ITEA Office
High Tech Campus 69 - 3
5656 AG Eindhoven
The Netherlands
T + 31 88 003 6136
E info@itea3.org
W www.itea3.org

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ITEA 3 PARTNER Project

D1.3: Patient Journey Future Ideal State Blueprint Report.

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Authors List

Leading Authors (*Editor*)		
Name / Surname	*Beneficiary Name (Short Name)*	*Contact email*
Martijn van Mourik	MvM	m.s.vanmourik@amc.nl
Henk Marquering	HM	h.a.marquering@amc.nl
Co- Authors		
Name / Surname	*Beneficiary Name (Short Name)*	*Contact email*
Joseph Yang	iClinic	JYang@iclinicemr.com
HyungChul Rah	CBNU	rah.remnant@gmail.com
Danny Deroo	Barco	danny.deroo@barco.com

Executive Summary

This deliverable consists of multiple parts. The optimized workflow for the TAVI use case was built with multiple partners of this project by picturing the current patient journey and the full clinical workflow. Ideal decision making charts are generated based on multiple sources of data. Several group discussions are happening and nine decision moments are clearly documented with source data and current difficulties and as such also improvements.. The second use case of Emergency Heart Failure shows a list of specific needs for improvement in this blueprint deliverable. Finally the third use case on cardiac rehabilitation describes the current way of working and obstacles towards the future ideal state.

Main bottlenecks that are addressed in every workflow are the access to data, decrease of multiple testing and the incorporation of mobile solutions for data collection (wearables) and smart analytics.

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List of abbreviations and acronyms

AMC	Academic Medical Center (Dutch Hospital)
Amsterdam UMC	Amsterdam University Medical Centers
GP	General Practitioner (Family Doctor)
TAVI	Transcatheter Aortic Valve Implantation (synonym of TAVR)
UBC	University of British Columbia
VGH	Vancouver General Hospital
CBNU	Chungbuk National University
TAVR	Transcatheter Aortic Valve Replacement (synonym of TAVI)
AoS	Aortic Valve Stenosis
MI	Myocardial Infarction
EMR	Electronic Medical Record
MDT	Multidisciplinary Team Meeting

1. D1.3 Current State Patient Journey and Workflow

Use case 1: Transcatheter aortic valve implantation (TAVI)

1.1. Introduction

For a good understanding of the TAVI workflow all Dutch partners have visited clinical partner AMC. Martijn van Mourik invited all partners for two different sessions:

1. TAVI Multidisciplinary Team Meeting (MDT): in the team meeting an interventional-cardiologist, cardiothoracic surgeon, cardio-radiologist, geriatrician, nurse practitioner and others involved in the TAVI process make a decision if a TAVI procedure is indicated for a patient and if yes, how the procedure should be performed. Data from the referring physician such as the medical history and current signs, together with additionally acquired imaging (computed tomography angiography, coronary angiography and echocardiography) and other tests such as the electrocardiogram and lung function testing, are used to make decisions and form a complete overview of the patient.

2. TAVI procedure: This minimally-invasive procedure takes about one to two hours and takes place at the (cardiac) catheterization laboratory or a hybrid operating room.

During the visit the industry partners were able to get an understanding of the process that takes place before a TAVI procedure is performed. A special focus was on the data is currently used in the decision making and how multidisciplinary team meetings take place.

1.2. TAVI workflow at the AMC

In the Netherlands referrals for the TAVI procedure are expected to come from cardiologists or other specialists in general hospitals. Referrals from the GP or primary care are not expected as patients with aortic valve stenosis are first seen by a general cardiologist. Alain Cribier performed the first TAVI[1] in humans in 2002 and since then there has been an incredible growth of this technique, supported by a substantial amount of research[2],[3].

In the past decade the TAVI treatment developed as a routine treatment of aortic valve disease (both aortic valve stenosis and aortic regurgitation) for those patients at intermediate- , high- or prohibitive risk for surgical aortic valve replacement.

General description of Aortic Valve Stenosis

Aortic valve stenosis (AoS) is a disease of the heart valve between the heart and the systematic circulation. It is in the Western population one of the most common heart valve diseases and the incidence is highly related with age. In the next years it is likely that the number of patients with

[1] Cribier A et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. Circulation. 2002;106:3006-8
[2] Salinas P et al. State of the art of Aortic Valve Implantation: indications, outcomes, and controversies. EMJ Cardiol. 2015;3: 10-20.
[3] Salinas P et al. Transcatheter aortic valve implantation: Current status and future perspectives. World J Cardiol. 2011;3:177-85

AoS will increase due to an ageing society and better detection as the disease is also underdiagnosed.

Patients becoming symptomatic feel complaints of exercise related dyspnoea, chest pain, exhaustion, dizziness and sometimes syncope.

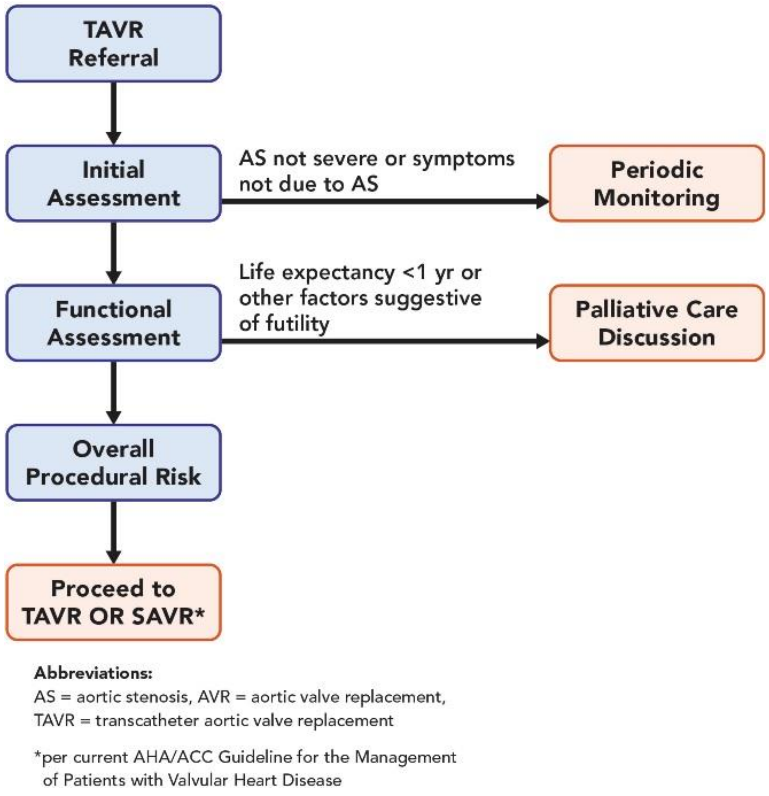


Figure 1: Pre-TAVR considerations by the Heart Valve Team, adapted from https://doi.org/10.1016/j.jacc.2016.12.006, Otto et al 2017, JACC , vol 69, issue 10, p1313-1346.

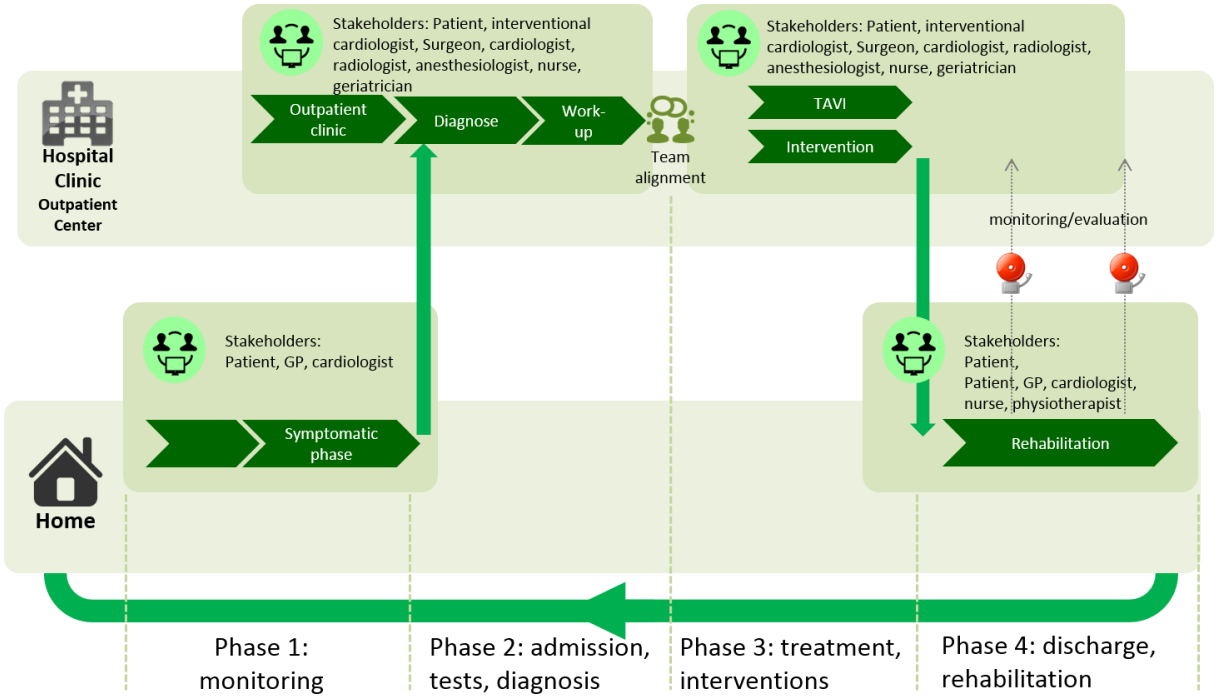


Figure 2: Four phase description TAVI workflow.

