

Underuse of Spironolactone and Barriers Experienced by VA Clinicians

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Background:

Underuse of Spironolactone

- ▶ 68,000 U.S. lives could be saved per year with optimal implementation of therapies in HFrEF
- ▶ Implementation of mineralocorticoid receptor antagonist therapy (MRA) was estimated to result in 1 / 3 of this potential benefit
- ▶ 3 RCTs have found MRAs to be a highly efficacious therapy with a low number needed to treat to save one life (NNT for 1 year \approx 18).
- ▶ Unfortunately, only 1 / 3 of eligible HF patients actually receive an MRA prescription at hospital discharge
 - Alongside the evidence of underuse, other studies have documented high rates of use (up to 1 in 6 patients) in non-ideal patients who are at high risk for hyperkalemia.
- ▶ Further, risk factors for hyperkalemia are common in patients with HF
 - Thus creating a need to balance use in ideal candidates with avoidance of use in those who are at risk for adverse consequences of therapy.

Study: Trends and Variation in MRA Use in Veterans

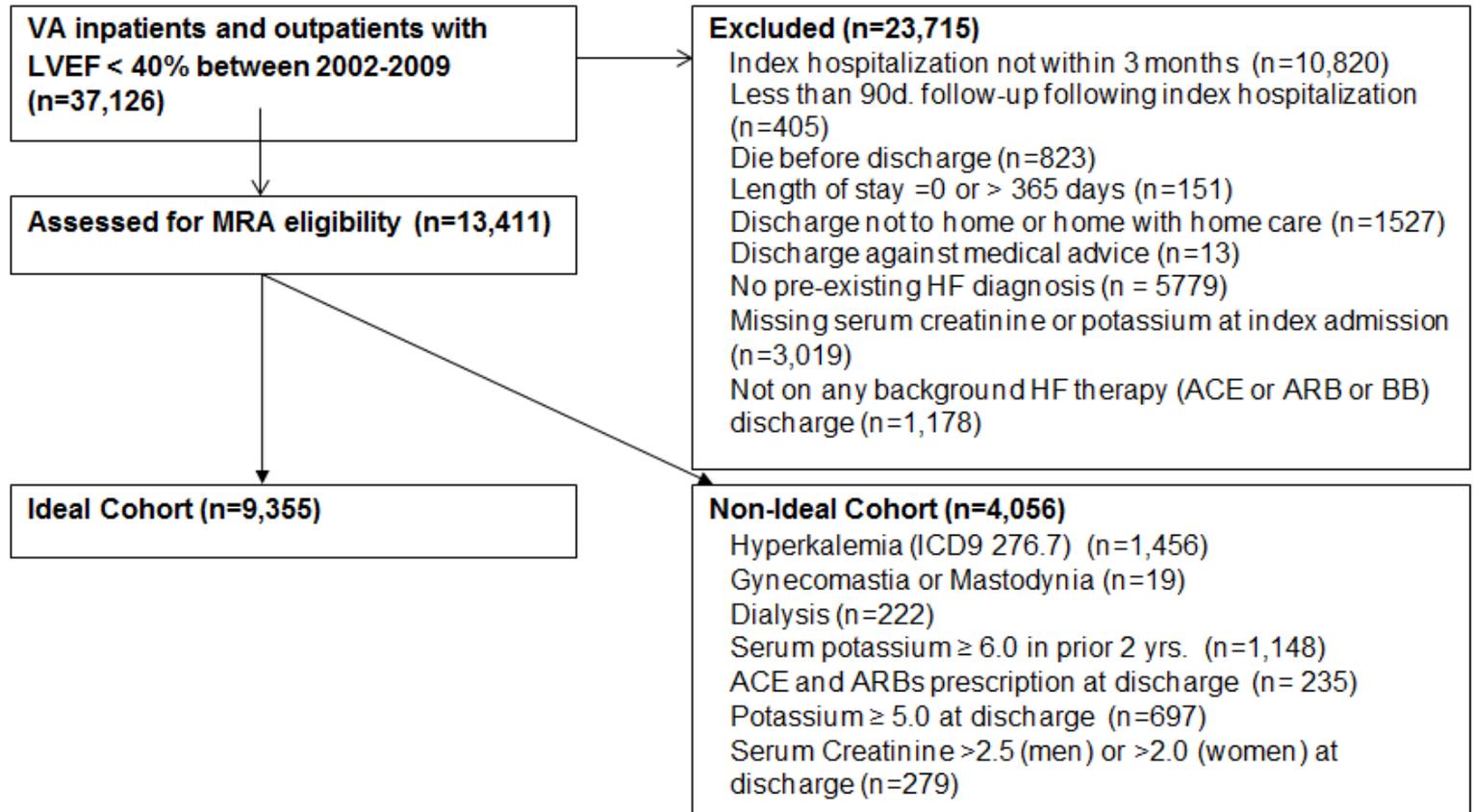
METHODS

- ▶ *Data Sources:* The VA External Peer Review Program (EPRP) is a nationwide inpatient and outpatient random sample of Veterans with at least two years of continuous enrollment who are evaluated for evidence-based performance measures.
