CCS TAVI QUALITY WORKING GROUP
Anita Asgar, Chair
Sandra Lauck, Vice-Chair
Corey Adams
Faisal Alqoofi
Eric Cohen
Vanita Gorzkiewicz
Malek Kass
Dennis Ko
Laurie Lambert
Najaf Nadeem
Garth Oakes
John Webb
Daniel Wong

TAVI TOOLKIT WORKING GROUP
Sandra Lauck
Anita Asgar
Laurie Lambert
Garth Oakes

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The Canadian Cardiovascular Society
222 Queen Street, Suite 1100
Ottawa, Ontario
Canada K1P 5V9
qualityproject@ccs.ca
THE CANADIAN CARDIOVASCULAR SOCIETY (CCS)
TAVI TOOLKIT OVERVIEW

The TAVI toolkit has been developed in an effort to:
• Complement the CCS TAVI Quality Indicators (QIs);
• Improve the data quality of the CCS TAVI Quality Report by providing guidance, resources, and practice-ready strategies;
• Strengthen collaboration and on-going commitment to the CCS TAVI Quality Report initiative;
• Share resources and capitalize on local initiatives to accelerate national quality improvement; and
• Support clinicians and programs to optimize care.

This module introduces the framework used to develop a suite of individual modules built to augment the CCS TAVI Quality Indicators.
HEART TEAM TREATMENT RECOMMENDATION MODULE

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MODULE OVERVIEW

In the TAVI Toolkit Heart Team Treatment Recommendation module, users are provided with:

• Objective and key considerations for documenting Heart Team Treatment Recommendation;
• Benefits and challenges of using a Heart Team decision-making approach;
• Practical tips to promote Heart Team decision making; and
• Helpful resources to support implementation.

Following review of this module, users will have strategies and tools to support the documentation of a Heart Team approach to treatment for this structural indicator.
1. **CCS QUALITY INDICATOR DEFINITION**

Documentation of Heart Team Treatment Recommendation aims to promote a multi-disciplinary decision-making process to support quality of care.

**Table 1. Heart Team Treatment Recommendation (CCS Quality Indicator)**

<table>
<thead>
<tr>
<th>Description</th>
<th>HEART TEAM TREATMENT RECOMMENDATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Heart Team should meet minimum requirements of an interventional cardiologist and cardiac surgeon but should ideally be composed of the patient's treating physician, geriatrician or internist, cardiac imaging specialist and TAVI nurse coordinator. This multi-disciplinary team should convene as a group on a regular basis to review and interpret clinical data to arrive at a consensus on the optimal treatment strategy for each patient.</td>
<td></td>
</tr>
<tr>
<td>Documentation of Heart Team Treatment Recommendation made by Heart Team at multidisciplinary meeting to review patients.</td>
<td></td>
</tr>
</tbody>
</table>

**Numerator**
Number of TAVI patients who have a documented treatment recommendation from a heart team (minimum of interventional cardiologist and cardiac surgeon) meeting at a center during the given observation period.

**Denominator**
Total number of patients referred for TAVI at a center in a given observation period.

**Method of Calculation**
This structure indicator would be confirmed annually by the participating sites (i.e., Does a multidisciplinary team that includes at minimum a cardiologist and cardiac surgeon meet regularly to discuss a consensus treatment recommendations for patients referred for TAVI?)

**Sources of Data**
- Institutional clinical data
- Hospital records (patient charts)

The Heart Team approach is widely endorsed in international guidelines as a strong recommendation. The primary purpose is to leverage multi-disciplinary expertise to guide the management of patients with complex severe valvular heart disease. A strong, collaborative Heart Team is widely accepted as a requisite component of TAVI programs.

At a minimum, the Heart Team is comprised of an interventional cardiologist and cardiac surgeons who share expertise in the management of complex structural heart disease. The additional contributions of imaging specialists (CT radiology and echocardiology) and nursing, as well as anaesthesiology, heart function specialists, and geriatric cardiology can augment the multi-disciplinary expertise.

