

# Beyond the RCT

Are there pragmatic ways we can collect high quality data to improve metabolic bariatric surgery practice?

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# Disclosures

- Received salary support as the Director of the Michigan Bariatric Surgery Collaborative; currently as Strategic Advisor
- Received research funding from Patient Centered Outcomes Research Institute (PCORI), Agency for Healthcare Research and Quality (AHRQ), and the National Institutes of Health (NIH)

# Objectives

- Discuss the role of registries
- Discuss the IDEAL pathway for new procedure development



# 8<sup>TH</sup> GLOBAL REGISTRY REPORT

# Purpose of the IFSO Global Registry

To aspire to provide the most credible and transparent information available on metabolic bariatric surgery. To achieve this mission, we aim to provide descriptive data about caseload / penetrance of surgery for metabolic disease and obesity in various countries as well as aspire to provide real-world post approval surveillance of procedures / devices.



# Contributions to 8<sup>th</sup> Global Registry Report

**24 National  
or Regional  
Registries**

**480,970  
procedures**

# BMJ Open What are the essential features of a successful surgical registry? a systematic review

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Rishi Mandavia,<sup>1</sup> Alec Knight,<sup>2</sup> John Phillips,<sup>3</sup> Elias Mossialos,<sup>4</sup> Peter Littlejohns,<sup>2</sup> Anne Schilder<sup>1</sup>

*BMJ Open* 2017;**7**:e017373.

# Essential elements of a registry

1. Steering Committee
2. Clear registry objectives
3. Planning for initial and longitudinal funding
4. Strategic national collaborations among key stakeholders
5. Dedicated registry management team
6. Consensus meetings to agree registry dataset
7. Established data processing systems
8. Anticipating challenges
9. Implementing strategies to increase data completion





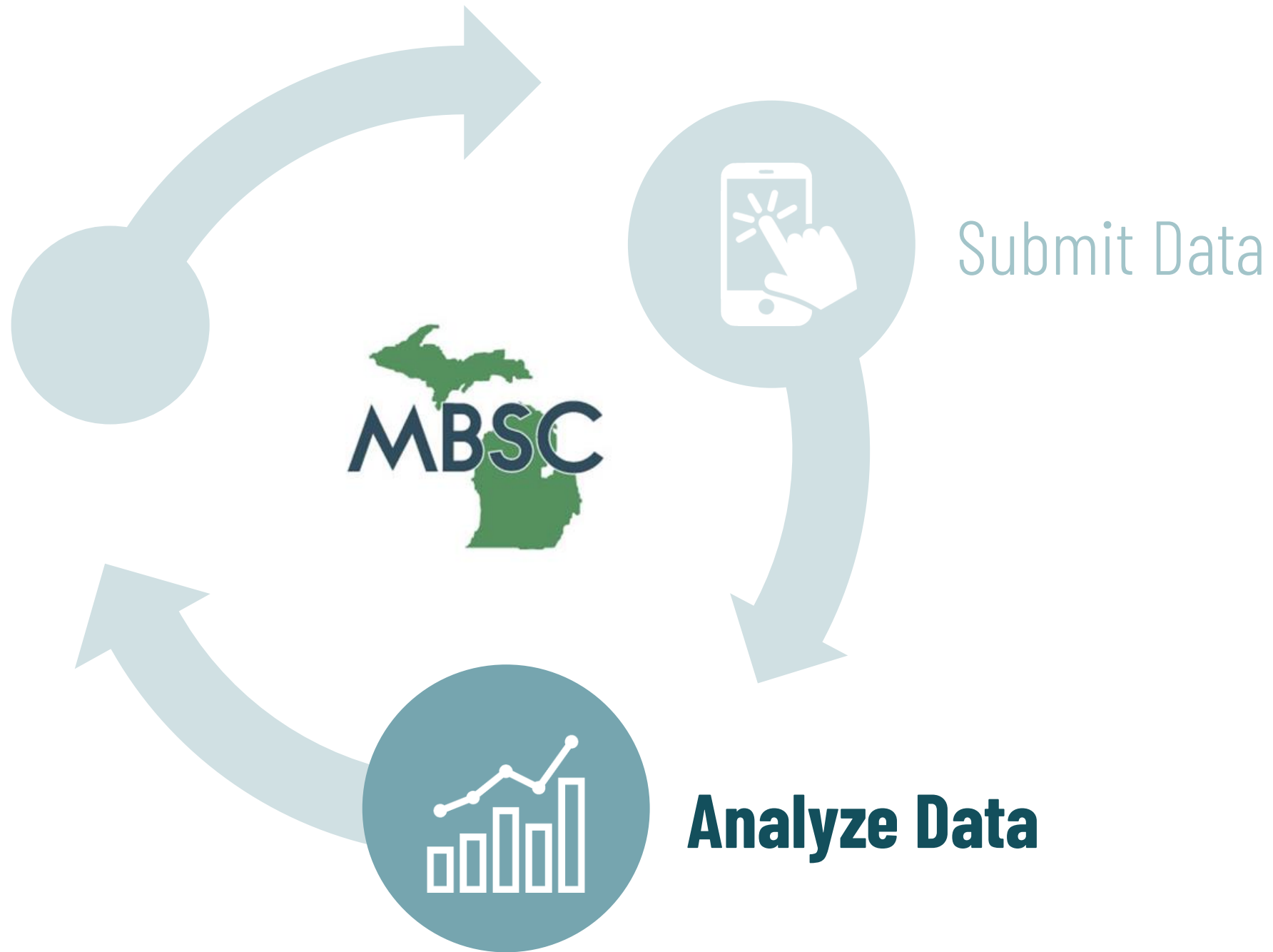
MICHIGAN BARIATRIC SURGERY COLLABORATIVE

