Success for Failure:
Heart Failure Management in 2017

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No relevant disclosures
Objectives

• Clinical presentation and diagnosis
• Evaluation and treatment strategies
• Chronic disease management and hospitalization prevention
Heart failure disease burden

- Lifetime risk of 20% in Americans ≥ 40 years old
- >650,000 new HF cases / yr
- Nearly 6 million HF patients in the US and 1 million hospitalizations with HF as primary diagnosis
- Nearly one in four patients hospitalized with HF is rehospitalized within 30 days of discharge
- 12-15 million outpatient visits a year
- Absolute mortality of 50% within 5 years
- Direct costs >$30 billion / yr

Clinical Diagnosis

MAJOR CRITERIA
• Orthopnea/paroxysmal nocturnal dyspnea
• Rales
• Cardiomegaly
• Acute pulmonary edema
• Jugular venous distention
• Hepatojugular reflux
• S3

MINOR CRITERIA
• Ankle edema
• Night cough
• Exertional dyspnea
• Hepatomegaly
• Pleural effusion
• Tachycardia (>120 bpm)
• Decreased vital capacity
• Weight loss with HF treatment

HF = 2 major or 1 major + 1 minor

# Definition of HF based on LVEF

<table>
<thead>
<tr>
<th>Classification</th>
<th>Ejection Fraction</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Heart Failure with Reduced Ejection Fraction (HF(_r)EF)</td>
<td>≤40%</td>
<td>Also referred to as systolic HF. Randomized clinical trials have mainly enrolled patients with HF(_r)EF and it is only in these patients that efficacious therapies have been demonstrated to date.</td>
</tr>
<tr>
<td>II. Heart Failure with Preserved Ejection Fraction (HF(_p)EF)</td>
<td>≥50%</td>
<td>Also referred to as diastolic HF. Several different criteria have been used to further define HF(_p)EF. The diagnosis of HF(_p)EF is challenging because it is largely one of excluding other potential noncardiac causes of symptoms suggestive of HF. To date, efficacious therapies have not been identified.</td>
</tr>
<tr>
<td>a. HF(_p)EF, Borderline</td>
<td>41% to 49%</td>
<td>These patients fall into a borderline or intermediate group. Their characteristics, treatment patterns, and outcomes appear similar to those of patients with HF(_p)EF.</td>
</tr>
<tr>
<td>b. HF(_p)EF, Improved</td>
<td>&gt;40%</td>
<td>It has been recognized that a subset of patients with HF(_p)EF previously had HF(_r)EF. These patients with improvement or recovery in EF may be clinically distinct from those with persistently preserved or reduced EF. Further research is needed to better characterize these patients.</td>
</tr>
</tbody>
</table>
Prevalence of HFpEF is estimated at 50% of all HF.

K-M survival curves for HFpEF v. HFrEF patients

HF Etiologies

- Ischemic
- Familial
- Metabolic
- Thyroid
- Toxic (etoh, cocaine, chemo)
- Nutritional
- Tachycardia-induced
- Myocarditis
- HIV
- Chagas

- Connective tissue disease
- Peripartum
- Iron overload
- Amyloidosis
- Sarcoidosis
- Stress
- Storage disease
- Hypertrophic
- ARVC
- HFpEF

Initial evaluation

In all cases:

- History, exam, ECG
- Echocardiogram
- Laboratory testing
- Assessment of functional capacity
- Assessment for CAD in patients at risk

In selected cases:

- Cardiac catheterization
- Cardiac MRI
- Endomyocardial biopsy
- Genetic testing

A complete history and physical examination should be obtained/performed in patients presenting with HF to identify cardiac and non-cardiac disorders or behaviors that might cause or accelerate the development or progression of HF.

In patients w idiopathic DCM, a 3-generational family history should be obtained to aid in establishing the diagnosis of familial DCM.

Volume status and vital signs should be assessed at each patient encounter:
- Weight
- JVP
- Peripheral edema
- Orthopnea
Initial labs in patients presenting with HF should include:
- CBC, BMP with BUN and Cr, Hepatic Panel
- UA, TSH, Lipid Profile

Serial monitoring, when indicated, should include serum electrolytes and renal function.

