provide oversight structure for IRB as “gatekeeper” of data
  - Requires IRB application to access data (or samples) for research or QI purposes
  - Ensures consultation between IRB and Legal Services regarding data use to ensure HIPAA and Human Subjects Research compliance

Project Management

- Routine clinical care-related data fields developed (per standard process)
- "Clinical care team" charged with several key tasks:
  - Commit to initial standard of care (evidence + opinion-based)
  - Determine three high-value research questions that would advance their field
  - Develop research data fields to collect key info for above
  - Develop research data elements to populate these fields
- Hospital EHR team charged with building these into EHR
- Clinical team in-serviced for clinical / research data entry

Data Management

- Clinical + research data fields entered at point of care
- All data collected as part of billable patient encounters
- Data collected in EHR migrated to Data Mart
- Initial confirmation of power of LFEP program:
  - # of patients "enrolled" in first year in our single site was noted to be comparable to a similar NIH-funded multi-site clinical trial over three years!

LFEP Pilot Program

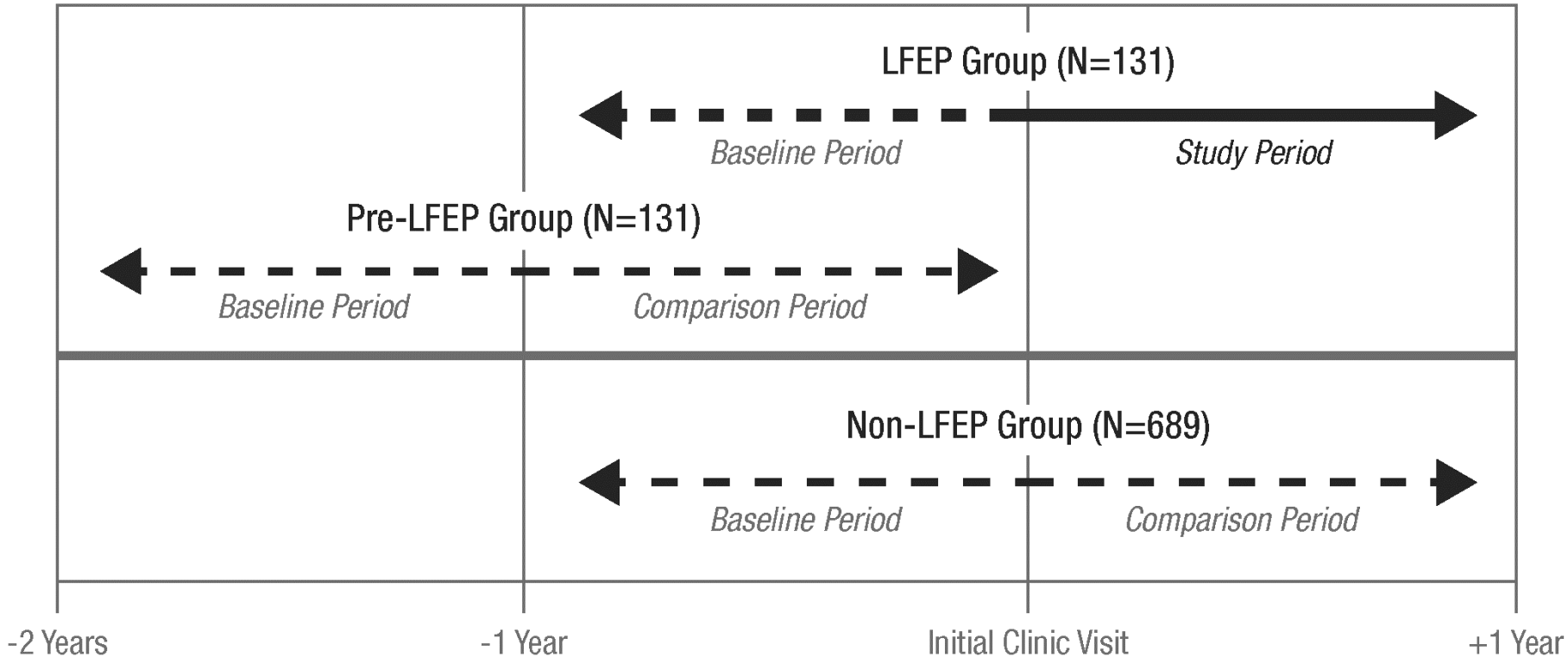
- ***Hypothesis**:* A "Learning Health System" can be cost-effectively developed and implemented to systematically drive both clinical quality improvement and reduced healthcare costs
- Developed, implemented, and evaluated a model of EHR-supported care in a cohort of 131 children with CP which integrates:
  - Clinical care
  - Quality improvement
  - Research
- Compared changes in healthcare <u>utilization rates</u> and healthcare <u>charges</u>