**MBSC**

**15 YEARS**  
& counting



**Submit Data**



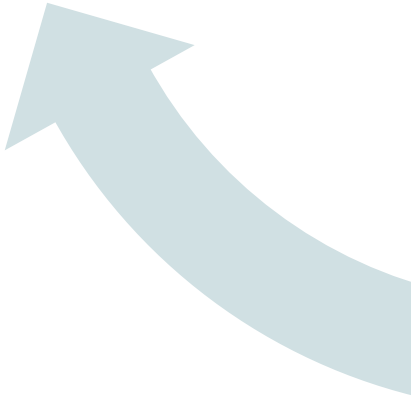
**Design  
Strategy**



Submit Data



Analyze Data





# MBSC Mission Statement

MBSC aims to advance the science and practice of bariatric surgery—  
in Michigan and across the United States.

MBSC rests on the core pillars of collaborative quality improvement:  
collection of detailed clinical data on outcomes and practice;  
timely, rigorous performance feedback to clinicians;  
and continuous improvement based on empirical analysis and  
collaborative learning.

# Registry Driven Assessment

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- Technical Skill
- IVC Filter utilization



# Technical Skill/Coaching

- Espouses the core values of surgery and quality improvement
- Requires trust, reliability of data, and collaboration



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# The “Black Box” of Surgery



