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ORIGINAL ARTICLE

European Society of Cardiology quality indicators for the care and outcomes of adults undergoing transcatheter aortic valve implantation

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Aims

To develop a suite of quality indicators (QIs) for the evaluation of the care and outcomes for adults undergoing transcatheter aortic valve implantation (TAVI).

Methods and results

We followed the European Society of Cardiology (ESC) methodology for the development of QIs. Key domains were identified by constructing a conceptual framework for the delivery of TAVI care. A list of candidate QIs was developed by conducting a systematic review of the literature. A modified Delphi method was then used to select the final set of QIs. Finally, we mapped the QIs to the EuroHeart (European Unified Registries on Heart Care Evaluation and Randomized Trials) data standards for TAVI to ascertain the extent to which the EuroHeart TAVI registry captures information to calculate the QIs. We formed an international group of experts in quality improvement and TAVI, including representatives from the European Association of Percutaneous Cardiovascular Interventions, the European Association of Cardiovascular Imaging, and the Association of Cardiovascular Nursing and Allied Professions. In total, 27 QIs were selected across 8 domains of TAVI care, comprising 22 main (81%) and 5 secondary (19%) QIs. Of these, 19/27 (70%) are now being utilized in the EuroHeart TAVI registry.

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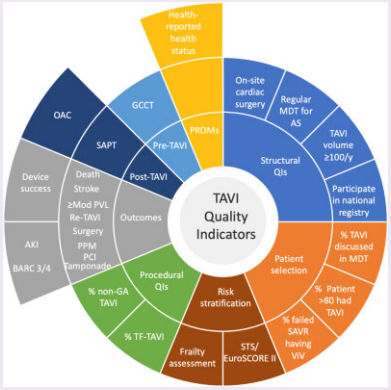
Conclusion We present the 2023 ESC QIs for TAVI, developed using a standard methodology and in collaboration with ESC Associations. The EuroHeart TAVI registry allows calculation of the majority of the QIs, which may be used for benchmarking care and quality improvement initiatives.

Graphical Abstract Central illustration. The 2023 ESC quality indicators for TAVI. AKI, acute kidney injury; AS, aortic stenosis; GA, general anaesthesia; GCCT, gated cardiac computed tomography; MDT, multidisciplinary team; OAC, oral anti-coagulant; PCI, percutaneous coronary intervention; PROMs, patient-reported outcome measures; PVL, paravalvular leak; PPM, permanent pacemaker; QI, quality indicator; SAPT, single antiplatelet therapy; TAVI, transcatheter aortic valve implantation; TF, transfemoral; ViV, valve-in-valve.



Keywords TAVI • Quality indicators • Clinical practice guidelines • Quality improvement • Outcomes • Data • EuroHeart

Introduction

The management of severe symptomatic aortic stenosis (AS) has been transformed by the development and utilization of transcatheter aortic valve implantation (TAVI). When initially introduced into clinical practice, TAVI was reserved for patients unable to undergo surgical aortic valve replacement (SAVR) due to high or prohibitive surgical risk.[1–3] Randomized clinical trials have subsequently demonstrated TAVI to be a viable alternative to SAVR irrespective of surgical risk.[4–8] These developments have led to a rapid expansion in the use of TAVI, which is projected to continue. It is estimated that 300 000 TAVI procedures per year will be performed by 2025, a number equal to the total volume undertaken between 2007 and 2017.[9]

Given the expanding indications for and increasing use of TAVI, it is necessary that TAVI-capable centres do so in a way that adheres to recognized standards—thereby ensuring high quality of care for patients. Quality indicators (QIs) represent a means by which adherence to such standards can be measured, allowing for greater provision of audit and feedback to drive improvement in services. In 2019, the Canadian Cardiovascular Society developed QIs for a range of cardiovascular domains, including TAVI.[10] However, given the rapidity of development in this field, there remains a need for TAVI QIs that are contemporary, internationally endorsed, and applicable to European healthcare systems. This document presents the 2023 European Society of Cardiology (ESC) QIs for TAVI.

Methods

The ESC methodology for the development of QIs for the quantification of cardiovascular care and outcomes was employed.[11] In brief, the methodology involves (i) the identification of the key domains of processes of care and outcomes of the topic of interest by constructing a conceptual framework of care; (ii) the development of candidate QIs by conducting a systematic review of the literature; (iii) the selection of the final set of QIs using a modified Delphi method, and (iv) the evaluation of the feasibility of the developed QIs.[11]

The ESC QIs may be classified into structural, process, and outcome indicators.[11] Structural QIs are those measures that assess the quality of care at the institutional level, while process QIs evaluate care quality at the individual patient level. Outcome QIs capture outcomes that are believed to be relevant to the condition itself (such as disease complications), its treatment (such as adverse events to a therapy), or patient-reported outcome measures (PROMs) such as health-related quality of life (HRQoL). Furthermore, the ESC QIs comprise main and secondary indicators, whereby the main QIs were deemed to have higher validity and feasibility by the Working Group members and thus may be used for performance measurement across regions and over time.[1] Both main and secondary QIs may be used for local quality improvement activities.

