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Best Practice Recommendations for Optimizing Care in Structural Heart Programs: Planning Efficient and Resource Leveraging Systems (PEARLS)

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ABSTRACT

The COVID19 pandemic brought unprecedented disruption to healthcare. Staggering morbidity, mortality, and economic losses prompted the review and refinement of care for structural heart disease (SHD). To mitigate negative impacts in the face of crisis or capacity constraints, this paper offers best practice recommendations for Planning Efficient and Resource Leveraging Systems (PEARLS) in structural heart programs. A systematic assessment is recommended for hospital capacity, Heart Team roles and functions, and patient and procedural risks associated with increased resource utilization. Strategies, tactics, and pathways are provided for the delivery of patient-centered, efficient and resource-leveraging care from referral to follow-up. Through the optimal use of capacity and resources, paired with dynamic triage, forecasting, and surveillance, Heart Teams may aspire to plan and implement an optimized system of care for SHD.

Abbreviations: AS: aortic stenosis; ASD: atrioseptal defect; COVID19: Coronavirus disease 19; LAAO: left atrial appendage occlusion; MI: myocardial infarction; MR: mitral regurgitation; PFO: patent foramen ovale; PVL: paravalvular leak; SHD: structural heart disease; SAVR: surgical aortic valve replacement; SDM: shared decision-making; TAVR: transcatheter aortic valve replacement; TMVr: transcatheter mitral valve repair; TMVR: transcatheter mitral valve replacement; TEE: transesophageal echocardiography; TTE: transthoracic echocardiography.

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The COVID19 pandemic, as tragic as it is, has shined a bright light on many of our processes and created an opportunity to refine patient care for SHD. During the initial surge, case rates decreased markedly for time-sensitive structural heart (SH) procedures. In a survey of cath lab operators (N = 509), 31% reported that SH procedure volumes (TAVR, MitraClip, LAAO) decreased by $\geq 90\%$.¹ Patients waiting for TAVR were found to have a cardiac event rate of 10% in the first month and 35% within 3 months.² Staff were eliminated or took pay cuts; furloughs occurred in over 266 hospitals.³ Financial losses in the U.S. are estimated to be 202 USD billion or 51 USD billion per month from canceled elective surgeries, deferred non-elective surgeries, and outpatient treatment.⁴ Case rates and deaths continue to

increase, revealing staggering regional variation in hospital capacity and health disparities.⁵

The “new normal” remains elusive as vaccinations are not yet widely available and the virus continues to mutate. Societal statements describe what the Heart Team should do in the face of this crisis; however, there is minimal information on *how* new and experienced SHD programs might accomplish these efforts during the COVID19 pandemic or another future event. To mitigate negative impacts in the face of crisis or capacity constraints, this paper offers best practice recommendations to implement optimal care in SH programs. As clinicians and leadership with responsibility for best practice utilization and its oversight, we propose a framework with operational detail for SH programs to use at the front-line.

Planning Efficient and Resource Leveraging Systems (PEARLS)

Envisioning optimal care

Optimal care is informally described as *the right care for the right patient in the right place at the right time*.⁶ Patient goals and preferences are at the center of the treatment plan.^{7,8} A risk versus benefit analysis incorporates patient, physician, and hospital-level considerations. Novel to this decision-making process in the U.S. are the principles of resource allocation and resource leveraging.⁹ A systematic assessment is recommended for hospital capacity, Heart Team roles and functions, and patient and procedural risks associated with increased resource utilization. A common taxonomy and framework of strategies, tactics, and pathways can facilitate the delivery of patient-centered, efficient, and resource-leveraging care from referral to follow-up. These PEARLS imperatives (Figure 1) apply but are not limited to TAVR, TMVr (MitraClip), TMVR, including mitral valve-in-(surgical prosthetic) valve and valve-in-native mitral annular calcification (valve-in MAC), paravalvular leak closure, LAAO, and transcatheter closure of PFO or ASD.

Assess capacity and constrained resources

A meaningful increase in demand reveals existing constraints of *capacity*: the staff, supplies, and space (also collectively referred to as resources) required for care delivery.¹⁰ Prior to the COVID19 pandemic, the exponential growth of transcatheter SHD therapy coupled with declining hospital capacity created a surge state for many programs. From 2014 to 2018, U.S. procedural volumes

increased 278% for TAVR and 523% for TMVr.¹¹ The tsunami of valvular heart disease swells with an aging population, advancements in technology, and expanding therapeutic indications.¹² Epidemiological models predict an annual demand of 80,076 eligible U.S. candidates.¹³ Capacity planning to accommodate these patients, however, is fraught with challenges. The U.S. private health system has no central governance, little integration and coordination, and limited access to care. Due to mergers, closures, and labor shortages, the numbers of hospitals and staffed hospital beds have grown less than 5% in the last 5 years.¹⁴ Emergency room diversion, delayed hospital transfers and discharges, prolonged lengths of stay, and staffing shortages negatively affect access, quality, and costs.^{15,16} Prolonged wait times to treatment, particularly for patients with symptomatic severe valvular heart disease, are associated with increased morbidity, mortality, and costs.¹⁷⁻²⁰ Ultimately, external factors (e.g., geographical COVID19 penetration), hospital capacity, and their constraints determine the restriction or ramp-up of services.²¹ The capacity continuum includes three phases.