- ▶ *Study Cohort:*
- ▶ VA EPRP data FY2003–2009
- ▶ Veterans with HF_rEF, defined as LVEF < 40% (n=37,126) (Figure 1). Our choice of LVEF < 40% was due to the availability of VA EPRP HF performance measure data

Study Cohort

Figure 1.

CONSORT DIAGRAM



Study: Trends and Variation in MRA Use in Veterans

- ▶ *Outcomes Measures and Definitions:*
- ▶ The primary outcome measure was prescription (≥ 14 pills) of an MRA within 90 days of hospital discharge in Ideal and Non-Ideal candidates.

Study: Trends and Variation in MRA Use in Veterans

- ▶ *Statistical Analysis:*
- ▶ *Patient-level analyses:*
 - Proportions of patients who received an MRA prescription within 90 days
Trend test to assess temporal trends across the study period (FY2003–2009).
 - Correlates of MRA use
 - To determine the effects of practice variation in MRA prescription (in Ideal and Non-Ideal cohorts), we calculated the median odds ratio (MOR)
- ▶ *Hospital-level analyses:*
 - To describe institutional-level variation in MRA prescription among Ideal and Non-ideal patients, we assessed the distributions of MRA prescription by institution.
 - In this analysis, we excluded hospitals with less than two eligible patients per fiscal year.