When applying the four phases earlier described to the TAVI case:

Phase 1: chronic progressive phase of aortic AoS. Periodic monitoring is indicated in case of not severe enough aortic valve stenosis for treatment or symptoms not likely be caused by aortic valve stenosis.

Phase 2: TAVI screening: screening the severity of the AoS, possible treatment options and eligibility for TAVI

Phase 3: TAVI procedure: hospital admission for TAVI procedure and immediate post-procedural monitoring

Phase 4: Discharge and rehabilitation: after discharge rehabilitation and follow-up after the TAVI procedure

1.2.1. Collaborative decision making

The TAVI decision pathway is characterized by multidisciplinary decision making. Each patient is discussed in at least two different team meetings: 1) the Heart Team (consisting of at least an interventional cardiologist and cardiothoracic surgeon), and 2) the Transcatheter Heart Intervention – THI – team (consisting of an interventional cardiologist, cardiothoracic surgeon, cardioradiologist, specialized nurse and geriatrician). Figure 1 describes the currently used guidelines.

The TAVI workflow is provided in a “swimming-lane”-flowchart of which an example can be found in Figure 4 and a full version as supplement to this document.

Communication from the AMC to the referral hospitals is done via Epic, using specialised modules for electronic transfer of letters like ZorgMail (encrypted e-mail)l or by regular mail.

1.3. Quality standards for the TAVI clinical pathway

Judicious selection of patients for TAVI is a complex process that requires thorough consideration. For a procedure to be deemed useful (as opposed to futile), it must offer a positive impact on life expectancy and quality of life. The best strategy for maximizing the utility of the procedure and minimizing its futility takes into account the patient's morbidity profile, the potential risks and anticipated benefits and the uncertain durability of the implants, in addition to economic considerations such as the burden placed on the health care system and the costs of the procedure[4].

1.4. Overview current hospital Imaging data Cardiology

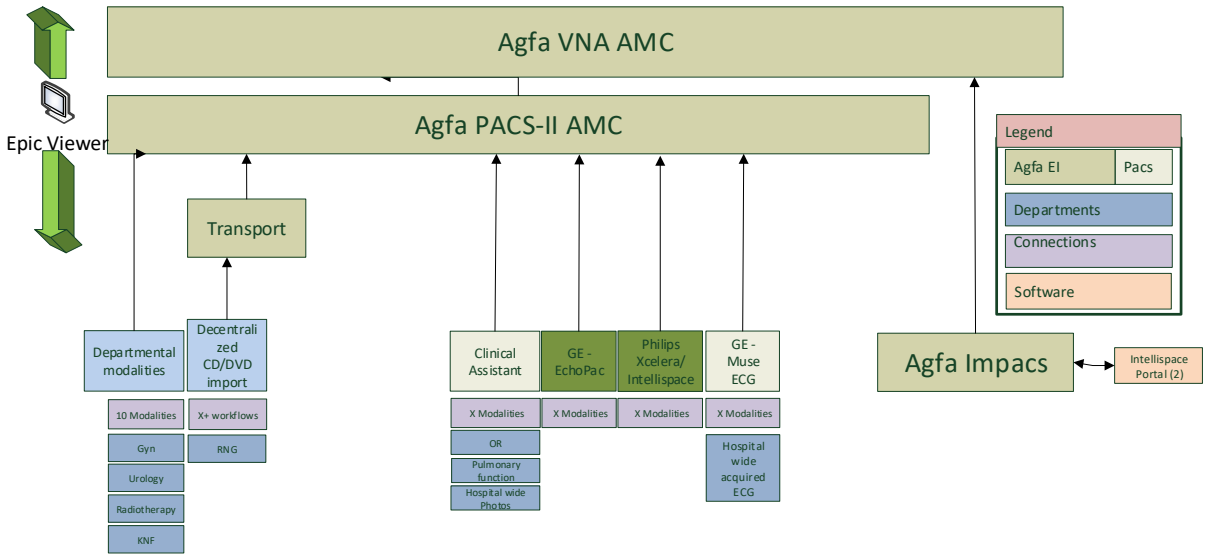


Figure 3: Imaging data cardiology AMC. Agfa PACS II and Agfa VNA AMC are visible through the Electronic Medical Record by viewers.

[4] Abdelghani and Serruys, 2016

Example flowchart/swimming lane TAVI process: (see supplement “S2-FlowChart-TAVI” for full version).

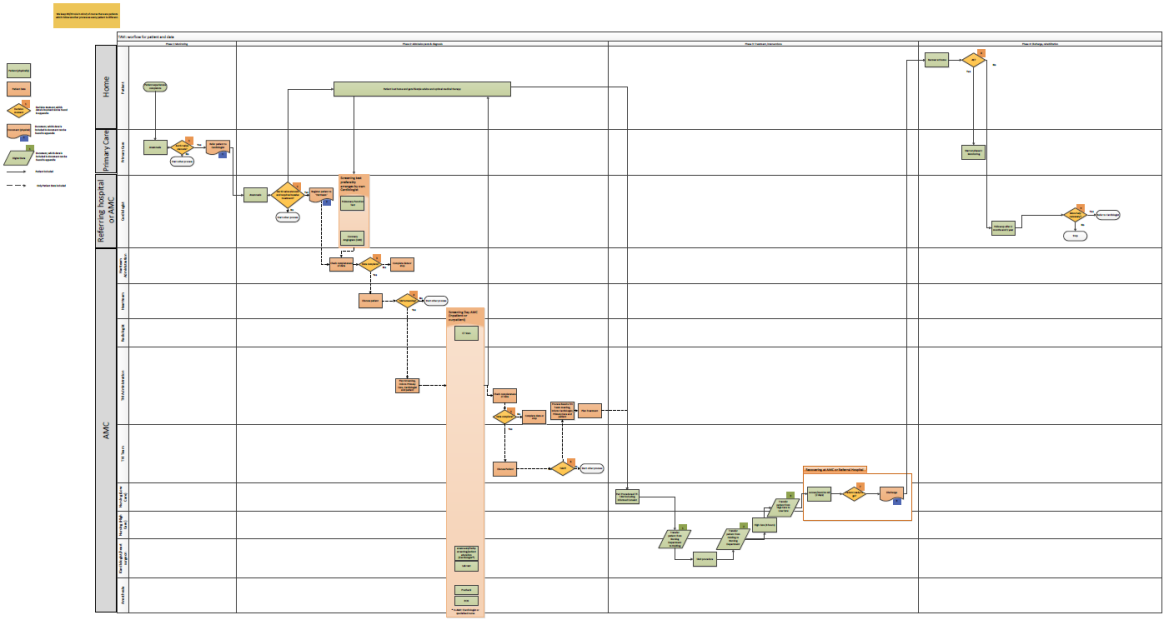
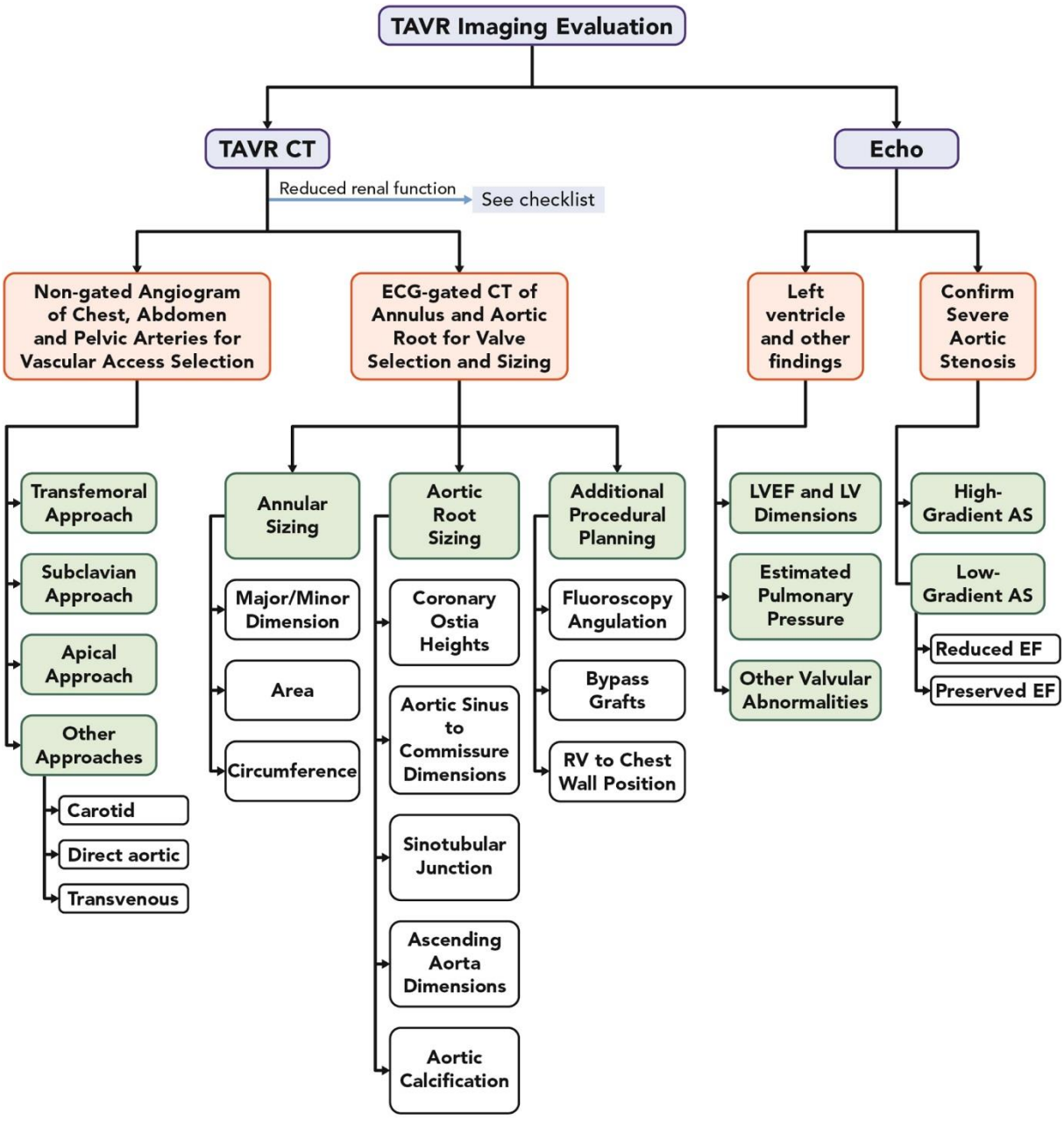