A 12-lead ECG should be performed initially on all patients presenting with HF.

Screening for hemochromatosis or HIV is reasonable in selected patients who present with HF.

Diagnostic tests for rheumatologic disease, amyloid, pheo are reasonable, when suspected.
### Classification of HF

<table>
<thead>
<tr>
<th>ACCF/AHA Stages of HF</th>
<th>NYHA Functional Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong> At high risk for HF but without structural heart disease or symptoms of HF.</td>
<td>None</td>
</tr>
<tr>
<td><strong>B</strong> Structural heart disease but without signs or symptoms of HF.</td>
<td>I No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF.</td>
</tr>
<tr>
<td><strong>C</strong> Structural heart disease with prior or current symptoms of HF.</td>
<td>I No limitation of physical activity. Ordinary physical activity does not cause symptoms of HF.</td>
</tr>
<tr>
<td></td>
<td>II Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in symptoms of HF.</td>
</tr>
<tr>
<td></td>
<td>III Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes symptoms of HF.</td>
</tr>
<tr>
<td></td>
<td>IV Unable to carry on any physical activity without symptoms of HF, or symptoms of HF at rest.</td>
</tr>
</tbody>
</table>

Brain natriuretic peptide

Pro-BNP = common 108-AA precursor
Cleaved into BNP and NT-pro BNP
BNP in ER patients with dyspnea

BNP ≥100 pg/mL:
- Positive predictive value 79%
- Negative predictive value 89%

NT-proBNP ≥900 pg/mL:
- Positive predictive value 77%
- Negative predictive value 92%

BNP: Limitations

- Levels may increase with age, female gender, pressure overload, CKD
- Levels decrease with obesity, treatment (eg, carvedilol, spironolactone)
- Levels are lower in HF with preserved EF
- BNP-guided therapy trials: mixed results
  - Favorable metanalyses
  - Ongoing prospective trial
**Recommendations for BNP**

In ambulatory patients with dyspnea, pro-BNP is useful to support the **diagnosis of HF**, especially when uncertain.

Measurement of BNP or NT-proBNP is useful for **establishing prognosis or disease severity** in chronic HF.

BNP- or NT-proBNP guided HF therapy can be useful to achieve optimal dosing of GDMT in select clinically euvolemic patients.

Using serial BNPs to reduce hospitalization
Using other biomarkers for additive stratification
Patients with suspected or new-onset HF, or ADHF, should undergo a **chest x-ray** to assess heart size and pulmonary congestion, and detect items on differential diagnosis.

A **2-dimensional echocardiogram with Doppler** should be performed during initial evaluation to assess ventricular function, size, wall thickness, wall motion, and valve function.

**Repeat measurement of EF** and measurement of the severity of structural remodeling are useful to provide information in patients with HF who:

1. Have had a significant change in clinical status
2. Have experienced or recovered from a clinical event
3. Have received treatment, including GDMT, that might have had a significant effect on cardiac function
4. May be candidates for device therapy.
Noninvasive Cardiac Imaging

Noninvasive detection of myocardial ischemia and viability is reasonable in patients presenting with de novo HF who have known CAD and no angina, unless the patient is not eligible for revascularization of any kind.

Viability assessment is reasonable in select situations when planning revascularization in HF patients with CAD.

Ventriculogram or magnetic resonance imaging can be useful to assess LVEF and volume when echocardiography is inadequate.

Magnetic resonance imaging is reasonable when assessing myocardial infiltrative processes or scar burden.
Routine repeat measurement of LV function assessment in the absence of clinical status change or treatment interventions should not be performed.
Treatment strategy
HFrEF Guideline-Directed Medical Treatment

**ACE/ARB**
- First line therapy
- NYHA Class I-IV

**Beta-Blockers**
- First line therapy
- NYHA Class I-IV
- Carvedilol, metoprolol succinate, bisoprolol

**Aldosterone Antagonists**
- Underutilized
- Indicated in almost all NYHA II-IV
- Lab cutoffs: K < 5.0, GFR > 30, SCr < 2.5 (Men) and 2.0 (Women)