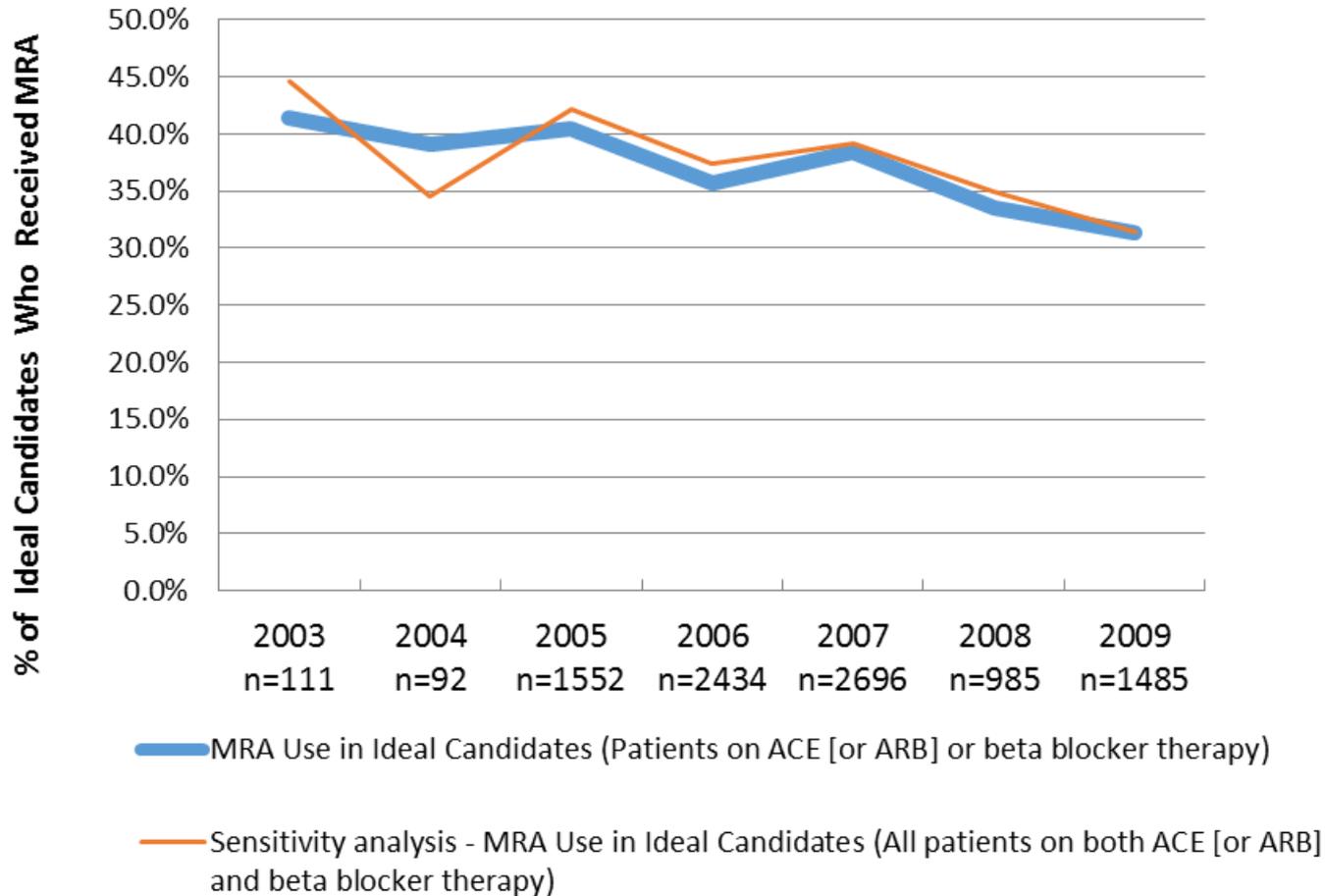
Baseline Characteristics

	Overall	Ideal MRA Candidates	Non-Ideal MRA Candidates
	N=13,411	n=9,355	n=4,056
Demographics			
Age at index date, mean (SD)	71 (11)	71 (11)	71 (11)
Female, n (%)	131 (1%)	88 (1%)	43 (1%)
Race			
White	8,783 (69%)	6,154 (70%)	2,629 (68%)
African-American	3,373 (27%)	2,313 (26%)	1,060 (27%)
Other	504 (4%)	323 (4%)	181 (5%)
Medications prior to index admission (<90 days)			
MRA (spironolactone, eplerenone)	306 (2%)	178 (2%)	128 (3%)
Medications at discharge/within 90 days			
Loop diuretics, %	12,739 (95%)	9,010 (96%)	3,729 (92%)
Thiazide diuretics, %	2,325 (17%)	1,453 (16%)	872 (22%)
Beta blocker (all), %	12,386 (92%)	8,740 (93%)	3,646 (90%)
ACEI or ARB, %	12,025 (90%)	8,811 (94%)	3,214 (79%)
Warfarin	4,380 (33%)	3,135 (34%)	1,245 (31%)
Digoxin	5611 (42%)	3,984 (43%)	1,626 (40%)

