Achieving Optimal GDMT in Heart Failure with Reduced Ejection Fraction (HFrEF)

1

Case

64 yo Male
- RHD and NICM for 15 yrs on furosemide, digoxin and enalapril
- LVEF 30%, LVIDd 7.0 cm
- Afib, DM2
- Cardiologist 6-12 months
- No recent hospitalizations

Progressive Symptoms
- Admitted, progressive N/V, moderately elevated AST and ALT with Tbili 2.5 and Cr of 2.0 (baseline 1.5).

2

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Progressive Symptoms
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Diagnostics
- Mildly abnormal gastric emptying scan
- Liver US with a few gallstones but no dilatation of the CBD.
- Advised to undergo cholecystectomy

Worsening Post Operative Course
- Post operatively he develops worsening renal failure, hypotension, and pulmonary edema with the inability to extubate.
- He is started on pressors. Cardiology is consulted and eventually started on inotropes in addition to pressors

3

Agenda

- **The Problem: Heart Failure**
- **The Solution: Guideline-Directed Medical Therapy (GDMT)**
- **How We are Doing So Far?**
- **Barriers to Optimal Care**
- **Changing Landscape of How We Approach Inpatient Management**
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Why Heart Failure?

Currently, there are 7M HF patients with an expected 46% increase in the next 10 years

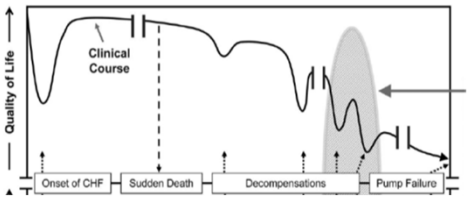
HF High Burden
- HF is 8.5% of the total burden of all cardiovascular disease
- Annual Incidence: 960,000
- Costs: $70B annual estimated expenditure in 2030.

Resource Intensive
- 15 million annual office visits
- High readmission rates
  - 20% by 1 month
  - 50% by 6 month
- 80% in the hospital at end of life

Source: Medicare.

6

Median survival for HF is 5 years



Transition to Advanced HF
- GDMT therapies are failing
- Frequent hospitalizations
- Progressive decline in health status

Adapted, Circulation. 2012;125

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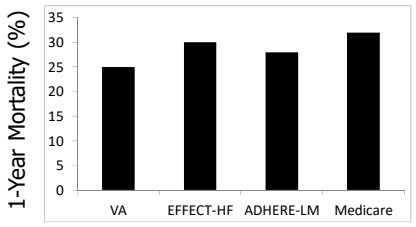
1-Year Mortality After Index HF Hospitalization



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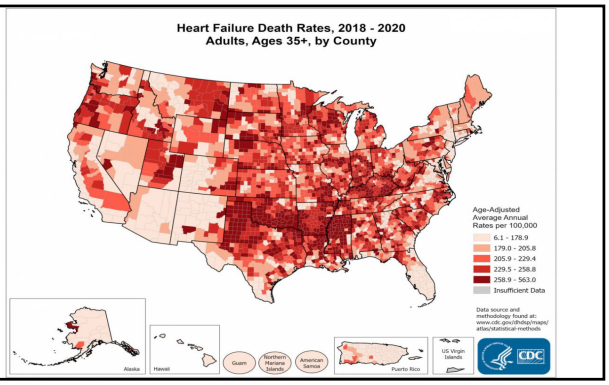

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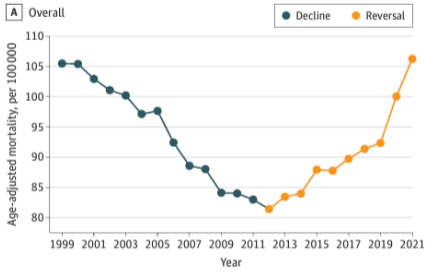
Heart Failure Mortality in the US are Rising, 1999 to 2021



Sayed et al. *JAMA Cardiol*. Published online April 24, 2024

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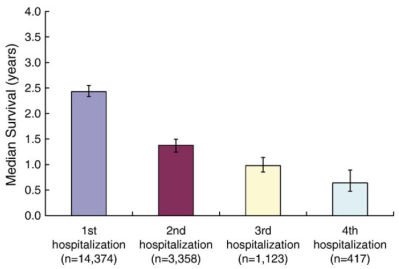
What does a HF Hospitalization Mean Prognostically?



