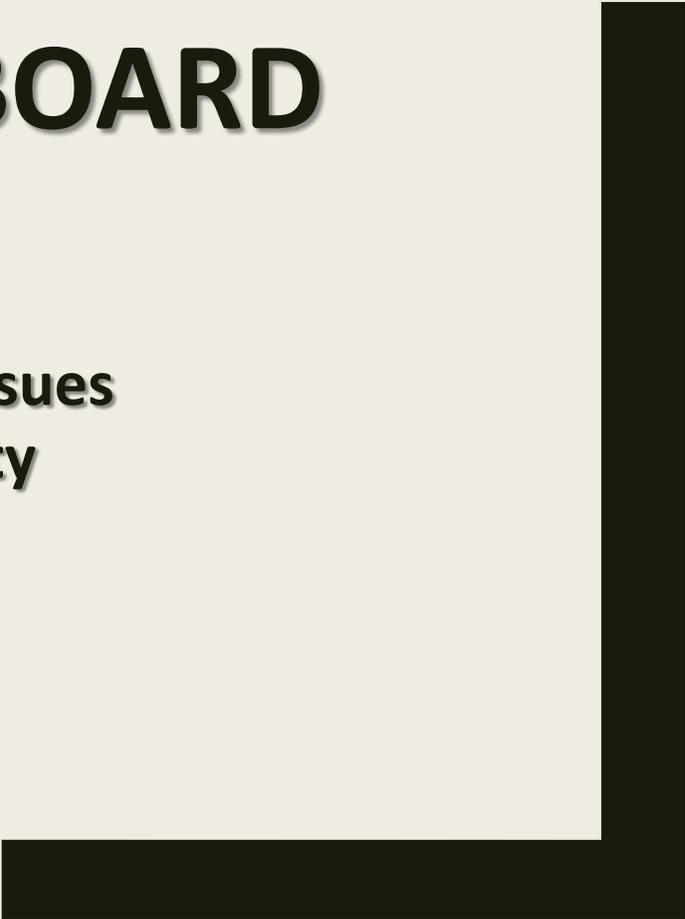


RESEARCH HOSPITAL BOARD

JULY 20, 2018

**NIDDK Perspectives and Ongoing Issues
Patient Safety and Clinical Quality**

**James E. Balow, MD
Clinical Director, NIDDK**



NIDDK Overview (1)

Leadership

- Director: Griffin Rodgers, MD
- Deputy Director: Gregory Germino, MD
- Executive Officer: Camille Hoover, MSW
- Scientific Director: Michael Krause, PhD

Scope of Research

- Broad range of basic sciences (9 Basic Science Labs)
- Diabetes, Endocrinology, Nutrition, GI, Liver, Kidney (10 Clinical Branches, including one in Phoenix)

NIDDK Overview (2)

Clinical Staff

- Senior Clinical Investigators: 30
- Tenure-Track Investigators 3
- Assistant Clinical Investigators: 2
- Staff Clinicians: 10
- Nurse Practitioners, Physician Assistants: 12
- Research Nurses, Protocol Coordinators: 12
- Protocol Navigators: 3
- Research Monitoring and Compliance: 1 + ad hoc's
- IRB Protocol Managers: 3

NIDDK Overview (3)