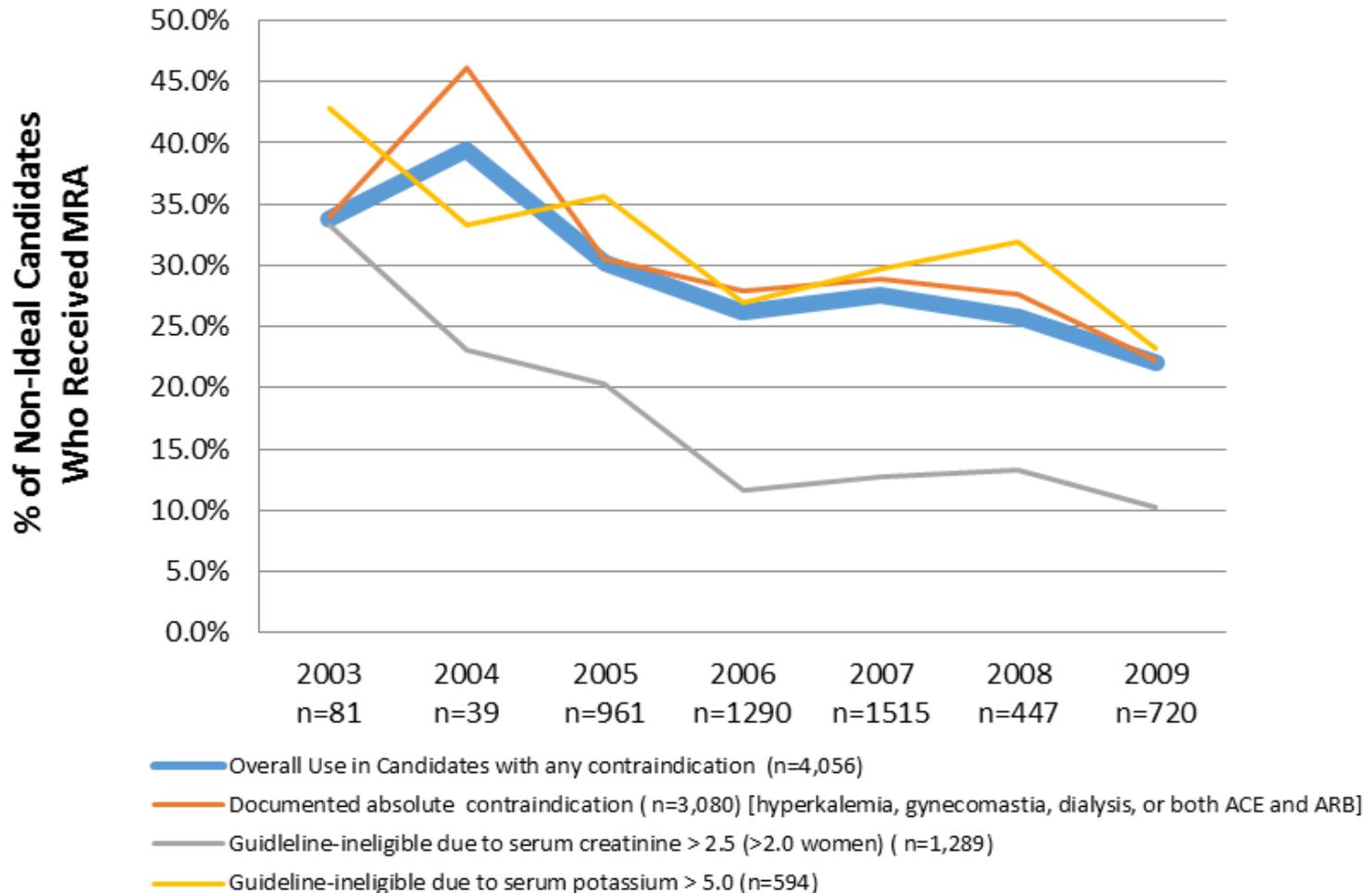
Baseline Characteristics

	Overall	Ideal MRA Candidates	Non-Ideal MRA Candidates
Admission Vitals			
Systolic BP, mmHg, mean (SD)	130 (26)	130 (25)	129 (27)
Pulse, beats/minute, mean (SD)	83 (19)	84 (19)	82 (19)
Discharge Lab Values			
Sodium, MEQ/L, mean (SD)	138 (5)	138 (4)	137 (6.58)
Potassium, MEQ/L, mean (SD)	4.1 (0.5)	4.1 (0.4)	4.3 (0.6)
Serum Creatinine, MG/DL, mean (SD)	1.6 (1.2)	1.4 (0.4)	2.3 (1.9)
Blood Urea Nitrogen, MG/DL, mean (SD)	32 (20)	28 (14)	44 (27)
Hemoglobin, g/dL, mean (SD)	12.3 (1.9)	12.6 (1.9)	11.7 (1.9)
Comorbid conditions			
Total Comorbidities (Elixhauser ¹¹), mean (SD)	4.8 (2.6)	4.3 (2.4)	6.0 (2.6)