AHJ Setoguchi, 2007

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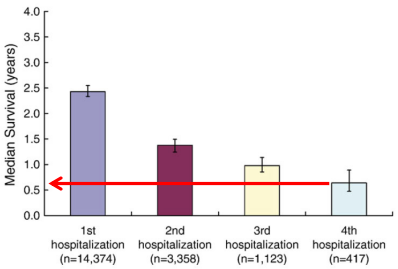

AHJ Setoguchi, 2007

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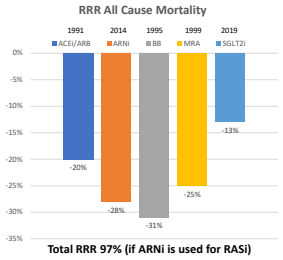
Reduction in Mortality and Readmission with GDMT



Total RRR 97% (if ARNi is used for RASi)

Dixit et al. US Cardiology Reviews 2021.
https://www.uscjournal.com/node/14412?check_logged_in=1

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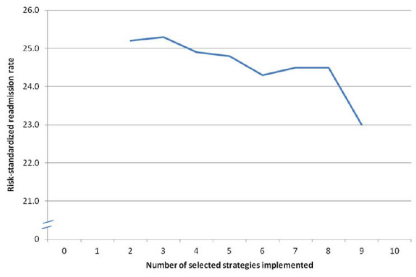
Multi-pronged Approach to Reduce Hospital Readmissions



Bradley, E et al. *Circ Cardiovasc Qual Outcomes.* 2013;6:444-450

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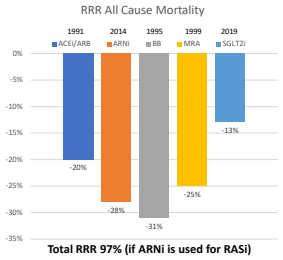
Reduction in Mortality and Readmission with GDMT



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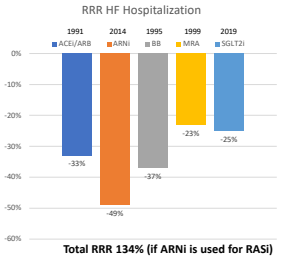

Total RRR 134% (if ARNi is used for RASi)

Dixit et al. US Cardiology Reviews 2021.
https://www.uscjournal.com/node/14412?check_logged_in=1

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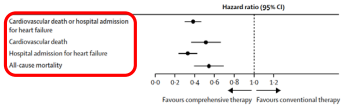
Lifetime Benefit of contemporary GDMT

Modeled 3 interventions based on 3 RCTs (PARADIGM, EMPHASIS, DAPA – HF):
- Change from ACEi to ARNi
- Start MRA
- Start SGLT2i



Vaduganathan et al. Lancet 2020; 396: 121–28

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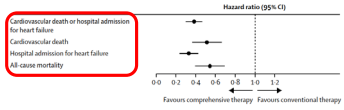

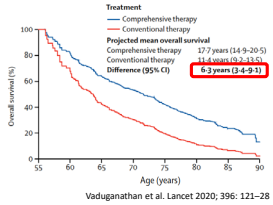

Vaduganathan et al. Lancet 2020; 396: 121–28

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How often do you see HF patients with stable symptoms?

- Most patients are titrated during clinic visits.
- If you see a HFrEF patient every 6 months: it takes 6 years to achieve target GDMT
- Median survival for heart failure is 5 years

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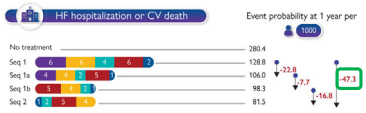
Accelerated and Personalized GDMT



Assumes titration 22-week (5.5 month) titration is standard of care, which may be optimistic

Shen et al. European Heart Journal (2022) 00, 1–15

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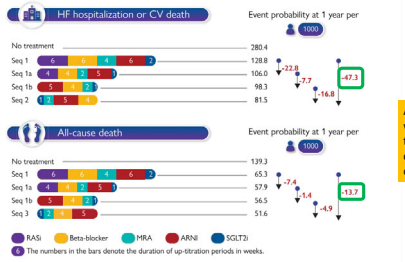
Accelerated and Personalized GDMT



Assumes titration 22-week (5.5 month) titration is standard of care, which may be optimistic

Shen et al. European Heart Journal (2022) 00, 1–15

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What is Success in HF?

