NURSE PRACTITIONER
2021 Virtual CE Summit

Effective Management of Patients With Heart Failure During and After the COVID-19 Pandemic: Updates and Key Considerations for the Nurse Practitioner

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Faculty Disclosures

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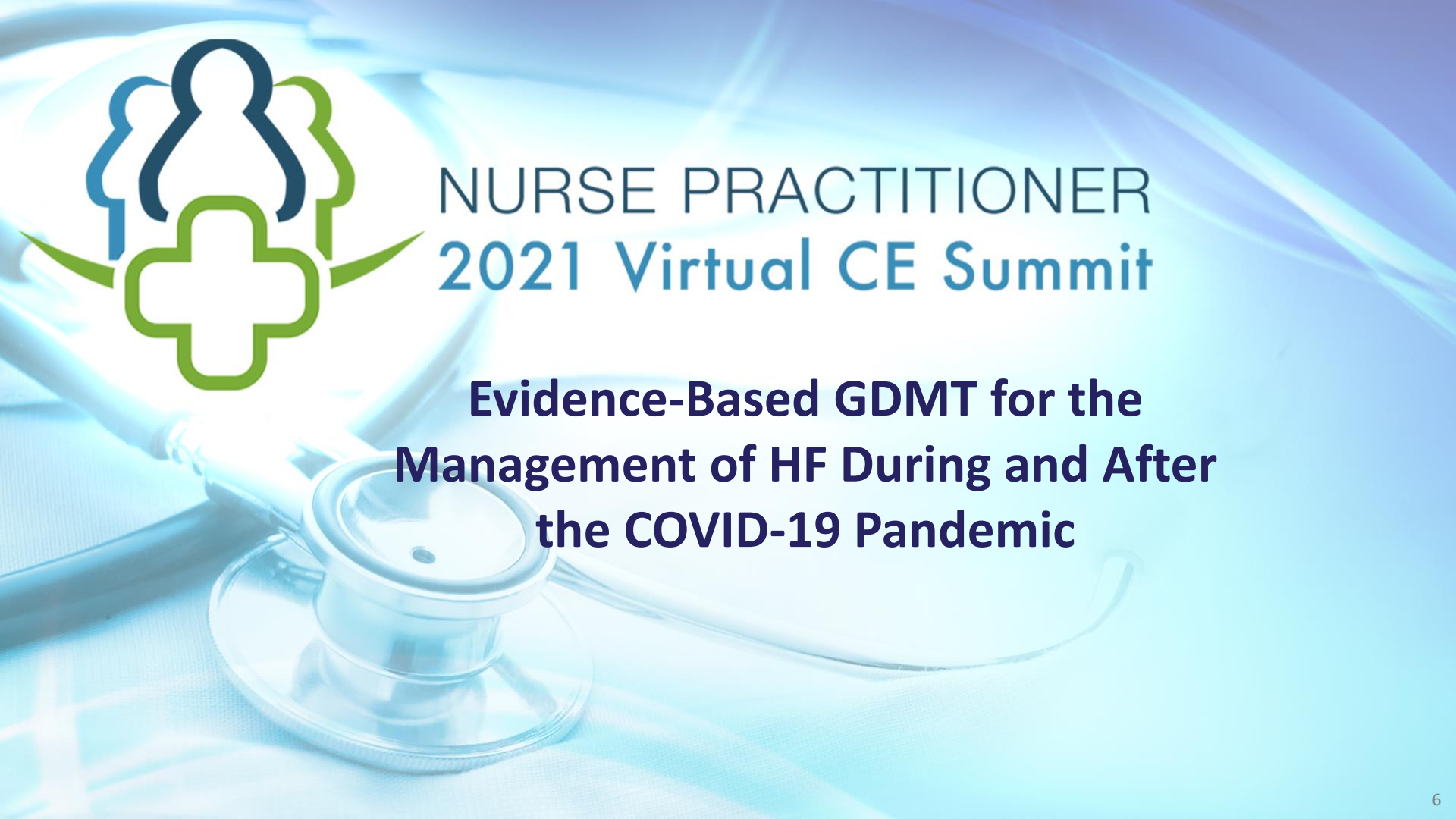
Learning Objectives

- Discuss the safety of RAAS antagonist use in patients with CV and related comorbidities during the ongoing COVID-19 pandemic
- Outline how to apply evidence-based GDMT into the management of patients with HF
- Explain the burden of COVID-19 on patients with CV and related comorbidities
- Discuss how to integrate telemedicine initiatives into the effective management of patients with HF

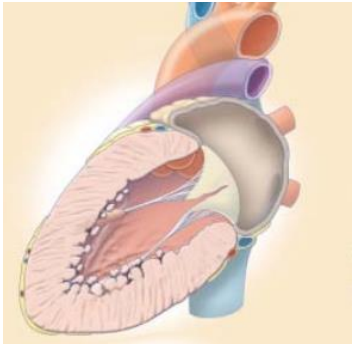
COVID-19, coronavirus disease 2019; CV, cardiovascular; GDMT, guideline-directed medical therapy; HF, heart failure; RAAS, renin-angiotensin-aldosterone system.



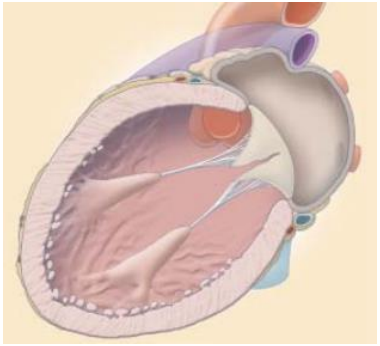
Evidence-Based GDMT for the Management of HF During and After the COVID-19 Pandemic

Definition of HF

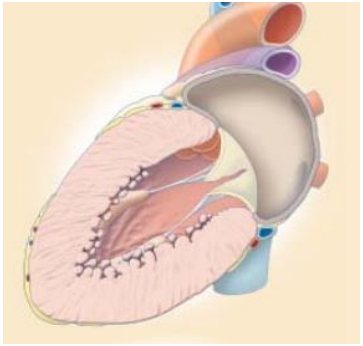
A clinical syndrome that results from any structural or functional impairment of ventricular filling or ejection of blood



Normal Heart



HF with Reduced Ejection Fraction (HF*r*EF)



HF with Preserved Ejection Fraction (HF*p*EF)

Major clinical manifestations: dyspnea, fatigue, and fluid retention*

*Patient presentation varies.

Jessup M, Brozena SA. *New Engl J Med.* 2003;348:2007-2018; Yancy CW, et al. *Circulation.* 2013;128:e240-e327.

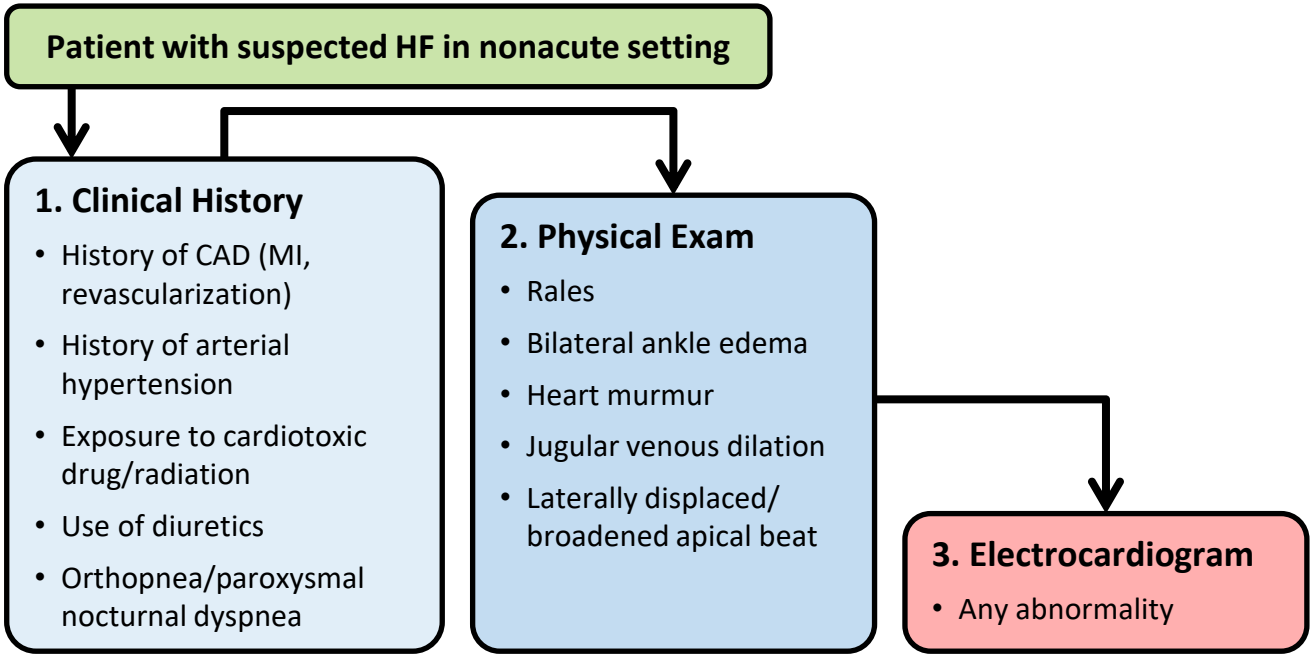
Classification of HF

Classification	EF (%)	Description
HF*r*EF	**≤40**	Also referred to as **systolic HF**. RCTs have mainly enrolled patients with HF*r*EF; to date, only in these patients have effective therapies been demonstrated.
HF*mr*EF	**41-49**	HF with **mid-range ejection fraction**. New category with overlapping characteristics of HF*r*EF and HF*p*EF. Clinical course and mortality are more like HF*r*EF than HF*p*EF.
HF*p*EF	**≥50**	Also referred to as **diastolic HF**. Several different criteria have been used to further define HF*p*EF. Diagnosis of HF*p*EF is challenging because it largely involves excluding other potential noncardiac causes of symptoms suggestive of HF. To date, no effective therapies have been identified.