Members of the Working Group

The Working Group involved representatives from the European Association of Percutaneous Coronary Intervention, the European Association of Cardiovascular Imaging, the Association of Cardiovascular Nursing and Allied Professions, members from the Quality Indicator Committee, and international experts with respect to TAVI care and outcomes.

Domains of TAVI care

The ESC methodology for QI development recommends the identification of the domains of care at an early stage of the process.[11] Such domains serve as the framework that encapsulates the delivery of TAVI care and the structure that supports its quality assessment. To accomplish this task, the Working Group considered the domains of the European Unified Registries on Heart Care Evaluation and Randomized Trials (EuroHeart) TAVI registry.[12] EuroHeart is an ESC initiative that has developed registries for cardiovascular diseases that may be used for the continuous capture of patient information for the purpose of improving care.[13]

Systematic review

Search strategy

Members of the Working Group (S.A., N.A., G.B., B.B., and T.Y.) conducted a systematic review of the published literature in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) statement (*Table A1*).[14] Relevant medical subject heading (MeSH) terms were used to construct different search strategies for MEDLINE and Embase via OVID® (*Table A2*).

We included two types of studies: randomized clinical trials (RCTs) and controlled observational studies, including publications from clinical registries. Sub-studies and secondary analyses of landmark studies were excluded. The specifications of the search strategy are shown in *Table A2*.

Eligibility criteria

We included studies that met the following inclusion criteria: (i) the study population comprised adult patients (≥18 years old) with severe AS considered for TAVI; (ii) the study explicitly defined a structural and/or process aspect of TAVI care; (iii) the study reported at least one outcome measure (e.g. mortality, re-admission, and/or PROMs) with a clear definition of this outcome; and (iv) the study was a peer-reviewed RCT or controlled observational study.

Study selection

The systematic review team (S.A., N.A., G.B., B.B., and T.Y.) used the reference management software EndNote X9 to remove duplicates and independently examine the abstracts of the retrieved articles. Each abstract was evaluated against the inclusion criteria by two reviewers and disagreements were resolved by involving a third reviewer.

Quality assessment and data extraction

All studies that met the eligibility criteria were included to ensure that the review spanned the full spectrum of TAVI. The full texts of the included articles were reviewed by the systematic review team, and for each study, the team extracted the pertinent variables and respective definitions to a unified Excel spreadsheet.

Clinical practice guidelines and existing QIs

In addition to the systematic review, existing QIs for TAVI[15,16] and relevant Clinical Practice Guidelines[17,18] were reviewed to extract candidate QIs. Guideline recommendations with a strong evidence base (typically classes I and III) were assessed for their suitability to serve as QIs using the ESC criteria for QIs (*Table A3*).

Data synthesis

Modified Delphi process

The structure, process, and outcomes of TAVI care that were extracted from the systematic review as well as those derived from existing guidelines and QIs were used to form a list of candidate QIs. This list was shared with all the members of the Working Group alongside the ESC criteria for QI development (*Table A3*).[11] The modified Delphi method was used to arrive at the final list of 2023 ESC QIs for TAVI. Each candidate QI was individually voted upon by all members of the group via online questionnaires using a 9-point ordinal scale for the two criteria of validity and feasibility.[11] A series of teleconferences and face-to-face meetings were conducted between voting rounds to present the results and clarify any ambiguities.

Analysing voting results

Each QI was scored separately for validity and feasibility using a 9-point ordinal scale: a score of 1–3 meant that the QI is not valid/feasible, 4–6 meant that the QI is of uncertain validity/feasibility, and ratings of 7–9 meant that the QI is valid/feasible. For each candidate QI, the median and the mean deviation from the median were calculated to evaluate the central tendency and the dispersion of the votes. Indicators with median scores ≥7 for validity, ≥4 for feasibility, and minimal dispersion (defined as mean deviation from the median <1.5) were included in the final set of QIs.[11] Candidate QIs meeting the inclusion criteria in the first voting round were classified as main QIs, while those included in subsequent voting rounds were classified as secondary QIs.

Results

Domains of TAVI care

The Working Group identified eight domains of TAVI care incorporating the pathway of managing patients with severe symptomatic AS: (i) structural QIs; (ii) patient selection; (iii) risk stratification; (iv) PROMs; (v) pre-procedural measures; (vi) procedural considerations; (vii) post-procedural care; and (viii) outcomes (*Figure 1*).