Temporal Trend in Prescribing in Ideal Candidates

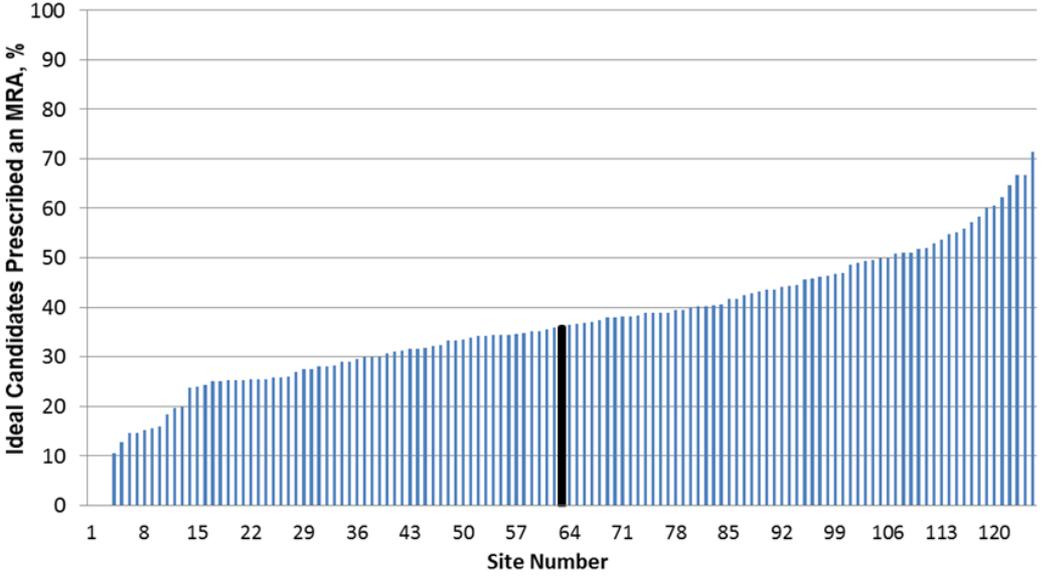


Temporal Trend of MRA Prescribing in Non-Ideal Candidates

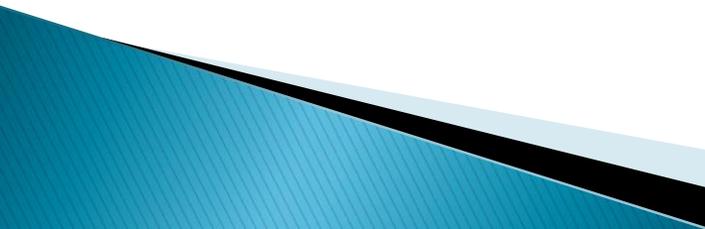
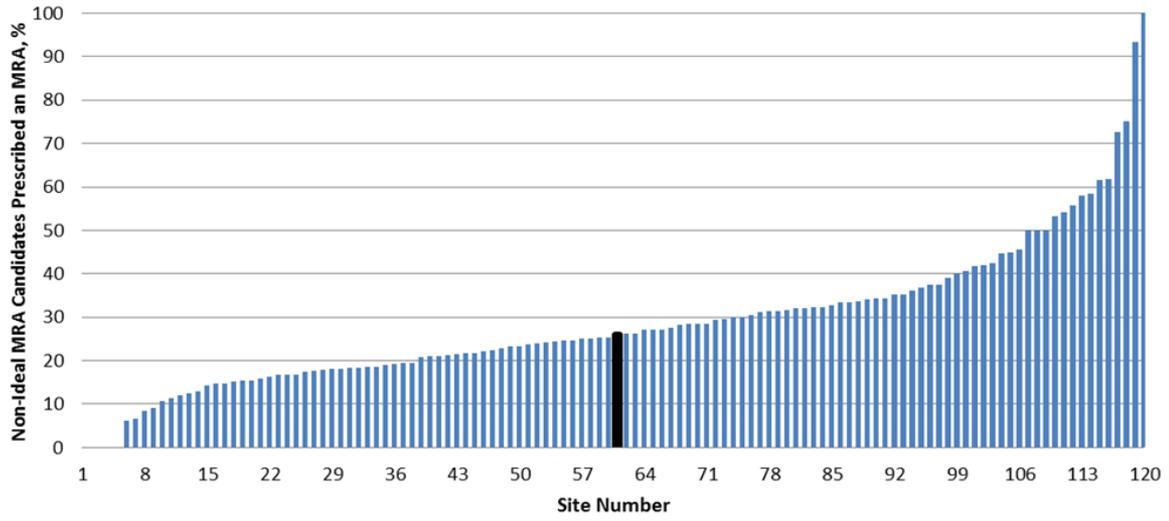


Variation in Hospital-level MRA Prescribing Rate

Site-Level Variation in Proportion of Ideal Candidates Prescribed an MRA



Site-Level Variation in Proportion of Non-Ideal Candidates Prescribed an MRA



Study: Trends and Variation in MRA Use in Veterans

- ▶ **Conclusions:**
 - ▶ MRA prescribing decreased 2002–2009 both in non-ideal *and* ideal candidates. Why?
 - ▶ Low rates of MRA prescribing in ideal candidates
 - ▶ Higher rates of non-ideal prescribing than other studies
 - ▶ Significant hospital variation suggesting the importance of system factors
 - ▶ Attempts to stimulate greater use of MRA should be accompanied by surveillance for potential overuse.
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Background:

Understanding Provider Barriers to MRA Prescription and Monitoring

- ▶ In a sample of 133 VAMCs and >142,000 patients with a diagnosis of HF, the hospital-level average for patients receiving potassium monitoring within 14 days after initiation of an MRA was 42%.