RCTs, randomized control trials.

Yancy CW, et al. *Circulation*. 2013;128:e240-e327; Bhambhani V, et al. *Eur J Heart Fail.* 2018;20(4): 651–659.

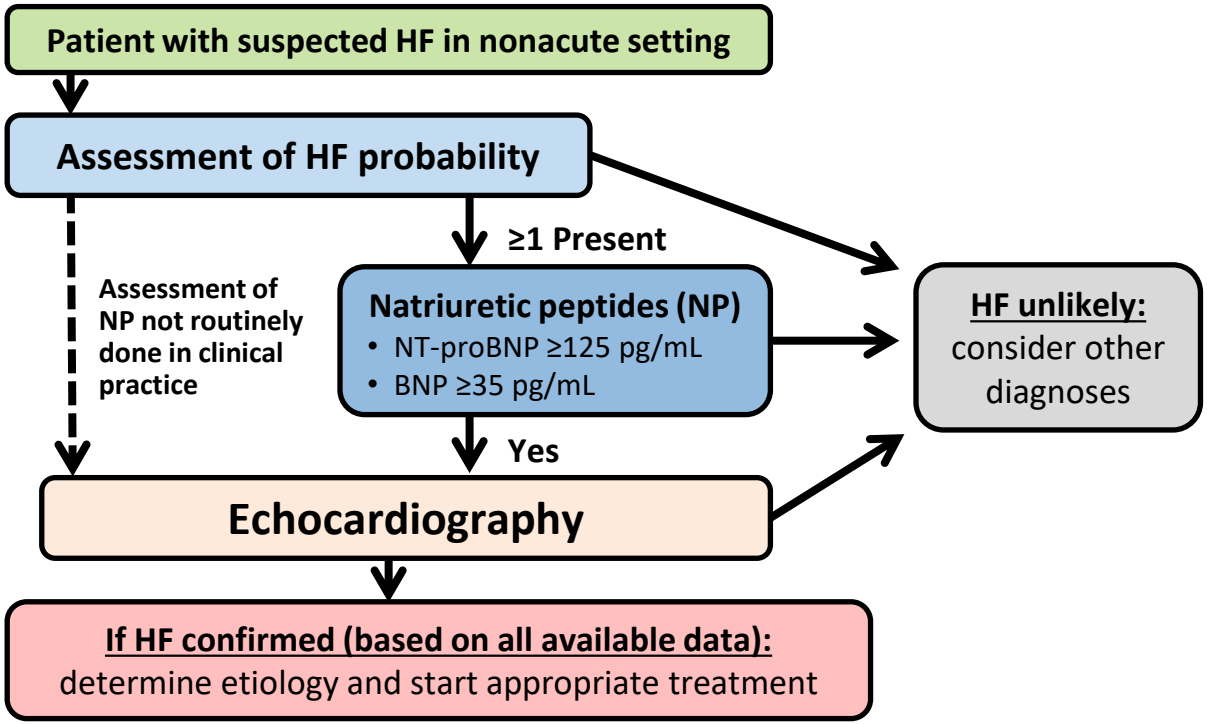
Assessment of HF Probability



CAD, coronary artery disease; MI, myocardial infarction.

Ponikowski P, et al. *Eur J Heart Fail*. 2016;18(8):891-975.

Diagnosis of HF



BNP, B-type natriuretic peptide; NT-proBNP, N-terminal pro BNP.

Ponikowski P, et al. *Eur J Heart Fail*. 2016;18(8):891-975.

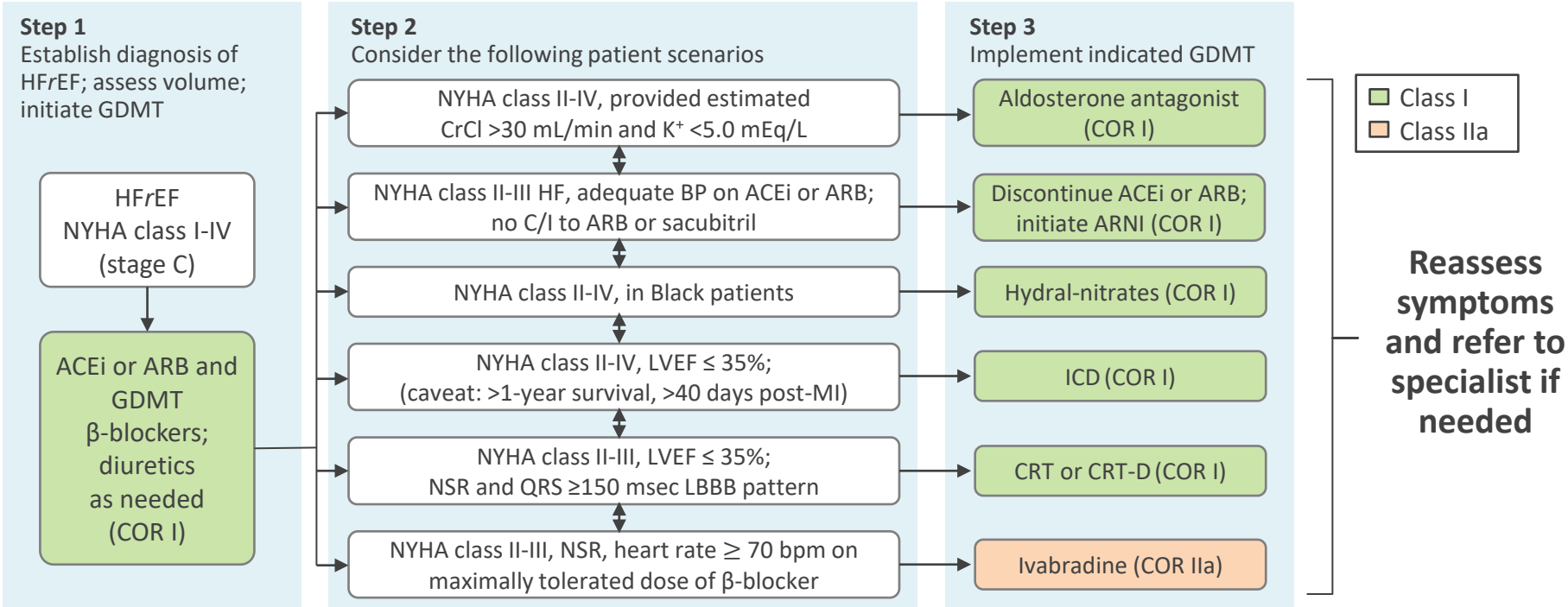
ESC Guidance on Management of CVD During the COVID-19 Pandemic

- The risk of COVID-19 infection may be higher in chronic HF patients due to the advanced age and presence of several comorbidities.
- Ambulatory stable HF patients (with no cardiac emergencies) should refrain from hospital visits.
- GDMT (including beta-blocker, ACE inhibitor, ARB, or sacubitril/valsartan and MRA), should be continued in chronic HF patients, irrespective of COVID-19.

ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; CVD, cardiovascular disease; MRA, mineralocorticoid receptor antagonist.

The European Society for Cardiology. ESC guidance for the diagnosis and management of CV disease during the COVID-19 pandemic. Updated June 10, 2020. https://www.escardio.org/Education/COVID-19-and-Cardiology/ESC-COVID-19-Guidance

Treatment of Stage C-D HF*r*EF



ARNI, angiotensin receptor–neprilysin inhibitor; C/I, counterindication; COR, class of recommendation; CrCL, creatinine clearance; CRT, cardiac resynchronization therapy; CRT-D, CRT with device; ICD, implantable cardioverter-defibrillator, LBBB, left bundle branch block; LVEF, left ventricular ejection fraction; NSR, normal sinus rhythm; NYHA, New York hear association.

Yancy CW, et al. *Circulation*. 2013;128(16):e240-e327; Bloom MW, et al. *Nat Rev Dis Primers*. 2017;3:17058.

2017 Focused Update of the 2013 Guideline for the Management of HF

Class (Strength) of Recommendation		Level (Quality) of Evidence	
I (Strong)	Benefit >>> Risk	A	High quality
IIa (Moderate)	Benefit >> Risk	B-R	Moderate quality, randomized
IIb (Weak)	Benefit ≥ Risk	B-NR	Moderate quality, non-randomized
III: No Benefit (Moderate)	Benefit = Risk	C-LD	Limited data
III: Harm (Strong)	Risk > Benefit	C-EO	Expert opinion

Yancy CW, et al. *Circulation*. 2013;128(16):e240-e327.