- For those who are eligible
- Placing on GDMT
- Achieving target doses used in clinical trials

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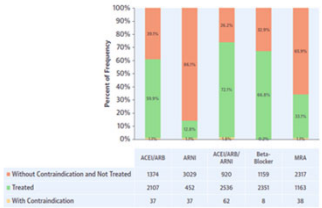
CHAMP - HF

Prospective, observational registry of adult outpatients with HFrEF (EF ≤40% within 12 mo and were receiving at least 1 oral medication for HF)



Among eligible patients
- 27% were not prescribed ACEI, ARB, or ARNI
- 33% were not prescribed an evidence-based beta-blocker
- 67% were not prescribed an MRA.
- <25% of eligible US patients with HFrEF were simultaneously receiving all 3

Greene et al. J Am Coll Cardiol. 2018;72(4):351–66

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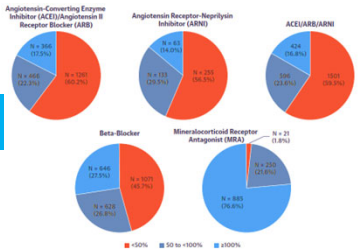
Prospective, observational, nonrandomized registry of adult outpatients with HFrEF (EF ≤40% within 12 mo and were receiving at least 1 oral medication for HF



Among patients treated
60% were ≤50% of target dose RASi
46% were ≤50% of target dose beta-blocker

Greene et al. J Am Coll Cardiol. 2018;72(4):351–66

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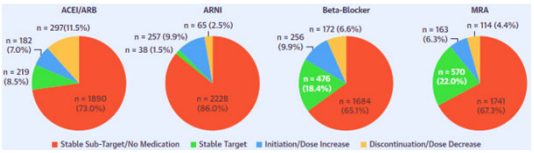
CHAMP - HF

prospective, observational, nonrandomized registry of adult outpatients with HFrEF (EF ≤40% within 12 mo and were receiving at least 1 oral medication for HF

Dose of Medication at 12-Month Follow-Up Compared with Baseline



When Followed over 12 months: Up to 50%-80% of patients eligible for GDMT remain on stable sub-target doses or no dose indefinitely

Greene et al. J Am Coll Cardiol 2019;73:2365–83

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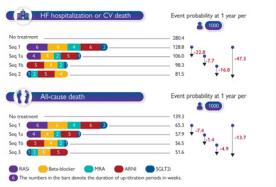
Provider Barriers to GDMT

Provider

- Understaffing
- Poor HF medication knowledge

- Fewer follow-up visits
- Under-prescription or dosing of HF medications

- Nurse-led HF clinics
- Electronic decision support systems



- Centralized titration
- Transition Clinic
- EMR Decision Support (PROMPT-HF)

Fewer Hospitalization + Fewer Deaths = Better Care

Tromp et al. European Heart Journal (2022) 43, 2588–2590
Shen et al. European Heart Journal (2022) 00, 1–15

28

Health Service/Insurance Barriers to GDMT

Health Service/Insurance

- High out-of-pocket costs
- Hospital case-based financing

- Financial treatment barriers
- Reduced length of hospital stay
- Fewer follow-up consultations

- Increase HF medication insurance coverage
- Rewarding quality care

Pharmacists
Medication Access Teams
SW
Case Managers

- Manufacturer coupon cards (non-government insurance program)
- Manufacturer patient assistance program (income requirement)
- County Assistance program
- Innovative assistance provided by hospital for high-risk patients during high-risk times

Tromp et al. European Heart Journal (2022) 43, 2588–2590

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Patient Barriers to GDMT

Patient

- Poor awareness of HF medications' benefits

- Reduced HF medication adherence

- Comprehensive team management and patient education

No one cares how much you know until they know how much you care

- Patient education
  - Centralized education, group education
  - Videos (short and focused)
  - Memes
  - Patient centered (language, characters that are like them)
- Patient activation/motivating
- Optimize CR and innovative options like HBCR