Figure 4: Flowchart/swimming lane, example of full version supplement.

1.5. Decision making based on medical Imaging



Abbreviations:
AS = aortic stenosis, CT = computed tomography, Echo = echocardiography, ECG = electrocardiogram, EF = ejection fraction, LV = left ventricular, LVEF = left ventricular ejection fraction, RV = right ventricular, TAVR = transcatheter aortic valve replacement

Additional evaluation including coronary angiography also is recommended as detailed in the Checklist shown in Table 2. This also includes the approach for patients with reduced renal function.

Figure 5: Imaging studies performed for TAVI for clinical decision making. Adapted from https://doi.org/10.1016/j.jacc.2016.12.006, Otto et al 2017, JACC , vol 69, issue 10, p1313-1346.

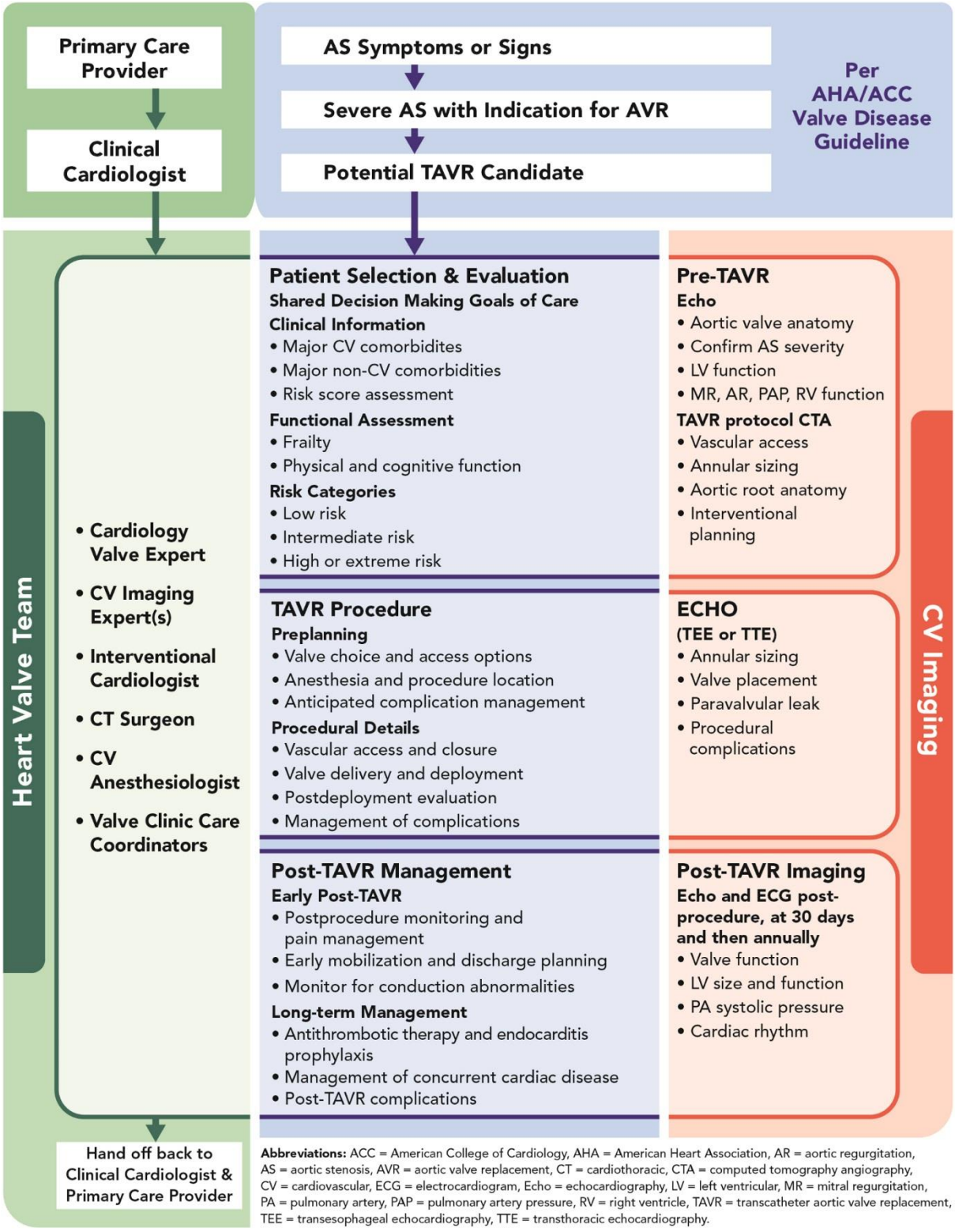


Figure 6: TAVI decision pathway ACC: https://doi.org/10.1016/j.jacc.2016.12.006, Otto et al 2017, JACC , vol 69, issue 10, p1313-1346 . This is taken from the latest American guidelines on TAVI treatment. Both the European (by the ESC: European Society of Cardiology) and the ACC/AHA (American College of Cardiology /American Heart Association).

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1.6. Clinical decision making questions

Decision making for TAVI – overview steps

The path from monitoring, diagnosis and intervention is interwoven with data collection, data interpretation to information in order to answer certain clinical questions in order to make decisions at decision making points. The different decision making points are indicated in the accompanied flowchart. A more detailed overview of all variables used at the different timepoints We addressed and defined the items as follows:

Clinical question

Used parameter(s): which parameters are used from a specific test or source?
Used interface: in which interface is the information displayed/visualized?
Source/data format: what is the source of the data and which format is used (eg. PACS/images)
Source/origin and storage: where is the data stored/retrieved from
Is and how is data transferred: if data needs to be transferred from external system to AMC, how is data transferred/converted?
Difficulty to retrieve information: how easy is it to find the data, especially in a categorized form or pre-defined datafield

Example

Clinical question []	Used parameter(s) []	Used interface [EPIC]	Source/data format [eg CT-dicom]	Source/origin and storage [PACS origin referring center]	How is data transferred to AMC or N/A? [EVOCS]	Difficulty to retrieve information (easy/moderate/difficult)
What is the effective orifice area of the aortic valve	Aortic Valve Area (cm2)	ISCV	Echocardiography images	Echo-pacs	EVOCS	moderate

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Decision moment 1: Primary care

All referrals to a tertiary TAVI treatment center are done by a cardiologist.

Clinical question	Used parameter(s)	Used interface	Source/data format	Source/origin and storage	How is data transferred to AMC or N/A?	Difficulty to retrieve information (easy/moderate/difficult)
Symptoms	Level of dyspnea					difficult
Medical history	Known diseases, previous treatments					difficult
Medication	Prescription					difficult

Decision moment 2: (referring) Cardiologist

Clinical question	Used parameter(s)	Used interface	Source/data format	Source/origin and storage	How is data transferred to AMC or N/A?	Difficulty to retrieve information (easy/moderate/difficult)
Severity of the aortic valve stenosis?	Aortic Valve Area (cm^2)	GE echoweb / Philips	Echocardiography + report	Referral letter	Electronically by EVOCS	Moderate (especially measurements often not used in standardized

	Indexed Aortic Valve Area AoV Pressure gradient (mmHg)	IntelliSpace Cardiovascular			*or* by Fax/regular mail	format)
Other valvular disease?	Mitral valve stenosis/regurgitation Tricuspid valve stenosis/regurgitation	GE echoweb / Philips IntelliSpace Cardiovascular	Echocardiography + report	Referral letter	Electronically by EVOCS *or* by Fax/regular mail	Moderate (especially measurements often not used in standardized format)
Overall heart function?	Left ventricular ejection fraction Wall motion Systolic Pulmonary Artery Pressure	GE echoweb / Philips IntelliSpace Cardiovascular	Echocardiography + report	Referral letter	Electronically by EVOCS *or* by Fax/regular mail	Moderate (especially measurements often not used in standardized format)