- (1) Conventional capacity: space, staff, and supplies are consistent with daily practice within the institution.
- (2) Reduced capacity: space, staff, and supplies are not consistent with daily practice but maintain minimal impact on usual patient care practices; what is used when demands exceed resources.
- (3) Restricted capacity: Adaptive spaces, staff, and supplies are not consistent with the usual standard of care but provide sufficient care in the setting of severe restrictions in services (e.g., pandemic).

Capacity should be assessed to determine whether processes and timelines to treatment must be reset. A hospital with conventional capacity may treat patients without restrictions. In contrast, a hospital with restricted capacity may defer procedures. For certain types of crisis (e.g., pandemic, natural disasters) a *parallel care pathway* may be designated for urgent and time-sensitive treatment, particularly if patient care must be contained in a designated area to prevent undue risk (e.g., infection transmission or injury). In the current context, a distinct COVID19-negative pathway may be defined locally with supportive screening, testing, and staffing protocols.

Triage incorporates acuity, risk stratification, and resource utilization

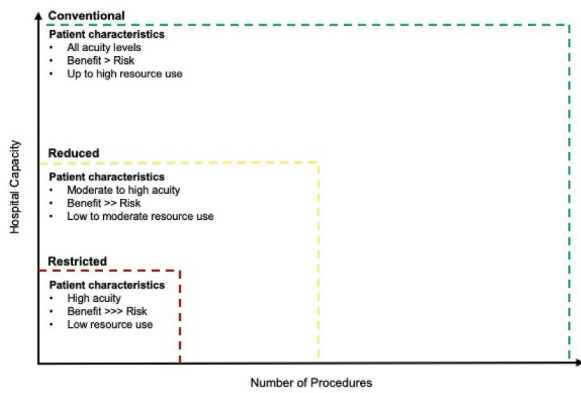
The Heart Team should adopt a system for site-specific triage,²² forecasting, and surveillance that is evidence-based, guideline-directed, effectively communicated, and aligned with the clinical pathway.^{8,23} Triage is defined here as a process of sorting patients into priority groups according to their needs, risks, and the resources available.²² Patients most likely to survive or benefit and require the least resources are given the highest priority in traditional triage models.²² Conversely, guidelines for SHD triage have not explicitly characterized the use of resources along with

PEARLS

Planning Efficient and Resource Leveraging Systems

- **Assess hospital capacity and constrained resources**
- **Triage based on acuity, benefit vs. risk analysis, resource utilization**
- **Forecast timeline to treatment according hospital capacity and triage**
- **Provide surveillance and dynamic triage between clinical touchpoints**
- **Designate roles and cross-train the team**
- **Minimize gaps from referral to follow-up across the system of care**
- **Communicate frequently and routinely to share successes and challenges**

Figure 1. PEARLS imperatives.



	Restricted Capacity Severe restriction of services	Reduced Capacity Moderate restriction of services	Conventional Capacity Site-specific 'normal' provision of services
Procedures	Cases may include • TAVR • TMVr	Cases may include • TAVR • TMVr • TMVR	May include all typical cases, including but not limited to: TAVR, TMVr, TMVR, LAAG, PVL closure, PFO/ASD closure
Case cadence	• Hold most cases • Patient referral to an alternate facility if warranted and feasible	• Re-evaluate normal case cadence • Reset thresholds for triage and timelines to treatment	Consistent with hospital norms
Heart Team functions	Essential Heart Team functions	Heart Team functions may be modified and reassessed	Conventional Heart Team functions
Resource utilization	Judicious use of resources	Resource utilization may be modified and reassessed	Conventional resource utilization
Capacity assessment	Ongoing dynamic assessment of available staff, space, and supplies	Reassess availability of staff, space and supplies daily	Reassess availability of staff, space, and supplies weekly
Operational assistance	Regional assistance required May require national assistance	Health system assistance required May require regional assistance	No assistance required

Figure 2. Provision of services based on capacity and triage.

treatment urgency and patient risk.^{24–26} PEARLS triage schema categorizes four elements: (1) patient goals, benefit and risk stratification; (2) patient acuity; (3) patient estimated resource utilization, emphasizing periprocedural risk stratification and procedural needs, anticipated length of stay, discharge disposition, and patient needs for recovery;^{27–33} and (4) capacity and provision (restriction) of services^{21,24} (Figure 2). Triage criteria are differentiated prior to (Figure 3) and after treatment (Figure 4).