Study: Understanding Provider Barriers

- ▶ METHODS
- ▶ Survey
 - 6 groups of providers from internal medicine (hospitalist, residents), cardiology (NP/attending, fellows), primary care, clinical pharmacists
 - Internet-based survey
 - Familiarity with MRAs, knowledge of prescription and monitoring, perception of barriers
- ▶ Focus groups with semi-structured interview guide

Characteristics of Study Participants

Total Number of Providers Within Scope of Study	Number (n=53)	Percent (%)
Survey participation only	8	15%
Survey and focus group	39	74%
Survey and focus group and interview	3	6%
Interview only	3	6%
Characteristic of Survey Participants	Number (n=50)	Percent (%)
Department		
Primary Care	11	22%
Pharmacy	13	26%
Internal Medicine	13	26%
Cardiology	12	24%
Other	1	2%
Professional Title		
Staff Physician	15	30%
Mid-level (NP or PA)	7	14%
Resident Physician	14	28%
Pharmacist	14	28%
VA Primary Work Location		
Main Hospital	43	86%
Community Clinic - metro area	4	8%
Community Clinic - rural	3	6%
Total years in practice (including residency), median (IQR) ¹	9 (3,15)	
Years in practice at Phoenix VA (including residency) ¹ median (IQR)	6 (1,10)	