Literature review results

In total, 3225 articles were identified (1219 RCTs and 2006 observational studies). Of those, 464 (14.4%) were included for full-text review and data extraction, following which 85 candidate QIs were developed. An additional 17 indicators were derived from existing QIs and Clinical Practice Guidelines.

Delphi results

Following the first voting round, 28 (27.4%) QIs were included as main QIs, 55 (54%) were excluded, and 19 (18.6%) were inconclusive. Subsequent to this, 6 of the 28 main QIs were merged, bringing the total to 22 main QIs in the final set. Of the inconclusive QIs, five (26.3%) were selected as secondary QIs following the second Delphi round. The Working Group proposed textual modifications (phrasing and grouping of QIs rather than the measured aspects of care) for some of the QIs, leading to a third Delphi round ensuring consensus was reached for the changes.

Domain 1: structural framework

Four main QIs were included in this domain. The first captures the availability of on-site cardiac surgery at the healthcare facilities where TAVI is undertaken. This measure aligns with the recommendations of the 2021 ESC/European Association for Cardio-Thoracic Surgery (EACTS) guidelines for the management of valvular heart disease.[17] The second QI in this domain assesses the establishment of a Heart Team for discussion of potential TAVI cases. It aligns with the ESC/EACTS guidelines,[17] and also ensures that lifetime management strategies are considered at the time of index procedures.[19] The third QI measures the number of TAVI centres performing ≥100 procedures per annum, based upon evidence of improved outcomes associated with increased procedural numbers.[20] The final QI in this domain identifies the centres that participate in a national registry for TAVI. Such registries can be used to address important clinical questions as well as provide temporal and geographic trends in TAVI care and outcomes (*Table 1*).[21]

Domain 2: patient selection

This domain evaluates the decision-making process prior to TAVI, including a patient-level assessment of a Heart Team discussion, the proportion of patients with symptomatic severe AS aged 80 years and over who undergo TAVI, and the proportion of those with failed SAVR who are treated with valve-in-valve (ViV) TAVI (*Table 1*).

Domain 3: risk stratification

Risk stratification is a key component of TAVI work-up and preparation. While risk prediction models have been developed for TAVI,[22–24] Clinical Practice Guidelines recommend the use of the European