Forecast according to triage and hospital capacity

Informed by triage, forecasting describes actively projecting a timeline and assigning a date for evaluation and treatment. In other words, a schedule is forecasted according to patient-level data (e.g., patient goals, coordination needs, and triage class), combined with hospital-level data (e.g., projected capacity). When capacity is affected by major events like pandemics, modeling tools may be used to assist with this process.⁵ As the SH program leverages available resources at all levels of hospital capacity, triage and forecasting functions akin to the management of a transplant waitlist however with ubiquitous device therapy.

A crisis like the COVID19 pandemic may result in team/staff absences or redeployments. Resources may be

redistributed to another service. Together these impacts may limit not only treatment but also the availability of diagnostic studies and consulting clinicians. Patients and families must be fully supported by the clinical coordination team and made aware of the possibility of schedule changes. Setting the expectation of a dynamic schedule may create a degree of stress for patients and families but less so than an unexpected cancellation. This also allows for patients with flexibility in scheduling to be evaluated or treated sooner should the opportunity arise. In the event of limited physician availability, coverage by another qualified provider should be arranged whenever possible.

Forecasting requires that program capacity and demand are quantified. A mismatch results in the expansion or restriction of services. It is recommended that the Heart Team track the number of patients referred (possible procedural demand); the yields and wait times from referral to treatment (throughput); and the total number of patients for which the program is responsible from referral to follow-up (known total demand). Attention must be paid in particular to patients with symptomatic severe AS awaiting TAVR. Observational data suggest that mortality increases waiting for treatment. Malaisrie and colleagues¹⁷ found that mortality waiting for TAVR (N = 1108) was 10.4%, 23.3%, and 27.5% at 3, 6, and 12 months, respectively.¹⁷ Attesting to the limited evidence and tenuous nature of these patients, specific wait time thresholds for forecasting TAVR cases are not described in societal guidelines.^{34,35} During the COVID19 pandemic, Shah et al.³⁵ specified a 3 month period of postponement for truly asymptomatic clinically stable patients. Weekly surveillance was recommended although this may not be necessary for all patients or, depending on staffing, feasible for all programs.³⁵

Continue surveillance between intervals of care

Surveillance frequency is aligned with the acuity and triage class (i.e., a higher risk patient requires more frequent surveillance). Triage and surveillance should continue at routine intervals until a patient is evaluated and treated and after treatment. Surveillance before treatment is focused on preventing clinical deterioration and delays in care. Surveillance after treatment is focused on ensuring safe, optimal recovery and preventing adverse events such as readmission³⁶ (see Figures 3 and 4). Telehealth may decrease resource utilization and exposure risk when distancing is required due to a pandemic. Successful telehealth implementation must ensure logistics are favorable for patients and clinicians. Attention must be paid to factors that may increase health disparities such as access to technology and language barriers. Surveillance must also be reframed to continue over the lifespan, in partnership with the primary cardiologist and primary care provider, especially for younger patients who are anticipated to require subsequent intervention.

	Level 1 High 1 criteria	Level 2 Moderate	Level 3 Low
Acuity			
Symptoms and presentation	<ul style="list-style-type: none"> • Cardiogenic shock • Syncope • NYHA Class IV • New or unstable angina • Acute valve failure or LV dysfunction • Inpatient presentation 	<ul style="list-style-type: none"> • NYHA Class II-III • Heart failure with reduced EF • Titration of diuretics • Urgent presentation 	<ul style="list-style-type: none"> • NYHA Class II • Stable medication regimen • Elective presentation
Patient Benefit vs. Risk Analysis			
Patient goals	<ul style="list-style-type: none"> • Ambivalent or misaligned with treatment strategy 	<ul style="list-style-type: none"> • Evolving due to dynamic changes in patient status 	<ul style="list-style-type: none"> • Aligned with treatment strategy
Social support	<ul style="list-style-type: none"> • Inadequate 	<ul style="list-style-type: none"> • Limited 	<ul style="list-style-type: none"> • Strong
Cognitive function	<ul style="list-style-type: none"> • Significant cognitive deficit at baseline 	<ul style="list-style-type: none"> • Cognitive deficit at baseline with minimal functional limitations 	<ul style="list-style-type: none"> • No cognitive deficits
Communication	<ul style="list-style-type: none"> • Barriers to accessing care and technology 	<ul style="list-style-type: none"> • Language barrier • Requires assistance or assistive device for health literacy 	<ul style="list-style-type: none"> • Access to care and technology
Frailty	<ul style="list-style-type: none"> • ≥ 2 indices of frailty 	<ul style="list-style-type: none"> • 1 index of frailty 	<ul style="list-style-type: none"> • Highly functional and independent
Chronic conditions	<ul style="list-style-type: none"> • 2 or more of the following chronic conditions: chronic lung disease, chronic kidney disease, liver disease, severe PVD, leukemia, cancer with solid tumor or metastasis 	<ul style="list-style-type: none"> • Atrial fibrillation requiring anticoagulation and/or rate control • Diabetes mellitus requiring pharmacologic therapy 	<ul style="list-style-type: none"> • Stable and well managed on current therapy
Resource Utilization			
Peri-procedural risks and requirements	<ul style="list-style-type: none"> • Anatomical features associated with high risk for conversion to surgery and/or complications • Conduction abnormalities associated with highest risk for PPM (eg, RBBB) • Requires surgical cutdown • Requires critical care 	<ul style="list-style-type: none"> • Anesthesia or TEE • Percutaneous non-transfemoral access • Conduction abnormalities 	<ul style="list-style-type: none"> • Normal rhythm and conduction • Permanent pacemaker • Suitable for percutaneous transfemoral procedure • Suitable for conscious or moderate sedation • Suitable for TTE
Estimated LOS	<ul style="list-style-type: none"> • > 2 days 	<ul style="list-style-type: none"> • 2 days 	<ul style="list-style-type: none"> • Next day discharge
Expected discharge disposition	<ul style="list-style-type: none"> • Post-acute care transfer to rehab or SNF 	<ul style="list-style-type: none"> • Requires additional support at home or baseline residence 	<ul style="list-style-type: none"> • Safe discharge to home
Surveillance			
Frequency of monitoring until procedure	<ul style="list-style-type: none"> • Up to daily 	<ul style="list-style-type: none"> • Weekly 	<ul style="list-style-type: none"> • Every 1-2 weeks