Study: Understanding Provider Barriers

▶ SURVEY RESULTS

- Top barriers:
 - 1) potential for side effects (56%), 2) polypharmacy (54%), 3) concern for starting ACE (ARB) and beta-blocker first (36%), and 4) lack of familiarity with MRAs (32%)
- 26% of all respondents felt that Cardiology specialists should initiate MRAs for HF patients.
- 51% of overall respondents were unfamiliar with eplerenone versus 6% with spironolactone ($p=0.23$).
- Respondents were well aware of MRA-related adverse effects, namely hyperkalemia (96%) and gynecomastia (92%).
- Most respondents reported that MRAs were easy/very easy to prescribe (90%) as well as monitor with laboratory testing (86%).

Study: Understanding Provider Barriers

▶ SURVEY RESULTS, continued

- 30% of respondents would order a lab test more than 2 weeks after a new MRA prescription
- While most correctly identified NYHA class 3/4 patients as MRA-eligible, less than half (42%) identified NYHA class 2 patients as eligible.
- Respondents were accurate in identifying eligibility for MRA based on LVEF and serum potassium.
 - However, when asked about the serum creatinine at which they would initiate an MRA, their responses for men (median response, 2.0 mg/dL) and women (median response, 1.8) were lower than the guideline-recommended maximum serum creatinine (< 2.5 in men, < 2.0 in women).

Patient-based Barriers

Perceived Barrier	Description
Patient Polypharmacy and Comorbidities	Providers are hesitant to add MRA when patients are on multiple medications and having multiple health issues
Adverse Effects of Drug Therapy	Providers are concerned, especially in patients who don't complete lab work, about the potential side effects associated with MRA namely hyperkalemia.
Perceived Patient Non-Adherence	Providers are concerned with patients' abilities and willingness to complete the necessary lab work follow-up appointments when on MRA or take consistently their medication.