**Hydralazine-ISDN**
- Consider in African-American with NYHA III-IV HFrEF
- Alternative to Ace/Arb
<table>
<thead>
<tr>
<th>Study Name</th>
<th>LVEF</th>
<th>Rx</th>
<th>Year</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>VHeFT-I</td>
<td>&lt; 45</td>
<td>Hyd-ISDN</td>
<td>1986</td>
<td>↓mortality @ 36 months; prazosin bad</td>
</tr>
<tr>
<td>VHeFT-II</td>
<td>&lt; 45</td>
<td>Hyd-ISDN vs. Enalapril</td>
<td>1991</td>
<td>Enalapril &gt; Hyd-ISDN (mortality)</td>
</tr>
<tr>
<td>A-HeFT</td>
<td>≤ 35</td>
<td>Hyd-ISDN in Af Am</td>
<td>2004</td>
<td>↓mort/hosp/better QOL in Af Am NYHA III-IV</td>
</tr>
<tr>
<td>CONSENSUS</td>
<td></td>
<td>CXR/IV Enalapril vs. Placebo</td>
<td>1987</td>
<td>↓mortality (250 pts)</td>
</tr>
<tr>
<td>SOLVD</td>
<td>≤ 35</td>
<td>Enalapril vs. Placebo</td>
<td>1991/2</td>
<td>Improved survival and prevention of CHF</td>
</tr>
<tr>
<td>ELITE-2</td>
<td>≤ 40</td>
<td>Losartan vs. Captopril</td>
<td>2000</td>
<td>No change in mortality, SCD</td>
</tr>
<tr>
<td>Val-HeFT</td>
<td>&lt;40</td>
<td>Valsartan BID vs. Placebo</td>
<td>2001</td>
<td>ARB &gt; placebo; none if added to ACE/BB</td>
</tr>
<tr>
<td>CHARM</td>
<td>≤ 40</td>
<td>Cande + ACE (added)</td>
<td>2004</td>
<td>Candesartan ↓ CV death/HF independent of ACEI</td>
</tr>
<tr>
<td>US Carvedilol</td>
<td>≤35</td>
<td>Coreg vs. Placebo</td>
<td>1996</td>
<td>↓ mortality</td>
</tr>
<tr>
<td>MOCHA</td>
<td>≤ 35</td>
<td>Coreg 6.25 range to 25 BID</td>
<td>1996</td>
<td>Benefit at 6.25, but best at 25 BID</td>
</tr>
<tr>
<td>MERIT-HF</td>
<td>&lt; 40</td>
<td>Metop Succ vs. Placebo</td>
<td>1999</td>
<td>↓ death, CV death, SCD, HF</td>
</tr>
<tr>
<td>COPERNICUS</td>
<td>&lt; 25</td>
<td>Coreg in severe HF</td>
<td>2001</td>
<td>↓ mortality, even in sick patients</td>
</tr>
<tr>
<td>COMET</td>
<td>&lt; 35</td>
<td>Coreg 25 vs Metop 50 BID</td>
<td>2003</td>
<td>Coreg &gt; Metop tartrate</td>
</tr>
<tr>
<td>RALES</td>
<td>≤ 35/III-IV</td>
<td>Spiro vs. Placebo</td>
<td>1999</td>
<td>↓ mortality</td>
</tr>
<tr>
<td>EPHESUS</td>
<td>≤ 40 p MI + HF/DM</td>
<td>Eplerenone vs. Placebo</td>
<td>2003</td>
<td>↓ mortality/HF</td>
</tr>
<tr>
<td>EMPHASIS</td>
<td>≤ 30/II</td>
<td>Eplerenone vs. Placebo</td>
<td>2011</td>
<td>↓ mortality/HF</td>
</tr>
<tr>
<td>DIG</td>
<td>≤ 45</td>
<td>Digoxin vs. Placebo</td>
<td>1997</td>
<td>no mortality change, ↓HF hosp</td>
</tr>
<tr>
<td>PARADIGM</td>
<td>&lt; 40</td>
<td>Entresto vs. Enalapril</td>
<td>2014</td>
<td>↓ death/HF hosp</td>
</tr>
<tr>
<td>SHIFT</td>
<td>≤ 35</td>
<td>Ivabradine vs. Placebo</td>
<td>2010</td>
<td>↓ HF admission</td>
</tr>
</tbody>
</table>
HFrEF Stage C  
NYHA Class I – IV  
*Treatment:*