Figure 3. Classification of patient characteristics for triage and surveillance before treatment. Criteria synthesized from multisocietal guidelines and Charlson Comorbidity Index. NYHA, New York Heart Association; LV, left ventricular; EF, ejection fraction; PVD, peripheral vascular disease; SNF, skilled nursing facility.

Designate the clinical coordination team

The Heart Team should designate a clinician-led ‘central command.’ Societal statements for structural heart intervention³⁵ and surge principles²¹ uphold this team as critical for triage, surveillance, and the optimal use of resources. In the U.S., this clinical coordination team may include one or more of the following:

physician; nurse practitioner; physician assistant; nurse coordinator, and/or scheduler.³⁷ The clinical coordination team member is frequently a unique combination of maven, salesperson, and connector. Key defining characteristics include (a) deep content and context expertise of the patients and the program, and (b) effective, routine, and direct communication with patients, families, and the



	Level 1 High 1 criteria	Level 2 Moderate	Level 3 Low
Cognitive and functional status	<ul style="list-style-type: none"> Significant change in cognitive or functional status 	<ul style="list-style-type: none"> Change in neurological status without change in functional status 	<ul style="list-style-type: none"> Unchanged from baseline
Device function	<ul style="list-style-type: none"> Significant insufficiency or leak Increased transvalvar gradient requiring imaging surveillance and new medications, change in medication dosage 	<ul style="list-style-type: none"> Moderate insufficiency or leak Increased transvalvar gradient requiring imaging surveillance 	<ul style="list-style-type: none"> Normal device function without insufficiency, leak or gradient
Cardiac conduction	<ul style="list-style-type: none"> New rhythm disturbance (eg, new onset AF) Placement of home monitoring device 	<ul style="list-style-type: none"> Progression of baseline conduction disturbance 	<ul style="list-style-type: none"> Preservation of baseline rhythm
Heart failure	<ul style="list-style-type: none"> Decompensated and hypervolemic Frequent medication titration EF < 20% 	<ul style="list-style-type: none"> Compensated and hypervolemic Diastolic dysfunction Discharged without diuretic Baseline reduced EF 	<ul style="list-style-type: none"> Euvolemic Stable, expected medication regimen
Bleeding or vascular complications	<ul style="list-style-type: none"> Bleeding complication Required transfusion of blood products New or worsening vascular complication (hematoma, pseudoaneurysm) 	<ul style="list-style-type: none"> Hematocrit and hemoglobin stable or recovering Access site stable or improved 	<ul style="list-style-type: none"> None
Antiplatelet/ anticoagulation	<ul style="list-style-type: none"> Warfarin with labile INR Antiplatelet and anticoagulation therapy 	<ul style="list-style-type: none"> New oral anticoagulation 	<ul style="list-style-type: none"> Stable, expected medication regimen
Renal function	<ul style="list-style-type: none"> Renal function with severe change in eGFR as compared to baseline 	<ul style="list-style-type: none"> Renal function with mild to moderate change in eGFR as compared to baseline 	<ul style="list-style-type: none"> Renal function at baseline
Surveillance	<ul style="list-style-type: none"> Discharge call(s) Interim visits likely before 30 days and 1 year by telehealth or in person 	<ul style="list-style-type: none"> Discharge call Determine if visit before 30 days is needed by telehealth or in person 30 days and 1 year by telehealth or in person 	<ul style="list-style-type: none"> Discharge call 30 days by telehealth or in person 1 year

Figure 4. Classification of patient characteristics for triage and surveillance after treatment. EF, ejection fraction; INR, international normalized ratio; eGFR, estimated glomerular filtration rate.

entire footprint of interdisciplinary services. To promote efficiency, it is recommended that these team roles are clearly delineated, and responsibilities are skill-task aligned (Table 1). With role ambiguity or staffing changes, duplicate work and skill-task misalignment may occur, thereby decreasing efficiency. Restoring top-of-license practice should be prioritized to decrease burnout and prevent turnover. An emergency plan and training are critical for waitlist management and patient surveillance should staff shortages (e.g., redeployment, furlough) occur.