Treatment of Stage C HF*r*EF

	COR	LOE	Recommendation
NEW	I	ACE-I: A ARB: A ARNI: B-R	The clinical strategy of **inhibition of the RAAS with ACEi's, ARBs, or ARNIs in conjunction with evidence-based β-blockers and aldosterone antagonists in selected patients is recommended for patients with chronic HF*r*EF** to reduce morbidity and mortality.
	I	ACE-I: A	The **use of ACEi's is beneficial for patients with prior or current symptoms of chronic HF*r*EF** to reduce morbidity and mortality.
	I	ARB: A	The use of **ARBs to reduce morbidity and mortality is recommended in patients** with prior or current symptoms of chronic HF*r*EF **who are intolerant to ACEi's** because of cough or angioedema.
NEW	I	ARNI: B-R	In patients with chronic symptomatic HF*r*EF NYHA class II or III who tolerate an ACEi or ARB, **replacement by an ARNI is recommended to further reduce morbidity and mortality**.
NEW	III: Harm	B-R	**ARNI should not be administered concomitantly with ACEi's** or within 36 hours of the last dose of an ACEi.
NEW	III: Harm	C-EO	**ARNI should not be administered to patients with a history of angioedema**.
NEW	IIa	Iva: B-R	**Ivabradine can be beneficial to reduce HF hospitalization for patients with symptomatic (NYHA class II-III) stable chronic HF*r*EF (LVEF ≤35%) who are receiving GDMT**, including a β-blocker at maximum tolerated dose, and who are in sinus rhythm with a heart rate of 70 bpm or greater at rest.

Iva, ivabradine; LOE, level of evidence.

Yancy CW, et al. *Circulation*. 2013;128(16):e240-e327.

Treatment of Stage C HF*p*EF

	COR	LOE	Recommendation
	I	B	**Systolic and diastolic blood pressure should be controlled** in patients with HF*p*EF in accordance with published clinical practice guidelines to prevent morbidity.
	I	C	**Diuretics should be used for relief of symptoms due to volume overload** in patients with HF*p*EF.
	IIa	C	Coronary revascularization is reasonable in patients with CAD in whom symptoms (angina) or demonstrable MI is judged to be having an adverse effect on symptomatic HF*p*EF despite GDMT.
	IIa	C	Management of AF according to published clinical practice guidelines in patients with HF*p*EF is reasonable to improve symptomatic HF.
	IIa	C	The **use of β-blockers, ACEi's, and ARBs in patients with hypertension is reasonable** to control blood pressure in patients with HF*p*EF.
NEW	IIb	B-R	In appropriately selected patients with HF*p*EF, **aldosterone receptor antagonists might be considered to decrease hospitalizations**.
	IIb	B	The use of **ARBs might be considered to decrease hospitalizations** for patients with HF*p*EF.
NEW	III: No Benefit	B-R	**Routine use of nitrates or phosphodiesterase-5 inhibitors to increase activity or QoL** in patients with HF*p*EF is **ineffective**.
	III: No Benefit	C	Routine **use of nutritional supplements is not recommended** for patients with HF*p*EF.

AF, atrial fibrillation; QoL, quality of life.

Yancy CW et al. *Circulation*. 2013;128(16):e240-e327.

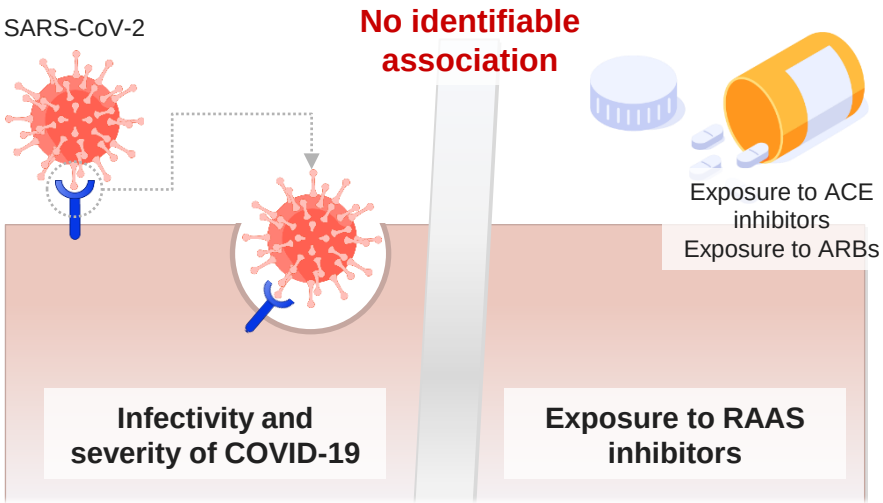
Recommendations for Hypertension

	COR	LOE	Recommendation
NEW	I	B-R	In patients at increased risk, stage A HF, the optimal blood pressure in those with hypertension should be **<130/80 mm Hg**.
NEW	I	C-EO	Patients with HF*r*EF (stage C) and hypertension should be prescribed GDMT titrated to **attain systolic blood pressure <130 mm Hg**.
NEW	I	C-LD	Patients with HF*p*EF and persistent hypertension after management of volume overload should be **prescribed GDMT titrated to attain systolic blood pressure <130 mm Hg.**

Yancy CW, et al. *Circulation*. 2013;128(16):e240-e327.

Use of RAAS Inhibitors & COVID-19

- Previous treatment with ACEi/ARB in patients with COVID-19 has ***no effect*** on mortality, HF, hospitalization, or ICU admission



SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

Son M, et al. *Hypertension.* 2020;76:742–749; Lopez-Otero D, et al. *Rev Esp Cardiol* (Engl Ed). 2020 Jun 5;
Sriram K, et al. *Clin Pharmacol Ther*. 2020 Aug;108(2):236-241

CV Society Recommendations on RAAS Antagonists in the COVID-19 Patient

Society	Pub Date	Recommendation
AHA/HFSA/ACC	Mar 17, 2020	Continuation of ACEis/ARBs in COVID-19 patients with preexisting indications (HF, HTN, CAD) Careful consideration prior to addition/ discontinuation of any CVD treatments in COVID-19 patients
Canadian CV Society	Mar 20, 2020	Continuation of ACEi/ARB/ARNi unless clinically contraindicated (symptomatic hypotension, shock, AKI, hyperkalemia)
ESC Council on HTN	Mar 13, 2020	Continue antihypertensive treatment
European Society of HTN	Apr 15, 2020	Stable COVID-19 patients should continue ACEi/ARB treatment according to 2018 ESC/ESH guidelines Assess COVID-19 patients with severe symptoms, sepsis, or hemodynamic instability on a case-by-case basis for the discontinuation of blood pressure lowering drugs, with consideration for current guidelines
HTN Canada	Mar 13, 2020	Continue antihypertensive treatment
International Society of HTN	Mar 16, 2020	Routine use of ACEi's/ARBs in hypertensive patients despite COVID-19 concerns

ACC, American College of Cardiology; AHA, American Heart Association; AKI, acute kidney injury; ESC, European Society of Cardiology; ESH, European Society of Hypertension; HFSA, Heart Failure Society of America; HTN, hypertension.

New Indications for HF*p*EF

- Sacubitril/valsartan
  - FDA advisory committee voted 12-1 to approve for **treatment of HF*p*EF**
  - PARAGON-HF trial
- Spironolactone
  - FDA advisory committee voted 8-4 to approve for **reduction of HF hospitalization**
    - **HF with mildly-reduced or midrange EF: LVEF of 40% to 57%**
  - TOPCAT Trial