Technique and Technical Skill

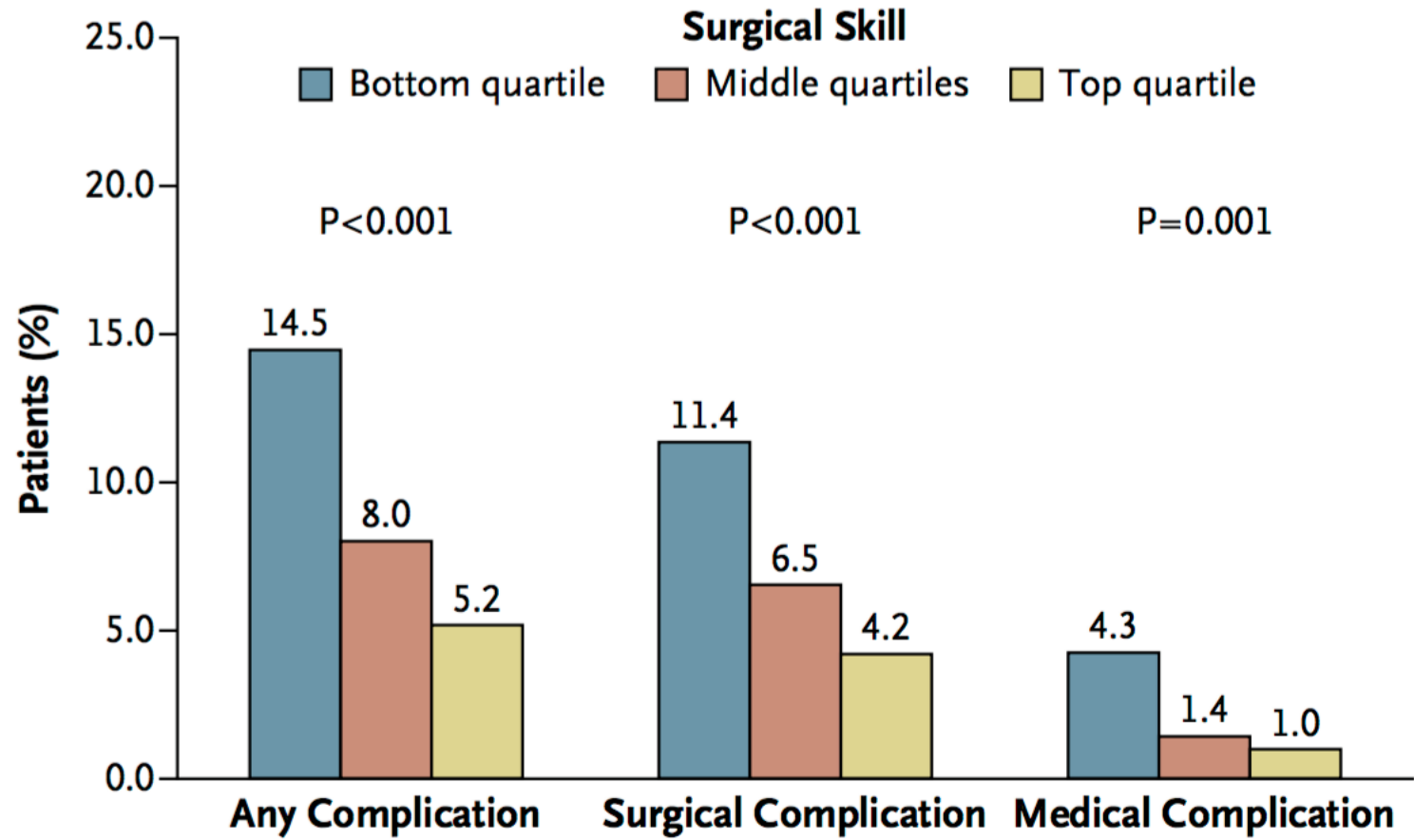


*The* NEW ENGLAND JOURNAL *of* MEDICINE

SPECIAL ARTICLE

## Surgical Skill and Complication Rates after Bariatric Surgery

John D. Birkmeyer, M.D., Jonathan F. Finks, M.D., Amanda O'Reilly, R.N., M.S.,  
Mary Oerline, M.S., Arthur M. Carlin, M.D., Andre R. Nunn, M.D.,  
Justin Dimick, M.D., M.P.H., Mousumi Banerjee, Ph.D.,  
and Nancy J.O. Birkmeyer, Ph.D., for the Michigan Bariatric Surgery Collaborative



**Figure 2.** Risk-Adjusted Complication Rates with Laparoscopic Gastric Bypass, According to Quartile of Surgical Skill.

