MHIF FEATURED STUDY:

EV ICD (Extravascular Implantable Cardioverter Defibrillator Pivotal Study)

OPEN AND ENROLLING

EPIC message: *Research MHIF Patient Referral*

CONDITION:	PI:	RESEARCH CONTACT:	SPONSOR:
life-threatening ventricular tachyarrhythmias	Charles Gornick, MD	Jessica Whalen Jessica.whelan@allina.com | 612-863-1661	Medtronic

DESCRIPTION:

The EV ICD system is designed to deliver lifesaving defibrillation and pacing therapy via a device the same size as traditional, transvenous ICDs, but with a lead (thin wire) placed outside the heart and veins. The EV ICD device is implanted below the left armpit (in the left mid-axillary region), and the lead is placed under the sternum (breastbone).

Purpose: to demonstrate safety and efficacy of the EV ICD System.

CRITERIA LIST/ QUALIFICATIONS:

Inclusion:

1. Class I or IIa indication for implantation of an ICD according to the ACC/AHA/HRS Guidelines, or ESC guidelines
2. Geographically stable and willing and able to complete the study procedures and visits for the duration of the follow-up

Exclusion:

1. Indications for bradycardia pacing or Cardiac Resynchronization Therapy (CRT) Class I, IIa, or IIb indication
2. Existing pacemaker, ICD, or CRT device implant or leads
3. History of these medical interventions: sternotomy, any medical condition or procedure that leads to adhesions in the anterior mediastinal space (i.e., prior mediastinal instrumentation, mediastinitis), abdominal surgery in the epigastric region, planned sternotomy, chest radiotherapy
4. Previous pericarditis that was chronic and recurrent, **or** resulted in pericardial effusion, **or** resulted in pericardial thickening or calcification
5. History of these medical conditions or anatomies: hiatal hernia that distorts mediastinal anatomy, marked sternal abnormality (e.g., pectus excavatum), decompensated heart failure, COPD with oxygen dependence, gross hepatosplenomegaly

HOPE DISCOVERED HERE™ Minneapolis Heart Institute Foundation® Creating a world without heart and vascular disease

The Cardiovascular Quality Improvement and Care Innovation Consortium (CV-QUIC):

Inception of a Multicenter Collaborative to Improve Cardiovascular Care

Steven M. Bradley, MD, MPH

Senior Consulting Cardiologist, Minneapolis Heart Institute (MHI)
Associate Director, MHI Healthcare Delivery Innovation Center
Medical Director, Inpatient Services, MHI at Abbott Northwestern
Associate Editor, JAMA Network Open

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Objectives

- Why do quality and innovation matter?
- What is lacking in quality improvement and care innovation?
- How will CV QUIC be different in achieving change?
- What are we doing now?

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Serendipity in Seattle

"It drives me crazy that we fail to apply what works in the patients it works for. At the same time, we do things that don't work despite evidence that shows it doesn't work."

"You're describing outcomes research."

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Outcomes Research

- Study of the end results of the health care system
  - "The goal is to increase the likelihood that patients achieve the outcomes they desire through better information, better decisions, and better health care delivery."

Institute of Medicine Aims for High Quality Care

$$\text{VALUE} = \frac{\text{OUTCOMES}}{\text{COST}}$$

Krumholz HM. JAMA. 2011;306(7):754-755.

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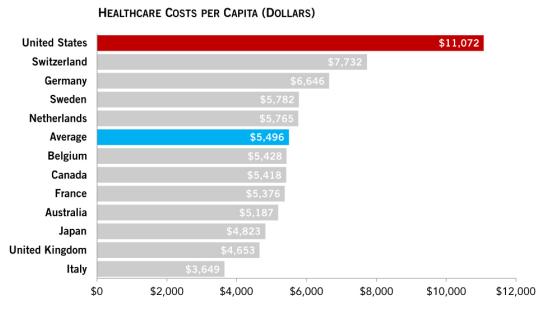
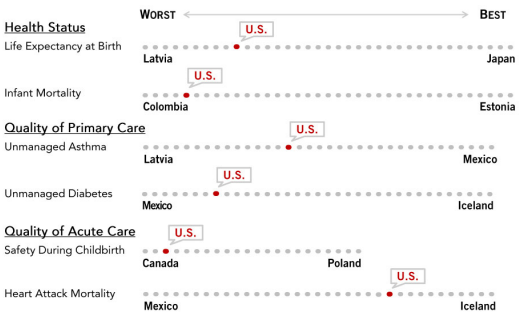
Why is Outcomes Research Important?