LFEP Intervention

- **LFEP Group** (During ***Study Period***) **:**
  - Initial Standardized Care provided to all patients
    - Evidence + Expert Opinion-based
  - Routine clinical data collected in EHR
    - Discrete data fields (categories)
    - Discrete data elements (choices within category)
  - Physician-inspired research data collected in EHR
  - Content-specific quality control of EHR data entry
  - *Standard Care Coordination provided*
- **Non-LFEP Group:**
  - Standard of care at NCH (but not standardized)
  - *Standard Care Coordination provided*

Learn From Every Patient ®

Study Design



NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

THE OHIO STATE UNIVERSITY
COLLEGE OF MEDICINE

Patient Demographics

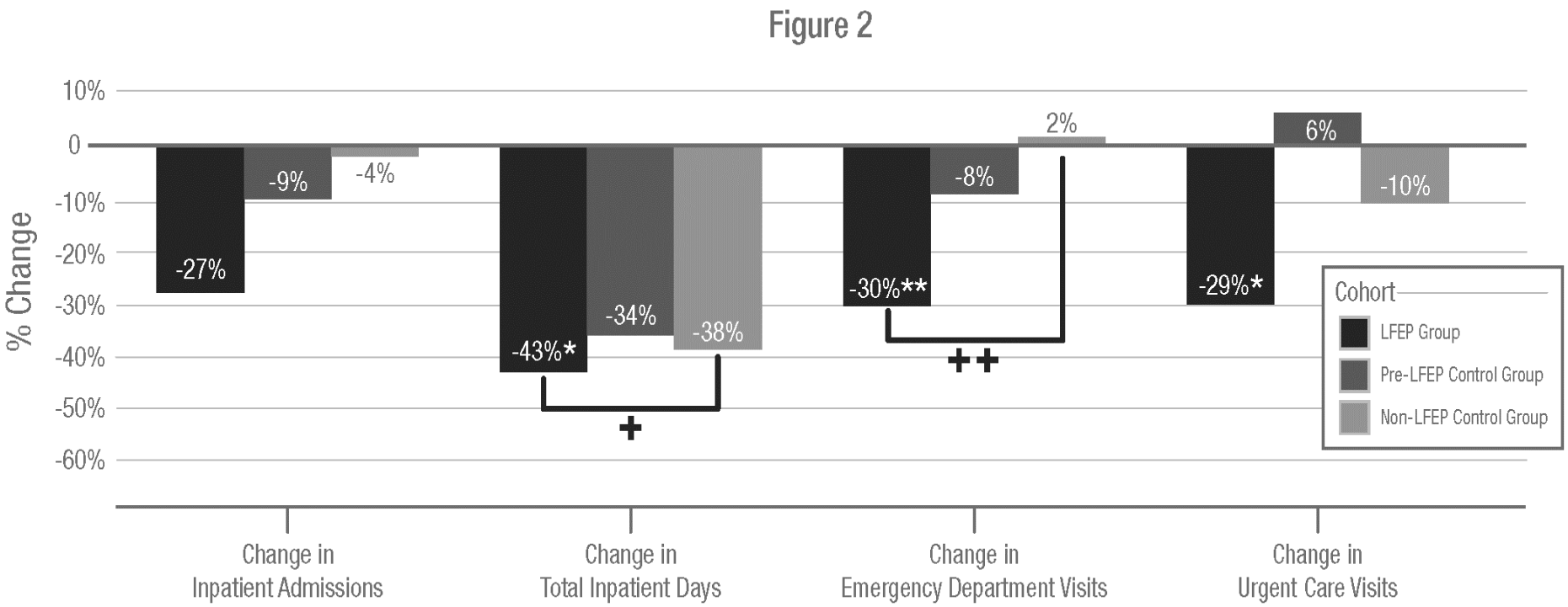
Table 1: Demographic Information for LFEP Group and Non-LFEP Control Group.