NIDDK Consult Services for CC Patients

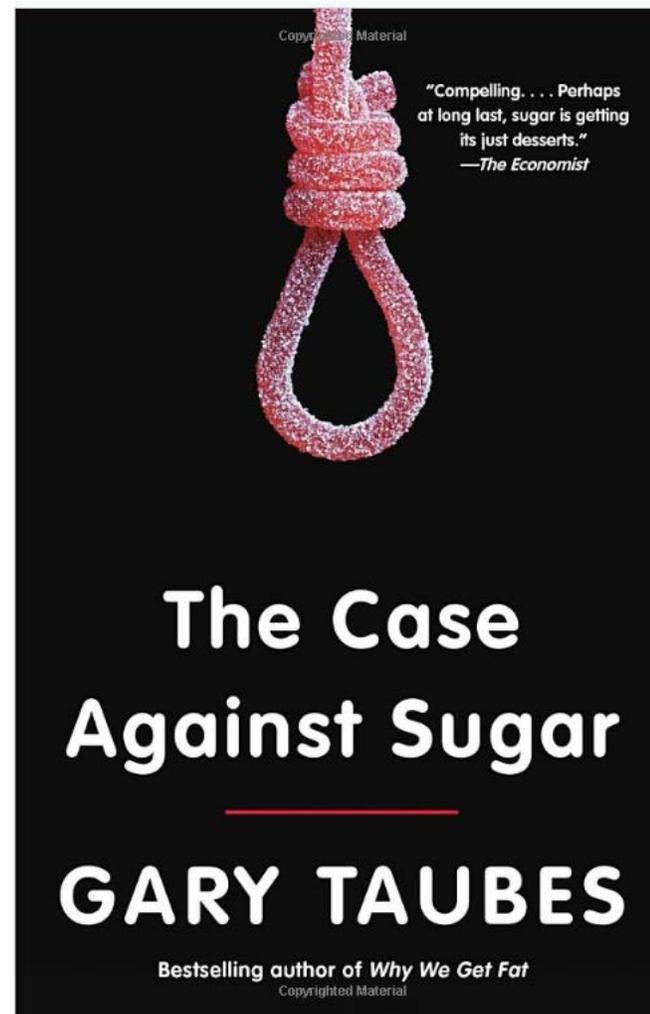
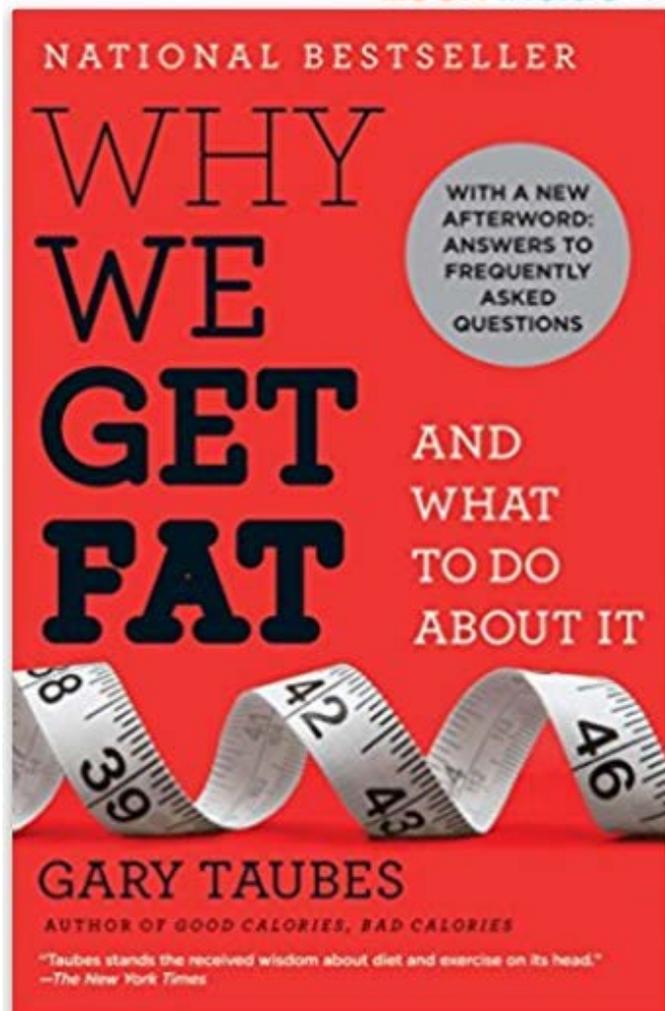
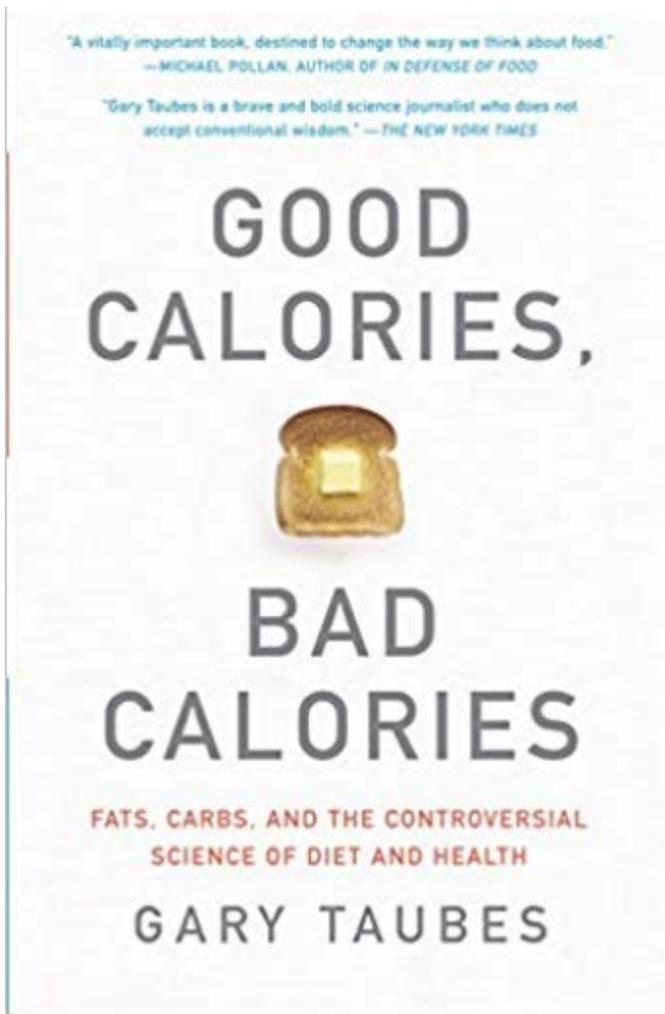
- Blood Glucose Management Service
- Endocrinology, Adult
- Gastroenterology, including endoscopy
- Hepatology
- Nephrology, including hemodialysis support