How Does the U.S. Healthcare System Compare to Other Countries? (pgpf.org)

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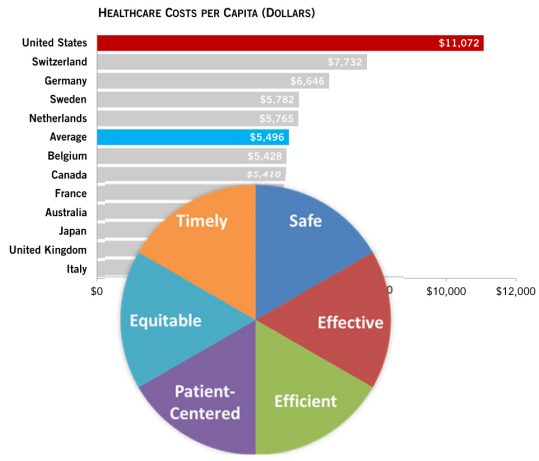
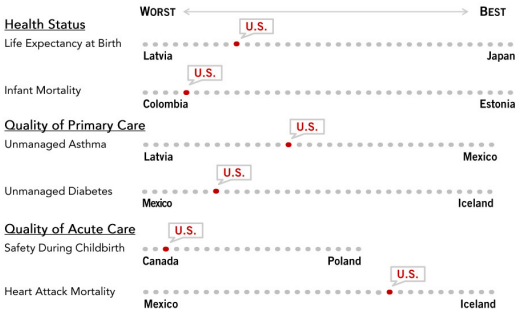
Why is Outcomes Research Important?





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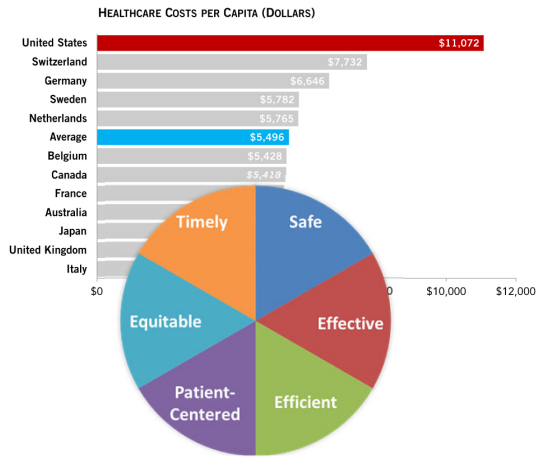

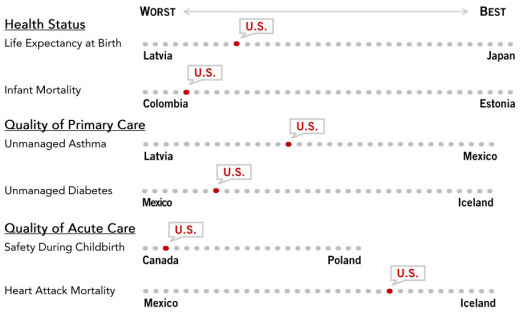

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How do we achieve the promise of our health care?

How Does the U.S. Healthcare System Compare to Other Countries? (pgpf.org)

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Categories of Outcomes Research

- Discovery – informing the determinants of outcomes
- Application – identifying and assessing tools and strategies that yield patient-centered change
- Surveillance – patterns and trends in care, identify opportunities for improvement, and accountability for our efforts

Krumholz HM. JAMA. 2011;306(7):754-755.

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Falling Short of Achieving the Goal

- "The research left unanswered the question about how best to remedy this safety issue."
- "After these disappointing studies, evidence is still lacking about how best to apply the lessons"

Krumholz HM. Circulation. 2008;118:309–318

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Categories of Outcomes Research

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Address quality gaps and unnecessary variation in healthcare delivery through novel patient-centered solutions

Optimize patient experience and health outcomes while reducing cost

Leverage existing Allina Data Infrastructure (EDW)

Clinical, operation, analytic oversight → SOLUTIONS

Position MHI and Allina as a national leader in healthcare change

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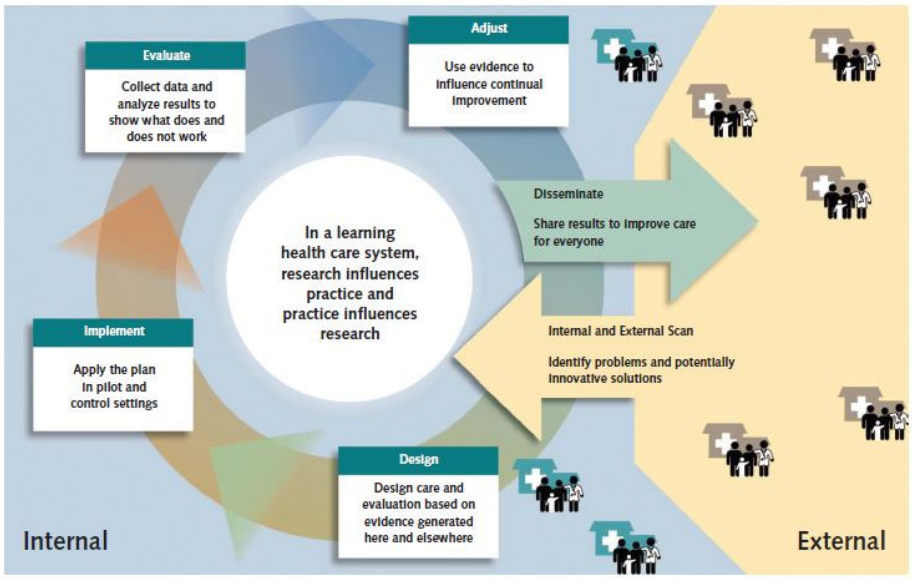
MHI HDI: A Learning Healthcare System