- **Class I, LOE A** 
  - ACEI or ARB **AND** Beta Blocker

- For all volume overload, NYHA class II-IV patients
  - Add
    - **Class I, LOE C** 
      - Loop Diuretics

- For persistently symptomatic African Americans, NYHA class III-IV
  - Add
    - **Class I, LOE A** 
      - Hydral-Nitrates

- For NYHA class II-IV patients. Provided estimated creatinine >30 mL/min and K+ <5.0 mEq/dL
  - Add
    - **Class I, LOE A** 
      - Aldosterone Antagonist

Medical Therapy for Stage C HFrEF: Magnitude of Benefit Demonstrated in RCTs

Table. Demonstrated Benefits of Evidence-Based Therapies for Patients With Heart Failure and Reduced Ejection Fraction

<table>
<thead>
<tr>
<th>Evidence-Based Therapy</th>
<th>Relative Risk Reduction in All-Cause Mortality in Pivotal Randomized Clinical Trial(s), %</th>
<th>NNT to Prevent All-Cause Mortality Over Time</th>
<th>NNT for All-Cause Mortality&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACEI/ARB</td>
<td>17</td>
<td>22 over 42 mo</td>
<td>77</td>
</tr>
<tr>
<td>ARNI&lt;sup&gt;b&lt;/sup&gt;</td>
<td>16</td>
<td>36 over 27 mo</td>
<td>80</td>
</tr>
<tr>
<td>β-Blocker</td>
<td>34</td>
<td>28 over 12 mo</td>
<td>28</td>
</tr>
<tr>
<td>Aldosterone antagonist</td>
<td>30</td>
<td>9 over 24 mo</td>
<td>18</td>
</tr>
<tr>
<td>Hydralazine/nitrate</td>
<td>43</td>
<td>25 over 10 mo</td>
<td>21</td>
</tr>
<tr>
<td>CRT</td>
<td>36</td>
<td>12 over 24 mo</td>
<td>24</td>
</tr>
<tr>
<td>ICD</td>
<td>23</td>
<td>14 over 60 mo</td>
<td>70</td>
</tr>
</tbody>
</table>

Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor neprilysin inhibitor; CRT, cardiac resynchronization therapy; ICD, implantable cardioverter defibrillator, NNT, number needed to treat.

<sup>a</sup> Standardized to 12 months.

<sup>b</sup> Benefit of ARNI therapy incremental to that achieved with ACEI therapy. For the other medications shown, the benefits are based on comparisons to placebo control.
Heart Failure 2016 Guideline Update

- Ivabradine
- Neprilysin inhibition
SHIFT Trial: Ivabradine

Inclusion Criteria
- NYHA II-IV
- Hospital in prior year
- LVEF < 35%
- NSR
- HR > 70 bpm

Primary endpoint
24 versus 29%
(CV Death/HF Hosp)

Does not reduce Death

Incremental benefits of ivabradine are more pronounced in patients with higher resting heart rates

Magnitude of heart rate reduction achieved with ivabradine + β blockade is the principal determinant of subsequent outcome
PARADIGM: Study design

Multicenter, international RCT

Primary endpoint: CV death/HF hospitalization

Kaplan-Meier Estimate of Cumulative Rates, %

15% at 1 year

Enalapril (n = 4,212)
1,117 (26.5%)
914 (21.8%)

Sacubitril/valsartan (n = 4,187)