Metabolic Clinical Research Unit (1)

- Established in 2007 to support research priority related to emerging, world-wide pandemic of type 2 diabetes and obesity
- Unit includes 10 rooms designed to accommodate severely obese adults and adolescents
- Monitored communal eating area for tightly controlled feeding studies
- Large bore MRI scanner housed in CC Radiology and staffed by NIDDK tenure-track imaging scientist
- Metabolic chambers (3) requiring high-tech engineering for precision energy measurements and rigid temperature control
- Body composition scanners
- Facilitate trans-Institute metabolic and nutrition research

Metabolic Clinical Research Unit (2)

- Specialized staff trained in arcane test methodologies, necessary for quality research data collection and patient safety:
 - *Controlled glucose and insulin metabolic clamp studies*
 - *Stable isotopes for studies of metabolic pathways involved in energy metabolism, gluconeogenesis, etc*
 - *Measuring energy balance during exercise physiology studies*
 - *Indirect calorimetry*
 - *Energy balance: caloric intake, absorption, excretion*
 - *Rigidly controlled research diets*
- **Key purpose of MCRU is to conduct small, scientifically rigorous pilot studies that will inform new approaches to definitive population based studies**



What if It's All Been a Big Fat Lie?

By GARY TAUBES JULY 7, 2002

Mouse Study Suggests That Dietary Fat, Not Carbs, Drives Obesity

NEWS

© Jul 16, 2018 | Original Press Release from the Chinese Academy of Sciences



Metabolic Clinical Research Unit (2)

- Currently, protocols from 8 Institutes are conducted on the Unit, including an **NIH/NYU** collaborative program to study energy changes associated with changes in manipulation of the human microbiome
- Other studies:
 - *Prospects of metabolic benefits of brown fat induction*
 - *Mechanisms and relative benefits of experimental obesity drugs*
 - *Effects of “ultraprocessed” foods on energy balance*
 - *Complex effects of artificial sweeteners on caloric balance*
 - *Functional MRI studies of brain in hunger, satiety, “food addiction”*
 - *Pathogenesis of hepatic steatosis and steatohepatitis*
 - *Studies of leptin deficiency and replacement in lipodystrophies*

Metabolic Clinical Research Unit (2)

- Other studies, ongoing and planned:
 - *Type 2 diabetes and obesity in childhood*
 - *Energy studies in patients with rare and undiagnosed diseases, particularly inborn errors of metabolism and other rare syndromes with undefined metabolic phenotypes*
 - *Energy balance in patients with Chronic Fatigue Syndrome*
 - *Metabolic aspects of DOD/NIH studies of Gulf War Syndrome*
 - *Changes in energy balance in pregnancy, breast feeding*
 - *Sickle cell disease*
 - *HIV-associated metabolic syndrome*

Metabolic Clinical Research Unit (3)

- **NIDDK Co-Directors:** Kong Chen and Stephanie Chung
 - *Oversee day-to-day operations and training*
 - *Advise interested PI's on study design and facilitate development of specialized studies to address metabolic hypotheses*
 - *Co-Directors are supported by an Advisory Board (cross-Institute members, as well as an external member)*

Metabolic Clinical Research Unit

Issue: Unit is susceptible to wide swings in utilization (1)

- Census readily captured, but protracted day-time testing and feeding studies need accurate tools to capture activity data
- Closing of Pharmaceutical Development Service (PDS) in 2015 imposed a major dampening on several research projects
- Substantial limitations on approved access to requisite alternative commercial sources