Tromp et al. European Heart Journal (2022) 43, 2588–2590

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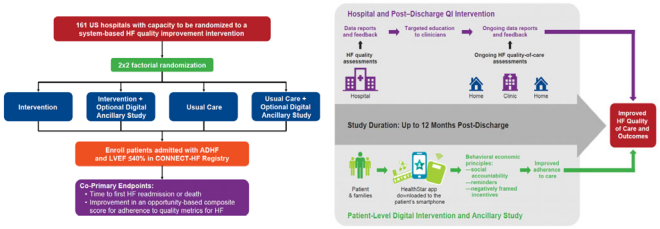
System Based QI Interventions: CONNECT-HF

Cluster RCT 161 US hospitals; 5647 HFrEF patients (2675 intervention vs 2972 usual care); 2017 to 2020



DeVore et al. *JAMA*. 2021;326(4):314-323

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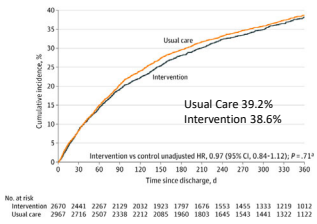
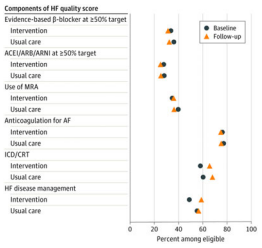
System Based QI Interventions: CONNECT-HF

1st HF admission or Death



No significant difference



DeVore et al. *JAMA*. 2021;326(4):314-323

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System Based QI Interventions: CONNECT-HF

Table 2. Primary and Secondary Outcomes

Outcome	Intervention at follow-up	Usual care at follow-up	Absolute difference	Unadjusted ratio measure, HR (95% CI)	P value	Adjusted ratio measure, HR (95% CI)[a]	P value
Primary[b]							
HF rehospitalization or death, Kaplan-Meier rate (95% CI)	38.6 (36.7-40.6)	39.2 (37.4-41.1)	−0.6	0.97 (0.84-1.12)	.71	0.92 (0.81-1.05)	.21
HF quality of care composite score, success/opportunities (%)[c,d]	4672/10 549 (44.3)	5363/12 017 (44.6)	−0.3	OR, 1.06 (0.94-1.20)	.31	OR, 1.06 (0.93-1.21)	.35
Secondary							
Clinical outcomes							
Total HF rehospitalizations, No. of events	1127	1326	−199	0.93 (0.82-1.06)	.29	0.87 (0.77-0.98)	.03
All-cause death, Kaplan-Meier rate (95% CI)	19.7 (18.1-21.2)	20.5 (19.0-22.1)	−0.8	0.94 (0.81-1.10)	.44	0.93 (0.81-1.06)	.28
HF discharge quality of care composite score, success/opportunities (%)[d]	8815/11 214 (78.6)	9709/12 477 (77.8)	0.8	OR, 1.11 (0.89-1.38)	.36	OR, 1.14 (0.90-1.45)	.28

Abbreviations: HF, heart failure; HR, hazard ratio; OR, odds ratio.

[a] Adjusted for site pretrial 30-day rehospitalization rates, geographic region, and hospital size as well as patient age, sex, race, diabetes, atrial fibrillation or flutter, chronic obstructive pulmonary disease, cerebrovascular accident/transient ischemic attack, chronic kidney disease, left ventricular ejection fraction, systolic blood pressure, discharge creatinine level, calendar time (months) at discharge from trial start, HF history vs new diagnosis, ischemic etiology, and 2 or more HF admissions in previous 12 months.

[b] Type I error rate (α) of .05 was split between 2 coprimary end points (.04 for the clinical end point and .01 for the quality-of-care end point).

[c] Also adjusted for baseline composite score. Baseline composite scores are reported in Table 1.

[d] The HF quality of care composite score evaluated the guideline-based recommendations for quality of care provided at the time of hospital discharge and during outpatient follow-up. The HF discharge quality of care composite score only evaluated the quality of care at hospital discharge.