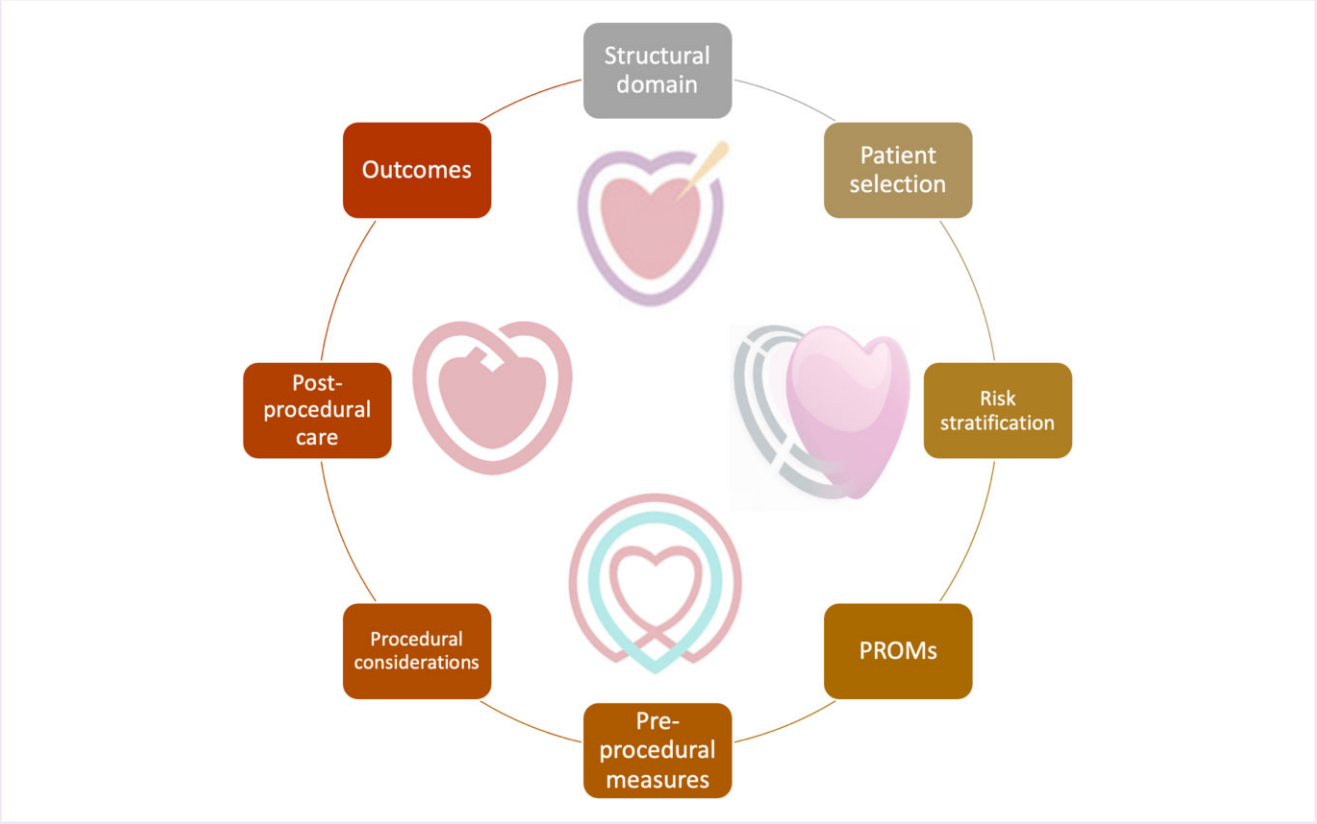


Figure 1 Domains of TAVI care.

System for Cardiac Operative Risk (EuroSCORE) II or the Society of Thoracic Surgeons (STS) scores.[17,18] As such, the first QI in this domain captures the proportion of patients in whom STS or EuroSCORE II is calculated, while the second QI assesses the routine evaluation of pre-procedural frailty, given the association between frailty and mortality after TAVI (*Table 1*).[25]

Domain 4: patient-reported outcome measures

The evaluation of self-reported health status at baseline and during follow-up was selected as a secondary QI due to its importance in delivering patient-centred care and its association with clinical outcomes (*Table 1*).[26] The evaluation of self-reported health status should be systematically assessed using a standardized validated PROM. Self-reported health status covers quality of life, HRQoL, as well as symptom burden.

Domain 5: pre-procedural measures

The QI for this domain captures the proportion of patients who undergo cardiac-gated cross-sectional imaging prior to TAVI. Pre-procedural cardiac-gated CT scanning has become the gold standard for TAVI, and the information obtained clarifies the diagnosis of severe AS,[17,18] allows for accurate annular measurement to guide valve selection, ensures adequate vascular access, and predicts the risk of prosthesis–patient mismatch (*Table 1*).[27]

Domain 6: procedural considerations

Performing TAVI via the transfemoral route has been shown to reduce vascular access complications and associated mortality compared with trans-apical or direct aortic approaches.[28,29] As such, adequate transfemoral access is a determining factor in the decision-making process between TAVI and SAVR according to Clinical Practice Guidelines.[17,18] Therefore, a main QI quantifies the proportion of TAVI procedures carried out via the transfemoral route (*Table 1*).

The other main QI within this domain quantifies the proportion of cases undertaken with local rather than general anaesthesia, as a means to streamline the TAVI process and improve patient experience (*Table 1*).[30]

Domain 7: post-procedural care

The QIs selected within this domain relate to post-TAVI antithrombotic regimes. The first quantifies the proportion of post-TAVI patients with atrial fibrillation and no recent history of percutaneous coronary intervention (PCI) who are treated with oral anti-coagulation as monotherapy (*Table 1*).[31] The second QI measures the proportion of post-TAVI patients with no indication for anti-coagulation or history of recent PCI who are treated with any single antiplatelet agent, as recommended by contemporary Clinical Practice Guidelines (*Table 1*).[17,18]

Domain 8: outcomes

This domain captures clinical outcomes that may be related to severe AS and/or TAVI. The Valve Academic Research Consortium 3 defines a comprehensive list of events relevant to TAVI.[32] The selected QIs in this domain provide a summarized version of important outcomes that were felt to be feasible to measure in practice (*Table 1*).

Table 1 The 2023 ESC QIs for TAVI

1	Structural QIs	EH	Details
1	Centres performing TAVI that have on-site cardiac surgery	X	
Numerator: Number of TAVI centres with on-site cardiac surgery			
Denominator: Number of TAVI centres			
2	Centres performing TAVI that have regular MDT meetings to discuss all patients with severe AS	X	
Numerator: Number of TAVI centres in which regular MDT meetings take place to discuss all patients with severe AS			
Denominator: Number of TAVI centres			
3	Centres performing TAVI that perform ≥100 procedures annually	X	
Numerator: Number of TAVI centres in which ≥100 TAVI procedures are performed annually			
Denominator: Number of TAVI centres			
4	Centre performing TAVI that participate in a national registry for TAVI	X	
Numerator: Number of TAVI centres that participate in a national TAVI registry			
Denominator: Number of TAVI centres			
2	**Patient selection**	**EH**	**Details**
5	Proportion of patients undergoing TAVI who have been discussed at an MDT meeting	✓	
Numerator: Number of patients undergoing TAVI who have been discussed at an MDT meeting			Heart team discussion = yes
Denominator: Number of patients undergone TAVI			All submitted cases
6	Proportion of patients >80 years of age with severe AS treated with TAVI	X	
Numerator: Number of patients >80 years of age with severe, symptomatic AS who have been treated with TAVI			
Denominator: Number of patients >80 years of age with severe, symptomatic AS			
7	Proportion of patients with failed SAVR who are treated with ViV TAVI	X	
Numerator: Number of patients with failed SAVR who are treated with ViV TAVI			
Denominator: Number of patients with failed SAVR			
3	**Risk stratification**	**EH**	**Details**
8	Proportion of patients undergoing TAVI who have their STS or EuroSCORE II score calculated prior to the procedure	✓	
Numerator: Number of patients undergoing TAVI who have their STS or EuroSCORE II score calculated			STS risk score ≠ unknown OR EuroSCORE II ≠ unknown
Denominator: Number of patients undergoing TAVI			All submitted cases
9	Proportion of patients undergoing TAVI who have their frailty assessed (using a validated tool) prior to the procedure	✓	
Numerator: Number of patients undergoing TAVI who have their frailty assessed (using a validated tool) prior to the procedure			Frailty ≠ unknown
Denominator: Number of patients undergoing TAVI			All submitted cases