	Ventricle and atrial dimensions					
Aortic valve stenosis symptoms?	Patient complaints: Description of complaints; focus on dyspnea (NYHA class), chest pain (CCS class), fatigue, syncope, dizziness	EPIC: scanned documents	Described symptoms	Referral letter	By Fax/regular mail/e-mail	Moderate
Are there other causes for complaints?	Pulmonary function testing Coronary Angiogram	EPIC: scanned documents Scanned documents/ images in IntelliSpace cardiovascular	Pulmonary function testing CAG	Referral letter / imaging	Fax/regular mail/e-mail Electronically by EVOCS *or* by Fax/regular mail and CD	Moderate moderate
Relevant comorbidities to deny for surgical aortic valve repair?	Medical history: Extracardiac arteriopathy	EPIC: scanned documents	Medical history	Referral letter	By Fax/regular mail/e-mail	Easy

	Poor mobility Previous cardiac surgery Chest radiation Chronic pulmonary pulmonary disease (also from pulm test) Diabetes Mellitus Left ventricular function Pulmonary hypertension Porcelain aorta Frailty					

	Severe liver disease					
What are the patients preferences?	Patient and family input	EPIC: scanned documents	Medical history/anamnesis	Referral letter	By Fax/regular mail/e-mail	Moderate

Decision moment 3: Heart team preparation

Clinical question	Used parameter(s)	Used interface	Source/data format	Source/origin and storage	How is data transferred to AMC or N/A?	Difficulty to retrieve information (easy/moderate/difficult)
Is all data complete for Heart team discussion for Aortic Valve Stenosis?	Referral letter Ultrasonography CAG	EPIC ISCV/EchoWeb ISCV	Scanned documents	N/A	Letters: fax, email, post Images: CD or EVOCS	moderate

Decision moment 4: Heart Team discussion

Clinical question	Used parameter(s)	Used interface	Source/data format	Source/origin and storage	How is data transferred to	Difficulty to retrieve information

					AMC or N/A?	(easy/moderate/difficult)
What is the severity of aortic valve stenosis?	Aortic Valve Area (cm^2) Indexed Aortic Valve Area AoV Pressure gradient (mmHg)	EPIC or ISCV	Referral letter	Scanned documents in EPIC or original images in IntelliSpace Cardiovascular or Echoweb	Letters: fax, email, post Images: CD or EVOCS	moderate
Is the patient symptomatic?	Description of complaints; focus on dyspnea (NYHA class), chest pain (CCS class), fatigue, syncope, dizziness Exercise intolerance	EPIC	Referral letter	Scanned documents in EPIC	: fax, email, post	moderate
Relevant comorbidities to	Medical	EPIC	Scanned documents/	Scanned documents	E-mail/Fax/Post	moderate

deny for surgical aortic valve repair?	history Pulmonary functioning testing	EPIC	Referral letter Scanned documents/ test report		E-mail/Fax/Post	easy
What are the patients preferences?	Referral letter	EPIC	Scanned documents/ Referral letter	Referring hospital EMR	E-mail/Fax/Post	moderate
Are extra tests necessary to make decision regarding TAVI?	Major comorbidities needing exploration: malignancies, anemia	EPIC	MDT note	Referring hospital EMR	E-mail/Fax/Post	moderate

Decision moment 5: THI team (Transcatheter Valve Team) preparation

Clinical question	Used parameter(s)	Used interface	Source/data format	Source/origin and storage	How is data transferred to AMC or N/A?	Difficulty to retrieve information (easy/moderate/difficult)

Is all data complete for THI-team discussion for TAVI?	-	-	-	-	-	-
Were all open items from Heartteam discussion solved?	Heart Team report	EPIC	Report of Heartteam	EPIC	N/A	Easy (but mostly free text)

Decision moment 6: THI team discussion

Clinical question	Used parameter(s)	Used interface	Source/data format	Source/origin and storage	How is data transferred to AMC or N/A?	Difficulty to retrieve information (easy/moderate/difficult)
What is the severity of aortic valve stenosis?	Aortic Valve Area, Aortic Valve Pressure gradient	EPIC	Ultrasonography images	IntelliSpace / GE-EchoPAC	Already imported Already imported	moderate

Is the patient symptomatic?	Medical history	EPIC	Clinical note	EPIC or referral letter	N/A	moderate
Baseline ECG?	Rhythm Conduction times (QRS, PR-interval, ST) Heart axis Abnormalities	EPIC	ECG	EPIC / Muse	N/A	easy
Relevant comorbidities to deny for surgical aortic valve repair?	Medical history Pulmonary functioning testing	EPIC EPIC	Scanned documents/ Referral letter Scanned documents/ test report	Scanned documents, referring hospital EMR	Already imported Already imported	Moderate moderate
What are the patients preferences?	Referral letter and medical history	EPIC	Scanned documents/ Referral letter And Clinical note	EPIC	E-mail/Fax/Post	moderate
Are extra tests necessary to make decision	Comorbidities needing	EPIC	MDT meeting note	EPIC	N/A	moderate

regarding TAVI?	exploration: malignancies, anemia, other					
TAVI prosthesis valve size?	CT-scan: Annulus area	EPIC	Report in EPIC / Images from PACS	PACS	N/A	easy
Femoral or non-femoral approach?	CT-scan: diameters of peripheral arteries and arterial trajectory to aortic valve	EPIC	Report in EPIC / Images from PACS	PACS	N/A	easy

Decision moment 7: Procedure

Clinical question	Used parameter(s)	Used interface	Source/data format	Source/origin and storage	How is data transferred to AMC or N/A?	Difficulty to retrieve information (easy/moderate/difficult)
Predilation	Aortic valve	EPIC	CT	PACS	N/A	Easy

necessary?	calcification					
Postdilation necessary?	Aortic valve regurgitation	Xcelera imaging system	Philips X-ray (Allura clarity)	Xcelera/IntelliSpace Cardiovscular	N/A	easy
Can the temporary pacemaker wire be removed?	Peri-procedural ECG	MacLab	MacLab		N/A	easy

Decision moment 8: Discharge

Clinical question	Used parameter(s)	Used interface	Source/data format	Source/origin and storage	How is data transferred to AMC or N/A?	Difficulty to retrieve information (easy/moderate/difficult)
No conduction disturbances?	QRS duratino	EPIC/Muse	ECG	Muse	N/A	easy
Bloodwork ok?	Complete blood work	EPIC	Lab data	Labtrain	N/A	easy
Access site free	Physical	EPIC	Clinical note	EPIC	N/A	moderate

from complications	examination					
Discharge medication	Medication prescription overview	EPIC	Clinical note	EPIC	N/A	Easy

Decision moment 9: Follow-up/monitoring

Clinical question	Used parameter(s)	Used interface	Source/data format	Source/origin and storage	How is data transferred to AMC or N/A?	Difficulty to retrieve information (easy/moderate/difficult)
Symptoms	Description of complaints; focus on dyspnea (NYHA class), chest pain (CCS class), fatigue, syncope, dizziness	EPIC or	Clinical note or outpatient clinic follow-up letter from referring hospital	Scanned documents in EPIC or original	E-mail/Fax/Post	Moderate

	Exercise intolerance					
Quality of life	SF-36, EQ5D questionnaires		Clinical note or outpatient clinic follow-up letter from referring hospital	Scanned documents in EPIC or original	E-mail/Fax/Post	Moderate
Antithrombotic therapy?	Medication prescription		Clinical note or outpatient clinic follow-up letter from referring hospital	Scanned documents in EPIC or original	E-mail/Fax/Post	Moderate
Bioprosthetic Valve function?	Aortic Valve Area (cm^2) Indexed Aortic Valve Area AoV Pressure gradient (mmHg)	EPIC or ISCV	Referral letter	Scanned documents in EPIC or original images in IntelliSpace Cardiovascular or Echoweb	Letters: fax, email, post Images: CD or EVOCS	moderate
Conduction disturbances?						

Stroke?						

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E info@itea3.org
W www.itea3.org

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Ideal state Use case 1: Transcatheter aortic valve implantation (TAVI)

1.7. Introduction

The process between a patient getting complaints of aortic valve stenosis and the eventual treatment consists of multiple steps and especially decision making using clinical data is important in this workflow. The transfer of data, interpretation of data and knowing where a patient specifically was in the process was identified by the team as a bottleneck.

The blueprint of the ideal future state of the TAVI workflow is based on the currently perceived bottlenecks in the workflow. In a workshop with most stakeholders involved in the TAVI pathway bottlenecks and issues within the described workflows were addressed.

1.8. Aim and expected results

The ideal future state description of this project will focus on the part of the carepath that starts from the cardiologist. The primary care provider will not be the within the scope of this ITEA3 project.

1.8.1. General remarks:

- In the ideal situation it is clear for everyone involved in the whole process (including patient/informal caregivers and referring cardiologist) in which phase of the workflow for a transcatheter heart valve implantation the patient is.
- The TAVI patient population is characterized by a high number of comorbidities and are often already treated by multiple medical specialist. In the ideal future state the knowledge and information about a patient that is with different specialists could be used to optimize the patient pathway and improve collaboration between the careteam and the patient/informal caregiver.