DeVore et al. *JAMA*. 2021;326(4):314-323

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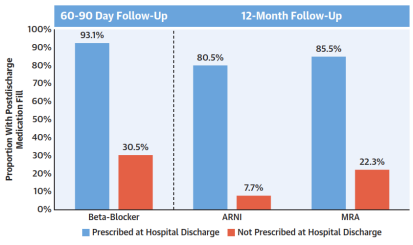
Hospitalization as a Seminal Moment: Prescription Status at Discharge and GDMT Use Post-discharge



Rao et al. J Am Coll Cardiol 2021;78:2004–2012

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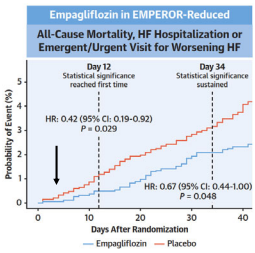
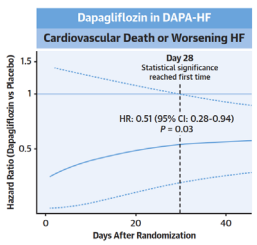
Early Benefit of SGLT2i in RCTs





Rao et al. J Am Coll Cardiol 2021;78:2004–2012

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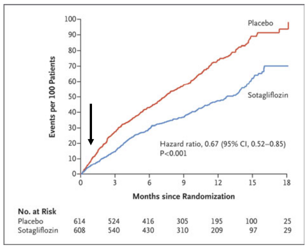
SOLOIST – WHF trial with Sotagliflozin (SGLT1/2i)

RCT, DM2 and WHF regardless of EF, 79% EF <50%, sotagliflozin initiated before or shortly after discharge, 1222 pts (stopped early due to funding)

The primary outcome CV death and HF hospitalizations and urgent visits (first and subsequent events)

Primary outcome per 100 patient-years: 51.0 vs. 76.3



Relative Risk for Primary outcome by EF

LVEF, %[1,2]		
<40	725	0.69 (0.51, 0.92)
≥40	494	0.68 (0.45, 1.03)

Bhatt et al. N Engl J Med 2021; 384:117-128

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SGLT2i in Hospitalized HF Patients: EMPULSE trial

530 patients hospitalized with AHF

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European Heart Journal (2022) 00, 1–11

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Sacubitril/valsartan in Hospitalized HF Patients: PIONEER-HF

RCT of 881 hospitalized acute HFrEF patients after initial stabilization; 8 week exploratory outcomes

Exploratory clinical outcomes — no. (%)			Hazard ratio (95% CI)§
Composite of clinical events	249 (56.6)	264 (59.9)	0.93 (0.78 to 1.10)
Death	10 (2.3)	15 (3.4)	0.66 (0.30 to 1.48)
Rehospitalization for heart failure	35 (8.0)	61 (13.8)	0.56 (0.37 to 0.84)
Implantation of left ventricular assist device	1 (0.2)	1 (0.2)	0.99 (0.06 to 15.97)
Inclusion on list for heart transplantation	0	0	NA
Unplanned outpatient visit leading to use of intravenous diuretics	2 (0.5)	2 (0.5)	1.00 (0.14 to 7.07)
Use of additional drug for heart failure	78 (17.7)	84 (19.0)	0.92 (0.67 to 1.25)
Increase in dose of diuretics of >50%	218 (49.5)	222 (50.3)	0.98 (0.81 to 1.18)
Composite of serious clinical events¶	41 (9.3)	74 (16.8)	0.54 (0.37 to 0.79)

ARR = 5.8% NNT = 18

Velazquez et al. N Engl J Med 2019;380:539-48

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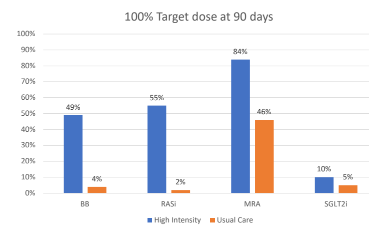
Rapid GDMT Titration in the Hospital: STRONG-HF

1078 pts (Stopped early by DSMB but intended to enroll 1800); 2018-2022; Pre-SGLT2i uptake; Any LVEF (EF ≤40% - 68%, EF >40% - 32%, EF 50% - 15%)



Office visits by 90 days

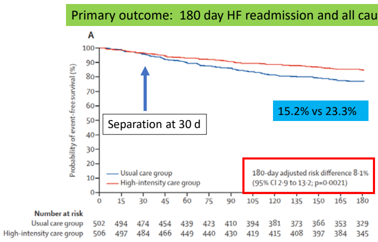
4.8 vs 1

40

Rapid GDMT Titration in the Hospital: STRONG-HF

1085 pts (Stopped early by DSMB but intended to enroll 1800); 2018-2022; Pre-SGLT2i; Any LVEF (EF ≤40% - 68%, EF >40% - 32%, EF 50% - 15%)