Table 1 Continued

4	**PROMs**	**EH**	**Details**
10	Proportion of patients undergoing TAVI who have their self-reported health status measured using a validated tool measured at baseline and during follow up	×	
Numerator: Number of patients undergoing TAVI who have their self-reported health status measured using a validated tool measured			
Denominator: Number of patients undergoing TAVI			
5	**Pre-procedural measures**	**EH**	**Details**
11	Proportion of patients considered for TAVI who undergo a pre-procedural cardiac-gated CT scan	×	
Numerator: Number of patients considered for TAVI who undergo a pre-procedural cardiac-gated CT scan			
Denominator: Number of patients considered for TAVI			
6	**Procedural considerations**	**EH**	**Details**
12	Proportion of TAVI procedures carried out via the percutaneous TF route	✓	
Numerator: Number of patients			TAVI access site = femoral
Denominator: Number of patients undergoing TAVI			All submitted cases
13	Proportion of patients undergoing TF TAVI without general anaesthesia	✓	
Numerator: Number of patients undergoing TF TAVI without general anaesthesia			General anaesthesia = no
Denominator: Number of patients undergoing TF TAVI			TAVI access site = femoral
7	**Post-procedural care**	**EH**	**Details**
14	Proportion of patients with AF and no recent PCI (within last 3 months) who are treated with OAC monotherapy post TAVI	✓	
Numerator: Number of patients with AF and no recent PCI (within last 3 months) who are treated with OAC monotherapy post TAVI			Atrial fibrillation/flutter = yes AND Prior cardiac interventions ≠ PCI OR Prior PCI, date >90 days AND Oral anticoagulants = vitamin K antagonist OR dabigatran etexilate OR rivaroxaban OR apixaban OR edoxaban OR other AND acetylsalicylic acid (aspirin) = no AND P2Y12 inhibitors = no
Denominator: Number of patients with AF and no recent PCI (within last 3 months) undergoing TAVI			Atrial fibrillation/flutter = yes AND Prior cardiac interventions ≠ PCI OR Prior PCI, date >90 days

Table 1 Continued

15	Proportion of patients with no indications for OAC or recent PCI (within last 3 months) who are treated with SAPT	✓	
Numerator: Number of patients with no indications for OAC or recent PCI (within last 3 months) who are treated with SAPT			Atrial fibrillation/flutter = no AND Prior cardiac interventions ≠ PCI OR Prior PCI, date >90 days Acetylsalicylic acid (aspirin) = yes OR P2Y12 inhibitors = clopidogrel OR prasugrel OR ticagrelor OR other AND oral anticoagulants = no
Denominator: Number of patients with no indication for OAC or recent PCI (within last 3 months) undergoing TAVI			Atrial fibrillation/flutter = no AND Prior cardiac interventions ≠ PCI OR Prior PCI, date >90 days
8	**Outcomes**	**EH**	**Details**
16	All-cause death	✓	In-hospital stroke = yes
17	Stroke	✓	In-hospital stroke ≠ no
18	Vascular complications = VARC-3 criteria	✓	Vascular complications ≠ no
19	Moderate or severe paravalvular regurgitation	✓	Post deployment aortic regurgitation ≠ no/trace
20	Re-intervention on the valve	✓	In-hospital cardiac intervention = re-do TAVI
21	Conversion to open heart surgery	✓	Procedural events = conversion to sternotomy
22	New permanent pacemaker implantation post-TAVI	✓	In-hospital implantable cardiac device ≠ no
23	Coronary obstruction/bailout PCI	✓	Procedural events = bailout PCI
24	Cardiac tamponade	✓	Procedural events = tamponade
25	Device success = correct positioning of a single prosthetic valve into proper anatomical location	✓	Valve implanted successfully = yes
26	AKI post-TAVI requiring dialysis	✓	In-hospital renal replacement therapy ≠ no
27	Type 3 or 4 bleeding (BARC)	✓	In-hospital major bleeding = yes