Metabolic Clinical Research Unit

Issue: Unit is susceptible to wide swings in utilization (2)

- Nadir of Unit census occurred in 2017, both be limited access to study reagents and re-designing of protocols
- New protocols and modified existing protocol activity has rebounded in 2018 to median of past several years, though limitations on research reagents persists
- New considerations:
 - *Proposals to use Unit for other emerging initiatives and priorities*
 - *User Institutes are open to use of Unit as flex space*
 - *Opposed to decommissioning of rooms with specialized facilities*

Selected QA/QI Activities

- Subspecialty Rounds: review research and consult patients
- Monthly Senior Clinical Staff meetings (fellow representative)
- Multi-D Conferences
 - *Case based: complex cases with ambiguous adverse events*
 - *Topic based: practice-changing advances in clinical research*
- Improving the quality of CRIS Progress Notes – an important method to ensure:
 - *Effective communication*
 - *Reduce factual errors*
 - *Enhance clinical practice and patient safety*

Considerations for Highly Impactful QI Projects

Improving Effective Communication, Patient Care and Safety by Re-inventing the Quality of Progress Notes

- Quality content and effectiveness are universal concerns with EHR
 - *IT tools make **bulk** entries easy with minimal time and effort*
 - ***Quantity** characteristically overshadows **Quality***
 - *Clutter, repetition, obfuscation, unedited mistakes*
 - *To highlight and communicate Critical Thinking, EHR mostly fails*
 - *Copy forward is mostly counterproductive (but not necessarily)*
 - *Notes should not be cluttered with reams of impertinent results or data better retrieved by other informatics tools*
 - *Commercial products mostly to document entries for BILLING*

Potential Highly Impactful QI Projects

Issues Bearing on Quality of Progress Notes

- *Similar concerns apply to Nursing Notes*
- *Impact suboptimal on considerations of medical team*
- *Too many checkboxes cluttered with non-impactful data*
- *Too few assessments*
- *Should communicate what the front-line nurse is THINKING*

- **Concerns supported by impending changes in CMS EHR Meaningful Use program**

Progress Notes

- Create a **Performance Measure** based on **Quality**
- Make documentation of **Critical Thinking** the primary objective
- Use Problem Lists and Problem-Oriented Structure
- Limit use of Copy Forward tool
- Ensure that progression in PN reflects a progression of thinking
- Limit regurgitation of unfocused, uninformative test results
- Focus on pertinence
- Build graphics for key data trends... “picture worth thousand words”

Quality of Consult Services and Primary Care Practices

- Valid data depends on an IT system to continuously sample peer-based, bidirectional assessments of practices, performance and clinical quality of **consultants** and **requesters** of consults
- General surveys that are not case-based are suboptimal approaches to quality assurance
- Opportunities for Quality Improvement by clinical leaders (both Consult Services and Primary Clinical Teams) depend heavily on information on peer assessments of individual performances
- Current IT methods, STARS, are focused mainly on systems failures, are suboptimal for capturing data on quality of practice by individuals

Requester's Evaluation of the Consultant Team

	YES	NO
Was it difficult to contact the Consulting Team?		
Did a Senior Consultant participate in the consultation?		
Was the Consult Note entered in CRIS in a timely fashion?		
Did the Consult Note focus on relevant clinical issues?		
Did the Consult Note reflect the <u>THINKING</u> of the Consult Team?		
Did the Consult Team provide appropriate follow-up?		
<i>Please add additional comments and recommendations for QI</i>		

Consultant's Evaluation of Requesting Primary Care Team

	YES	NO
Were the key clinical questions to be addressed by the Consult Team clearly delineated in the request?		
Was the urgency of the consult properly represented?		
Were relevant baseline data available at the time of the consult request?		
Did existing Progress Notes clearly document the key clinical issues?		
Were you able to communicate effectively with the referring team?		
Did the requesting team follow your key recommendations?		
<i>Please add additional comments and recommendations for QI</i>		

Overview and On-Going Concerns

- **Future capacity of Metabolic Clinical Research Unit**
- **Alternative sources of pharmaceutical research reagents**
- **Sources for placebos and controls for clinical studies**
- **Ensuring clinical practice quality and patient safety by:**
 - *Improving quality of Progress Notes*
 - *Expanding specialty practice updates*
 - *Promoting Multi-Disciplinary Clinical Care Conferences*
 - *Bidirectional Peer-Review of Consultants and Primary Providers*