A Heart Team approach is well suited to conduct the complex evaluation of patients with heart valve disease. The approach relies on their collective understanding of the risks and benefits of different treatment options to determine if TAVI is indicated, technically feasible, and reasonable. The Heart Team can present treatment options to patients and their family to foster shared decision-making.
Figure 1. CCS Position Statement: Clinical decision trees for patients with AS²
2. OPPORTUNITIES AND CHALLENGES

Opportunities

TAVI owes much of its success to the Heart Team given the integral role they play in this (among other) complex cardiac management programs. This has been attributed to the multi-disciplinary approach the Team takes which prioritizes the interests of clinicians and patients, as well as the advancement of transcatheter heart valve innovation. Patient selection remains a significant challenge, especially as evidence continues to evolve. The goal is for the multidisciplinary team to move away from a system of fragmented care and offer a balanced and complementary approach to guide the management of patients with complex heart valve disease.

The expertise of cardiology and cardiac surgery provides complementary input to build a consensus treatment recommendation for each patient and contribute to individualized procedure planning. In addition, the input of imaging specialists, anaesthesiologists, nurses, geriatric medical specialists and other engaged experts can augment the quality of case selection and the anticipation of procedural and post-procedural needs.

The role of the TAVI nurse coordinator is pivotal to coordinate the complex aspects of patients’ assessment and procedure planning, facilitates effective and streamlined multi-disciplinary collaboration, and serves as a central point of contact for patients and their family. Centres can capitalize on the availability and interest of diverse stakeholders by including them in the multidisciplinary assessment, the treatment recommendation meetings, and the in-hospital care. This “large Heart Team” concept can be an effective approach to implement coordinated and comprehensive strategies along patients’ journey of care from referral to follow-up.

Figure 2. Conceptualization of a “Large” Heart Team approach to care of TAVI patients.
Challenges

Canadian centres have reported the following challenges in promoting a Heart Team approach:

- There is no clear consensus on the definition, desired goals, means of implementation, and metrics to assess success and unintended consequences of a Heart Team approach. There is a need to study the hypothesized benefits, understand how the Heart Team improves care, and identify the structural and operational factors that are central to its success. Metrics are required to measure the timeliness and appropriateness of recommendations and outcomes.

- A Heart Team approach requires time and collaboration between stakeholders across disciplines who may not routinely meet. Finding a suitable time to discuss patients and ensuring the key stakeholders are present can be challenging. Overcoming these logistical barriers can be perceived as excessively difficult in spite of the support of the Team.

- There can be uneven buy-in from different disciplines about the value-add of the process. There are few studies reporting evidence about the value of a Heart Team approach.

- If a program is built on a traditional model of referrals to individual cardiologists or surgeons rather than the endorsement and operationalization of a centrally coordinated program, the timing and impact of a Heart Team meeting can be problematic.

- The documentation of the Heart Team’s recommendation is not standardized. It is unclear how the process can help improve TAVI programs and multi-disciplinary communication.

3. PRACTICAL TIPS AND BEST PRACTICES

Using Documentation of Heart Team Recommendations to Improve Communication

The development of a program-endorsed form that serves as a template for recording individual treatment recommendations and provides a preliminary procedure plan that can be a helpful clinical tool.

Data elements that can be helpful include:

- Basic patient demographics, including urgency (e.g., elective out-patient vs. urgent in-patient);
- Treatment recommendations, including reasons patient may not be accepted for TAVI;
- Procedure planning, including planned procedural approach, pre-procedure requirements, etc.;
- Record of Heart Team members present for discussion.

See Resources for examples of forms used in Canadian centers to document Heart Team Recommendations. These forms can be adapted to meet local needs.

Using Documentation of Heart Team Recommendation to Support Shared Decision-Making

As TAVI quality indicators evolve, it will become increasingly important to support patients’ treatment recommendation. Helping patients opt for SAVR or TAVI, or on-going medical management when treatment may not be recommended or would be futile, requires a concerted approach by the Team. To this end, the Heart Team becomes a vehicle to facilitate joint decision-making.

Shared decision-making is a process by which clinicians and patients work together to select treatment based on clinical evidence and the patient’s informed preferences. It involves the provision of evidence-based information about options, outcomes and uncertainties, together with decision support counselling and a system for recording and implementing patients’ informed preferences. Shared decision-making improves decision quality and patient satisfaction and, in some cases, results in more cost-effective care.
Resources for Clinicians:
The translation of clinical practice guidelines is an important step to facilitate the uptake of evidence in clinical care. International guidelines continue to evolve rapidly to keep pace with clinical trials, new procedural approaches and devices, and a large volume of emerging evidence. In 2016, an international panel of experts considered the evidence of three linked rapid systematic reviews; it produced an interactive set of recommendations for clinicians to consider when making a treatment recommendation.