EH, EuroHeart (tick indicated that the data pertinent to QI are available in the EuroHeart registry); AKI, acute kidney injury; AS, aortic stenosis; EH, EuroHeart; GA, general anaesthesia; GCCT, gated cardiac computed tomography; MDT, multidisciplinary team; OAC, oral anticoagulant; PCI, percutaneous coronary intervention; PROMs, patient-reported outcome measures; PVL, para-valvular leak; PPM, permanent pacemaker; QI, quality indicator; SAPT, single antiplatelet therapy; TAVI, transcatheter aortic valve implantation; TF, transfemoral; ViV, valve-in-valve.
✓ Implemented in the EuroHeart registry for TAVI.
X Not implemented in the EuroHeart registry for TAVI.

Evaluation of feasibility

Of the 22 main and 5 secondary QIs, 70% (15 main and 4 secondary) can be measured directly from, and are therefore being implemented in, the EuroHeart TAVI registry. The structural QIs are not currently implemented because of the difficulty in collecting this information. The remaining QIs that cannot currently be captured using the EuroHeart registry are the proportion of patients above the age of 80 with severe symptomatic AS who are treated with TAVI, the proportion of patients with failed SAVR who are treated with ViV TAVI, and the proportion of patients undergoing TAVI who have their self-reported health status measured using a validated tool.

Discussion

This document presents the first ESC suite of QIs for the evaluation of care for adults undergoing TAVI. The QIs are derived from evidence, underpinned by expert consensus, and provide a means for quality improvement initiatives. The *a priori* identification of key domains that span the continuum of TAVI care, as well as the engagement of Working Group members from diverse backgrounds and expertise, helps ensure that the QIs presented in this document are relevant to clinical practice and cover the breadth of TAVI care.

In recent years, QIs have become increasingly recognized as important tools within the healthcare environment. They enable assessment, monitoring, and reporting of the quality of care as well as associated improvement initiatives. QIs also support the adoption of guideline recommendations into clinical practice by translating key messages into specific and measurable targets. To date, the ESC has developed several suites of QIs spanning cardiovascular diseases.[33–39]

The Canadian Cardiac Society published a position statement for TAVI in 2019, which included a range of recommendations across three domains.[10] These were developed specifically for Canadian practice; we felt that there was an opportunity to develop contemporaneous TAVI QIs tailored to the European healthcare setting. Notably, since 2019 there have been advances in the field of TAVI such as a move away from general anaesthesia towards routine use of conscious sedation and local anaesthesia, ViV TAVI, chimney stenting, and Bioprosthetic or Native Aortic Scallop Intentional Laceration to Prevent Iatrogenic Coronary Artery Obstruction (BASILICA).[40–43]

TAVI has now become the dominant form of aortic valve intervention; the volume of TAVI procedures carried out has exceeded all forms of SAVR in Sweden since 2017, the USA since 2019, and the UK since 2020.[44–46] This expansion is forecast to continue increasing exponentially, which places greater emphasis upon ensuring that the quality of care delivered by centres performing TAVI is maintained. It is also anticipated that, by formalizing evidence-based recommendations into measurable targets in the form of QIs, this document may help reduce the geographic variation observed in TAVI cases, care, and outcomes. At present, there is a wide variation in the number of TAVI procedures carried out per million population (p.m.p.) both within and between European countries.[47,48] Differences between European countries with regard to deaths attributable to AS have also been reported; in an analysis of mortality trends from AS in Europe between 2000 and 2017, Germany and the Netherlands were the only countries that demonstrated plateauing or declining mortality rates for both sexes.[49] The authors noted that both countries were early adopters of TAVI and have well-established TAVI practices and registries. Adoption and use of the 2023 ESC TAVI QIs into routine delivery of care for patients receiving TAVI will highlight areas of sub-optimal practice, which can then be used to make targeted improvements. In addition, implementation of these QIs within the EuroHeart international quality improvement collaborations will help facilitate better standardization of the quality of TAVI care.

While our study has a number of strengths, we recognize its limitations. First, although the QIs were developed using a published methodology,[11] this relied upon expert opinion to arrive at a final set of QIs. Thus, the selection reflects the beliefs of the Working Group members as to what constitutes good QIs for TAVI, and this may be liable to bias. To mitigate this, we conducted a systematic review of the literature, used a modified Delphi method that independently involved experts' votes to select main and secondary QIs, and applied the ESC criteria to standardize the voting process. Therefore, the final selection was based on the overall assessment of the QIs against the ESC criteria. Previous QIs developed in relatively similar methodology were found to be valid, feasible, and inversely associated with mortality.[50] Finally, given that this field is rapidly progressive, we recommend that the QI suite be evaluated and refined as new evidence becomes available.