HR = 0.80 (0.73-0.87)
P = .0000004
Number needed to treat = 21

Patients at Risk

<table>
<thead>
<tr>
<th>Patients at Risk</th>
<th>LCZ696</th>
<th>Enalapril</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>4,187</td>
<td>4,212</td>
</tr>
<tr>
<td>180</td>
<td>3,922</td>
<td>3,883</td>
</tr>
<tr>
<td>360</td>
<td>3,663</td>
<td>3,579</td>
</tr>
<tr>
<td>540</td>
<td>3,018</td>
<td>2,922</td>
</tr>
<tr>
<td>720</td>
<td>2,257</td>
<td>2,123</td>
</tr>
<tr>
<td>900</td>
<td>1,544</td>
<td>1,488</td>
</tr>
<tr>
<td>1,080</td>
<td>896</td>
<td>853</td>
</tr>
<tr>
<td>1,260</td>
<td>249</td>
<td>236</td>
</tr>
</tbody>
</table>

PARADIGM: endpoints

**ARNI—Guideline update**

<table>
<thead>
<tr>
<th>COR</th>
<th>LOE</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>B-R</td>
<td>ACEI or ARB or ARNI in conjunction with β blockers + MRA (where appropriate) is recommended for patients with chronic HFrEF to reduce morbidity and mortality</td>
</tr>
<tr>
<td>I</td>
<td>B-R</td>
<td>In patients with chronic, symptomatic HFrEF NYHA class II or III who tolerate and ACEI or ARB, replacement by an ARNI is recommended to further reduce morbidity and mortality</td>
</tr>
<tr>
<td>III</td>
<td>B-R</td>
<td>ARNI should NOT be administered concomitantly with ACEI or within 36 hours of last ACEI dose</td>
</tr>
<tr>
<td>III</td>
<td>C-EO</td>
<td>ARNI should NOT be administered to patients with a history of angioedema</td>
</tr>
</tbody>
</table>

What about HFpEF?
Guidelines for Treatment of HFpEF

• **Class I:**
  – Diuretics
  – HTN management

• **Class IIA:**
  – Management of AF
  – Coronary revascularization
  – Use beta blockers, ACE/ARB for HTN

• **Class IIB:**
  – ARBs to decrease hospitalization
Signs/Symptom:
- Fluid overload, renovascular congestion
- RV Dysfunction
- Acute HF
- Hospitalization

Pearls:
- Diuretics; consider change to Torsemide, Bumetanide
- Ultrafiltration
- Digoxin
- ? Dopamine
- ARB, Cardiomems, spironolactone
What about HFpEF?

Why have we failed at treatments?
- Limited pathophysiologic and basic mechanistic understanding
- Targeting wrong mechanism
- Small or no clinical trials
- Heterogeneous population
AHA Strategically Focused Research Network: Go Red for Women

Heart Failure with Preserved Ejection Fraction: Female Sex Hormones and Cyclic GMP-PKG Modulation of Cardiac Disease and Metabolism

Center PI: Pamela Ouyang, MBBS
Clinical Site PI: Kavita Sharma, MD
Basic PI: David Kass, MD
Population PI: Wendy Post, MD MS

ksharma8@jhmi.edu; 443 287 6720
HFpEF Future Directions

• Inorganic Nitrate Studies
  – Increased exercise capacity
  – Improved cardiac output reserve and ventricular reserve in setting of stress (exercise)

• Novel PDE targets

• LA mechanical unloading
  – Potential benefit seen in simulation model of low-flow, micropump-based LA decompression device
Disease Management and Hospitalization Prevention
Hospitalization for Heart Failure

New-onset or worsening HF requiring urgent therapy and hospitalization

- 15% mortality and 30% readmission rate in the 3-6 months after discharge

- Comprised of:
  - Worsening chronic HF (80%)
  - New-onset HF (15%)
  - Advanced/end-stage HF (5%)

Gheorghiade M et al. JACC 2013;61:391-403
HF hospitalizations increasing

Fang J et al. JACC 2008;52:428-434
HF hospitalizations and mortality

Setoguchi S et al. Am Heart J 2007;154:26026
Concept of recurring symptomatic clinical volume overload and congestion in chronic heart failure.
Recurrent congestion is common

- EVEREST trial: discharge composite congestion score

<table>
<thead>
<tr>
<th>Table 4 Outcomes (n, %) by composite congestion score at discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge CCS</td>
</tr>
<tr>
<td>---------------------</td>
</tr>
<tr>
<td>Total (n)</td>
</tr>
<tr>
<td>HHF</td>
</tr>
<tr>
<td>ACM</td>
</tr>
<tr>
<td>ACM + HHF</td>
</tr>
</tbody>
</table>