The Heart Team, which includes administrative leadership and the clinical team responsible for these processes, should establish and maintain frequent, routine communication. In addition to patient case review, clinical operations including forecasting and procedural scheduling are regularly incorporated into a multidisciplinary Heart Team meeting agenda, which may occur via teleconference.

Leverage resources to optimize the clinical pathway

The foundation of optimizing care is a clinical pathway that leverages resources and incorporates patient triage, forecasting, surveillance (Figure 5). This clinical pathway must also be aligned with the Heart Team expertise and patient

needs. Strategies and tactics for case selection are depicted in Figure 6.

Intake and evaluation

Optimal intake and evaluation are matched to the patient (Figure 7). At the time of referral (Phase 1), patient information may be limited; however, a TTE and robust note may suffice for preliminary screening of the disease mechanism and severity, symptoms, and sequelae and patient-specific risks of treatment. A phone call or telehealth visit may reveal other risks and illuminate the patient's goals of care and expectations. Much of the evaluation (Phase 2) is optimized by selecting only essential, clinically indicated diagnostic tests. Certain studies function as gatekeepers to treatment. For TAVR and TMVR, CT angiography (CTA) is performed unless contraindicated. Other tests may have less invasive, more efficient alternatives. For patients with low or moderate pretest probability for obstructive CAD, CTA may be used for coronary artery assessment in lieu of cardiac catheterization.^{8,38,39} Coronary angiography if warranted may be deferred to the time of the SH intervention.



Table 1. Skill–task aligned remote work.

	Remote work requirements	Administrative responsibilities	Coordination responsibilities	Direct patient care responsibilities
<i>Administrative staff</i>				
Scheduling coordinator	Computer access Forwarded fax Forwarded phone	<ul style="list-style-type: none"> Reschedule clinics Schedule televisits Schedule on-site visits Referral intake Outside records Schedule tests 		
Registry coordinator	Computer access Phone	<ul style="list-style-type: none"> Track missing data Track local follow-up data collection Submit data to registry 	<ul style="list-style-type: none"> Obtain KCCQ via phone Facilitate clinical data integrity 	
<i>Multidisciplinary team</i>				
Nurse coordinator	Computer access Telehealth access Phone	<ul style="list-style-type: none"> New patient calls Surveillance calls Follow-up calls Patient instruction calls 		
Outpatient advanced practice provider	Computer access Telehealth access Phone		<ul style="list-style-type: none"> Triage patients and forecast timeline for evaluation and treatment 	<ul style="list-style-type: none"> Initial televisits Pre-decision/pre-procedure televisits 30 days/1 year follow-up televisits Urgent in-person clinic as needed Triage and forecasting updates
Inpatient advanced practice provider	Computer access Telehealth access Phone		<ul style="list-style-type: none"> Triage inpatients and forecast timeline for evaluation and treatment 	<ul style="list-style-type: none"> Inpatient care for procedures Inpatient consults/rounding Urgent in-person clinic Televisits as needed
Physician	Computer access Telehealth access Phone		<ul style="list-style-type: none"> Triage patients and forecast timeline for evaluation and treatment 	<ul style="list-style-type: none"> Procedures Inpatient consults/rounding Urgent in-person clinic Initial televisits

KCCQ: Kansas City Cardiomyopathy Questionnaire.