Primary outcome: 180 day HF readmission and all cause mortality



Relatively few adverse events

- Hypotension 5% vs <1%
- Hyperkalemia 3% vs 0
- No difference in SAE or FAE
- Lower dose of diuretics in the high intensity group

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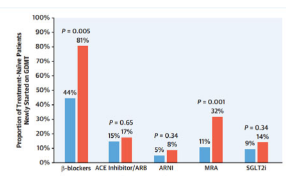
GDMT Titration During Hospitalizations: IMPLEMENT – HF

[illegible]

Non-randomized allocation

GDMT Intervention
Daily GDMT recs

Usual Care



Excluded:
LVEF ≤40%, Non-ICU admission, MCS/inotropes, ACS, CVA, Major CV surgery, SBP <90 in preceedinging 24 hrs, uncorrected vavles, RV dysfunction, COVID19, physician discretion.

Bhatt et al. J Am Coll Cardiol 2023;81:1680–169

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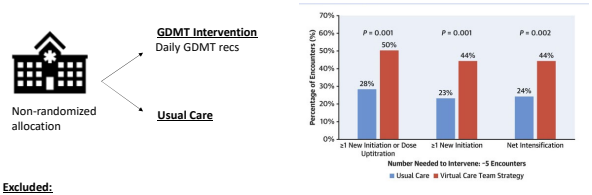
GDMT Titration During Hospitalizations: IMPLEMENT – HF



Excluded:
LVEF ≤40%, Non-ICU admission, MCS/inotropes, ACS, CVA, Major CV surgery, SBP <90 in preceedinging 24 hrs, uncorrected vavles, RV dysfunction, COVID19, physician discretion.

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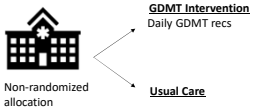

No Significant Change
- AKI
- Bradycardia
- Hypotension
- Hyperkalemia,
- Hospital LOS

Excluded:
LVEF ≤40%, Non-ICU admission, MCS/inotropes, ACS, CVA, Major CV surgery, SBP <90 in preceedinging 24 hrs, uncorrected vavles, RV dysfunction, COVID19, physician discretion.

Bhatt et al. J Am Coll Cardiol 2023;81:1680–169

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Some General Rules about Inpatient GDMT

- BB should be reserved for when people are compensated and closer to the end of the hospitalizations.
  - Caution should be used with rapid BB titration
  - Caution should be used with BB in those with low CO
- Cost needs to be taken into account
- Exclusions should be documented and appropriate

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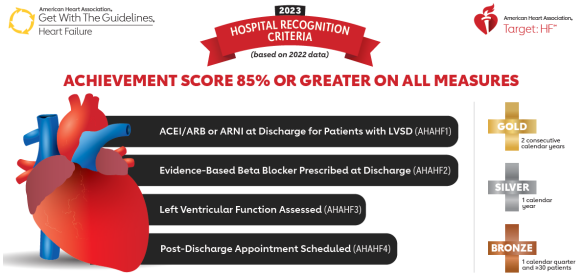

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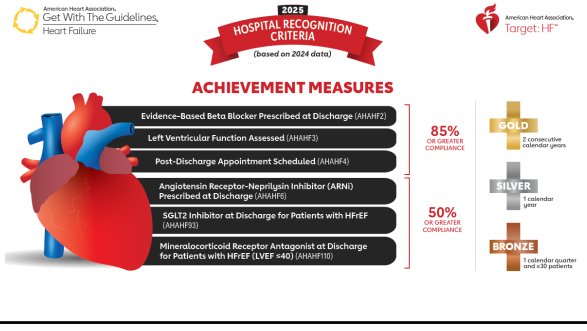

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AHA/ACC Heart Failure Guidelines for 2022

COR	LOE	Recommendations
1	B-NR	1. In patients with HFrEF requiring hospitalization, preexisting GDMT should be continued and optimized to improve outcomes, unless contra-indicated.[1–5]
1	B-NR	2. In patients experiencing mild decrease of renal function or asymptomatic reduction of blood pressure during HF hospitalization, diuresis and other GDMT should not routinely be discontin-ued.[6–11]
1	B-NR	3. In patients with HFrEF, GDMT should be initi-ated during hospitalization after clinical stability is achieved.[2,3,5,12–18]
1	B-NR	4. In patients with HFrEF, if discontinuation of GDMT is necessary during hospitalization, it should be reinitiated and further optimized as soon as possible.[19–22]