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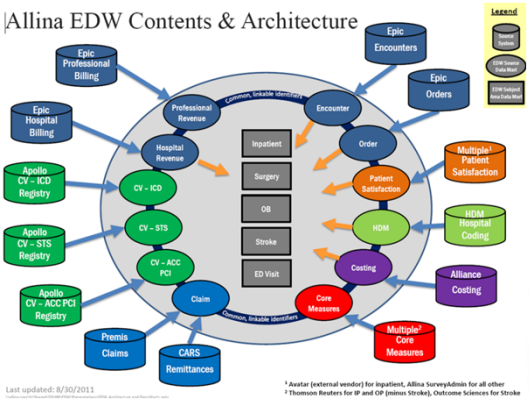
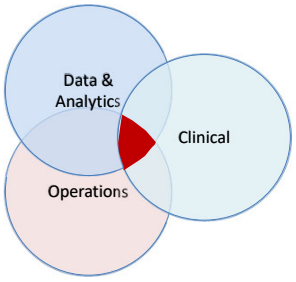
The Foundation for Success in a Learning Healthcare System

Data



Analytics

Alignment



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Objectives

- Why do quality and innovation matter?
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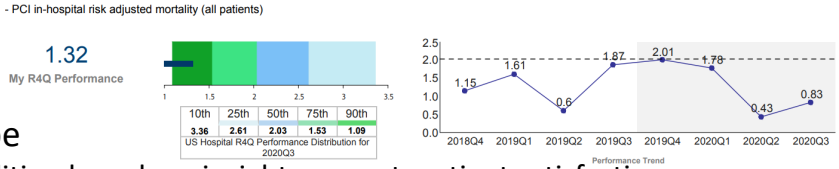
Existing Strategies and Remaining Gaps in Quality Improvement and Care Innovation

- Benchmarking
  - Limited in scope
    - Episodic, condition based, no insights on cost, patient satisfaction



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Existing Strategies and Remaining Gaps in Quality Improvement and Care Innovation

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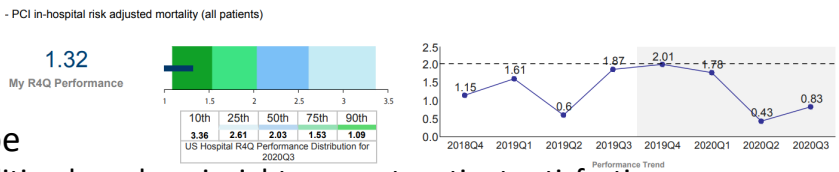
- Outcomes Research
  - Identifies, but often fails to close the gap
    - Not embedded in the clinical operations



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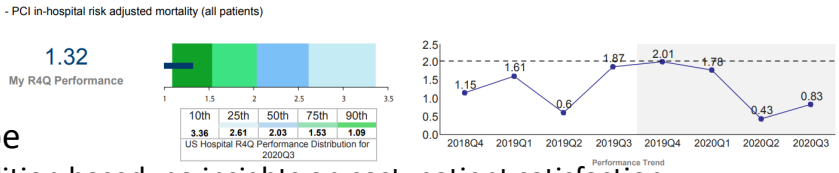

- Outcomes Research
  - Identifies, but often fails to close the gap
    - Not embedded in the clinical operations

- Health Systems
  - Perpetual QI work, but contained within the walls
    - Weak evaluation design, not generalizable

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Achieving the Promise of Outcomes Research

"The reward of research is having an impact on all the patients you will never get to see."

- How do we move from bird watching to action in outcomes research?
- How do we leverage the enormous work of individual centers and systems?

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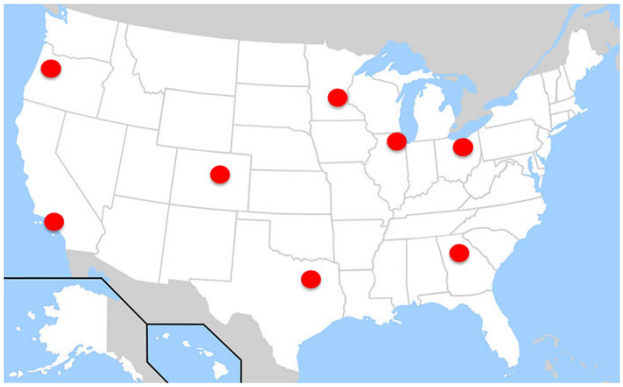
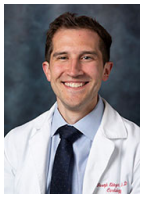
Finding the "Doers"





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A Beginning: June 2018 Call

- Objectives
  - Learning about ongoing quality and care improvement opportunities in cardiovascular disease
  - Finding outlets to share our work
  - Identifying others interested in adapting and adopting their work.
- Teleconference every three months:
  - Share previously completed quality improvement and care innovation projects from our individual sites
    - Minimize presentation time – Focus on how to best inform potential spread of projects across sites