(* = $P<0.05$ and ** = $P<0.01$ vs. LFEP Group)

Cohort	Age (years)	Gender	Race	Payer Category
LFEP Group (n=131)	Mean: 6.19 Median: 5 Range: 2-16	M: 67 (51%) F: 64	White: 89 African American: 30 Asian: 0 Other: 12	Commercial: 36.6% Medicaid: 62.6% Other: 0.8%
Non-LFEP Group (n=689)	Mean: 8.96 ** Median: 9 Range: 1-16	M: 392 (57%) F: 297	White: 503 African American: 113 Asian: 6 Other: 58 Unknown: 9	Commercial: 44.4% Medicaid: 53.9% * Other: 1.7%

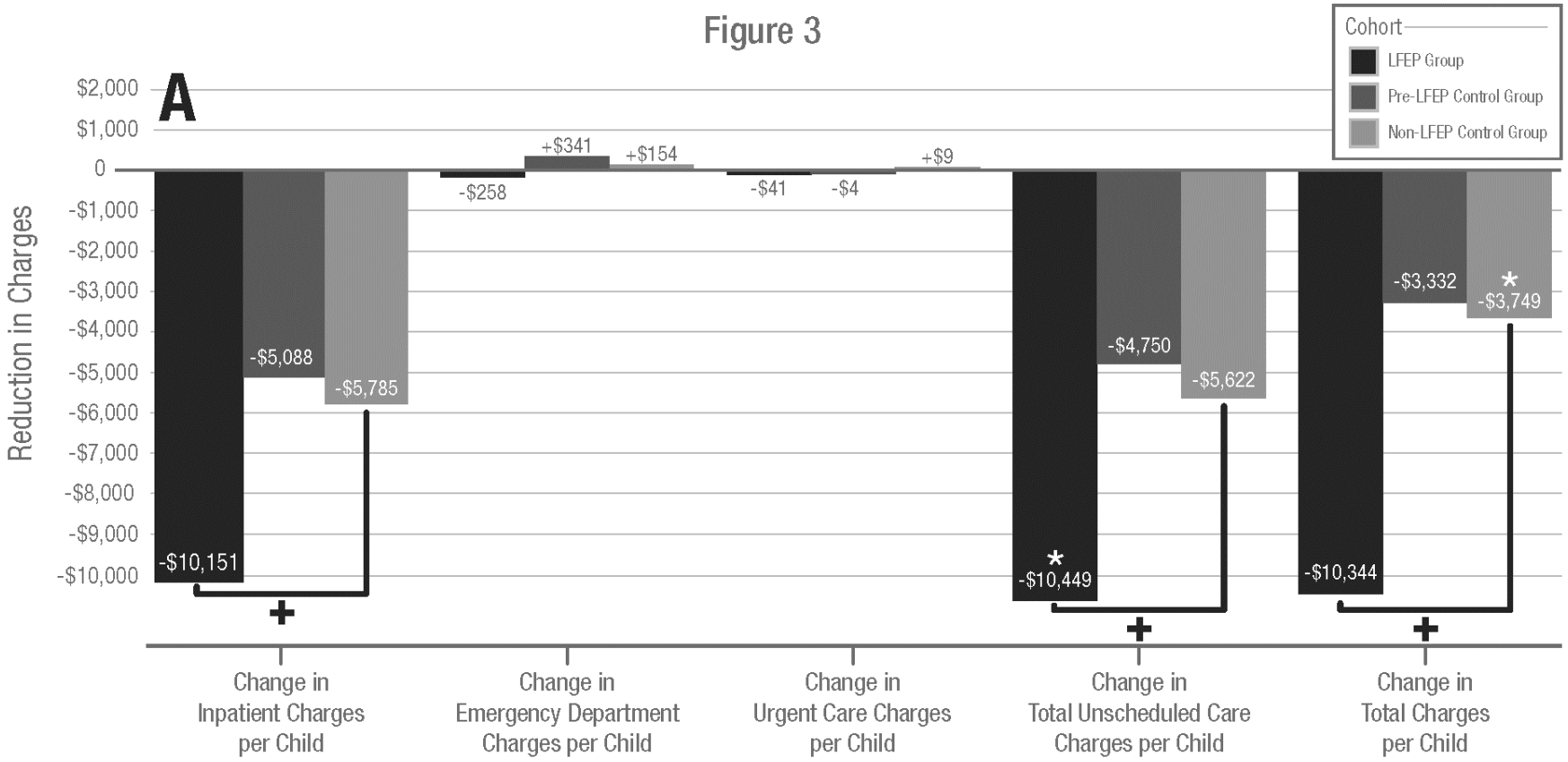
(Lowes LP, Noritz GH, Smoyer WE et al, ***Devel Med Child Neurol***, 2016; Smoyer WE, Embi PJ, Moffatt-Bruce S, ***J Am Med Assoc,*** 2016)