1.8.2. Monitoring and surveillance:

Pre-TAVI: monitoring of symptoms and detect changes

Post-TAVI: prevent deterioration

1.8.3. Test and Diagnosis:

- Reduction of time spent in data retrieval of
  - Medical images (ultrasound, coronary angiography, CT)
  - Medical history
  - Lab results
  - Pulmonary function testing
  - Medication
- Reduction of double diagnostics
- Optimal use of data available about a patient
- Patient reported information incorporated in medical file

1.8.4. Treatment and intervention:

- On a patient level prediction of mortality, functional improvement and complications (stroke, bleeding, valve
- Patient tailored pathway

1.8.5. Discharge and rehabilitation:

- Patient tailored length-of-stay and rehabilitation
- Detection of rhythm changes and conduction disturbances

1.9. Decision making based on medical Imaging

In the TAVI workflow the use of preoperative computed tomography angiography (CTA) is important for a) assessing the calcification of the aortic valve, b) assessment of access route and catheter pathway, and c.) valve size and type determination.

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The Netherlands
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# Current state flowchart	Description	Bottleneck of high importance?	Issue	Ideal situation
1	Primary care			
2	(Referring) Cardiologist	Low	1. No information available about waiting list 2. Data transfer in referral later not automated	1. A status per patient available with access for a referring cardiologist to check status 2. Electronic referral form
3	Heartteam preparation	High	1. No standardized format for patient referral 2. Unclear which information is needed on a patient level 3. No clear overview to check the status of diagnostic tests or information that should be retrieved before a patient can be discussed	1. Standardization 2. Per patient overview of necessary information and already retrieved information 3. See 2
4	Heartteam discussion	High	1. No overview of patient data that needs to be discussed 2. Information not up-to-date or unclear which information is still missing to make a good decision 3. No use of predictors to get a patient tailored risk prediction for success or complications 4. The referring cardiologist cannot easily be involved in the decision making	1. Standardized discussion format and overview of patient data 2. See 1 3. The implementation of a patient tailored risk and outcome prediction model 4. Give refereral easy access to discussed questions or be part of meeting

5	Transcatheter Valve Team (TVT/THI) preparation	high	1. Unclear which information is needed on a patient level 2. No clear overview to check the status of diagnostic tests or information that should be retrieved before a patient can be discusse 3. Patient not involved in care path chosen	1. Overview of information needed 2. Realtime check if information is already been transferred or tests are carried out 3. Give patient access to certain types of data and collect patient input
6	Transcatheter Valve Team Discussion	moderate	1. No overview of patient data that needs to be discussed 2. Information not up-to-date or unclear which information is still missing to make a good decision 3. No use of predictors to get a patient tailored risk prediction for success or complications 4. The referring cardiologist cannot easily be involved in the decision making	1. Standardized discussion format and overview of patient data 2. See 1 3. The implementation of a patient tailored risk and outcome prediction model 4. Give refereral easy access to discussed questions or be part of meeting
7	Procedure: valve implantation	low	1. Selection of valve device 2. Reduction of vascular complications 3. Reduction of vascular complications	1. Assessment of vascular access, vasculature and aortic valve 2. Tbd 3. Tbd

8	Discharge	moderate	1. No patient specific cate path 2. No telemonitoring for patients at higher risk for re-hospitalization deterioration	1. A more patient specific care path 2. Remote monitoring
9	Follow-up/monitoring	high	1. Currently no objective measure for symptom reduction measurement 2. No follow-up of patients	1. A patient centered outcome variable 2. Data retrieval of other healthcare providers

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E info@itea3.org
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2. Use case 2: Heart Failure Exacerbation (Emergency)

Monitoring Stage*	Motivation	Data needs of health professionals	Data needs of patients/caregivers
Heart Failure Stable Status	Community/home based monitoring to maintain wellness and patient optimization of self-management	Routine, episodic tracking of physiologic metrics, patient education	Awareness of physiologic metrics and self-monitoring for normality
Step-up monitoring and therapy adjustment	Community/home based, increased monitoring to prevent further deterioration, and adjustment of therapies to re-establish stability	More intense monitoring periods (e.g. daily, or even multiple times per day) of physiologic metrics, and adjustment of medications to ensure reversal of clinical course back towards stability or detection of deterioration requiring further stepping up of therapy or emergency admission	Partnership with health professionals to closely watch physiologic metrics, and adhere to increased therapies to watch of frequency of abnormalities and correlation of symptoms to try to re-establish stabilization or if worsen, seek further help or present self to emergency if danger level reached
Intense monitoring and acute therapy	Emergency based, intense monitoring to acutely correct life-threatening conditions to re-establish safe status of patient	Intense monitoring (e.g. hourly or even minute-by-minute) of physiologic metrics, and escalation or addition of medications to prevent life threatening status and de-escalate unstable clinical status	Report symptoms to health professionals and correlate with physiologic metrics so health professionals can support patients through this unstable and potentially life threatening stage
Hospital monitoring and therapy	Hospital based (ward or intense care unit) monitoring to titrate acute therapies to stabilize patients and re-achieve safe and non-life threatening health status	Intense (e.g. ICU) and gradually step down the frequency of monitoring (e.g. ward) when patients start to stabilize and recovering from life-threatening status, and titration of acutely prescribed medications to achieve therapeutic effects with minimum doses of medications or prevent side effects	Report symptoms to health professionals and correlate with physiologic metrics to health professionals can help tweak the medical therapies to achieve therapeutic goals without inadvertently increasing side effects or inducing adverse effects of therapy. Patients and caregivers can start self-management to experience recovery and level of activities and sense of wellness for potential return to home for convalescence in partnership with health professionals.
Rehabilitation monitoring and therapeutic de-	Community/home based monitoring to ensure gradual recovery of patients to	Gradually decrease intensity of monitoring (e.g. daily and then decreasing to every other day) to ensure	Partnership with health professionals to self-monitor physiologic metrics and reporting of symptoms during

escalation	their baseline status	continuity of stability, and also use this monitoring to guide gradual decrease in therapy back to patients' baseline medications or stoppage of some of them.	recovery, or any unexpected side effects from medicines. Ensure implementation of non-therapeutic approaches (e.g. reduce amount of fluid intake, increased gradual exercises) and partner with health professionals to ensure safe and effective rehabilitation.
Palliative monitoring and comfort therapy	Community/home based monitoring to ensure patient comfort	Infrequent monitoring or even withdrawal of monitoring when appropriate only to ensure patients remain comfortable, even if the physiologic metrics may continue to deteriorate.	Patients and caregivers report level of comfort (e.g. ensuring enough analgesics to reduce discomfort of shortness of breath) so health professionals can help adjust comfort care therapies to tailor to patient need.

A current state determination of Heart Failure patients transgress through the Emergency Department was performed (attached hereto as supplemental S2a). Figure 7 below shows the potential areas where monitoring of the patient can be improved by the introduction of wearables, both within the Emergency Department and continued to the community/home settings.