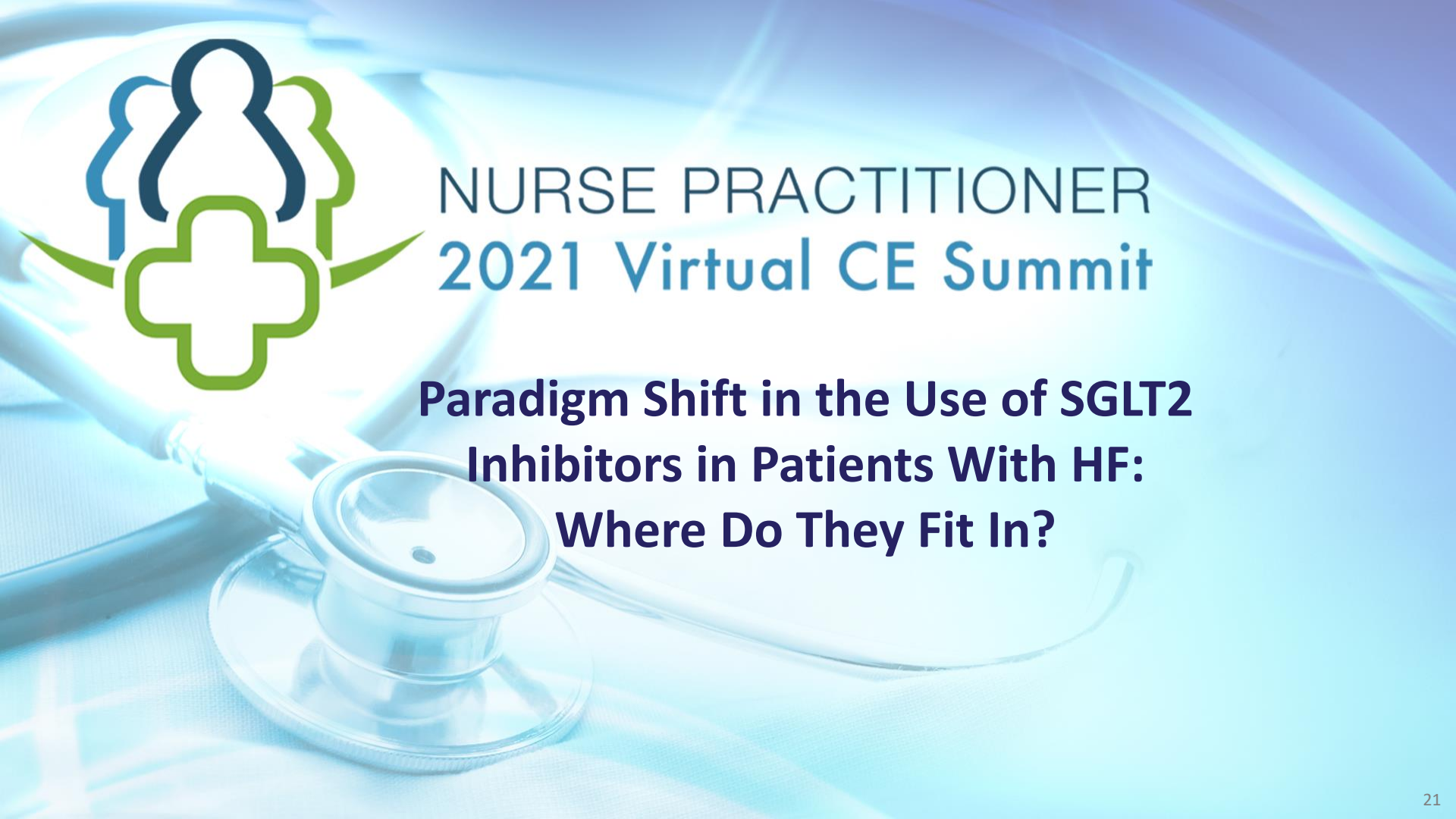
Keown A. Novartis' Entresto on track for new FDA approval following successful AdComm. Biospace. Dec 16, 2020. https://www.biospace.com/article/novartis-entresto-clears-fda-adcomm-for-hfpef
Buzby S. FDA advisory panel endorses spironolactone for HF hospitalization reduction HFpEF. Healio. Dec 16, 2020. https://www.healio.com/news/cardiology/20201216/fda-advisory-panel-endorses-spironolactone-for-hf-hospitalization-reduction-in-hfpef

New Indications for HF*p*EF

	CHARM-P N = 3023	TOPCAT N = 3445	PARAGON-HF N = 4800
Treatment Arms	Candesartan vs Placebo	Spironolactone vs Placebo	Sacubitril/Valsartan vs Placebo
LVEF Inclusion Criteria	LVEF > 40%	LVEF ≥ 45%	LVEF > 45%
Endpoint	First of either CVD or HFH	First of either CVD, HFH, or RSD	CVD and total HFH (first and recurrent)
Hospitalizations HR (95% CI)	HR 0.78 (0.59–1.03)	HR 0.98 (0.74–1.30)	HR 0.85 (0.72–1.00)
LVEF Subgroup	LVEF 40–49% HR 0.48 (0.33-0.70)	LVEF <50% HR 0.76 (0.46-1.27)	LVEF <57% HR 0.78 (0.64-0.95)

HFH, heart failure hospitalization.

Gronda E, et al. *Eur Heart J Suppl*. 2020;22(suppl):L77-L81.



Paradigm Shift in the Use of SGLT2 Inhibitors in Patients With HF: Where Do They Fit In?

DAPA-HF Trial

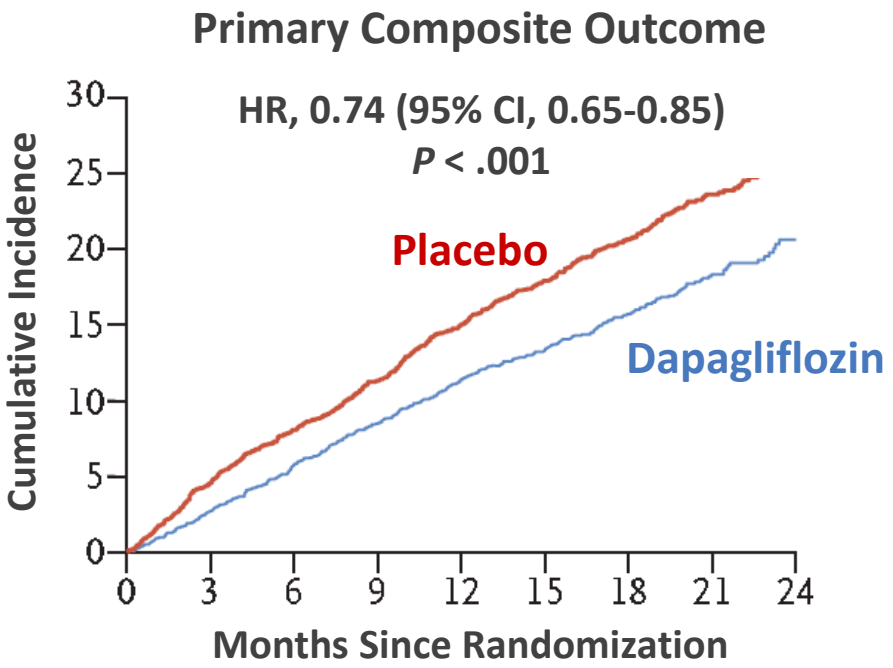
- Phase 3 placebo-controlled trial
- First to examine benefit of SGLT2 inhibitors in patients with HF
  - Regardless of DM status
- 4744 patients with HF*r*EF
  - NYHA Class II, III, or IV HF and LVEF ≤40%
- Dapagliflozin (10 mg once daily) or placebo
- Primary outcome: composite of worsening HF* or CV death

*Hospitalization or an urgent visit resulting in intravenous therapy for HF.
DM, diabetes mellitus; SGLT2, sodium-glucose transport protein 2.
McMurray JJV, et al. *N Engl J Med*. 2019;381(21):1995-2008.

DAPA-HF: Primary Outcome

Median follow-up:
18.2 months

	HR or RR or difference (95% CI)
Primary composite outcome	**0.74 (0.65 to 0.85) *P* < .001**
Hospitalization or an urgent HF visit	0.70 (0.59-0.83)
HHF	0.70 (0.59-0.83)
Urgent HF visit	0.43 (0.20-0.90)
CV death	0.82 (0.69-0.98)



RR, risk ratio.

McMurray JJV, et al. *N Engl J Med*. 2019;381(21):1995-2008.

EMPORER-Reduced Trial

- Results announced at ESC 2020
- Empagliflozin 10 mg daily vs placebo in 3730 patients
  - HF*r*EF
  - With or without diabetes
  - Already receiving standard of care for HF
- Median follow-up: 16 months
- Primary endpoint: CV death or HHF
  - HR 0.75, 95% CI 0.65-0.86, P < .0001
- Total risk of hospitalizations for HF reduced by 30%
- Adverse renal outcomes reduced by 50%

European Society of Cardiology. Hot line: not just in diabetes – empagliflozin improves outcomes in patients with heart failure in the EMPEROR-Reduced trial. Aug 29, 2020. https://www.escardio.org/Congresses-&-Events/ESC-Congress/Congress-resources/Congress-news/hot-line-not-just-in-diabetes-empagliflozin-improves-outcomes-in-patients-with-heart-failure-in-the-emperor-reduced-trial

VICTORIA Trial

- Phase 3, randomized, double-blind, placebo-controlled trial
- Examine effect of vericiguat* in patients with HF and reduced LVEF, with previous HF hospitalization within 6 months prior to randomization or IV diuretic treatment for HF (without hospitalization) within 3 months
- 5050 patients with CHF
- NYHA Class II-IV and LVEF <45% assessed within 12 months
- Vericiguat (target dose, 10 mg once daily) or placebo, in addition to guideline-based medical therapy
- Primary outcome: Time to first occurrence of composite endpoint of CV death or HF hospitalization

* novel oral soluble guanylate cyclase stimulator

Armstrong PW, Pieske B, Anstrom KJ, et al. Vericiguat in Patients with Heart Failure and Reduced Ejection Fraction. *N Engl J Med*. 2020;382(20):1883-1893. doi:10.1056/NEJMoa1915928; A Study of Vericiguat in Participants With Heart Failure With Reduced Ejection Fraction (HFrEF) (MK-1242-001). ClinicalTrials.gov. Accessed on April 29, 2021. ClinicalTrials.gov

Vericiguat MOA & Primary Outcomes*

Oral, Once-daily sGC Stimulator:

- HF is associated with impaired NO synthesis and decreased sGC activity, which can lead to myocardial and vascular dysfunction
- When NO binds to sGC, sGC speeds up production of intracellular cyclic guanosine monophosphate
- Activates sGC, independently and synergistically with NO, to increase intracellular cGMP levels, causing smooth muscle relaxation and vasodilation

sGC=An essential enzyme in the NO signaling pathway

NO=nitric oxide

cGMP=Second messenger that plays a role in management of vascular tone, cardiac contractility, and cardiac remodeling

Outcome	Hazard Ratio (95% CI)†	P Value‡
Primary composite outcome and components Vericiguat (N=2526); Vericiguat (N=2526)		
Death from cardiovascular causes or first hospitalization for heart failure	0.90 (0.82–0.98)	0.02
Death from cardiovascular causes§		
Hospitalization for heart failure		

*Data shown are through the primary analysis cutoff date (June 18, 2019). For patients with multiple events, only the first event that contributed to the composite outcome is counted. CI denotes confidence interval.
† Hazard ratios (vericiguat as compared with placebo) and confidence intervals were calculated with the use of Cox proportional-hazards models controlling for stratification factors (defined according to geographic region and race).
‡ P values were calculated by means of a stratified log-rank test with stratification factors defined according to geographic region and race.
§ Deaths included in the primary and secondary composite outcomes were not preceded by a hospitalization for heart failure.
Patients could have been hospitalized more than once.