# Measuring & improving surgeon skill

- Surgeons submitted video of “typical” laparoscopic gastric bypass video
- Blinded peer rating
- Technical skill rated according to modified OSATS instrument

**MBSC** Michigan Bariatric Surgery Collaborative

Blue Cross Blue Shield Blue Care Network Of Michigan


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Home Data Management Reports Decision Support Administrative Help Reviews

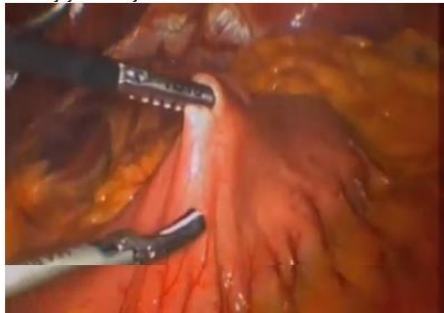
### Perform Review

Please take a moment to watch any media / video(s) and then complete the small questionnaire on the right to rate surgeon's skills. The answers to this survey will be kept completely anonymous.


**Gastric Pouch**



**Gastro-jejunostomy**



**Jejun-jejunostomy**



#### Surgeon's skill review

Please rate the surgeon's skill in the following categories using 1 as the lowest score and 5 as the highest

Respect for tissue *	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5
Exposure *	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5
Instrument handling *	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5
Time and motion *	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5
Flow of operation *	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5
Overall technical skill *	<input type="radio"/> 1 <input type="radio"/> 2 <input type="radio"/> 3 <input type="radio"/> 4 <input type="radio"/> 5

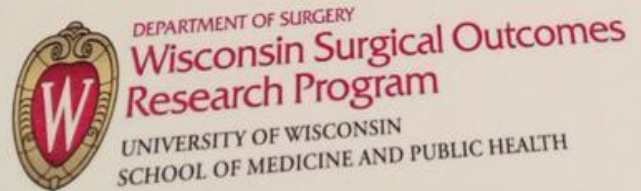
Comments

Submit



# Coach Resource Manual

Prepared for MBSC  
2015





# Registry Driven Assessment

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- Technical Skill
- **IVC Filter Utilization**



# IVC Filter Utilization

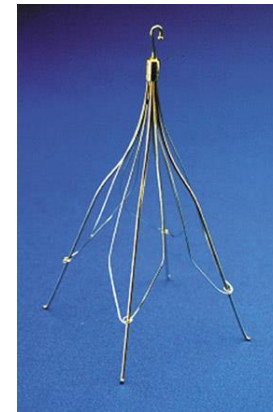
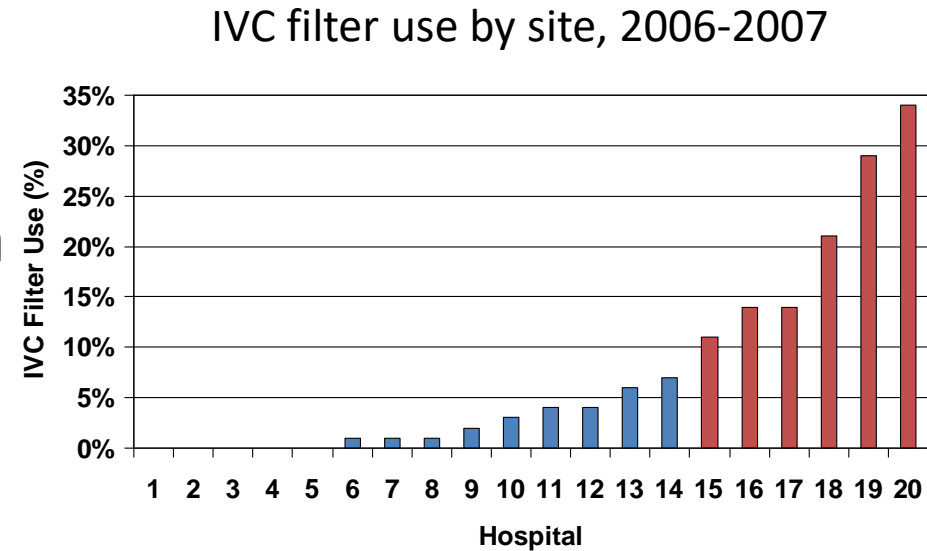
- Challenging to see the data without a registry
- Rapid practice assessment and change can come about with strong data