Figure 3. Flowchart for management of severe aortic stenosis

See Resources for further details.

Resources for Patients:
Decision aids are a part of a shared decision-making process. These tools help people take an active role in decision-making by making explicit the decision that needs to be made, providing information about the options and outcomes, and by clarifying personal values. They are used and presented by clinicians and are a means of helping people make informed choices about healthcare that take into account their personal values and preferences. They are designed to complement, rather than replace, counseling from a health practitioner.

The goals are:
- To inform people about the available options, from an evidence-based perspective
- To encourage active engagement with the decision-making process
- To help people think through what is important to them, so that they can make choices that reflect their own values and preferences
The ACC CardioSmart Decision Aids hub recently expanded to include two new free, downloadable TAVI Decision Aid Tools that help patients understand what AS is and what treatments are available.

The first tool guides patients with intermediate or high surgical risk through the treatment options available for severe AS and helps them choose between TAVI and surgery. The second tool is dedicated to patients with prohibitive surgical risk/patients who are inoperable to help them evaluate the proper treatment and choose between TAVI and symptoms management/palliative approach. See Resources for further details on this ACC resource.

**Incorporating the Measurement of Frailty in the Heart Team Treatment Recommendations**

Careful case selection remains an important component of TAVI program quality. In addition to the pivotal question about whether TAVR is anatomically and clinically feasible, there is strong evidence to support the consideration of patients’ frailty when making individual treatment recommendations and determining patients’ likelihood to derive benefit.

Frailty is different than aging; it is not captured in surgical risk scores and helps explain the heterogeneity of older adults. Frailty is a complex health state, often defined as an age-related, multi-system syndrome that increases health vulnerabilities and risks of adverse events (e.g., significant decline, functional impairment, death) when exposed to stressors (e.g., hospitalization, illness), compared to patients who are the same age.

Frailty may be associated with increased risk of major adverse events including in-hospital complications, longer length of stay, increased hospital readmission, worsening quality of life, falls, functional dependence, disability, and death. The predictive value of frailty was highlighted in early clinical trials and continues to play a role in international administrative registries and on-going studies. The cycle of frailty in cardiovascular disease is well documented:

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**Figure 4.** Cycle of frailty and cardiovascular disease⁴
Measuring frailty in clinical practice can be challenging to measure consistently and rigorously, and its value is often questioned. Upward of 20 frailty assessment tools have been developed, leading to significant confusion and variability in clinical care and research. The absence of consensus surrounding frailty assessment tools, the unstandardized measurements employed in research and clinical care, and the lack of validation in the TAVI population have been significant barriers to the seamless integration of frailty measurement in practice.

The recent publication of the Essential Frailty Toolset (EFT)\(^5\) gives clinicians a pragmatic and reliable tool to measure frailty in TAVI programs. The EFT is a simple assessment of four easily available indicators:

1. **Chair rises [Lower extremity strength]:** The capacity to perform five sequential chair rises with arms folded on chest. The timer starts when the patient is sitting on a flat chair and instructed to begin to stand; it is stopped when the patient stands at the completion of the last stand.

2. **Cognitive status [Short term memory and orientation]:** The score obtained on the Mini-Cog\(^\text{TM}\) measurement of three-word registration and clock drawing; alternatively, the following questions can be asked: (1) What day of the month is it? (2) What day of the week is it? (3) What hospital are you in? and (4) What floor are you on?

3. **Hemoglobin**

4. **Albumin**

The four indicators generate a score that is associated with a predictive risk of 1-year mortality for TAVI and SAVR. The EFT is quick to perform, does not require specialized equipment, and has high inter-observer reliability; it is available as a free smart phone application and does not require a license.

![Central Illustration: Essential Frailty Toolset in Older Adults Undergoing Aortic Valve Replacement](image)

**Figure 5.** Essential Frailty Toolset components and score\(^5\)

If measured, information about frailty should be shared with the Heart Team at the time of treatment recommendation. See **Resources** for an example of documentation of frailty using the Essential Frailty Toolset.
4. QUESTIONS AND ANSWERS

Does documenting a Heart Team approach mean that both interventional cardiologists and cardiac surgeons must participate in each procedure?