VERQUVO (vericiguat) for the Treatment of Heart Failure with Reduced Ejection Fraction. Clinical Trials Arena website; Verdict Media Limited 2021. https://www.clinicaltrialsarena.com/projects/verquvo-vericiguat.aspx. Published Feburay 05, 2021. Accessed May 10,2021. Armstrong PW, Pieske B, Anstrom KJ, et al. Vericiguat in Patients with Heart Failure and Reduced Ejection Fraction. *N Engl J Med.* 2020; 382:1883-1893. DOI: 10.1056/NEJMoa1915928. Accessed May 11, 2021.

2018 ACC Expert Consensus

Considerations for Drug Initiation & Monitoring in Patients Starting SGLT2 with Demonstrated CV Benefit

If A1c well-controlled at baseline/known history of frequent hypoglycemic events, reduce starting therapy dose:

- sulfonylurea 50%
- basal insulin 20%

Avoid hypovolemia
(reduce thiazide or loop diuretic dose)

Instruct patients to closely monitor glucose for first 4 weeks of therapy

Educate patients:

- low BP symptoms
- symptoms of diabetic ketoacidosis
- diabetic ketoacidosis can occur even if blood glucose readings are 150–250 mg/dL
- foot care and follow-up foot pulse examination (particularly canagliflozin)
- monitoring kidney function
- potential for genital mycotic infections

Das SR, et al. *J Am Coll Cardiol*. 2018;72(24):3200-23.

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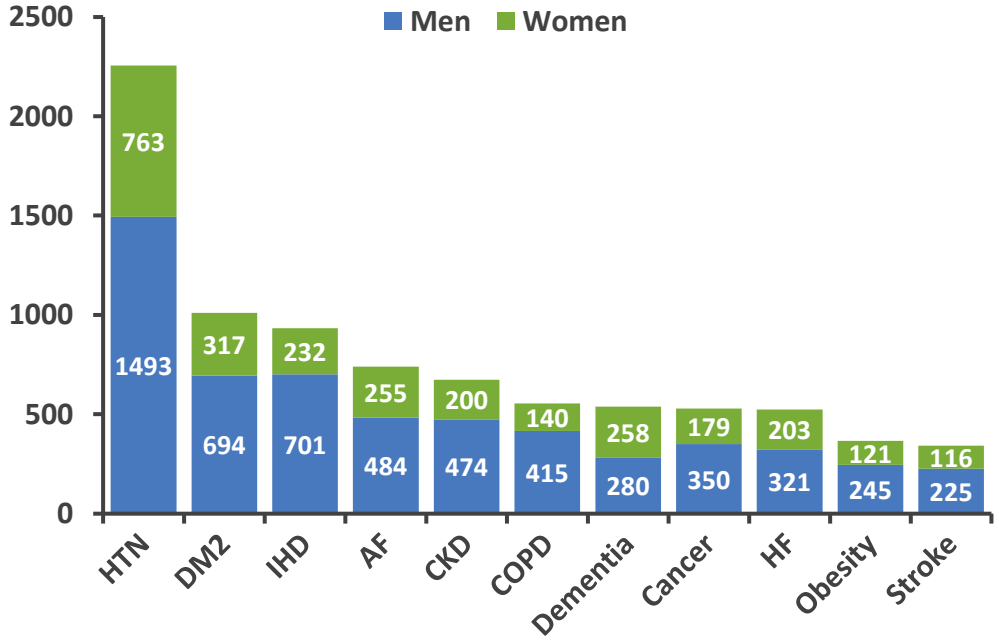
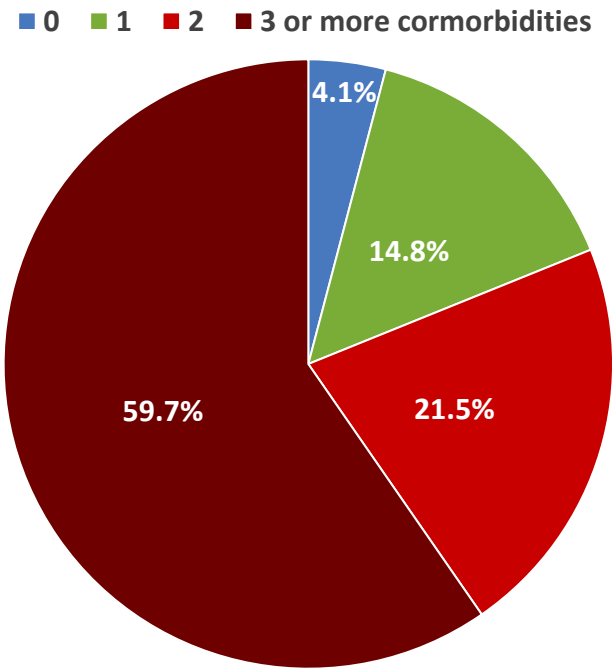
Understanding COVID-19 and Cardiovascular Comorbidities

CV-Related Comorbidities and COVID-19

Chronic Comorbidities Among 3335 Deceased COVID-19 Patients





AF, atrial fibrillation; CKD, chronic kidney disease; IHD, ischemic heart disease.

Mai F, et al. *J Cardiol.* 2020 Nov;76(5):453-458.

Increased Risks of Severe Illness

- Study of 6439 patients admitted for COVID-19
  - **422 (6%) had history of HF**
- Compared to those *without HF* and **independent of LVEF and RAASi treatment**, patients with HF had increased:
  - mLOS: 8 vs 6 days, *P*<0.001
  - Frequency of ICU care: OR 1.52, 95% CI 1.20-1.92, *P*=0.001
  - Intubation/mechanical ventilation: OR 2.18, 95% CI 1.71-2.77, *P*<0.001
  - Mortality: OR 2.02, 95% CI 1.65-2.48, *P*<0.001

33% Longer Hospitalization

52% Increase in ICU Care

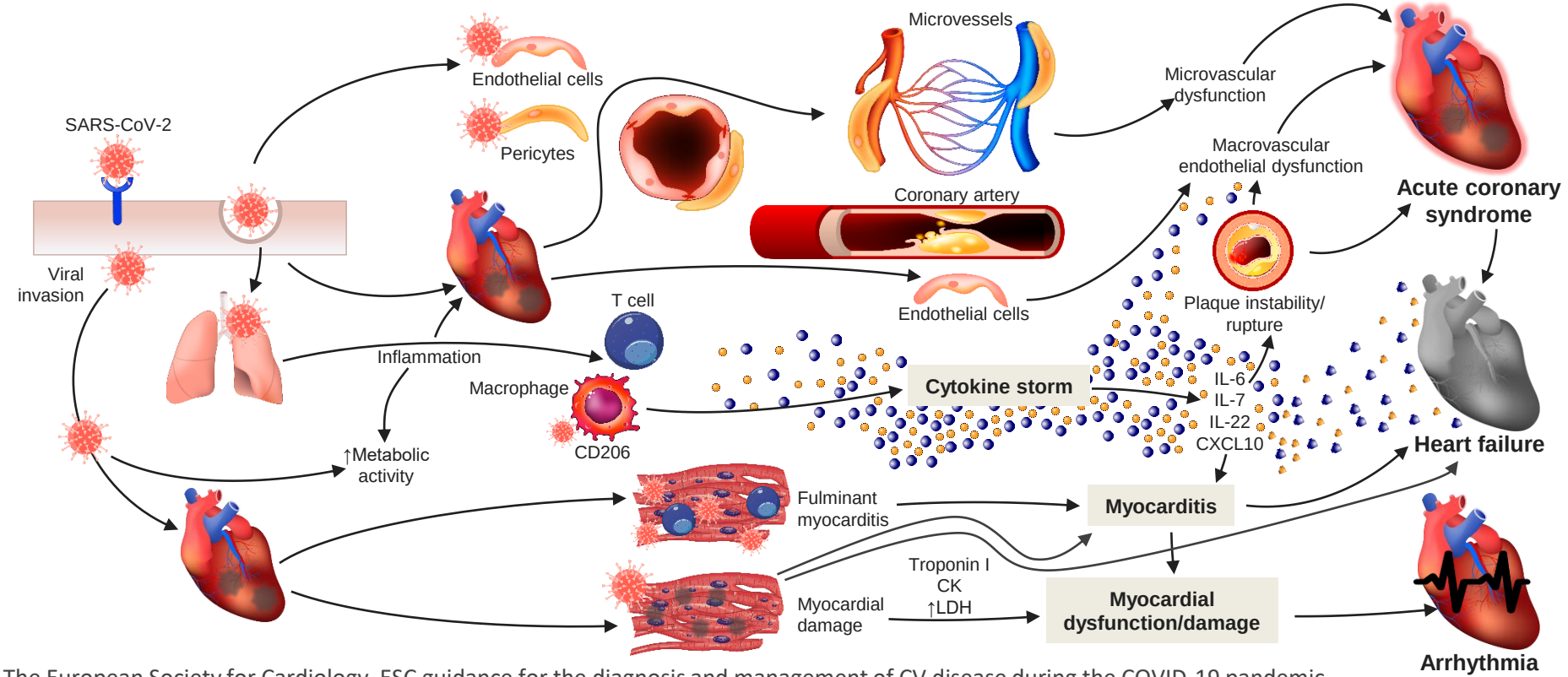
2x Intubation/ Mech. Vent.