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Initial Shared Projects

Project	Site and Project Lead	Impact	Dissemination Sites
Applying Queuing Theory to Optimize Heart Failure Follow-up Scheduling	Northwestern Medicine R. Kannan Mutharasan, MD	Application of queuing theory increased follow-up clinic visits within 14 days of heart failure hospitalization discharge from 43 to 93%	
Appropriate Telemetry Utilization	Providence St. Joseph Health Ty J. Gluckman, MD	Use of a time-defined, electronic heart record embedded telemetry order reduced monitoring time up to 20%	Northwestern Medicine MHI and Allina Health
Integration of High Sensitivity Troponin to Optimize Emergency Department Throughput	Parkland Health and Hospital System and the University of Texas Southwestern Medical Center Sandeep R. Das, MD, MPH, MBA	Chest pain protocol leveraging high sensitivity troponin increased the proportion of patients discharged to home from emergency department and decreased length of emergency department stay	
Optimal Use of Sternal Plating	MHI and Allina Health Steven M. Bradley, MD, MPH	Reduced variation in the use of sternal plating after sternotomy with associated $1 million annual savings and preserved clinical outcomes	
Heart Failure Checklist	Cleveland Clinic Umesh N. Khot, MD	Application of an electronic health record embedded heart failure discharge checklist associated with reduction in readmission from 21% to 18%	
Initial Diuretic Dosing for Acute Decompensated Heart Failure	Emory Divya Gupta, MD	Identification of a 1-day additional length of stay associated with insufficient initial diuretic dosing	Northwestern Medicine MHI and Allina Health

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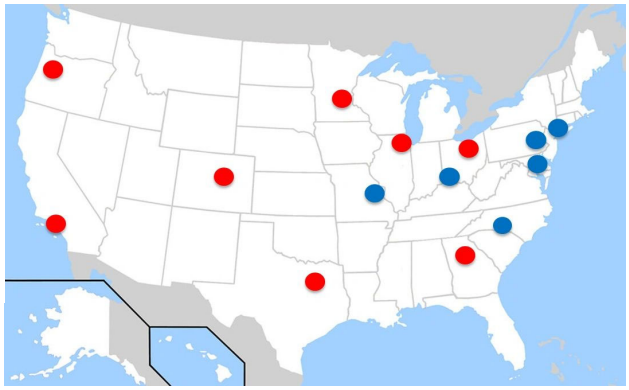
CV-QUIC: A Multicenter Collaborative

The Cardiovascular Quality Improvement and Care Innovation Consortium

Inception of a Multicenter Collaborative to Improve Cardiovascular Care

CV-QUIC Collaborators, Steven M. Bradley, Srinath Adusumalli, Amit P. Amin, William B. Borden, Sandeep R. Das, William E. Downey, Joseph E. Ebinger, Joy Gelbman, Ty J. Gluckman, ... See all authors

Originally published 12 Jan 2021 | https://doi.org/10.1161/CIRCOUTCOMES.120.006753 | Circulation: Cardiovascular Quality and Outcomes. 2021;14



Vision – Perfect cardiovascular care.

Mission –To rapidly improve cardiovascular care through the development, validation, and dissemination of novel strategies and and care delivery design.

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A Framework for Scalable Cardiovascular Quality Improvement and Care Innovation

- Cardiovascular Quality Improvement and Care Innovation Consortium(CV-QUIC)
  - Formally conceptualized June of 2019
- Success defined by:
  - "Recognition as the home for pragmatic cardiovascular quality and innovation efforts"
  - Projects that result in changes to care delivery with demonstrable impacts on the quality and outcomes of care across multiple health systems
- Areas of opportunity
  1. Developing, implementing, and evaluating multicenter projects using innovative care designs
  2. Resource for quality improvement and care innovation partners
  3. Establishing a presence within existing QI and care innovation structures

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A Framework for Scalable Cardiovascular Quality Improvement and Care Innovation

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Initial Diuretic Dosing: An Example Opportunity

- Randomized trial data of high-dose initial diuretic dosing (defined as 2.5 times home dose) is associated with more rapid decongestion
- Emory QI program for initial diuretic dosing was associated with decreased LOS
- What's the opportunity in Allina and at ANW?

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 MARCH 3, 2011 VOL. 364 NO. 9

Table 2. Secondary End Points for Each Treatment Comparison.

End Point	Low Dose (N=151)	High Dose (N=157)	P Value
AUC for dyspnea at 72 hr	4478±1550	4668±1496	0.04
Freedom from congestion at 72 hr — no./total no. (%)	16/143 (11)	28/154 (18)	0.09
Change in weight at 72 hr — lb	−6.1±9.5	−8.7±8.5	0.01
Net fluid loss at 72 hr — ml	3575±2635	4899±3479	0.001

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Allina Opportunity Assessment

- Population
  - Primary or secondary diagnosis of congestive heart failure
  - Received IV diuretic in first 24 hours
- Diuretic dosing logic
  - 40 Lasix = 20 torsemide = 1 bumex
  - Initial dose compared to 1/2 of 24 hour home dose (DOSE Trial)