Conclusion

This document presents the 2023 ESC QIs for TAVI processes, care, and outcomes, which were developed using a standardized methodology and in collaboration with pertinent ESC Associations. In total, 22 main and 5 secondary QIs have been identified across 8 domains. These TAVI QIs are now being implemented in the EuroHeart TAVI registry and can therefore be used to measure and improve TAVI care at scale.

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Appendix

Table A1 PRISMA checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	3
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g. Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g. PICOS, length of follow-up) and report characteristics (e.g. years considered, language, publication status) used as criteria for eligibility, giving rationale.	5
Information sources	7	Describe all information sources (e.g. databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	5–7
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	5–7
Study selection	9	State the process for selecting studies (i.e. screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	5–7
Data collection process	10	Describe method of data extraction from reports (e.g. piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5–7

Table A1 Continued

Section/topic	#	Checklist item	Reported on page #
Data items	11	List and define all variables for which data were sought (e.g. PICOS, funding sources) and any assumptions and simplifications made.	5–7
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	N/A
Summary measures	13	State the principal summary measures (e.g. risk ratio, difference in means).	5–7
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g. I^2) for each meta-analysis.	7

Table A2 Embase and MEDLINE search terms for the systematic review

Ovid MEDLINE(R) ALL < 1946 to July 23, 2021>		
1	Aortic valve/ab	3203
2	heart valve diseases/or exp aortic valve stenosis/	67 949
3	(aortic* adj stenosis).tw.	17 806
4	(valv* adj3 disease).tw.	18 635
5	or/1–4	84 252
6	((percutan* or transcath*) adj3 (heart* or aortic*) adj3 valve*).tw.	12 016
7	((percutan* or transcath*) adj3 valve*).tw.	15 006
8	PAVR.tw.	37
9	TAVR.tw.	3899
10	TAVI.tw.	4673
11	((transap* or transventric* or percutan* or transcath*) adj3 (deliver* or access* or approach* or minimal*)).tw.	9495
12	or/6–11	24 598
13	5 and 12	10 288
14	aortic valve.ab.	37 796
15	heart valve diseases/or exp aortic valve stenosis/	67 949
16	(aortic* adj stenosis).tw.	17 806
17	(valv* adj3 disease).tw.	18 635
18	or/14–17	100 060
19	((percutan* or transcath*) adj3 (heart* or aortic*) adj3 valve*).tw.	12 016
20	((percutan* or transcath*) adj3 valve*).tw.	15 006
21	PAVR.tw.	37
22	TAVR.tw.	3899
23	TAVI.tw.	4673
24	((transap* or transventric* or percutan* or transcath*) adj3 (deliver* or access* or approach* or minimal*)).tw.	9495
25	or/19–24	24 598
26	18 and 25	12 651
27	randomized controlled trial.pt.	538 117
28	controlled clinical trial.pt.	94 305
29	randomized.ab.	527 676
30	placebo.ab.	219 880
31	clinical trials as topic.sh.	196 742
32	randomly.ab.	362 052
33	trial.ti.	244 131
34	27 or 28 or 29 or 30 or 31 or 32 or 33	1 381 781
35	case report.tw.	339 699
36	letter/	1 144 611

Table A2 Continued

37	historical article/	364 552
38	or/35–37	1 831 884
39	34 not 38	1 356 652
40	26 and 39	1015
41	exp animals/not humans.sh.	4 864 720
42	40 not 41	1011
43	limit 42 to (english language and yr=‘2011 -Current’)	919
Embase < 1974 to 2021 July 23>		
1	aorta valve/	21 351
2	exp valvular heart disease/	155 292
3	aorta valve stenosis/	11 959
4	(aortic* adj stenosis).mp.	34 221
5	(aortic adj stenosis).tw.	28 994
6	(valv* adj3 disease).tw.	29 571
7	or/1–6	202 257
8	((percutan* or transcath*) adj3 (heart* or aortic*) adj3 valve*).tw.	21 714
9	((percutan* or transcath*) adj3 valve*).tw.	26 702
10	PAVR.tw.	103
11	TAVR.tw.	8144
12	TAVI.tw.	10 798
13	((transap* or transventric* or percutan* or transcath*) adj3 (deliver* or access* or approach* or minimal*)).tw.	15 318
14	or/8–13	42 978
15	7 and 14	21 744
16	Clinical Trial/	1 007 269
17	Randomized Controlled Trial/	667 186
18	controlled clinical trial/	463 482
19	exp RANDOMIZATION/	91 544
20	Double Blind Procedure/	185 835
21	Crossover Procedure/	67 568
22	Placebo/	368 717
23	randomi?ed controlled trial$.tw.	262 471
24	rct.tw.	42 785
25	(random$ adj2 allocat$).tw.	47 126
26	double blind$.tw.	221 552
27	((treble or triple) adj blind$).tw.	1393
28	placebo$.tw.	328 560
29	or/16–28	1 871 167
30	Case Study/	79 711
31	case report.tw.	455 315
32	abstract report/or letter/	1 203 955
33	Conference proceeding.pt.	0
34	Conference abstract.pt.	4 134 321
35	or/30–34	5 732 961
36	29 not 35	1 486 516
37	15 and 36	702
38	animals/not humans/	992 935
39	37 not 38	702
40	limit 39 to (english language and yr=‘2011 -Current’)	566