2x Mortality

mLOS, minimum length of stay.

Alvarez-Garcia J, et al. *J Am Coll Cardiol*. 2020;76(20):2334-2348.

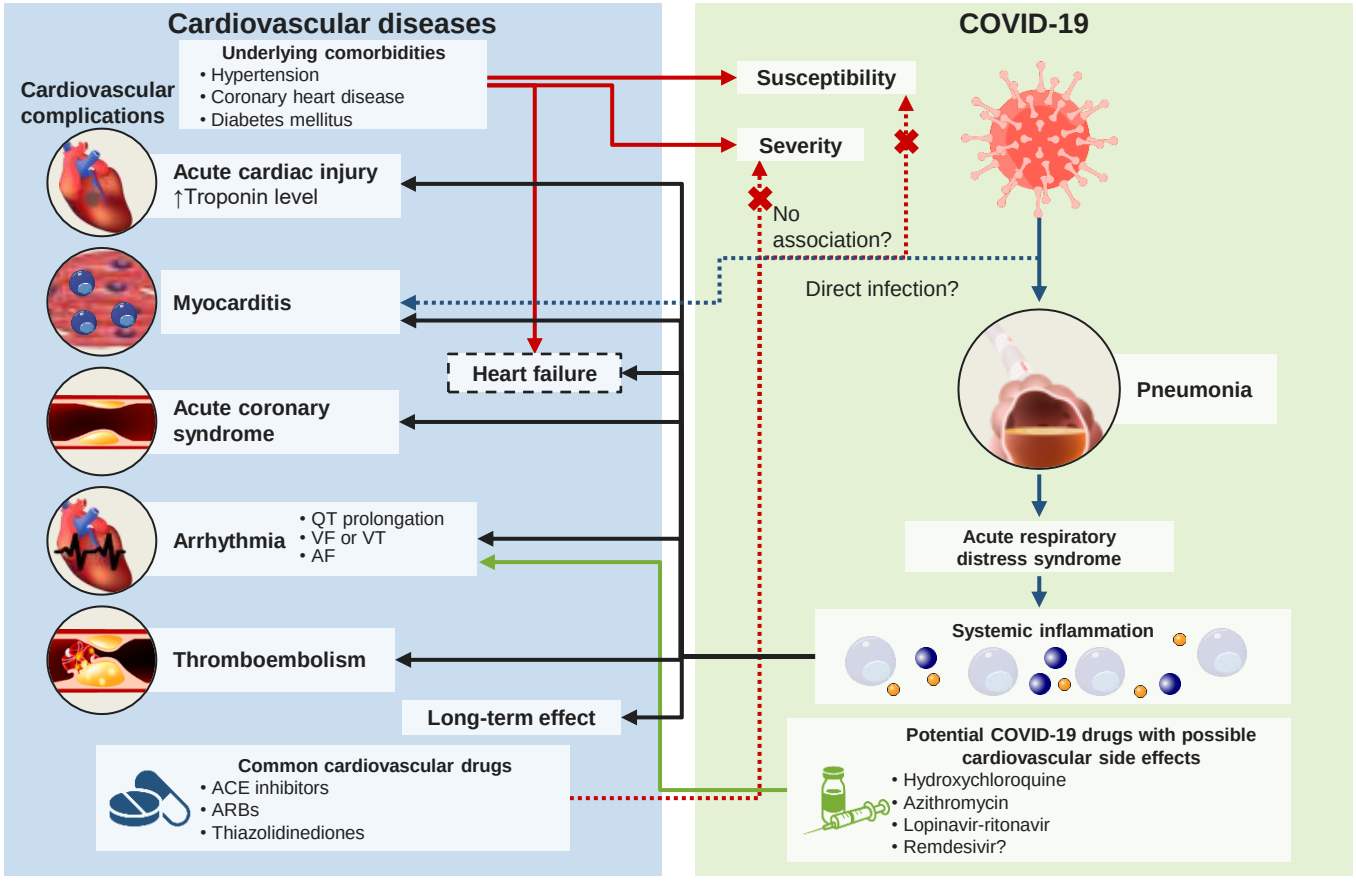
SARS-CoV-2 and COVID-19



The European Society for Cardiology. ESC guidance for the diagnosis and management of CV disease during the COVID-19 pandemic. Updated June 10, 2020. https://www.escardio.org/Education/COVID-19-and-Cardiology/ESC-COVID-19-Guidance

A Dangerous Cycle

Growing evidence suggests that ***patients who contract COVID-19 are at increased risk of developing CV-related comorbidities as a result of infection.***

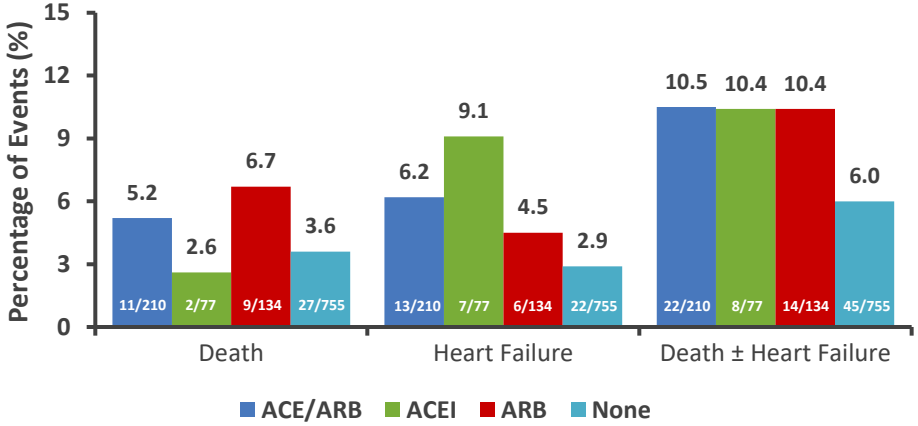


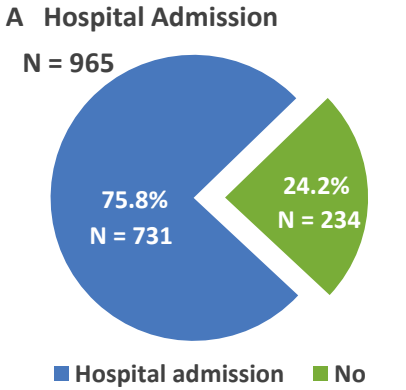
VF, ventricular fibrillation;
VT, ventricular tachycardia.

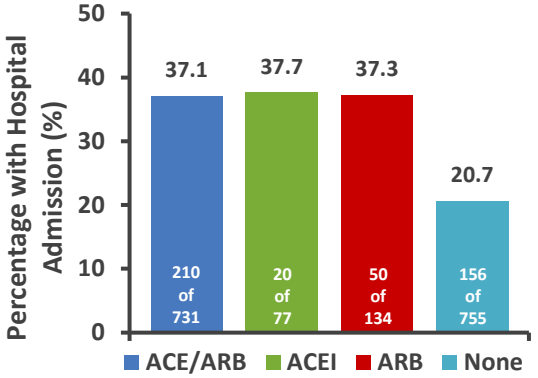
Nishiga M, et al. *Nat Rev Cardiol*. 2020;17(9):543-558.

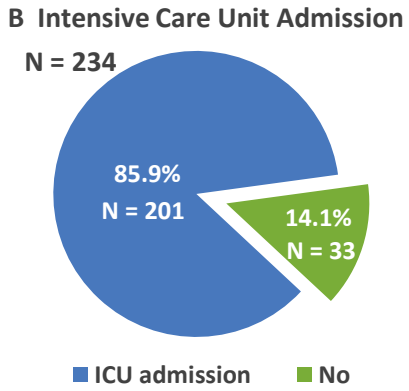
Use of RAAS Inhibitors & COVID-19

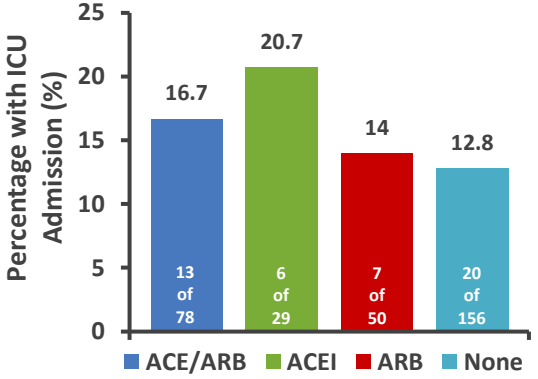
Outcome	OR (95% CI)	P-value
Mortality	0.62 (0.17-2.26)	*P* = .486
HF	1.37 (0.39-4.77)	*P* = .622
Hospitalization	0.85 (0.45-1.64)	*P* = .638
ICU admission	1.06 (0.39-2.83)	*P* = .915