Comparison of Changes in Healthcare Utilization Rates (%)



(Lowes LP, Noritz GH, Smoyer WE et al, ***Devel Med Child Neurol***, 2016; Smoyer WE, Embi PJ, Moffatt-Bruce S, ***J Am Med Assoc,*** 2016)

Comparison of Changes in Healthcare Charges ($)

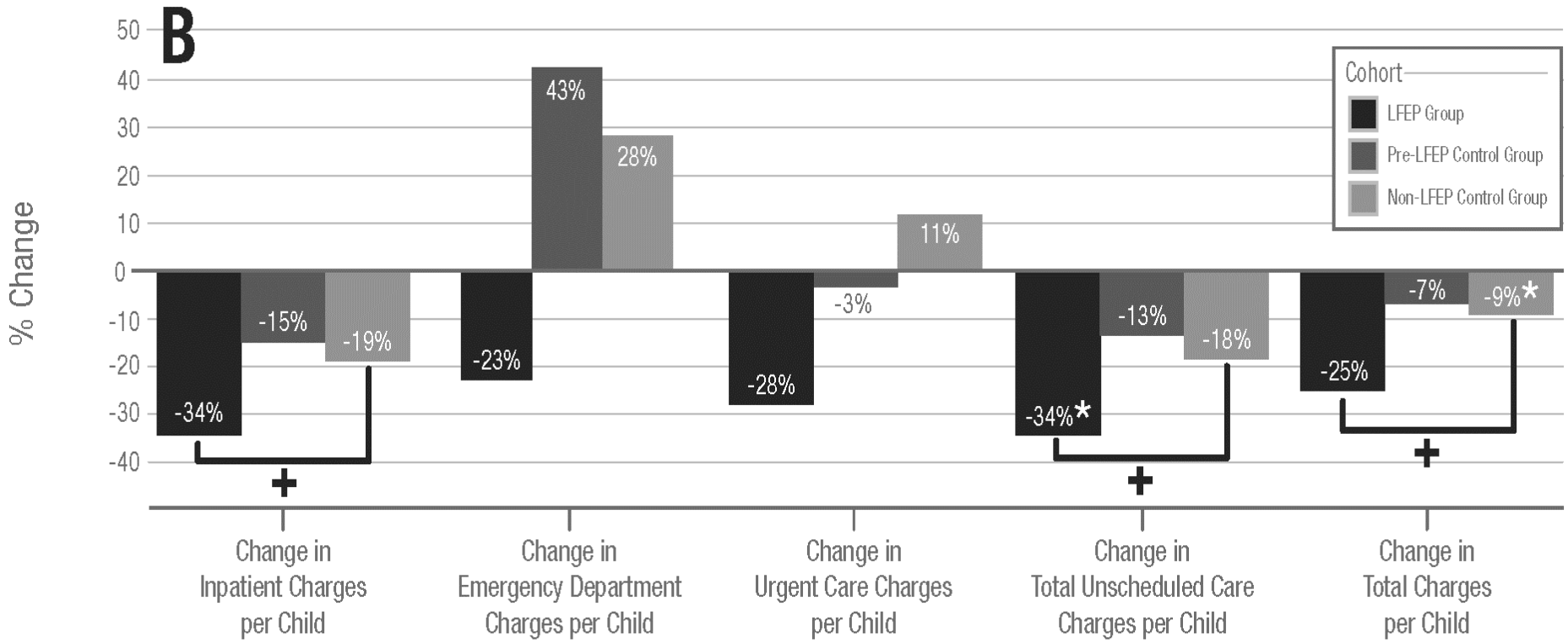


(Lowes LP, Noritz GH, Smoyer WE et al, ***Devel Med Child Neurol***, 2016; Smoyer WE, Embi PJ, Moffatt-Bruce S, ***J Am Med Assoc,*** 2016)

NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

THE OHIO STATE UNIVERSITY
COLLEGE OF MEDICINE

Comparison of Changes in Healthcare Charges (%)



(Lowes LP, Noritz GH, Smoyer WE et al, ***Devel Med Child Neurol***, 2016; Smoyer WE, Embi PJ, Moffatt-Bruce S, ***J Am Med Assoc,*** 2016)

Summary of Changes in Healthcare Utilization Rates

- 43% reduction in total inpatient days
  - 351 vs. 612 days (*P*=0.031 vs. prior 12-month period)
- 27% reduction in inpatient admissions
  - 72 vs. 98 admissions
- 30% reduction in ED visits
  - 109 vs. 155 visits (*P*=0.001 vs. prior 12-month period)
- 29% reduction in UC visits
  - 46 vs. 65 visits (*P*=0.046 vs. prior 12-month period)