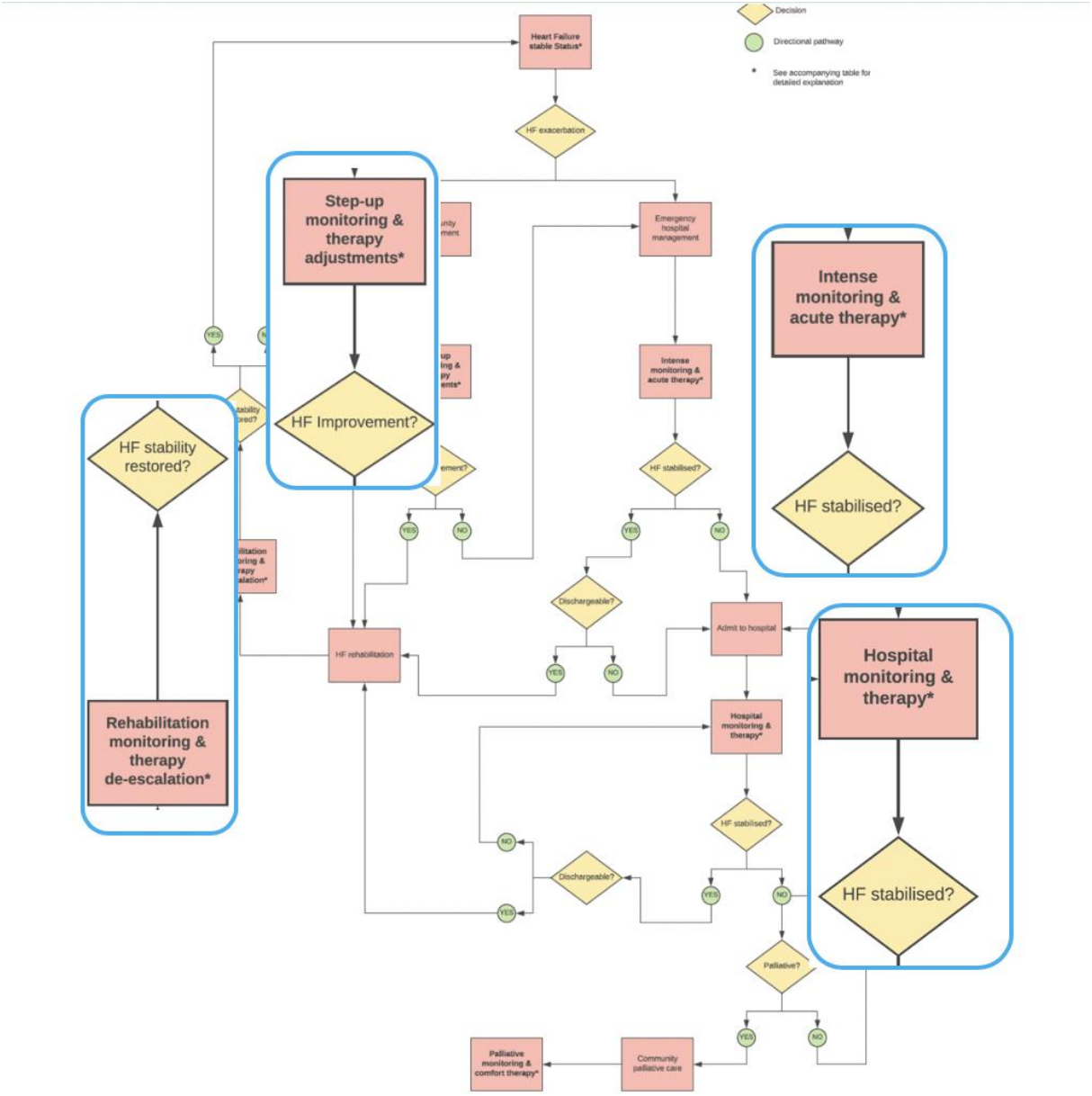


Figure 7: Workflow Heart Failure Exacerbation with identified targets for the use of wearables.

Heart Failure Stabilized (Out-patient clinic)

Upon stabilization of HF patients within the Emergency Department, the patients' care is transferred to the General Practitioner and/or to the HF clinic located within the hospital on an out-patient basis. There are other instances where a patient determined to be suffering HF may be directly referred to the Out-patient HF clinic by the General Practitioner.

A comprehensive analysis of the pathway of a stable HF patient reveals several points along the pathway that requires review of patient information and are determinative in the care of the patient.

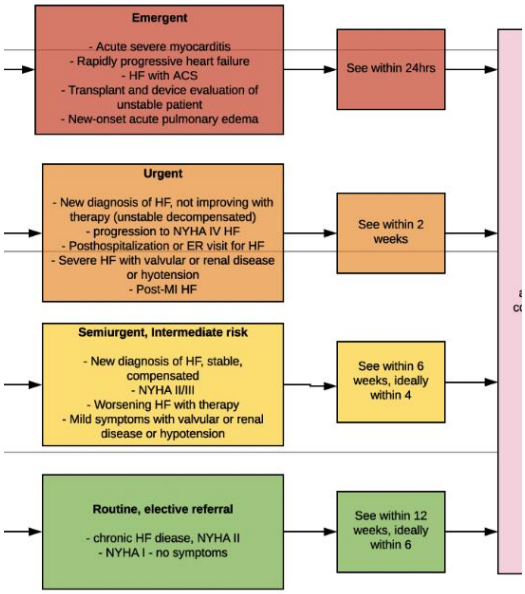
Heart Failure diagnosis is determined by clinical symptoms and confirmation from additional diagnostic investigations, as such, acceptance into the Out-patient HF clinic requires 'non-stale' investigations. The recency requirements of such investigations are outlined below:

EVIDENCE of HF	Accepted time range
Echo *or*	Within 1 year
BNP/NT-proBNP *or*	Within 3 month
Consult note *or*	Within 1 year
Discharge	Within 1 year

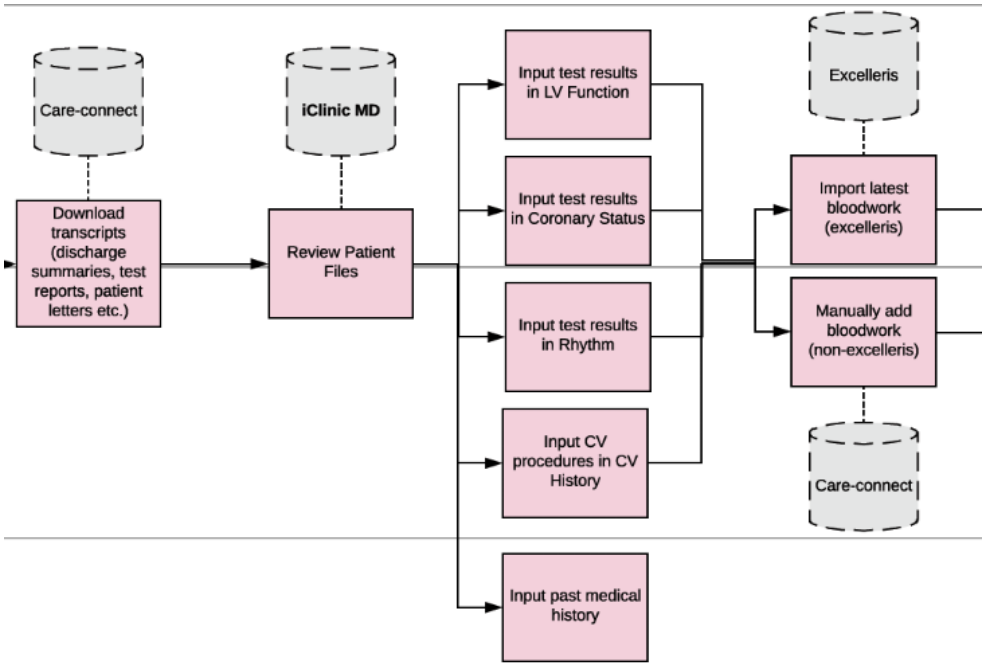
Order new tests	if aged more than:
Echo *or*	1 year
BNP/NT-proBNP *or*	1 month

CHART PREP	Max #	Max age (years)
Investigations		
Echo	3	5
BNP/NT-proBNP	1	1
Bloodwork	1	1
ECG	1	5
CXR	1	5
Holter	1	5
Exercise test	1	5
MUGA	1	5
MIBI	1	5
CTA	1	5
PET scan	1	5
Cardiac MRI	1	5
Letters		
Device follow-up	1	5
Cardiology consult	1	5
Medicine consult	1	5
Discharge	1	5
Procedures		
Cath Angiogram	1	Ever
Device implant	1	Ever
Ablation	All	Ever
PCI	All	Ever
Trans valve	All	Ever
Cardiac surgery	All	Ever

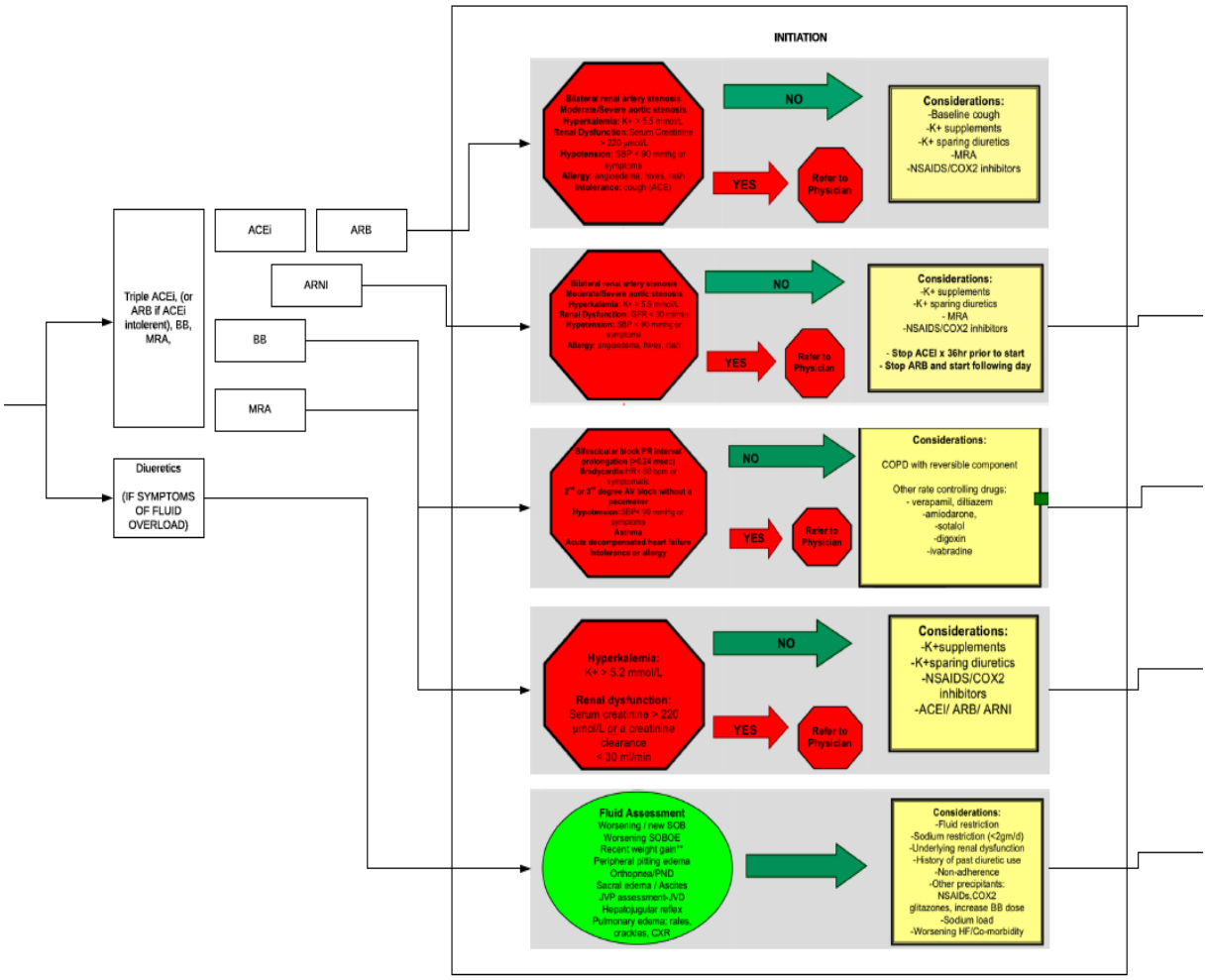
As part of the processing and triaging of patients within the Out-patient HF clinic, a classification of the urgency of the patient must be made determined by several criteria that dictates the timeframe within the patient must be seen within the Out-patient HF clinic.