Ambrosy AP et al. European Heart Jour 2013;34:835-843
Figure. Relationship between number of markers of decongestion above median* and time to 60-day risk of emergency department (ED) visit, rehospitalization, or death. *Median net fluid loss, 3.8 L; median net weight loss, 6.5 lbs; median percent reduction in N terminal B-type natriuretic peptide 24.3%.
Implantable monitors

• **CHAMPION:**
  - CardioMEMS pulmonary artery sensor
  - 550 pts, NYHA III
  - 28% absolute reduction in HF hospitalizations at 6 mon
  - Had recommendations on how to guide therapy

Abraham W et. al. Lancet 2011;377:658-666
Transitioning from hospital to home

Predischarge
- Patient education
- Discharge planning
- Medication reconciliation
- Appointment scheduled before discharge

Bridging the Transition
- Transition coach
- Instructions
- Provider continuity

Postdischarge
- Timely follow-up
- Timely PCP communication
- Follow-up telephone call
- Patient hotline
- Home visit

Patient self-care and monitoring

What patients are saying...

94 Pts with HFH surveyed

86 Said they have HF

72 Identified HF as reason for admission
What patients are saying...

Patient-identified reason for HF hospitalization, n=72

Reason for admission did not correlate with readmission rate

- Heart failure worsening: 51%
- Dietary noncompliance: 15%
- Missed or no appointment: 3%
- Other medical issue: 13%
- Other: 15%
- Medication issue: 3%
• 42/92 thought hospitalization was preventable

• Upon two physician review, 19 were felt to be preventable by both, 19 by one, and 54 by neither
  • Diet and meds

Patient-identified reason that admission was preventable, n=42

Readmission Rate vs. Median Time from Hospital Discharge

- Initial discharge to death timeline
- "Palliation and Priorities"
- "Transition Phase"
- "Plateau Phase"
Follow-up

- 38% of HF patients are seen by a clinician within one week of discharge
- Higher early follow up = lower 30-d readmission risk
- Patients more likely to be seen if appointment made before discharge

Hernandez AF et al. JAMA 2010;5:1716-1722
Figure 2. Models of HF care. The first panel reflects the traditional model of the ambulatory heart failure clinic as a focal point for intermittent assessment and chronic heart failure management. The second panel reflects a reengineered ambulatory heart failure treatment center with tighter linkage to home surveillance and options for active treatment as an alternative to hospitalization. HF indicates heart failure; ED, emergency department.
Heart failure disease management programs

• Improve medication dosing
• Decrease hospitalizations

• Outpatient IV diuresis clinics:
  – Less common
  – Literature describes referral of symptomatic patients only

Whellan DJ, Russell SD et al. Arch Intern Med 2001;161:2223-2228
Hebert K et al. Congest Heart Fail. 2011;17:309-313
JHH Heart Failure Bridge Clinic

- Opened in 2012
- Early post-discharge follow-up
- Nurse practitioner run
- Multidisciplinary approach: education, treatment, medication reconciliation
- Transition from hospitalization to home and establishment of outpatient specialty care
- Prevention of readmissions
- Referral to palliative care
JHH HFBC Experience

- May 2014 - July 2016
- 5070 clinic visits, 1336 unique patients seen an average of $3.8 \pm 4.3$ times
- IV furosemide administered 728 times to 300 patients
- Mean IV furosemide dose was $129 \pm 43$ mg
- The 30 day all-cause readmission rate for HFBC patients was 12.8% compared to 31.9% for those not seen in HFBC

Summary

- HF growing epidemic with rising hospitalizations and costs
- HF is a clinical diagnosis with broad etiologies
- HFrEF: goal is to get them on GDMT, referral for advanced therapies as needed
- HFpEF: treat comorbidities and volume overload, much to be learned about pathogenesis and treatment strategies
- Safe transitions, education and close follow up key in preventing hospitalizations
Thank you

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