The intent of this structural quality indicator is to promote the participation of both specialists in treatment recommendations. This joint expertise is essential for case selection and procedure planning. The configuration and expertise of implanting medical teams varies across centres and is not captured in this quality indicator.

There is no evidence that a Heart Team approach makes a difference for outcomes in the era of contemporary TAVI. Why should we continue to promote it?

There is widespread endorsement of the rationale for team-based care of complex patients in the rapidly evolving clinical context of transcatheter heart valve therapies. In spite of low levels of evidence, the recommendation for programs to maintain a Heart Team approach remains highly recommended in Canadian and international guidelines.

To comply with the CCS Quality Indicator, do people need to meet in-person to discuss patients, or can the discussion happen in other ways (e.g., telephone, e-mail, remote meetings)?

The spirit of the quality indicator is to favour in-person, focused recommendations that employ multi-modality imaging and promote multi-disciplinary input.

How should results of tests concerning frailty or shared decision-making be used by the Heart Team?

Ideally, the Heart Team conducts a comprehensive assessment inclusive of anatomical and functional (e.g., frailty) criteria, and patient perspective. The TAVI nurse coordinator is well suited to present findings related to the assessment of frailty and report on conversations with patients to highlight their goals of care.
5. RESOURCES

The following resources are provided for reference only and are reflective of local practices and clinical contexts. These examples may not be the most current in use at these sites and are shared to promote quality improvement only.

Resource #1: Documentation of Heart Team Treatment Recommendations for Procedure Planning from Canadian Centres

![THV Team Rounds – Aortic Program](image)

**Patient Details**

<table>
<thead>
<tr>
<th>Status:</th>
<th>Elective</th>
<th>In-Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment Completed:</td>
<td>Nursing Assessment</td>
<td>Angiogram</td>
</tr>
</tbody>
</table>

**Treatment Recommendation**

- Assessments reviewed:
  - Nursing Assessment
  - Angiogram
  - Echo
  - CT
- Decision:
  - Accepted for TAVI: TF
  - TF Subclavian
  - Not Accepted for TAVI: Re-Refer to Surgery
  - TA Consider Re-Referral for TAVI
  - Palliative Responsibility for Dictation:

**Risk Stratification**

- Anatomical/Peri-Procedure Risks:
  - Suitable for Cath Lab
  - Adequate femoral artery size and anatomy
  - No anticipated vascular percutaneous access or closure issues
  - No subannular calcification
  - eGFR > 30 ml/min
  - Able to lie flat
- Functional/Post-Procedure Risks:
  - Suitable for Next Day Discharge
  - No significant mobility issues
  - BMI < 30
  - ADL 6/6
  - Other:

**Procedure Planning**

- Planned TF access size: cm
- CT area: cm²
- X-ray angle:

**Valve eligibility:**

- Eligible for all standard devices
- Eligible for specific device(s) only: Device 1, Device 2, Device 3, Other:

**TF approach:**

- Local anaesthesia/conscious sedation
- General anaesthesia
- Hybrid OR

**Pre-procedure requirements:**

- None
- PCI: Pre-TAVI "or" Single stage
- BAV: Other:

**Surgical back-up:**

- Standard consent for TAVI/emergency intervention
- Not suitable for heart surgery:

**Screen for research:**

- Interventional cardiologist required
- Cath lab nurse required (e.g., high risk LM occlusion)

**Urgency:**

- Standard
- Urgent out-patient
- Urgent in-patient

**Present for discussion:**

- Blanke
- Boone
- Cheung
- Cook
- Leipsic
- Ye
- Webb
- Wood

**Comments:**

- Anticoagulation bridging: Prescribers’ orders completed
- Date:

---

**Figure 6.** Sample documentation of Heart Team treatment recommendations for procedure planning (Centre for Heart Valve Innovation, St. Paul's Hospital, Vancouver General Hospital)
Resource #2: Shared Decision-Making

Example #1: The following shared decision-making resource is published as a free, open access manuscript. The resource outlines the following statement:

“Severe aortic stenosis affects approximately 3 in 100 people over the age of 75 years. Patients typically experience symptoms of heart failure and reduced quality of life. Without aortic valve replacement, life expectancy is typically 50% at two years, with escalation of heart failure and reduced quality of life. These recommendations are for patients with symptoms and severe aortic stenosis: patients without symptoms or with milder disease are not considered here”.