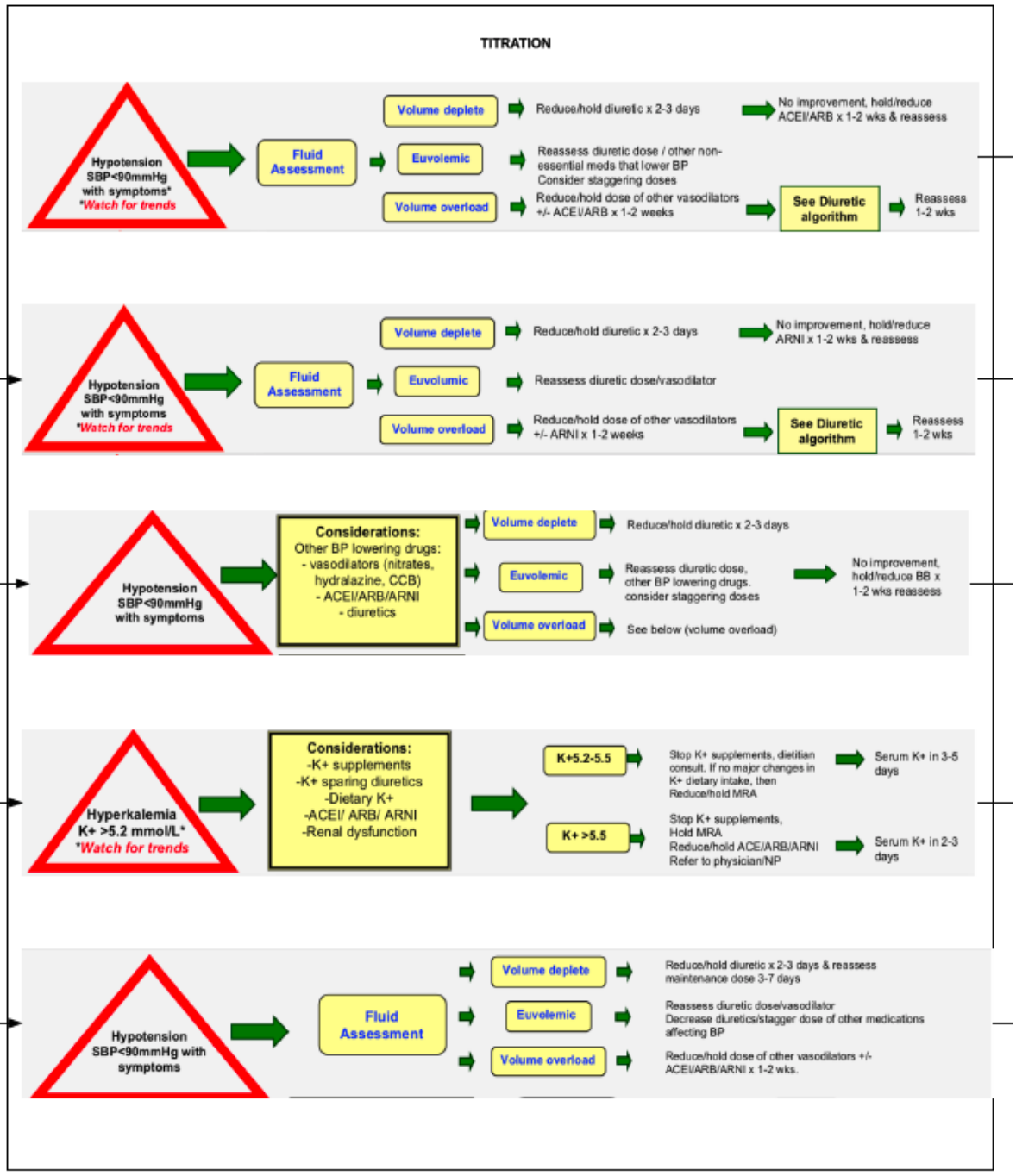
The clinical assessment of the patient from the Nurse Practitioner within the Out-patient HF clinic continues with a review of all the medical information of the patient accessed from various sources if not already assembled as depicted below.



An inherent important component of the treatment of a HF patient involves detailed collection of information that includes current symptoms, physical examination and additional exam room ECG testing, as well as a thorough review of the current medications the patient is on. The treatment protocol selected for the HF patient is determined by the classification of HF severity of the patient, that is largely dependent on the LVEF value of the patient. While the treatment protocol selection is discrete, the available medication options and the considerations involved in the appropriate selections is quite complex.



The monitoring of HF patients and timely adjustments of the medications accordingly is critical in the care of HF patients. A sample titration guideline is displayed below.



ITEA Office
High Tech Campus 69 - 3
5656 AG Eindhoven
The Netherlands
T + 31 88 003 6136
E info@itea3.org
W www.itea3.org

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Overlayed on top of the workflow diagram of the Out-patient HF clinic at Vancouver General Hospital are key areas where the resultant tools of the PARTNER project have the potential to have a transformational impact.

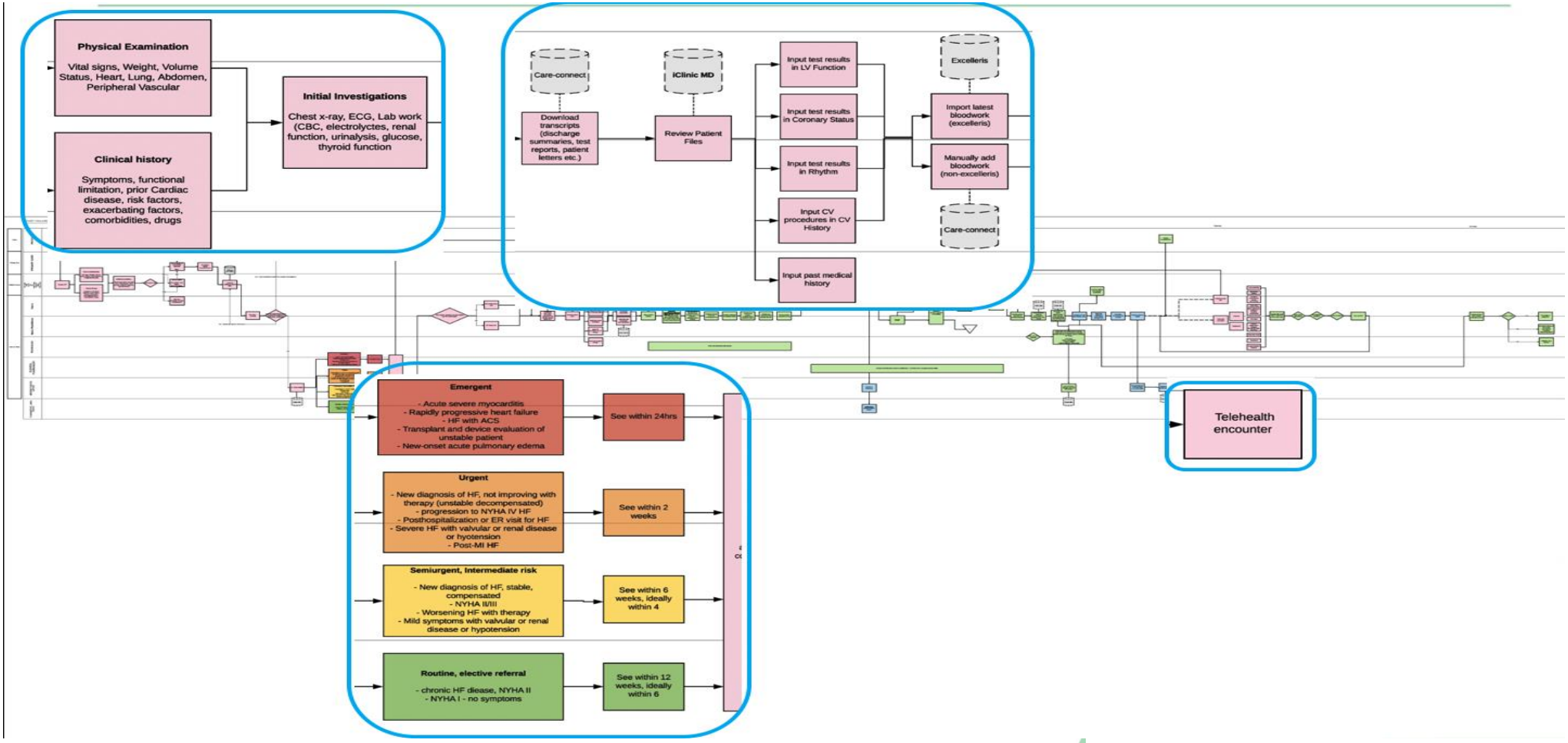


Figure 8: Workflow Heart Failure Vancouver General Hospital, swimming lane (full version supplemental S2b).