Table 1. Initial Inpatient Dose Relative to Home Dose

Location	Above Home Dose			Equivalent to Home Dose			Below Home Dose		
	#	%	LOS	#	%	LOS	#	%	LOS
ANW	1074	19.8%	7.64	421	7.71%	8.02	584	10.75%	8.71
MRC	1130	20.9%	5.30	435	8.05%	5.73	344	6.37%	6.03
UTD	782	14.4%	5.78	313	5.74%	6.42	244	4.48%	6.94
Grand Total	**2986**	**55.1%**	**6.27**	**1169**	**21.51%**	**6.74**	**1172**	**21.60%**	**7.56**

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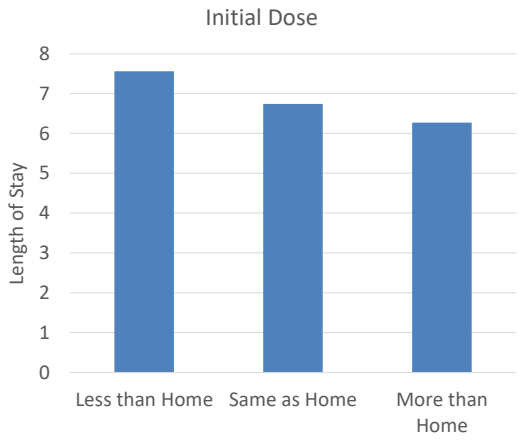
Allina Opportunity Assessment



Summary:

1. 50% of patients with initial diuretic dose that is equivalent or lower than home dose
2. Higher initial doses associated with ~1 day reduction in length of stay

Assuming 50% actionable gap

- 1,330 avoidable bed days
- $500,000 cost savings

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What's the Opportunity in the ED?

Initial Diuretic Dose Above Home Dose						
Dosing Category	**ED**	**Floor**	**Total**	**%**	**AVG LOS**	**Median LOS**
Below Goal ED and Floor	No	No	703	48%	5.95	4.94
Below Goal ED	No	Yes	304	21%	5.86	4.63
At Goal	Yes	Yes	466	32%	4.62	3.96

- Assuming 50% actionable gap
  - 350 avoidable bed days ANW alone
- Impact of early initiation of therapeutic dosed diuretic

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Addressing the Opportunity

- Initial diuretic dosing recommendations for HF
  - Initial IV dose above 24 hour home dose by furosemide equivalents
    - 40 mg furosemide = 20 mg torsemide = 1 mg bumex (no oral to IV conversion)
    - E.g. home dose furosemide 80 bid = 160 daily; first IV dose at least 100 mg
- Continued education/reminders and feedback
  - Hospitalist to ask what dose IV diuretic has been given
    - Trigger initiation of diuresis at goal dose
  - **Run reports and feedback starting January 2021**
- ED pharmacy
  - Review of dosing relative to home dose with recommendations

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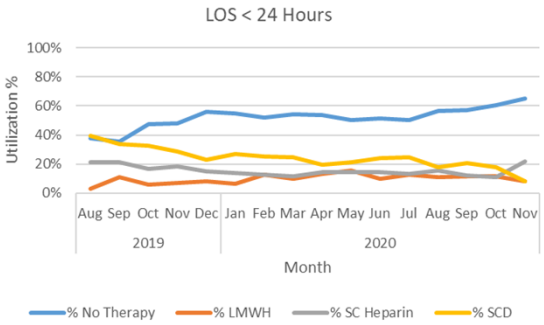
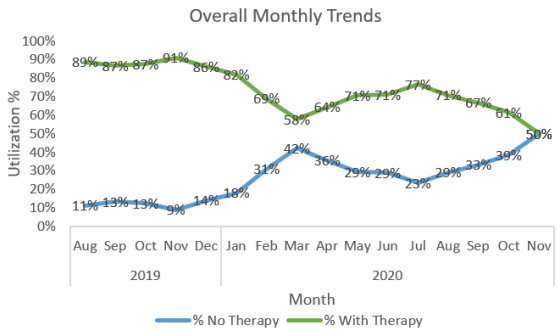
Run Reports and Feedback Loop

- Example of VTE Prophylaxis Project in Partnership with Allina Hospitalists Quality and Innovation Consortium (HQIC)





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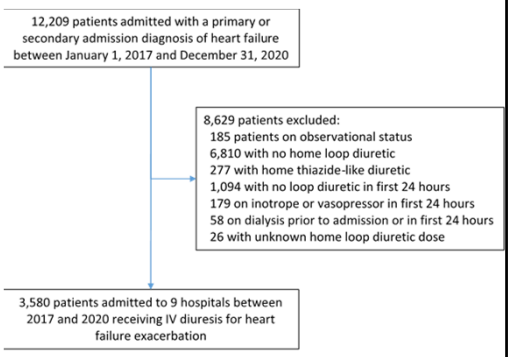
Developing Multicenter Projects: Opportunity Assessment

- Shared processes of cohort identification, exposure, and outcomes

	Initial Diuretic Dose Relative to Home Dose		
Characteristic	Below, N (%) 555 (15%)	Equivalent, N (%) 756 (21%)	Above, N (%) 2,269 (64%)
Length of stay, days mean (SD)	6.39 (4.99)	5.32 (3.90)	4.95 (3.73)
Acute kidney injury, N (%)	152 (27%)	159 (21%)	539 (24%)