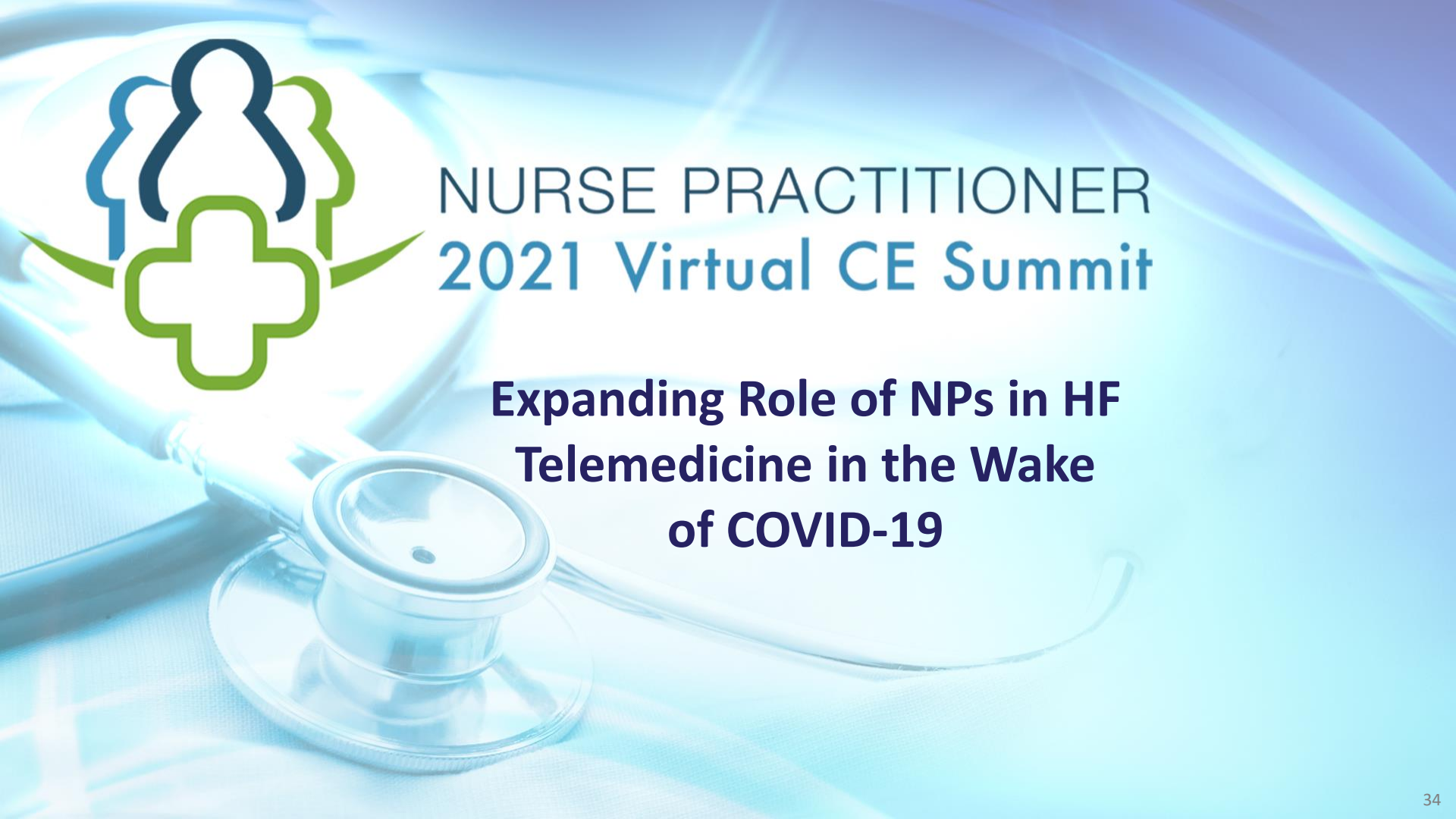








Lopez-Otero D, et al. *Rev Esp Cardiol* (Engl Ed). 2020 Jun 5.



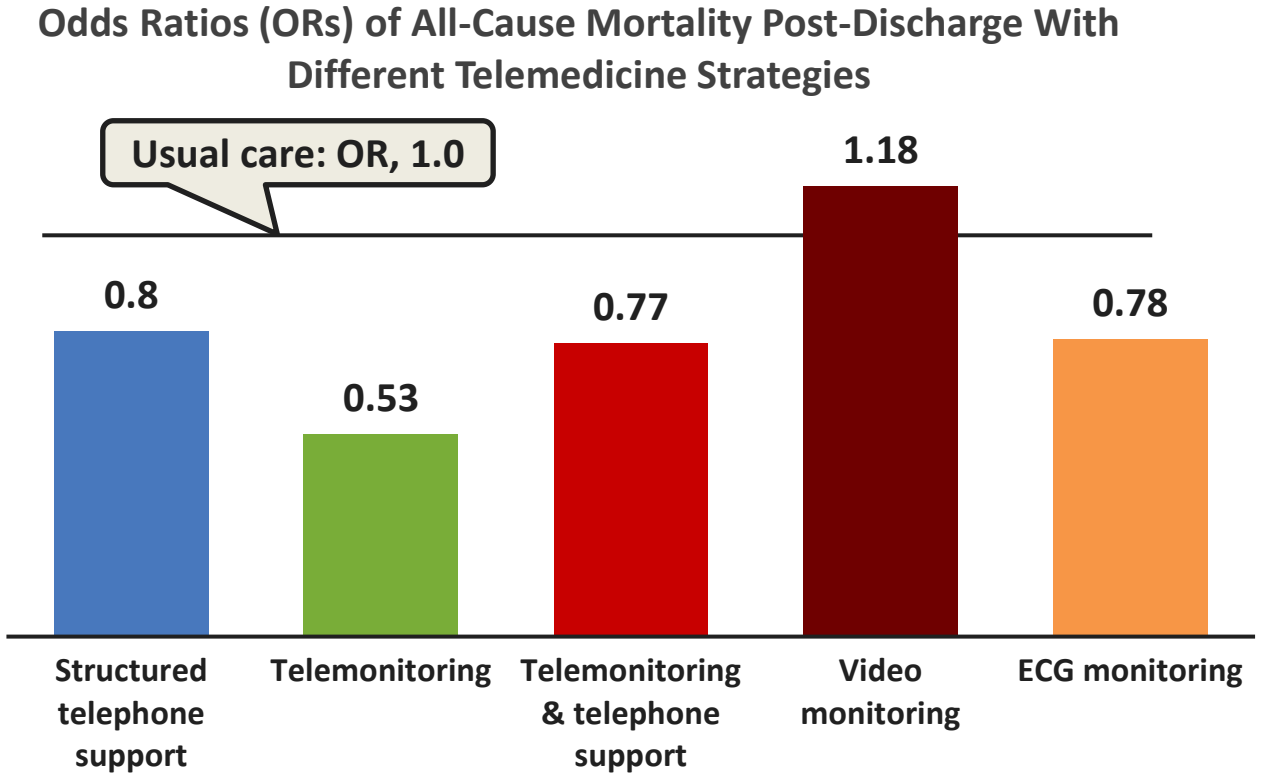
Expanding Role of NPs in HF Telemedicine in the Wake of COVID-19

Telemedicine: CMS & How We Got Here

- To reduce transmission of COVID-19, healthcare systems have transitioned to noncontact care delivery
- In early March 2020, CMS broadened access to telehealth services
  - Coronavirus Preparedness and Response Supplemental Appropriations Act
- Through telehealth, physicians can
  - Maintain face-to-face interactions with their patients
  - Gain familiarity with patients' domestic circumstances
  - Obtain vital sign measurement through home blood pressure cuffs, pulse oximeters, and scales
  - Perform limited physical examinations for jugular venous distention, peripheral edema, peripheral catheter and driveline site integrity, and functional capacity
  - Reconcile medications through direct visualization of pill containers
  - Interact with caregivers

Telemedicine Is an Effective Care Component

- Improve CV outcomes
- Reduces
  - Hospitalizations
  - ED visits
  - Illness severity
  - Financial burden

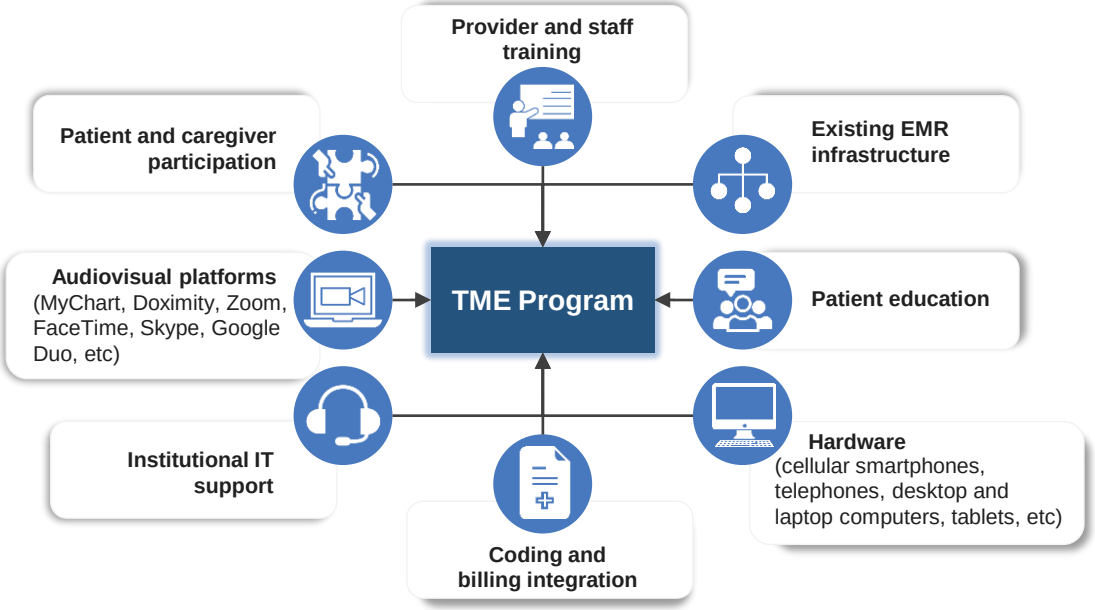


ECG, electrocardiogram; ED, emergency department.
Kotb A, et al. *PLoS One.* 2015;10(2):e0118681.