Figure 7. Key considerations for patients with symptoms and severe AS

![Diagram showing choice of intervention for those with severe aortic stenosis and key uncertainties.]

![Diagram showing choice of intervention for people with severe aortic stenosis who are unsuitable for TAVI by transfemoral approach.]

Figure 7. Key considerations for patients with symptoms and severe AS
**Figure 8.** Practical considerations that may influence a patient’s choice of procedure³
Resources #3: Decision Aids

The ACC/CardioSmart has published two decision aids that reflect current evidence. Both brochures call on patients to consider:

• Their goals for treating AS;
• Their concerns related to treatment options;
• Additional questions for their clinician?

1. **ACC/CardioSmart decision aid for severe AS treatment options (TAVR vs. Symptom Management)**

   Purpose: “This booklet will help you understand what aortic stenosis (AS) is and what treatment options are available. This booklet is specifically for individuals who cannot have open-heart surgery. You, your family, and your clinicians can begin to discuss which treatment option is best for you”. The content focuses on:

   (1) Understanding AS;
   (2) Treatment options (TAVR vs. symptom management);
   (3) Benefits;
   (4) Risks; and
   (5) Introduction to palliative care.

2. **ACC/CardioSmart decision aid for treatment options for severe aortic stenosis for patients deciding between TAVR and surgery**

   Purpose: “This booklet will help you understand what aortic stenosis (AS) is and what treatment options are available. You, your family, and your clinicians can begin to discuss which treatment option is best for you”.

   The following are illustrations of this brochure:

---

### UNDERSTANDING AS

Aortic Stenosis (AS) is tightening of the aortic valve in the heart. This can get worse over time. AS makes it harder for the heart to do its job.

**SYMPTOMS OF SEVERE AS INCLUDE:**

- feeling dizzy like you might pass out
- feeling tired
- trouble breathing
- chest pain
- swelling of the legs

You may be experiencing some of these symptoms. They may make it harder to do the things you want to do. If left untreated, these symptoms usually get worse over time and can lead to death. **Prior to the decision, you may need to have additional testing to help your clinician understand what your options are.**

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Figure 9. Understanding AS

---
Every patient is different, and we cannot see into the future to know how long your new valve will last. At this time, we know more about how long surgically replaced valves last than we do about TAVR valves. While valve replacements are durable, eventually your new valve may need to be replaced. The timing of this is different for every patient. Talk to your clinician about any concerns you have about how long your valve might last, and what your options might be if it ever needs to be replaced.

Figure 10. TAVR and SAVR overview

TREATMENT OPTIONS

**TAVR**

**Transcatheter Aortic Valve Replacement**

**WHAT:**
TAVR is a procedure where a new valve is placed in the heart through a small tube (called a “catheter”) typically in the leg.

**HOW:**
This procedure involves a small incision where a catheter is inserted to access the heart to replace the valve.

**WHO:**
This method is an option for both patients who are and those that are not candidates for open-heart surgery.

**HOSPITAL STAY:**
On average, 2-3 days

**RECOVERY TIME:**
On average, 1-2 weeks

**VALVE TYPE:**
A bioprosthetic valve is used

**SAVR**

**Surgical Aortic Valve Replacement**

**WHAT:**
SAVR is open-heart surgery where a new valve is placed in the heart directly, replacing the old valve.

**HOW:**
This surgery usually involves an incision along the breastbone to access the heart to replace the valve.

**WHO:**
Those without other severe health problems are good candidates for open-heart surgery.

**HOSPITAL STAY:**
On average, 1 week

**RECOVERY TIME:**
On average, 6-8 weeks

**VALVE TYPE:**
A bioprosthetic valve or mechanical valve is used

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7 Every patient is different, and we cannot see into the future to know how long your new valve will last. At this time, we know more about how long surgically replaced valves last than we do about TAVR valves. While valve replacements are durable, eventually your new valve may need to be replaced. The timing of this is different for every patient. Talk to your clinician about any concerns you have about how long your valve might last, and what your options might be if it ever needs to be replaced.
THE RISKS & BENEFITS OF YOUR OPTIONS