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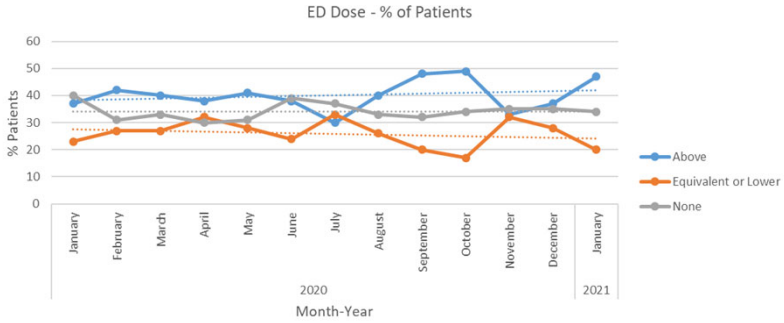
Developing Multicenter Projects: Intervention Development

Generalizable



Tailored to environment (clinical decision support)

APPROXIMATE LOOP DIURETIC EQUIVALENCY DOSES

Drug	PO (mg)	IV (mg)
Furosemide	40	40
Bumetanide	1	1
Torsemide	20	---

**Patients with acute decompensated heart failure who are treated with a high-dose IV diuretic dosing strategy (higher than the patient's equivalent home dose) appear to have more rapid diuresis and shorter hospital length of stay without a significant increase in complications (DOSE Trial link).

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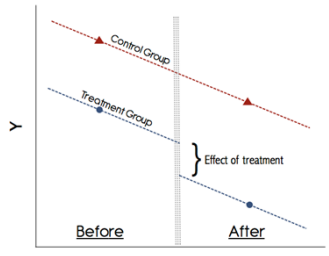
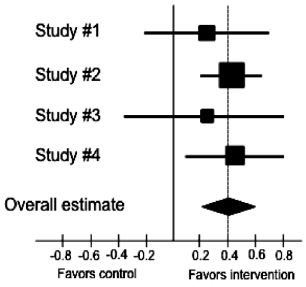
Improving the Quality of Quality Improvement Research

- Concurrent control group
  - Before and after studies are insufficient
- Blinding of outcomes assessment and randomization where possible
- Results that are **generalizable** (impact on one center or system insufficient)
  - Focus on better health outcomes, rather than on changes in health care processes, use, or costs alone
- Difference-in-differences Analysis and Leveraging Multisite Participation





Grady D, et al. JAMA Intern Med. 2018;178(2):187.

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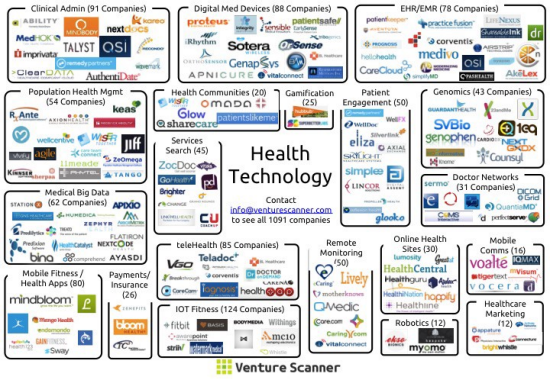
CV-QUIC Opportunities

- Resource for Care Innovation Partners



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CV-QUIC Opportunities

- Establishing a Presence within Existing Structures
  - AHA QCOR 2019
  - AHA 2021
  - CV QUIC Training

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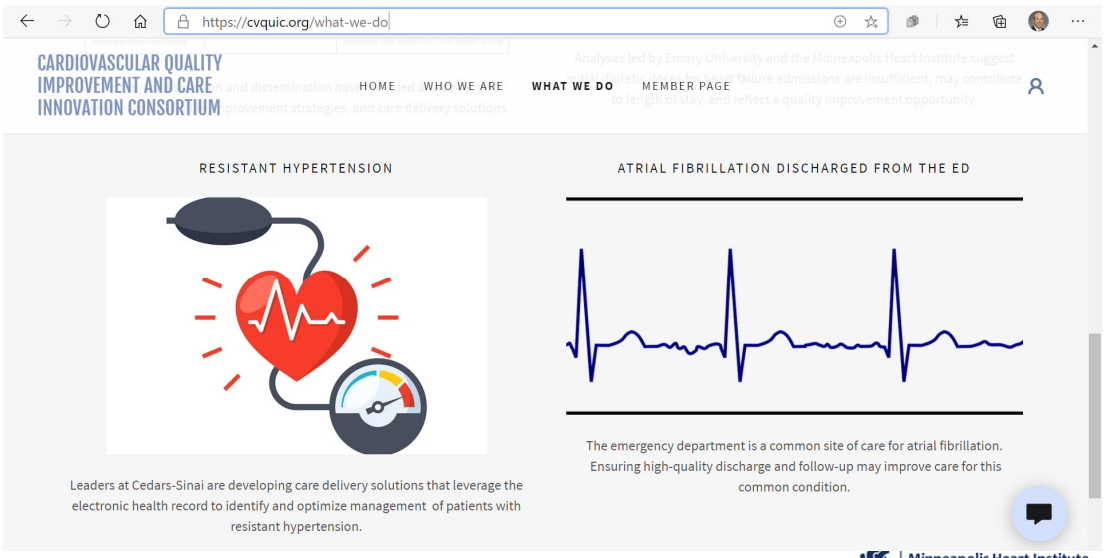
cvquic.org



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HDI: Thinking Differently to Address Quality Gaps

- Clinical decision support/quality triggers often based on a push
  - Alert fatigue
    - Wrong patient
    - Wrong time
    - Too many

- Can we create pull?