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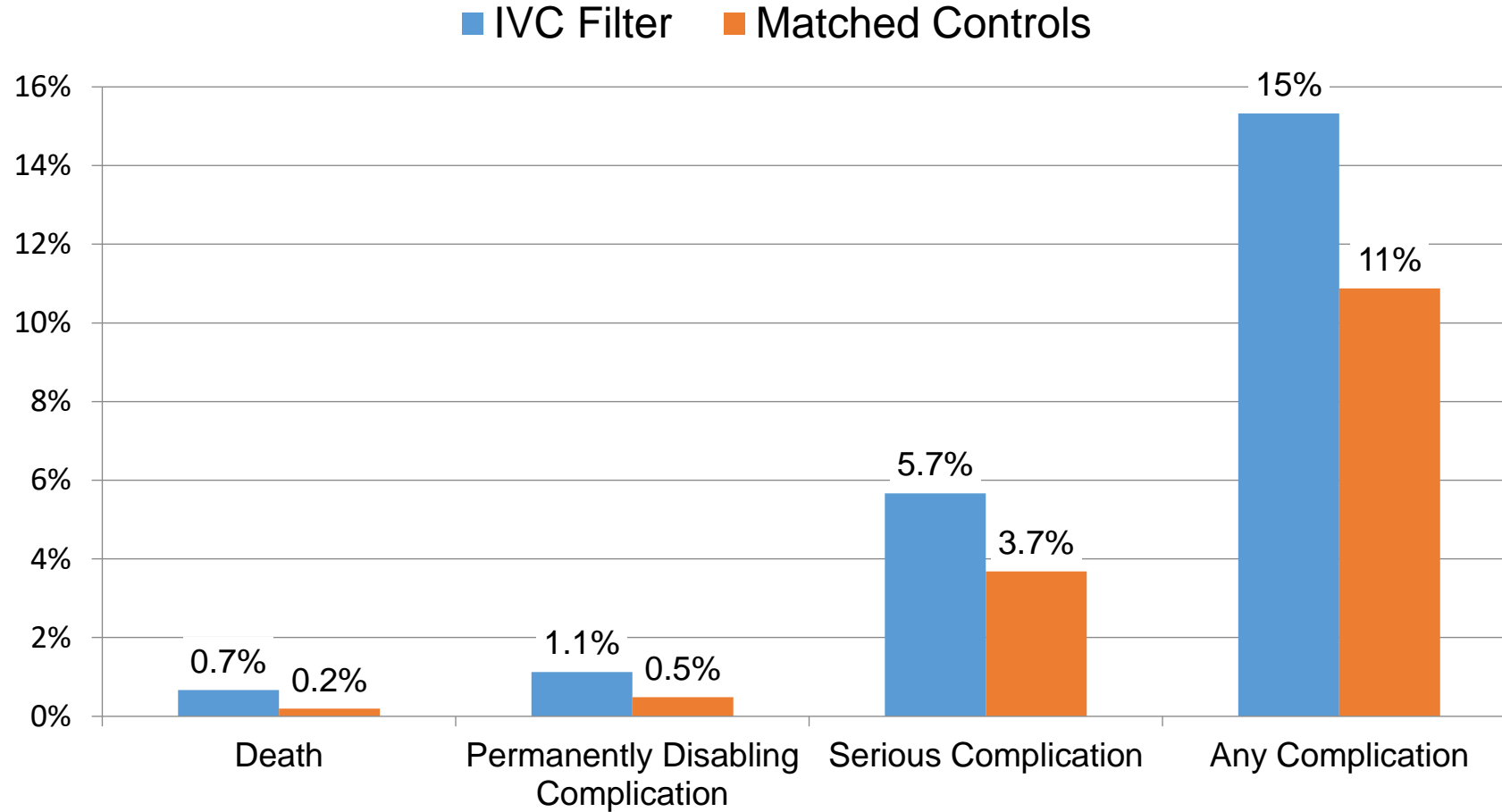
# IVC Filter Utilization