TAVR vs. SAVR: Which is the best decision for me?*


<table>
<thead>
<tr>
<th>TAVR</th>
<th>SAVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>BENEFITS:</td>
<td>BENEFITS:</td>
</tr>
<tr>
<td>• Helps you live longer</td>
<td>• Helps you live longer</td>
</tr>
<tr>
<td>• Helps you feel better</td>
<td>• Helps you feel better</td>
</tr>
<tr>
<td>• Less invasive procedure</td>
<td>• Over 50 years of experience with procedure</td>
</tr>
<tr>
<td>• Shorter recovery time</td>
<td></td>
</tr>
</tbody>
</table>

Nearly 9 in 10 patients are still living within two years and just over 1 in 10 patients will die.

86% live 14% die

Nearly 1 in 10 patients suffer from a stroke within 2 years

8%

Nearly 1 in 10 patients suffer from serious injury to blood vessels

9%

2 in 10 need a pacemaker within 2 years

20%

RISKS:

IN SUMMARY:

- TAVR and SAVR are each effective options for helping your aortic valve
- The risk for needing a pacemaker implanted is higher after TAVR
- TAVR is a less invasive procedure
- More is known about how long mechanical valves last (used in SAVR)

Both TAVR and SAVR have POTENTIAL PROCEDURAL RISKS including:

- Death
- Bleeding
- Stroke
- Heart attack
- Infection
- Blood clots

These risks are different for different patients. Talk to your doctor about your individual risks.

8% 8% 86% live 14% die

85% live 15% die

8% 8% 86% live 14% die

85% live 15% die

IN SUMMARY:

- TAVR and SAVR are each effective options for helping your aortic valve
- The risk for needing a pacemaker implanted is higher after TAVR
- TAVR is a less invasive procedure
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Both TAVR and SAVR have POTENTIAL PROCEDURAL RISKS including:

- Death
- Bleeding
- Stroke
- Heart attack
- Infection
- Blood clots

These risks are different for different patients. Talk to your doctor about your individual risks.

Figure 11. Risks and Benefits of TAVR and SAVR®
TREATMENT SCENARIO 1

JANE IS AN 80-YEAR-OLD WOMAN WITH SEVERE AS.
- She also has moderate lung disease and diabetes.
- She has shortness of breath when she walks across a room.
- Her clinician thinks it might be related to her aortic valve. Jane talked to her clinician to better understand the risks and benefits involved with her options.

Option 1: Choose TAVR
- TAVR is less invasive.
- The recovery time is shorter.
- Jane can expect similar results.

Option 2: Choose SAVR
- TAVR is a newer procedure, while SAVR has been around for a long time.
- Jane knows people who have had open-heart surgery.

After talking to her clinician, Jane decided the TAVR procedure was the best option for her. She is concerned her other illnesses will make recovering from open-heart surgery more difficult.

Figure 12. TAVR vs. SAVR case study

CANADIAN CARDIOVASCULAR SOCIETY

TOOLKIT: TRANSCATHETER AORTIC VALVE IMPLANTATION
### Resource #4: Clinical documentation to support TAVI case selection using EFT

#### Essential Frailty Toolset (EFT)

<table>
<thead>
<tr>
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<th>Score</th>
<th>EFT Points</th>
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<tbody>
<tr>
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</tr>
<tr>
<td>Cognition: Items</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Cognition: Clock</td>
<td>Normal</td>
<td></td>
</tr>
<tr>
<td>Albumin</td>
<td>3.0 g/dL</td>
<td>1</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>12.1 g/dL</td>
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**EFT Score**

1/5  
(Predicted 1-yr mortality: 6% - All access)

#### Other Frailty Indicators

<table>
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<tr>
<th>Measure</th>
<th>Score</th>
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<tr>
<td>5-Metre Gait</td>
<td>6 Sec.</td>
<td>✔️</td>
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#### Overall Nursing Recommendation

**Comments:** ✔️

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**Figure 13.** Sample clinical documentation to support TAVI case selection using EFT (Centre for Heart Valve Innovation, St. Paul's Hospital, Vancouver General Hospital)
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