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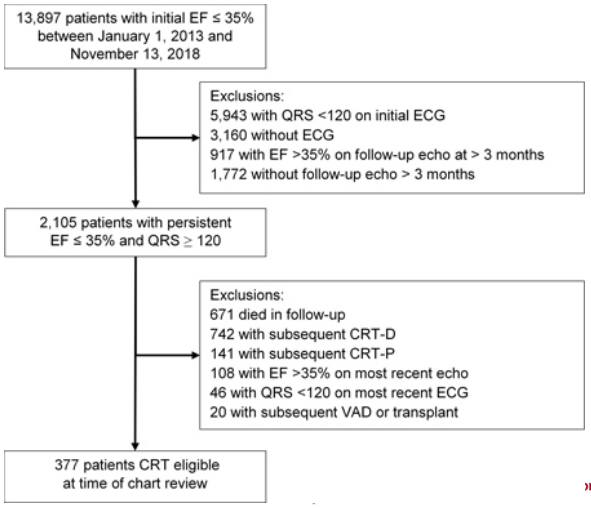
Addressing Gaps in Use of CRT: Why a Push Would Fail

- 26% apparent gap in CRT utilization
- Detailed chart review → 7%
  - BPA would misfire 75%
- Provider review
  - 41 providers
  - 21 of 83 patients eligible
    - **1.7% true gap**



Bradley SM, et al. J Heart Failure. 2020; 26 (8):739-741.

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HDI: Creating Pull to Address Quality Gaps

Patients Discharged From ED with Afib
- 50% without clinical follow-up
- 50% not anticoagulated

→ EP Review and Triage

Patients with Severe AS
- 50 patients a year with no cardiology follow-up

→ Valve Team Review and Triage

Patients with Persistently Reduced EF and Recent Hospitalization
- 81 patients a year

→ Valve Team Review and Triage

- Pulling patients to the clinical experts
  - **Important for the patient in achieving optimal outcomes**
  - **Growth of the practice (referral and leakage)**

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Where Else do We Need to Be?

- 80% of Americans have smartphones

- Integrated with smart devices

…underused to support healthcare

- Changing expectations

OpenTable amazon +Babbel

- Episodic → continuous

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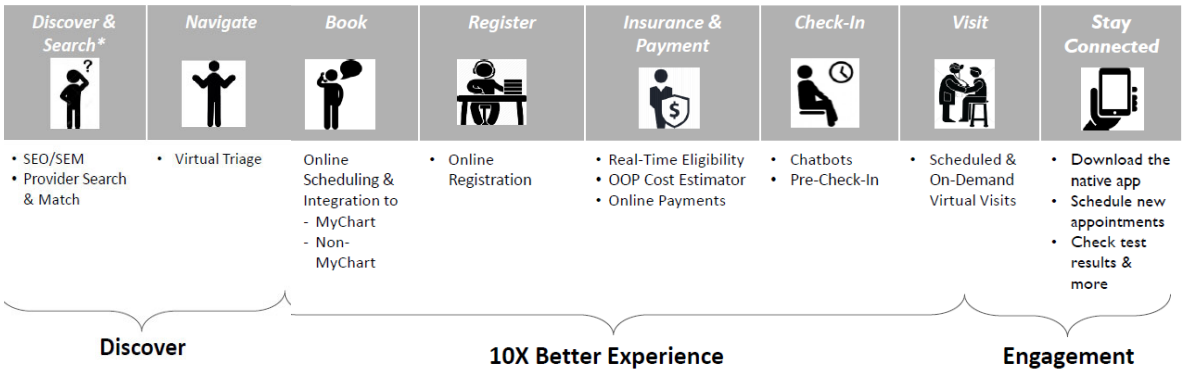
Digitizing the Healthcare Consumer Journey

Mission: To provide convenient access and efficient care delivery by connecting patients to MHI and MHI to patients



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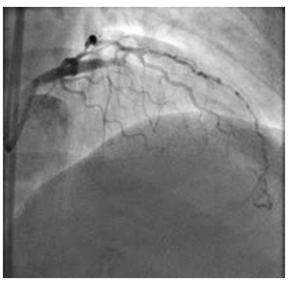
Audience Segmentation

- Focus on **care pathways**
  - Sets of expert content, clinical guidance, and continuity tasks
- Version 1: coronary angiography/PCI
  - In-demand procedure
  - Specific mobile content/interactions to improve care
  - Readily extensible to other care pathways