- Prophylactic IVC filter placement in ~10% of patients
- Wide variation in use from 0% to 35% across hospitals





# Adjusted rates of complications according to severity in IVC filter patients and in matched controls



# Death/disabling complications in patients with IVC filters

Half of the IVC filter patients with the most serious complications, had a PE or a complication specifically related to the IVC filter

<b>Specific Examples:</b>
Filter migrated to R heart (POD #3), open heart surgery for removal
Bilateral lower extremity thrombosis, vena cava filter thrombosis (POD 4,5), reintubated (POD 5), <u>death</u>
ED (POD14) for PE, reintubated, cardiac arrest, <u>death</u>
ED/readmitted (POD 13) for excessive anticoagulation and intra-abdominal bleeding, PE/cardiac arrest (POD 16), <u>death</u>
ED (POD 15), readmitted (POD 16) IVC filter occlusion leading to vascular collapse, shock (POD 17), cardiac arrest (POD 17, 18), <u>death</u>

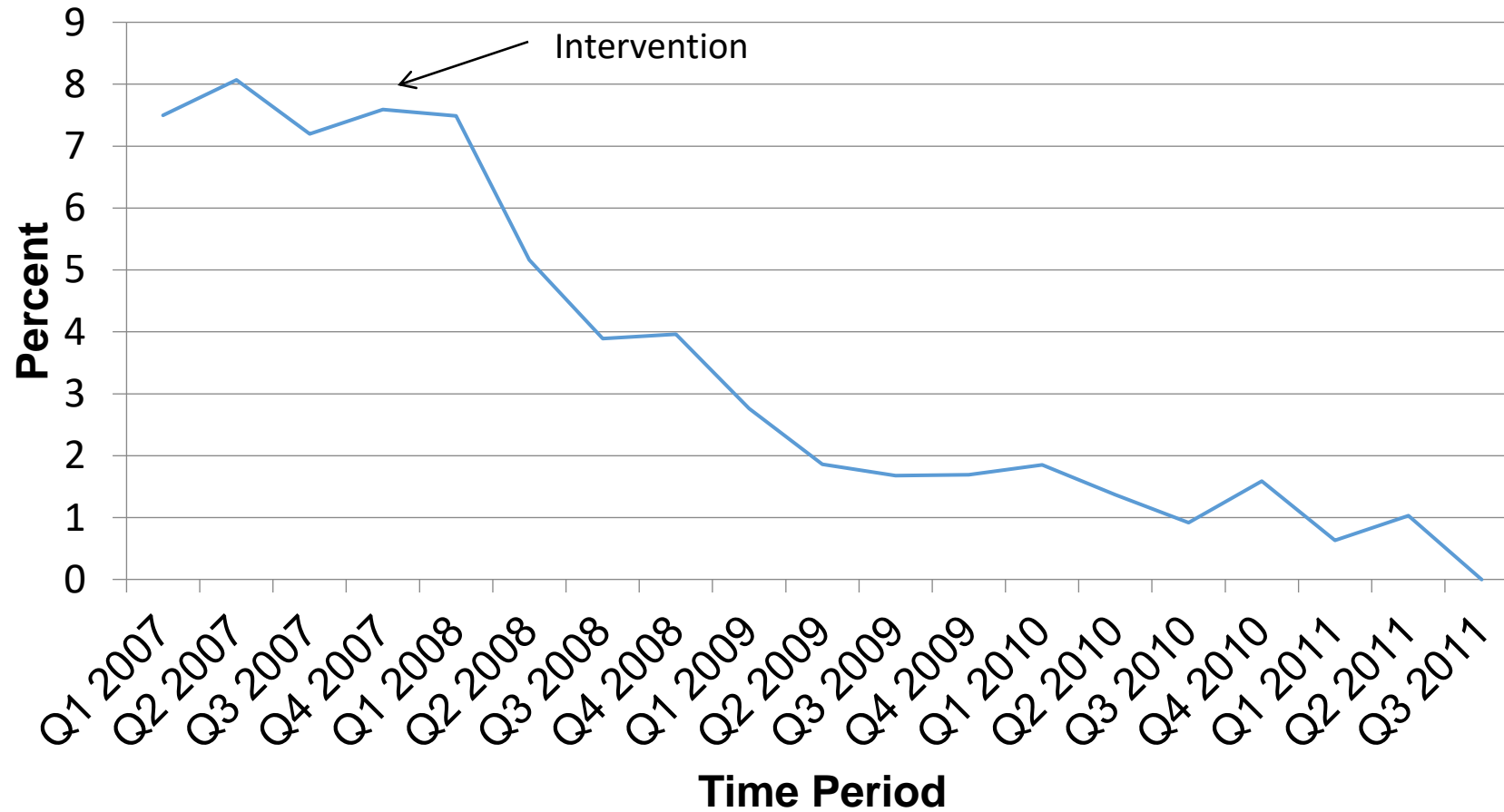
ORIGINAL ARTICLES

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Preoperative Placement of Inferior Vena Cava Filters and  
Outcomes After Gastric Bypass Surgery

*Nancy J. O. Birkmeyer, PhD,\* David Share, MD, MPH,† Onur Baser, PhD,\* Arthur M. Carlin, MD,‡  
Jonathan F. Finks, MD,\* Carl M. Pesta, DO,§ Jeffrey A. Genaw, MD,‡ and John D. Birkmeyer, MD\*; for the  
Michigan Bariatric Surgery Collaborative*

# Trends in the Use of Prophylactic IVC Filters in Bariatric Surgery in Michigan



# Objectives

- Discuss the role of registries
- Discuss the IDEAL pathway for new procedure development