Summary of Changes in Healthcare Charges

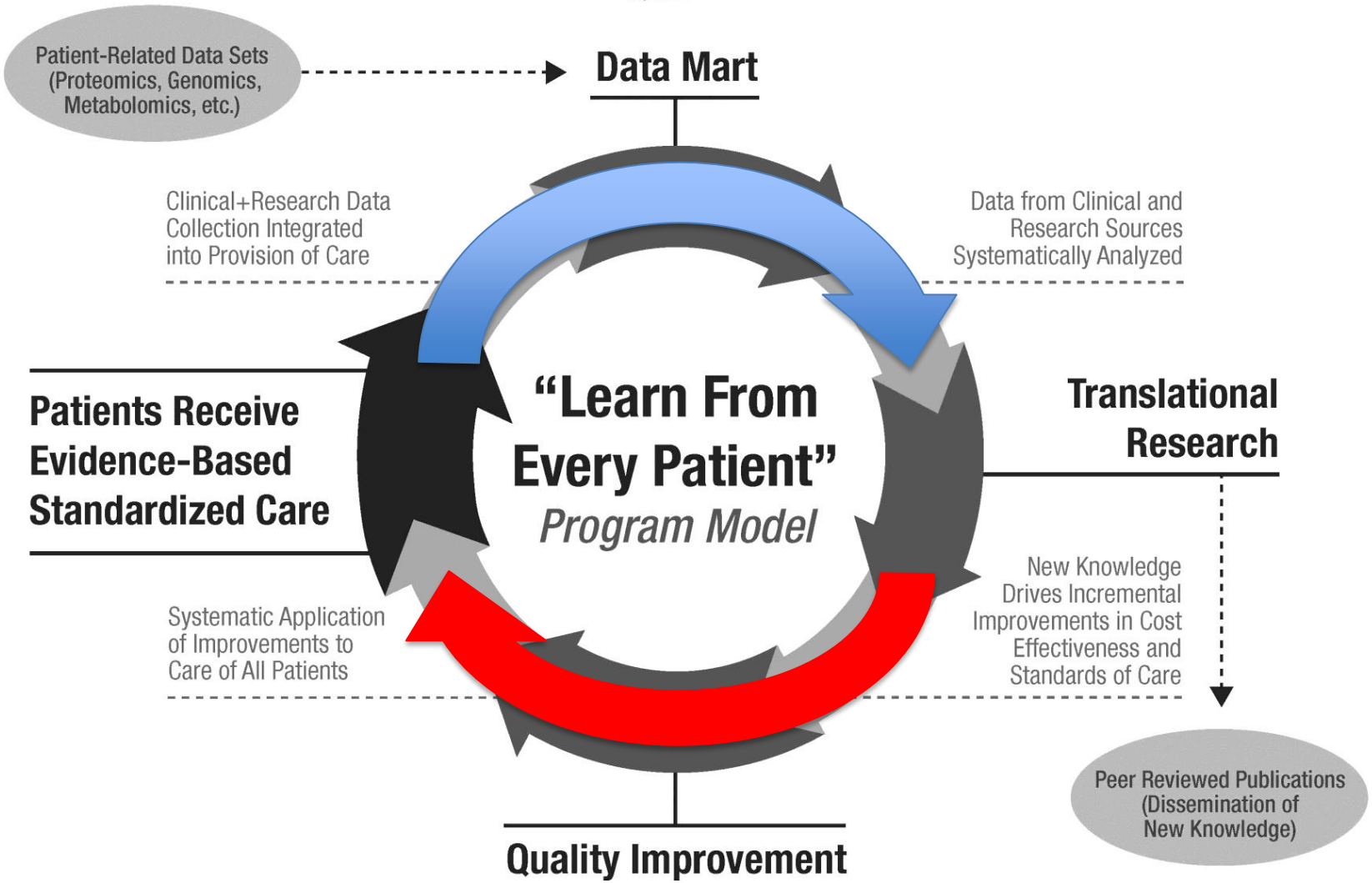
- 34% reduction in total inpatient charges
  - **$1.33 M ($10,151 per child)**
- 34% reduction in total unscheduled care charges
  - $1.37 M ($10,449 per child)
    - (*P*=0.03 vs. prior 12-month period)
- 23% reduction in ED charges
  - $258 per child
- 28% reduction in UC charges
  - $41 per child

Summary of Incremental Reductions in Healthcare Charges

- **210% reduction** in total healthcare charges vs. Pre-LFEP Group (*Time Control*)
  - $7,012 per child
- **176% reduction** in total healthcare charges vs. Non-LFEP Group (*LFEP Program Activities Control*)
  - $6,595 per child
- **120% reduction** in "unscheduled care charges" vs. Pre-LFEP Group (*Time Control*)
  - $5,698 per child
- **86% reduction** in "unscheduled care charges" vs. Non-LFEP Group (*LFEP Program Activities Control*)
  - $5,698 per child