	Phase 1 Intake	Phase 2 Evaluation	Phase 3 Treatment	Phase 4 Follow-Up
1 Triage	<ul style="list-style-type: none"> Elicit patient goals Assess acuity Triage using guideline-based criteria Assess coordination requirements Educate patient and family 	<ul style="list-style-type: none"> Elicit patient goals Expressly invite patient to state goals of treatment and engage in shared decision making with the team Evaluate patient with all required team members and data required to make shared decision 	<ul style="list-style-type: none"> Determine optimal clinical pathway Ensure history and physical, orders/tests, consent obtained and reviewed to eliminate delays or cancellations Admit patient on day of procedure 	<ul style="list-style-type: none"> Evaluate patient, ECG, device structure and function, access site(s) Assess complications, hospital admissions, new or worsening symptoms, labs Note new or held high-risk medications
2 Forecast	<ul style="list-style-type: none"> Estimate resource intensity Project optimal timeline for evaluation and treatment amidst current wait list Educate patient and family 	<ul style="list-style-type: none"> Estimate resource intensity, now also incorporating procedure plan and risks, likely LOS and discharge disposition Assess patient and family flexibility with dynamic schedule changes Project optimal timeline for treatment Address impact of case scheduling on current wait list, especially for current inpatients or urgent cases 	<ul style="list-style-type: none"> Estimate resource intensity, now also incorporating actual procedure requirements, complications, LOS and discharge disposition Project day/time for optimal throughput, based on case, LOS and discharge disposition ✓ Avoid complex cases in PM, or during periods with minimal coverage ✓ Begin day and week with straightforward cases 	<ul style="list-style-type: none"> Estimate resource intensity, now incorporating complications, status at discharge, patient risks, and coordination needs
3 Surveillance	<ul style="list-style-type: none"> Triage to determine surveillance frequency until evaluation For subsequent touchpoints until evaluation, review symptoms and new patient data to re-triage Assess program capacity and need to reschedule Educate patient on dynamic schedule for diagnostic tests and consult Educate patient to call with changes in status 	<ul style="list-style-type: none"> Triage to determine surveillance frequency until treatment For subsequent touchpoints until treatment, review new data on patient and program capacity to re-triage and reschedule Educate patient on dynamic procedure schedule Educate patient to call with changes in status Monitor wait times 	<ul style="list-style-type: none"> Partner with cath lab, OR, inpatient services, and bed flow to optimize procedural throughput, admits, transfers, discharges Monitor case delays, cancellations, and urgent cases (eg, STEMI, transplant) that may require SH cases to be rescheduled 	<ul style="list-style-type: none"> Triage to determine surveillance frequency, considering regulatory and quality (registry) requirements Review new patient data and re-triage between follow-up visits Obtain required records and imaging studies Educate patient to call with changes in status
Resource Leverage	<ul style="list-style-type: none"> Communicate directly with patient and referring provider to educate and assess expectations Use telehealth for rapid evaluation, especially when triage warrants, data are limited, and if multiple visits are required Skill task-align care coordination 	<ul style="list-style-type: none"> Use telehealth if suitable Obtain essential, clinically indicated testing only, and locally as appropriate Bundle encounters to decrease the number of visits, especially if difficult to return Bundle Level 3 patients to improve efficiency As safe and feasible, discharge inpatients referred for treatment As demand grows, bundle clinicians, clinic, and testing by disease state and designate blocks 	<ul style="list-style-type: none"> Match patient care to staff, location, and resources, and as safe and feasible: <ul style="list-style-type: none"> ✓ Use cath lab ✓ Avoid invasive airway, imaging, lines ✓ Avoid cutdowns ✓ Avoid ICU, PACU ✓ Discharge to home Bundle similar cases and operators Bundle Level 3 patients to improve efficiency Perform procedures with only essential personnel and supplies 	<ul style="list-style-type: none"> Perform essential testing locally, as appropriate Use telehealth if suitable Assign designated clinic days for follow-up visits with TTEs Educate and empower APPs to lead follow-up clinics

Figure 5. PEARLS to optimize the clinical pathway. LOS, length of stay; STEMI, ST elevation MI; ICU, intensive care unit; PACU, post anesthesia care unit; ECG, electrocardiogram; APP, advanced practice provider.

The standard for evaluation may flex when capacity is restricted; Heart Teams are tasked to be more judicious about repeating studies or obtaining invasive tests with certain risks. TTEs may be avoided due to aerosolization (e.g., COVID19 pandemic) or capacity constrained resources (echocardiographer, anesthesiologist, personal protective equipment). A Heart Team may determine that patients referred for MitraClip with a high-quality TTE, no contraindications for TEE, and no concerns for intraprocedural imaging quality could undergo TEE in the

procedural room and if favorable, may proceed with treatment. This scenario may also apply to LAAO, particularly if a CTA has been obtained, or if Heart Team imaging competency includes intracardiac echo. These decisions to tailor the standard of care are made locally, with careful analysis of expertise, safety, and patient likelihood to benefit.

Other studies including but not limited to pulmonary function testing⁴⁰ (PFT) and carotid artery ultrasound⁴¹ are performed only if clinically indicated. In fact, the American

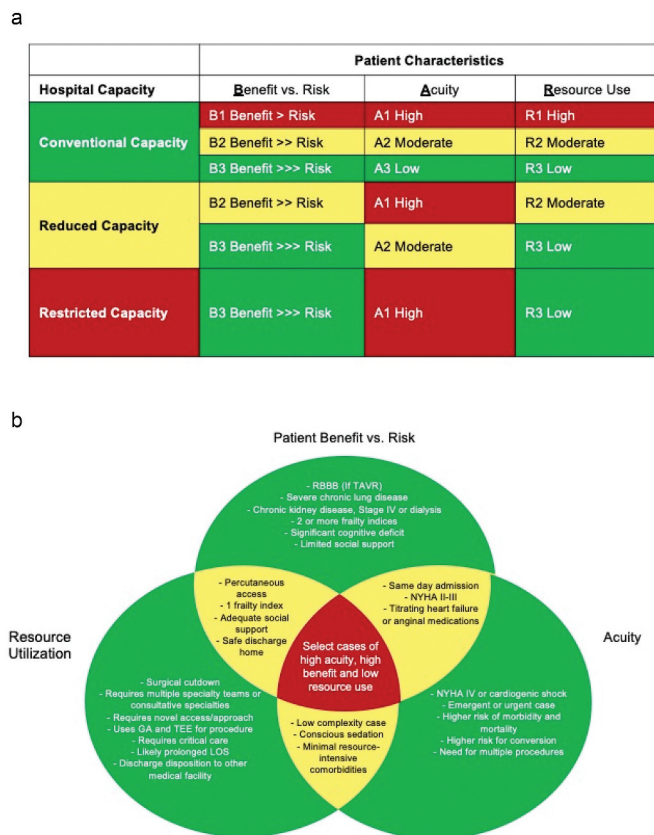


Figure 6. (a) Set the BAR: Benefit, Acuity, and Resource Use. Algorithm legend based on hospital capacity and patient characteristics. (b) Examples of triage criteria to consider at each capacity level.