# What is the IDEAL Collaboration?

- The IDEAL Framework is for improving research in surgery, devices, and non-pharmacological interventions.
- The IDEAL Framework describes the stages through which surgical therapy innovation normally passes, describing the characteristics of each of five stages: Idea, Development, Exploration, Assessment and Long-term follow-up.
- <https://www.ideal-collaboration.net>

# The IDEAL evaluation pathway

defines the types of evaluation which are appropriate at successive stages in the life cycle of complex interventions



## CREATING

Evaluation describes the new intervention in its first live demonstration: what it is, how it works and what the first experience taught us.

Idea

Development

## REFINING

Evaluation records the iterative improvement of the intervention until it reaches a stable form. What was changed, when, why, and with what impact on outcomes?

## AGREEING

Evaluation focuses on defining the intervention's indications, and the standards for acceptable quality of delivery by collaborative prospective cohort study by multiple groups, including analysis of learning curves.

Exploration

Assessment

## COMPARING

Evaluation of the intervention against current practice is now possible, preferably in an RCT. Mechanisms to neutralize effects of any deficit in investigator equipoise are important.

## MONITORING

Evaluation involves large-scale surveillance of outcomes in routine use of the intervention, looking for trends, and unexpected late or rare effects.

Long-term  
Study

# Thank you!

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[MichiganBSC.org](http://MichiganBSC.org)