Learn From Every Patient® Program Model

Figure 1

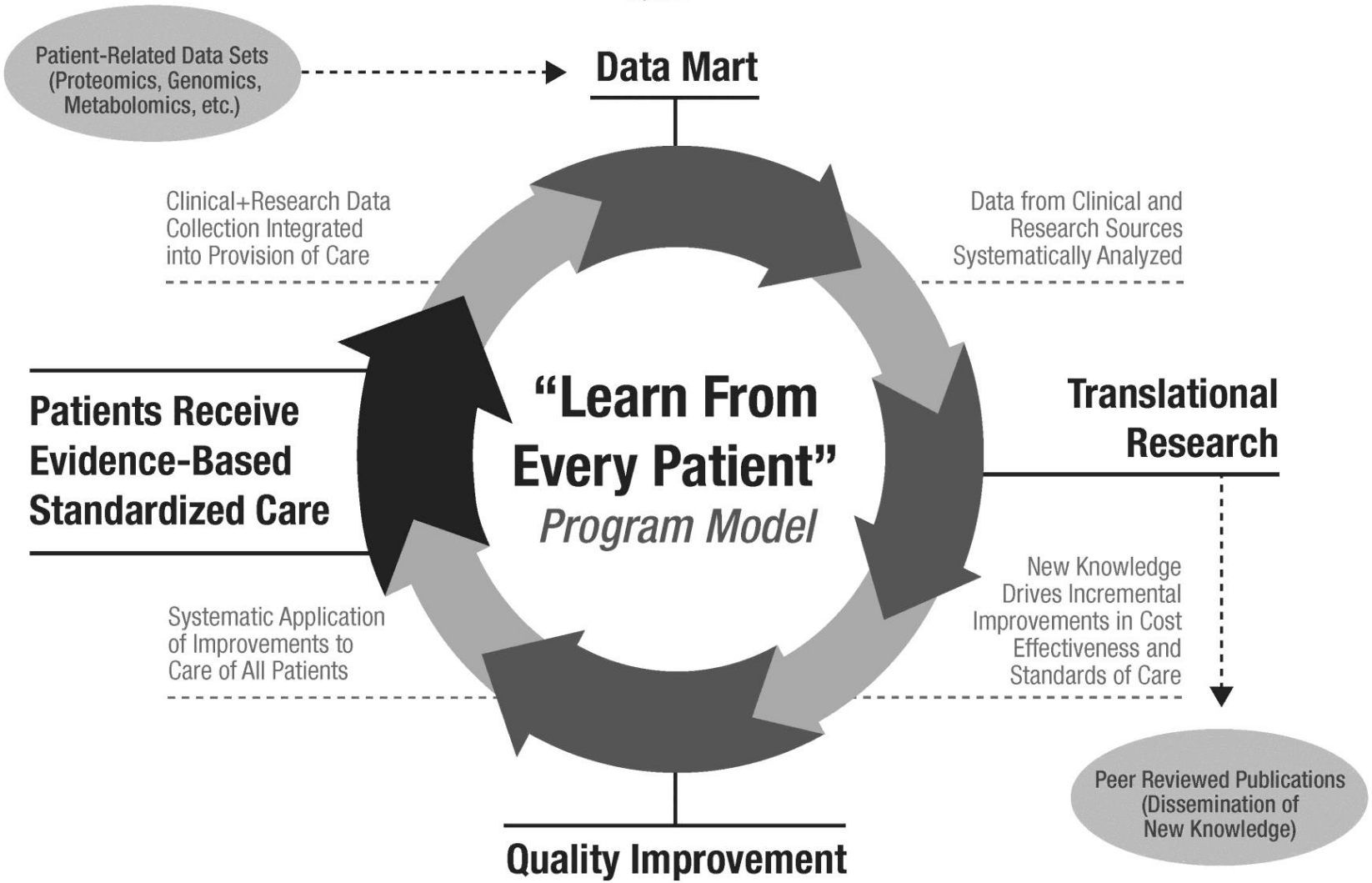


NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

THE OHIO STATE UNIVERSITY
COLLEGE OF MEDICINE

Learn From Every Patient® Program Model

Figure 1



…

……

NATIONWIDE CHILDREN'S
When your child needs a hospital, everything matters.℠

THE OHIO STATE UNIVERSITY
COLLEGE OF MEDICINE

LFEP "Learning Projects" Underway

LFEP Research Questions	Research Progress to Date	Direct Impact on Clinical Care
Are routine hip films useful for screening all children with CP?	Data collected and analyzed **Manuscript in preparation**	**Altered practice patterns already implemented to reduce hip X-rays in patients with mild CP**
Does the use of prophylactic tobramycin improve the health of children with tracheostomies?	Data collected and analyzed Abstract accepted **Manuscript in preparation**	Clinical care changes to be implemented pending results
Is the Communication Functional Classification Scale (CFCS) stable over time?	Data collected and analyzed Abstract presented **Manuscript in preparation**	LFEP Program in first 12 months completed more evaluations with this scale than any other program in US
Should children with CP and severe GE reflux undergo a Nissen or have a GJ tube inserted?	Data collected and under analysis	Clinical care changes to be implemented pending results
What do CP patients' parents feel are the most burdensome aspects of care?	Data collected Abstract presented **Manuscript Published**	**New programs already implemented to address identified family concerns**

Conclusions

- Results demonstrate that a "Learning Health System" can be developed and implemented in a cost-effective manner
  - Costs ($225K) ~16% of first-year charge reduction
  - **$6 saved per $1 spent**
- Such programs can systematically drive <u>simultaneous</u> clinical quality improvement and reduced healthcare costs
- LFEP model ideally suited for Accountable Care Organizations (ACOs)