Board of Internal Medicine (ABIM) and Society of Thoracic Surgeons' (STS) Choosing Wisely Campaign recommends against routine PFTs and carotid ultrasound prior to cardiac surgery.⁴² In patients who underwent screening carotid artery Doppler before AVR (N = 996), Condado and colleagues⁴³ found no association between intracarotid artery stenosis severity and procedure-related stroke after TAVR or SAVR. This result supports the recommendations from the Society for Vascular Surgery⁴¹ as well as the ABIM and STS.⁴² In patients with no clinical indication, routine screening with PFTs and carotid artery US prior to SH procedures is not warranted.

Particularly when capacity is restricted or reduced, the Heart Team should carefully assess risk factors that can increase resource utilization (see Figures 3 and 4). For example, right bundle branch block (RBBB) is a readily identifiable risk factor of new arrhythmia and permanent pacemaker implantation after TAVR; both are common procedural complications⁴⁴ and predictors for a prolonged length of stay.⁴⁵ Generally, in-hospital resource use is highest for patients with more comorbidities^{33,44–46} and non-transfemoral access.^{28,47}

Heart Team SDM reflects the discussion of patient goals and patient-specific risks and benefits. The Heart

Team should incorporate the three essential components of the SDM process: current clinical information regarding risks, benefits, and available options; patient preferences; and provider-patient dialogue.⁴⁸ Elicitation of patient goals must include an additional comprehensive discussion of the risks and restrictions associated with proceeding versus the associated risks of postponing intervention for SHD. Specific risks related to a crisis must be reviewed and incorporated into the risk-to-benefit ratio as part of SDM (i.e., risk of COVID19 transmission). Further, each new indication (lower surgical risk, asymptomatic patients) for treatment expands the conversation, which prompts the efficient Heart Team to reset their agreements or profiles for patient selection.

Treatment and follow-up

Treatment (Phase 3) encompasses all care from admission to discharge during the procedural hospitalization. To increase efficiency, decrease resource utilization, and decrease costs, the general principle is to optimally use essential resources for the greatest possible benefit, aligned with Heart Team expertise and patient preferences. For uncomplicated procedures, patients at low risk for complications or prolonged length of stay may

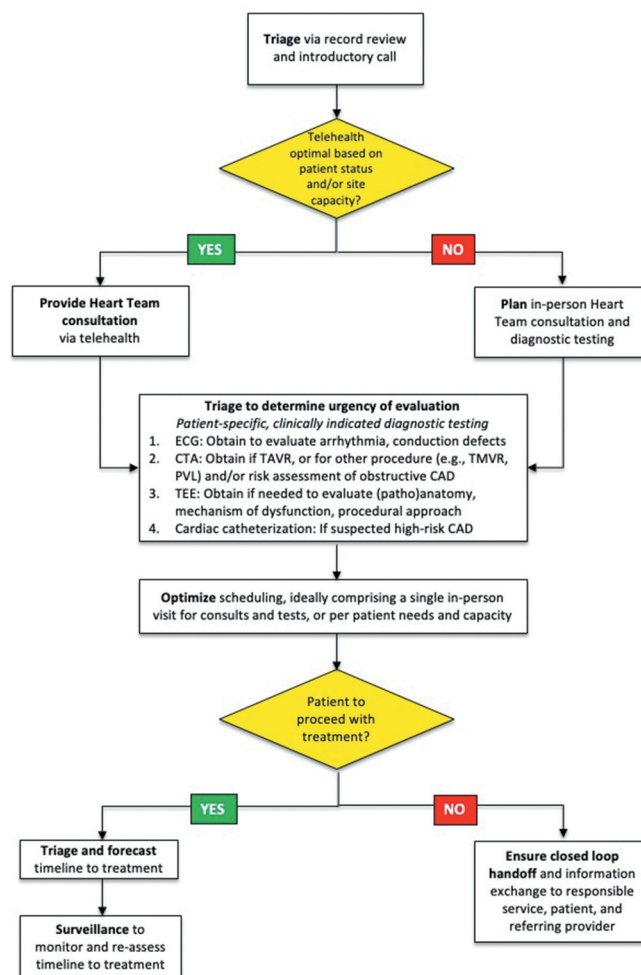


Figure 7. Intake and evaluation pathway. ECG, electrocardiogram; CTA, computerized tomography angiography; CAD, coronary artery disease.

have an expedited post-procedure recovery and early discharge to home.^{29,44} Risks and predictors of procedural complications or prolonged length of stay are reviewed in Figure 3.^{27,28} At a minimum, follow-up (Phase 4) is required at 30 days and 1 year after discharge due to the quality registry and payer requirements. Triage after the procedure determines whether a follow-up visit sooner or more frequently is warranted.