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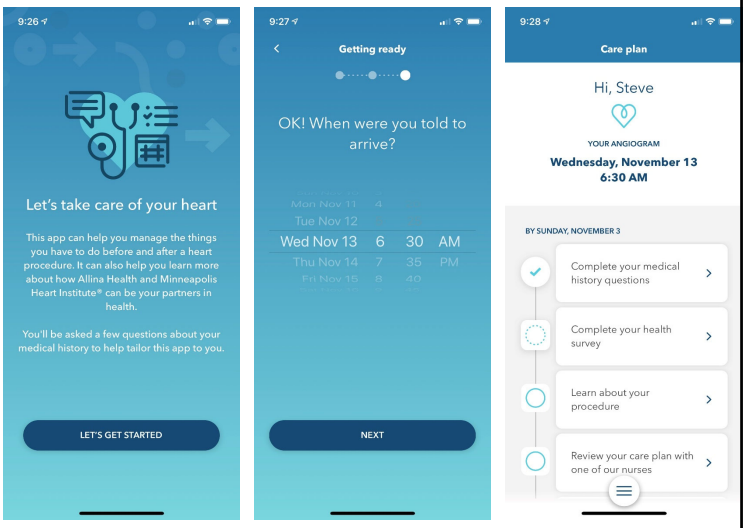
Phase I Features (MINIMUM lovable product)

- General content
  - Education, location/services
  - Low-tech scheduling
- Personalized
  - Interactive pre-procedure instructions
  - Reminders and notifications
  - Instructions/prep
  - Data capture



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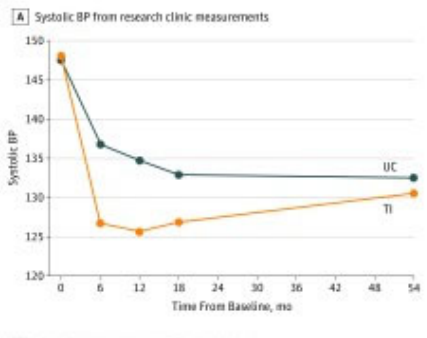
Remote Care Programs

- Remote HTN monitoring with pharmacist management



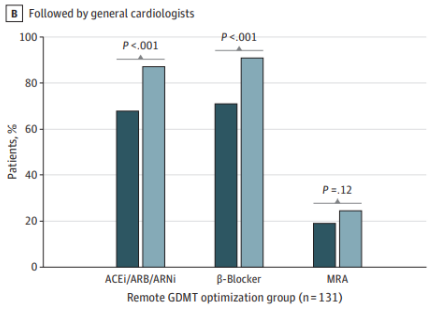
jamacardiology_desai_2020_remote CHF optimization.pdf

- Remote Cardiac Rehab

AACVPR/AHA/ACC SCIENTIFIC STATEMENT

Home-Based Cardiac Rehabilitation: A Scientific Statement From the American Association of Cardiovascular and Pulmonary Rehabilitation, the American Heart Association, and the American College of Cardiology

- CHF and Lipid Management



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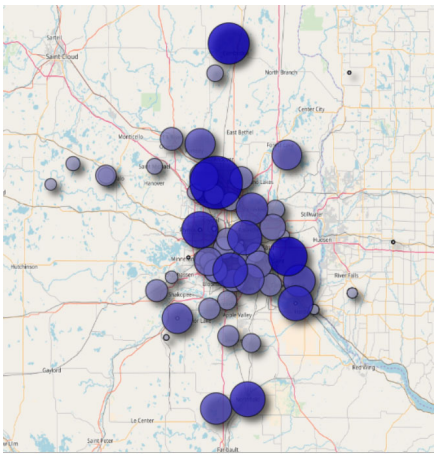
Lessons from Efforts to Implement New HTN Guidelines

Blood Pressure	CKD or DM	Age	ASCVD History and Risk	Patient Count	New diagnosis HTN
SBP ≥150 or DBP ≥90	NA	NA	NA	28,659	9,441
SBP 140-149 or DBP ≥90	Y	NA	NA	5,990	600
SBP 140-149 or DBP ≥90	N	< 60	NA	8,385	4,930
SBP 140-149 or DBP ≥90	N	≥ 60	NA	10,186	3,092
SBP 130-139 or DBP 80-89	Y	Any	NA	22,350	4,359
SBP 130-139 or DBP 80-89	N	Any	Y or 10-y risk ≥ 10%	29,586	10,192
SBP 130-139 or DBP 80-89	N	Any	N and 10-y risk < 10%	43,983	28,370
SBP 120-129 and DBP <80	NA	Any	NA	104,539	NA
SBP <120 and DBP <80	NA	Any	NA	284,581	NA



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Moving From Dream to Reality?

"We could be entering an era in which we conduct virtually real-time research with expansive and responsive surveillance systems with the ability to evaluate rapidly the adoption and effects of innovations in care."

Krumholz HM. Circulation. 2008;118:309–318

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Conclusions

- Outcomes research can help achieve the promise of ideal healthcare through discovery, application, and surveillance of the end results of our care
- CV QUIC is poised to lead rapid improvements through a pragmatic multicentered approach that addresses gaps in quality improvement and care innovation
- MHI HDI is leading this charge nationally in the development and implementation of novel solutions to care optimization

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Thank you

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