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Agenda

- The Problem: Heart Failure
- The Solution: Guideline-Directed Medical Therapy (GDMT)
- How We are Doing So Far?
- Barriers to Optimal Care
- Changing Landscape of How We Approach Inpatient Management
- **Changing Landscape of How We Approach Outpatient Management**

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Remote Titration of GDMT

Case-control study on remote, algorithm-driven, navigator-administered (supervised by pharmacist, APP, MD) medication optimization program could enhance implementation of GDMT in HFrEF

QI Project to increase GDMT

Cases
Agreed to QI project

Controls
Did not agree to QI project

Desai et al. JAMA Cardiol. 2020;5(12):1430-1434

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Remote Titration of GDMT

Case-control study on remote, algorithm-driven, navigator-administered (supervised by pharmacist, APP, MD) medication optimization program could enhance implementation of GDMT in HFrEF

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Cases
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Controls
Did not agree to QI project

At 3 months

- Intervention group
  - RASi (138 [70.1%] to 170 [86.3%]; P < .001)
  - BB (152 [77.2%] to 181 [91.9%]; P < .001)
  - MRA (51 [25.9%] to 60 [30.5%]; P = .14)
  - Doses for each category of GDMT increased from baseline
- Usual-care group
  - no changes from baseline in the proportion of patients receiving GDMT or the dose of GDMT in any category

Desai et al. JAMA Cardiol. 2020;5(12):1430-1434

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Pharmacist Led Titration Clinic: PHARM - HF

Prospective observational study evaluated the impact of implementing pharmacist led titration clinic

$N = 80$	Baseline	90-day post-enrollment	P-value
Primary Outcome			
Quadruple therapy[#]	2 (2.5%)	17 (21.3%)	0.001
Triple therapy[#]	15 (18.8%)	29 (36.3%)	0.020
Secondary Outcomes			
Target or maximally tolerated GDMT achieved for both ACEI/ARB/ARNI and Betablocker[#]	3 (3.8%)	26 (32.5%)	< 0.001
Target GDMT for both ACEI/ARB/ARNI and Betablocker[#]	2 (2.5%)	10 (12.5%)	0.021
Target or maximally tolerated GDMT for ACEI/ARB/ARNI[#]	19 (23.8%)	38 (48.8%)	< 0.001
Target GDMT for ACEI/ARB/ARNI[#]	19 (23.8%)	32 (40.0%)	0.011
Target or maximally tolerated GDMT for HF-specific Betablocker[#]	5 (6.3%)	35 (43.8%)	< 0.001
Target GDMT for HF-specific Betablocker[#]	5 (6.3%)	24 (30.0%)	< 0.001
ARNI	18 (22.5%)	39 (48.8%)	0.011
Aldosterone antagonists[#]	18 (22.5%)	31 (38.8%)	0.041
SGLT2 inhibitors[#]	6 (7.5%)	26 (32.5%)	0.001
Health care utilization	**90-day pre-enrollment**	**90-day post-enrollment**	P-value
Combined HF-related hospitalization and ER visits[#]	30 (37.5%)	14 (17.5%)	0.008
HF hospitalization[#]	12 (15.0%)	6 (7.5%)	0.210
ER visits[#]	18 (22.5%)	8 (10.0%)	0.002

Patil et al. J Cardiovasc Transl Res. 2022 May 2:1–12

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EMR Alerts: PROMPT-HF

Pragmatic EMR based cluster RCT of 100 providers
- 1320 patients
- 69% MDs, 31% APPs
- LVEF ≤40% and not on quadruple therapy

- EF, BP, HR, K, Cr, eGFR
- GDMT
- Allergies
- Order set with med options

Usual Care

Ghazi et al. J Am Coll Cardiol 2022;79:2203–2213

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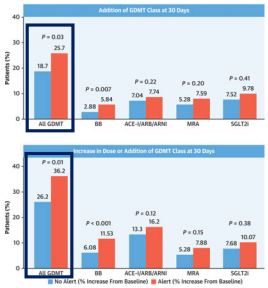
Usual Care