Implementation Guide for Rapid Integration of an Outpatient Telemedicine Program amidst the COVID-19 Pandemic

"Telemedicine should be considered whenever possible to provide medical advice and follow up of stable HF patients."

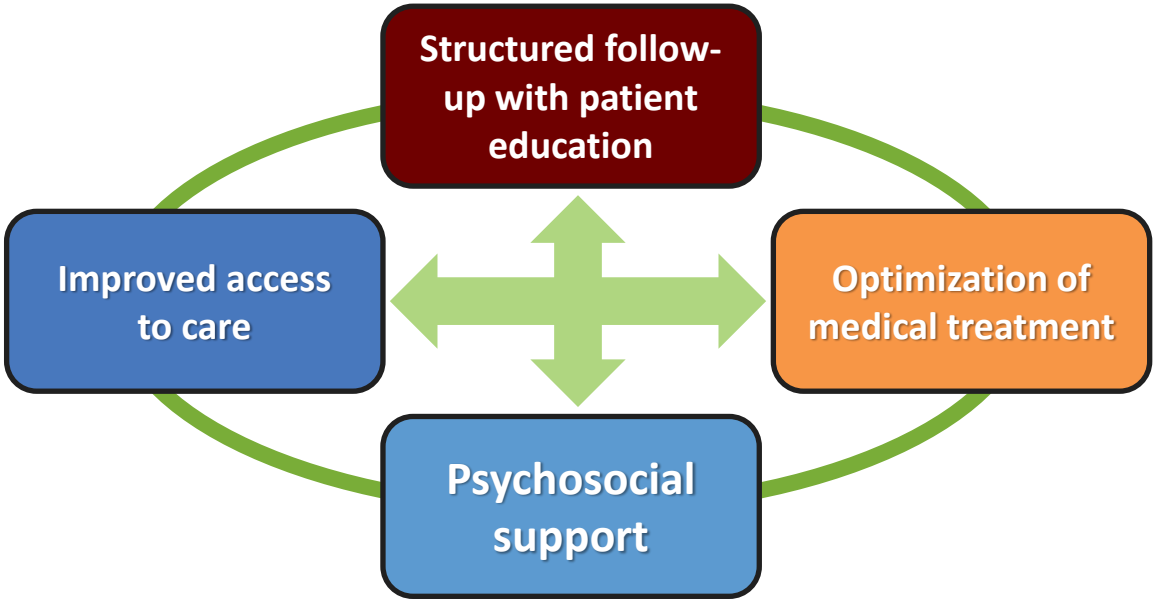
–ESC Guidance on Management of CVD During the COVID-19 Pandemic



The European Society for Cardiology. ESC guidance for the diagnosis and management of CV disease during the COVID-19 pandemic. Updated June 10, 2020. https://www.escardio.org/Education/COVID-19-and-Cardiology/ESC-COVID-19-Guidance
Adapted from Smith WR, et al. *J Am Coll Surg.* 2020;231(2):216-222.e2. Available at: https://www.eurekalert.org/multimedia/pub/230767.php

Effective Transitions of Care

"The goal of management of HF is to provide a 'seamless' system of care that embraces both the community and hospital throughout the health care journey."



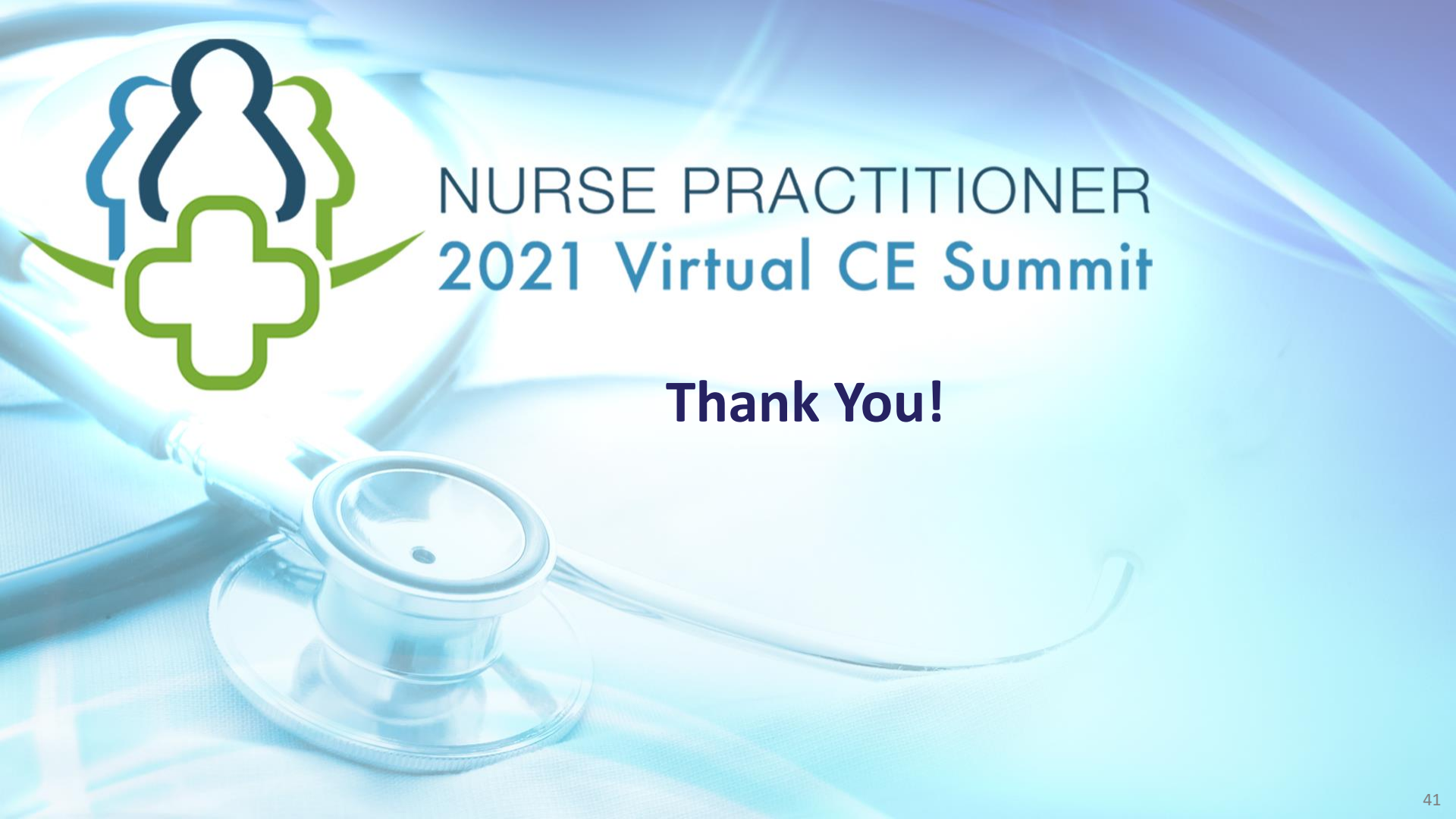
Ponikowski P, et al. *Eur J Heart Fail*. 2016;18(8):891-975.

Summary

- Echocardiography is key to the diagnosis of HF
- Therapy initially relies on the use of ACE inhibitors and beta blockers
- Patients with NYHA class II or III HF and on ACE inhibitors should be transitioned to ARNI
  - ARNI further reduces morbidity and mortality
  - Must have 36-hour washout period between ACE inhibitor and ARNI
  - Sacubitril/valsartan and spironolactone are now approved for HF*p*EF
  - No established risk to patients with RAAS inhibitors/COVID-19
- SGLT2 inhibitors have evolved into cardiovascular risk reduction therapies independent of glycemic control

Summary

- COVID-19 has radically altered the world, particularly healthcare
- Dangerous cycle: COVID-19 infection increases risk of CV comorbidities, and CV comorbidities increase risk of COVID-19 infection
  - Maintaining GDMT more important now than ever
- Telemedicine
  - CMS broadened telehealth in wake of pandemic
  - Should be used whenever possible
  - Important implementation takeaways
  - Patient information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Thank You!