Table A2 Continued

Embase < 1996 to 2021 week 29>		
1	aorta valve/	18 037
2	exp valvular heart disease/	133 616
3	exp aorta valve stenosis/or exp aortic valve stenosis/	4230
4	(aortic* adj stenosis).mp.	30 738
5	(aortic adj stenosis).tw.	25 556
6	(valv* adj3 disease).tw.	24 870
7	or/1–6	169 978
8	((percutan* or transcath*) adj3 (heart* or aortic*) adj3 valve*).tw.	21 694
9	((percutan* or transcath*) adj3 valve*).tw.	26 627
10	PAVR.tw.	103
11	TAVR.tw.	8143
12	TAVI.tw.	10 798
13	((transap* or transventric* or percutan* or transcath*) adj3 (deliver* or access* or approach* or minimal*)).tw.	14 411
14	or/8–13	41 996
15	7 and 14	21 066
16	exp cohort analysis/or exp longitudinal study/or exp prospective study/or exp follow up/or exp Registries/or cohort$.tw.	3 163 343
17	15 and 16	8908
18	exp animal/or nonhuman/	22 831 514
19	17 not 18	325
20	limit 19 to (english language and yr=‘2011 -Current’)	91
Ovid MEDLINE(R) <1946 to July Week 3 2021>		
1	Aortic valve/ab	3202
2	heart valve diseases/or exp aortic valve stenosis/	67 872
3	(aortic* adj stenosis).tw.	15 646
4	(valv* adj3 disease).tw.	16 428
5	or/1–4	80 076
6	((percutan* or transcath*) adj3 (heart* or aortic*) adj3 valve*).tw.	9604
7	((percutan* or transcath*) adj3 valve*).tw.	11 969
8	PAVR.tw.	36
9	TAVR.tw.	2955
10	TAVI.tw.	3762
11	((transap* or transventric* or percutan* or transcath*) adj3 (deliver* or access* or approach* or minimal*)).tw.	8017
12	or/6–11	20 039
13	’exp cohort analysis/or exp longitudinal study/or exp prospective study/or exp follow up/or exp Registries/or cohort$.tw.	1 229 477
14	5 and 12 and 13	2056
15	exp animals/not humans.sh.	4 861 766
16	14 not 15	2055
17	limit 16 to (case reports or letter)	44
18	16 not 17	2011
19	limit 18 to (english language and yr=‘2011 -Current’)	1914

Table A3 Criteria for the development and evaluation of the ESC quality indicators for cardiovascular disease

Domain	Criteria
Importance	QI reflects a clinical area that is of high importance (e.g. common, major cause for morbidity, mortality, and/or health-related quality of life).
	QI relates to an area where there is gap in care delivery and/or variation in practice.
	QI implementation will lead to a meaningful improvement in patient outcomes.
	QI may address under- and/or over-use of a test or treatment.
Evidence base	QI is derived from clearly defined, acceptable evidence consistent with contemporary knowledge.
	QI aligns with the respective ESC Clinical Practice Guideline recommendations.
Specification	QI has clearly defined patient group to whom the measurement applies (denominator), including explicit eligibility criteria.
	QI has clearly defined patient group for whom the QI is met (numerator), including explicit definition of QI meeting criteria.
	QI has a minimum population level.
Validity	QI is able to correctly assess what it is intended to, adequately distinguishes between good- and poor-quality care, and compliance with the indicator would confer health benefits.
Reliability	QI is reproducible even when data is extracted by different people and estimates of performance on the basis of available data are likely to be reliable and unbiased.
Feasibility	QI may be identified and implemented with reasonable cost and effort
	Data needed for the assessment is (or should be) readily available and easily extracted within an acceptable time frame.
Interpretability	QI is interpretable by healthcare providers, so that practitioners can understand the results of the assessment and take actions accordingly.
Actionability	QI is influential to the current practice where a large proportion of the determinants of adherence to the QI are under the control of healthcare providers being assessed.
	This influence of QIs on behaviour will likely improve care delivery.
	QI is unlikely to cause negative unintended consequences.

ESC, European Society of Cardiology; QI, quality indicator.

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