79% of providers strongly agreed the alerts were effective in improving

Ghazi et al. J Am Coll Cardiol 2022;79:2203–2213

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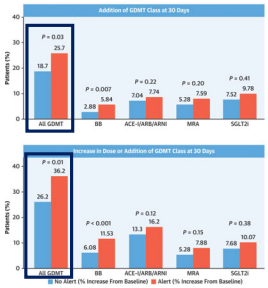

TABLE 2 Clinical Outcomes at 30 Days According to Alert vs No Alert

	Alert (n = 685)	No Alert (n = 625)	Unadjusted RR (95%CI)	Adjusted RR* (95% CI)
Emergency department visits not resulting in hospitalization	45 (6.6)	30 (4.8)	1.37 (0.87-2.14)	1.45 (0.92-2.29)
Emergency department visits resulting in hospitalizations	41 (6.0)	47 (7.5)	0.81 (0.52-1.26)	0.85 (0.58-1.25)
Direct hospitalization	6 (0.9)	16 (2.6)	0.35 (0.14-0.87)	0.36 (0.15-0.87)
Death	7 (1.0)	7 (1.0)	0.89 (0.35-2.28)	0.98 (0.36-2.63)

79% of providers strongly agreed the alerts were effective in improving

Ghazi et al. J Am Coll Cardiol 2022;79:2203–2213

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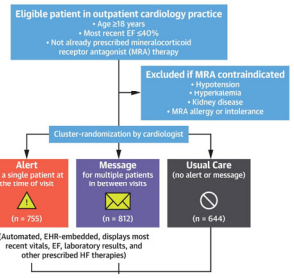
EMR Alert vs Message vs Usual Care: BETTER CARE-HF

2,211 patients were randomized among 180 cardiologists (60 cardiologists per arm)



Mukhopadhyay, et al. J Am Coll Cardiol. 2023 Apr, 81 (14) 1303–1316

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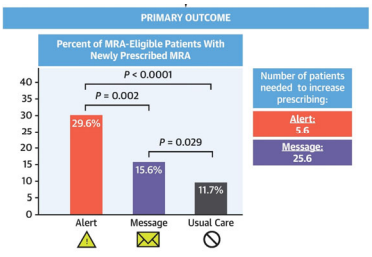
EMR Alert vs Message vs Usual Care: BETTER CARE-HF



Secondary Outcome: Patient Level Newly Rx MRA in 30 days
- Alert: 24.6%
- Message: 5.8%
- UC: 6.5%

Secondary Outcome: Patient Level Newly Rx BB or RAASi in 30 days
- No change between group

Mukhopadhyay, et al. J Am Coll Cardiol. 2023 Apr, 81 (14) 1303–1316

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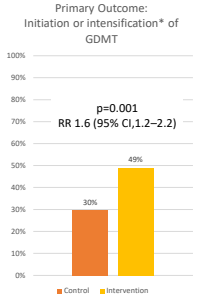
Patient Activation Tools: EPIC-HF

RCT
- 290 patients
- LVEF ≤40%

Patient activation tool using DTCA and SDM
- 3-minute video
- 1-page checklist

Usual Care



Allen et al. Circulation. 2021;143:427–437

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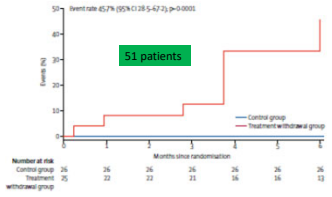
Stopping HF Medications Causes Recurrent HF Events: TRED-HF

- H/o dilated CMP (<40%) that improved to 50% greater, normal volume and NT pro BNP < 250.
- RCT of stepwise withdrawal of medical therapy over a max 16 weeks.

11 (44%) in the initial w/d group
9 (36%) in the cross over group



Halliday et al. *Lancet* 2019; 393: 61–73

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Summary

The problem is heart failure is a high morbidity and high mortality disease state marred by frequent hospitalizations or ER visits and high costs.

We have great therapies that improve survival and reduce admission. However, the implementation of effective, evidence-based care is suboptimal.

Success can be defined as optimizing GDMT for HF patients which translates to better outcomes

Understanding barriers in your practice environment can help pave the way for innovative solutions for improving GDMT use

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