  - Monthly per patient payments regardless of healthcare usage

LFEP Program Summary

- Broad-based "buy-in" essential for programmatic success
  - Clinical / Research / Financial / Political
- "Integration" requires significant culture change !!!
  - Physicians (drop-down menus; radio buttons; etc.)
  - Nurses (documentation; etc.)
  - Clinical Staff (documentation; etc.)
  - Administrators (clinic flow; charge documentation; etc.)
- Culture change largest barrier to realizing benefits of LHS
- Technical challenges already addressable and are not a true barrier to LHS creation!

LFEP Program Summary

- Huge opportunities for those willing / able to change !
  - Systematic improvement in clinical care
  - Reductions in healthcare expenditures
  - Expected market advantage for robust delivery of evidence-based care
  - Unprecedented phenotyping of biologic samples
    - Genomics / Proteomics / Metabolomics / Transcriptomics
  - Incorporation of Patient-Reported Outcomes (PROs)
  - Career advancement of academic faculty (Publications)
- LFEP model ideally suited for Accountable Care Organizations (ACOs)

Future Challenges for LFEP Program

- Is the LFEP Program scalable?
- Can LFEP be successfully applied to adult care?
- Can LFEP be successfully applied to surgical care?
- Is LFEP transferable to other institutions?

- ***These are testable questions !***
- ***We are interested in answering them !***

Final Perspective on LFEP …

"Progress is impossible without change: And those who cannot change their minds cannot change anything."

George Bernard Shaw,

Irish playwright

Acknowledgements

- Linda P. Lowes, PhD
- Garey Noritz, MD
- Amy Newmeyer, MD
- Peter Embi, MD
- Susan Moffatt-Bruce, MD
- Jeffery Schmidt
- Laura Rayburn-Savage, BSN
- Justin Golias
- Han Yin, M.S., PhD
- Michelle Miller, MD
- Lamara Love, BSN
- Abigail Tidball, PT

NATIONWIDE CHILDREN'S

When your child needs a hospital, everything matters.℠

THE OHIO STATE UNIVERSITY

COLLEGE OF MEDICINE

Nationwide Children's Hospital