ITEA Office
High Tech Campus 69 - 3
5656 AG Eindhoven
The Netherlands
T + 31 88 003 6136
E info@itea3.org
W www.itea3.org

3. Use case 3: Cardiac Rehabilitation

3.1. Introduction

Cardiac rehabilitation of myocardial infarction may reduce recurrence of coronary artery diseases (CAD) by 15 – 20% and CAD mortality by 25 – 40%.

• Due to the concerns that exercise may be dangerous for CAD patients, doctors are reluctant to order or recommend exercise to CAD patients and patients are reluctant to participate in exercises at homes or work places.

- However, monitored exercise, especially with the help of wearable EKG monitoring, may lower any risk during exercises and eventually reduce recurrences of CAD-related events.

• Obstacles that keep cardiac rehabilitation patients from participating at below 5%

- Obstacles include lack of time for patients to visit hospitals with cardiac rehabilitation facilities daily for 8 weeks (many of the patients are in the age groups that have one of the highest employment rates), low recognition rate, far distance to hospitals with cardiac rehabilitation facilities (only 21 hospitals in Korea), no coverage by national health insurance, difficult transportation, lack of caregiver to bring patients to hospitals, etc. (See current sate patient journey workflow)

- Low participation rate needs improvement by monitored exercises with the help of wearable patient-monitoring devices.

3.2. Aim and Expected results

The aim is to provide patients who need cardiac rehabilitation with a solution for healthy life with well-managed cardiovascular risk factors. (See future ideal state workflow)

- High-risk patients must be monitored in the hospital and low-risk patients should be encouraged to engage in exercises in the home or workplace.

- By using wearable devices, smartphone apps, and platform to integrated monitoring of patient's condition, patient's condition can be constantly monitored at their residency.

Bio-signals of patients are to be monitored within device and by caregivers, and evaluated at the time of hospital visits by physicians.

• Expected results

- Patient compliance to be improved by providing feedback from physicians to patients during their visits to hospitals

- Participation rate of cardiac rehabilitation to be improved from 5% up to 30%.

- CAD recurrence rate and CAD mortality to be reduced by 15-20% and by 25-40%, respectively.

3.3. Participants and Data collection

• **Participants**

- Clinicians: physicians from interdisciplinary collaboration including rehabilitation medicine and cardiology

- Patient Caregivers: Caregivers or patient's family members who take care of patients at patient's residency

- Patients: recovering patients who were hospitalized or had coronary intervention or coronary artery bypass graft for acute coronary artery syndrome,

• **Data collection**

- Wearable device for bio-signals of patients: passive monitoring of electrocardiogram for arrhythmia, blood pressure for low blood pressure, heart rate for exercise intensity, and step count for activity

- Smartphone apps: active data input by patients on rate of perceived exertion and on life style and diet

3.4. Obstacles against Future Ideal State

Lack of certified wearable patient monitoring devices and current regulatory policies have been obstacles against future ideal state which are listed below:

- Lack of medical-grade wearable patient monitoring devices

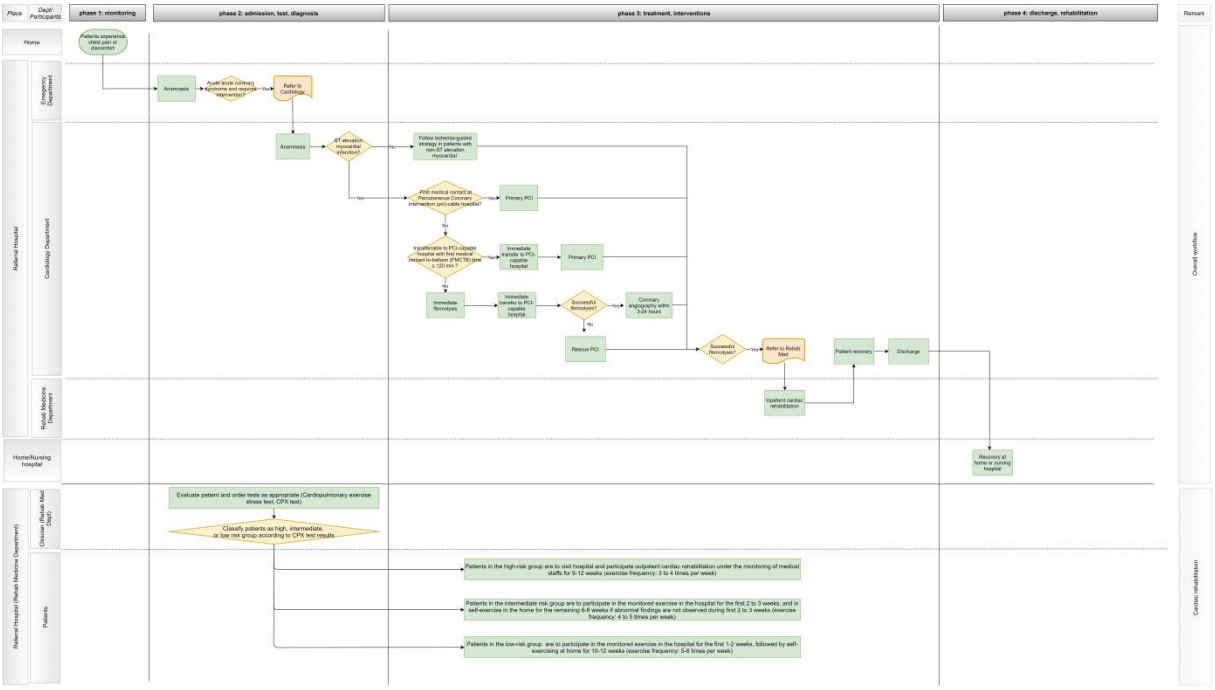
- Regulatory policies that prevent hospital EHR data from being stored outside hospital computation system

- Hospital computation systems that limit access to hospital EHR data from outside

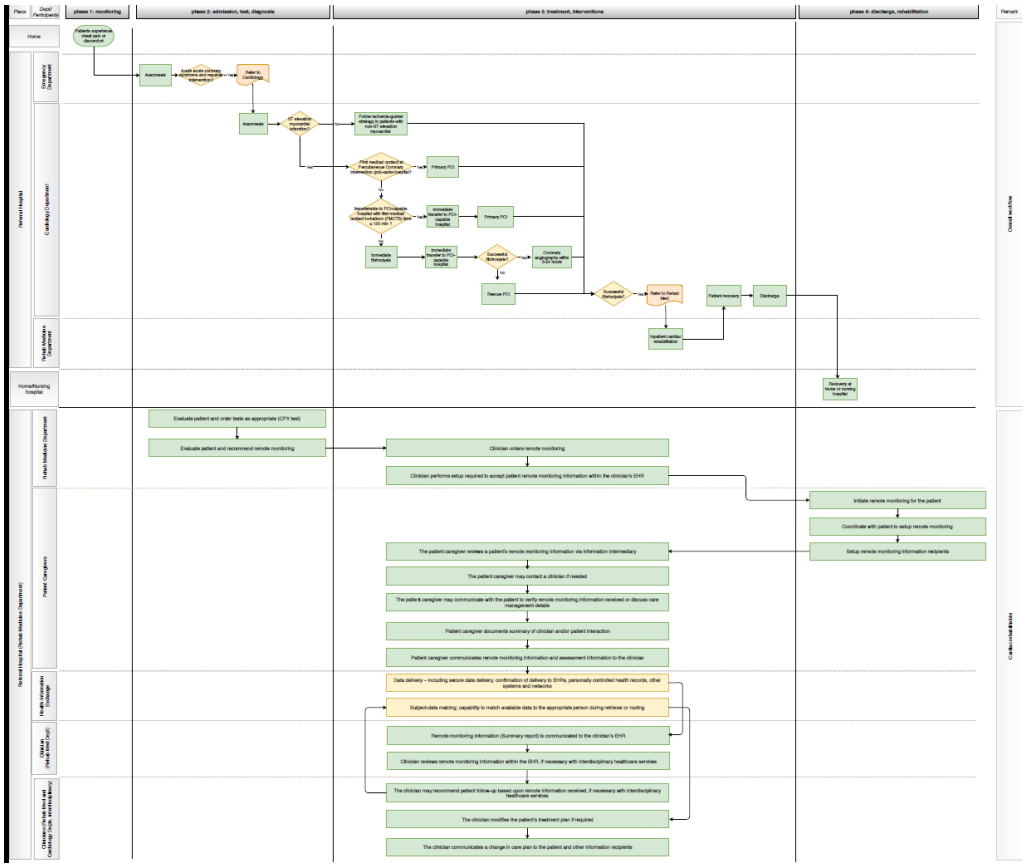
- Regulatory policies that prevent lifelog data of uncertified wearable monitoring devices from being incorporating into hospital EHR data

3.5. Flowchart example (see supplement for full version)

Current sate patient journey



Future Ideal State



Obstacles against Future Ideal State