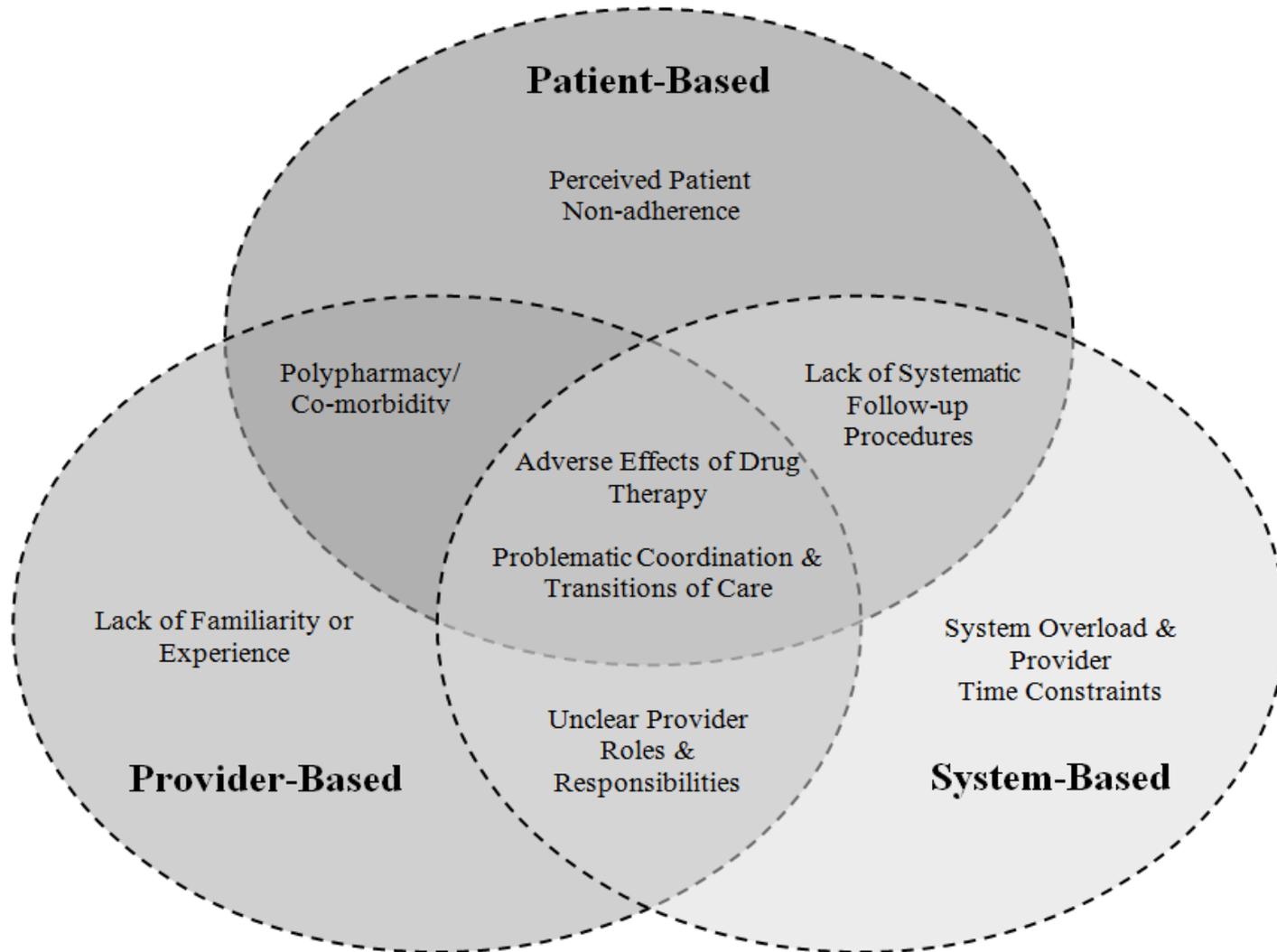
Provider-based Barriers

Perceived Barrier	Description
Unclear Provider Roles and Responsibilities	Some providers noted that providers may defer treatment of HF to cardiology specialists, but that all providers should be responsible for treating and overseeing heart failure and prescribing MRA if it's considered an effective treatment.
Coordination and Transitions of Care	Monitoring HF patients across departments can be difficult to maintain. Communication among providers (i.e. pharmacists, cardiology, PCPs, hospitalists) can be unclear making it difficult to prescribe MRA or monitor patients.
Lack of Familiarity or Experience with MRA Use	Non-cardiology providers describe having less experience, familiarity, or comfort in using MRAs. It's not a drug they commonly use, and they might experience a lack of knowledge about prescribing, monitoring, or using MRAs

System-based Barriers

Perceived Barrier	Description
System overload and Provider Time Constraints	Both patients and providers may experience difficulties prescribing and taking/monitoring MRA because of difficulties encountered in the VA system. Some providers, namely PCPs, also noted issues with monitoring when they have high patient caseloads
Lack of Systematic Follow-up Procedures	Data suggests lack of a clear, systematic plan for consistent follow-up with patients on MRAs.

Model of Barriers to MRA Use



Study: Understanding Provider Barriers to MRA Prescription and Monitoring

CONCLUSIONS

- ▶ Knowledge gaps
 - Appropriate time interval for potassium monitoring
 - Mild HF symptoms (i.e., NYHA class 2)
- ▶ Familiarity / Experience gap
 - Only 9% of PCPs were familiar with eplerenone, a non-formulary drug in the VHA. It appears that MRA use is not part of the cultural norm for non-cardiology providers
 - As PCPs defer to the expertise of cardiology, they do not gain experience and familiarity with the drug

Study: Understanding Provider Barriers to MRA Prescription and Monitoring

CONCLUSIONS

- ▶ Whose responsibility is MRA therapy?
 - The survey findings reinforce this observation in that half of cardiology providers and 86% of primary care providers felt that cardiology providers should be responsible for MRA prescribing.
- ▶ Coordination of care, especially during transitions
 - Residents physicians in training
- ▶ What interventions would help?

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