Optimizing a system of care

Now more than ever it is essential for Heart Teams to work synergistically with Structural Heart programs in a *system of care*. The trajectory and ultimate resolution of capacity constraints, particularly in crisis, may be unclear. These uncertainties may further postpone treatment. Structural Heart programs that function collaboratively not only within their organizations but also within their health-care systems and regions – teleconferencing, sharing resources, integrating clinical pathways – may be primed to optimize patient care (Figure 8). Just as humanitarian efforts delivered ventilator

support, medications, and personal protective equipment to colleagues hardest hit by COVID19, there may be opportunities to work creatively in partnership with centers and regions in need of assistance with structural heart interventions or clinical trials (Table 2).

Leading the way

The COVID19 pandemic brought extraordinary disruption to health care. Through optimal use of capacity and resources, paired with triage, forecasting, and surveillance across the continuum, this proposal aspires to the prescient multisocietal vision of an optimized system of care for valvular heart disease.⁷ That said, the most important resource to leverage in these efforts is an empowered, effective team with shared goals, clear roles, mutual trust, effective communication, and measurable processes and outcomes.⁴⁹ After all, the rapid diffusion of SH innovation into mainstream care, and the Herculean efforts to recover from the COVID19 crisis, are poignant reminders that systems alone do not transform care. People do.

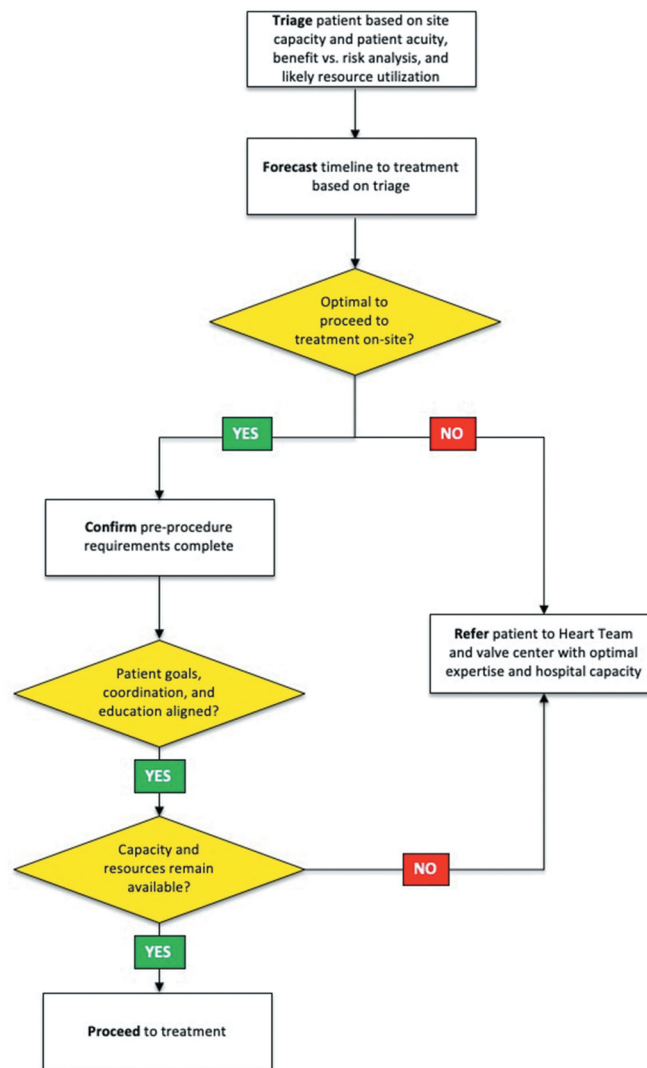


Figure 8. System of care treatment pathway: referral or out of hospital transfer.

Table 2. Key considerations for a system of care.

Key considerations	Description
Establish triage and transfer for patients that cannot receive care Set expectations for preparedness of receiving hospitals	Consider thresholds for capacity, patient acuity, wait time, and any combination thereof for the Heart Team/organization requesting the patient transfer.
Design a coordination process	Transferring and receiving Heart Teams/organization should be able to gather and get information about patients, assisted by the triage team and telehealth. In crisis states, balancing patient loads regionally may accommodate larger patient volumes than expected.
Coordinate resource requests and transportation needs	Align patients to the appropriate destinations and resources for all expected treatment the patient may require, including the procedure and care from other services and transport to other areas.
Ensure access to content and context (subject matter) expertise	Often experts are engaged in direct care; thus, protocols should ensure the ability to contact Heart Teams/organizations that provide desired expertise or capacity required.

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