Appendix 1. Korean guidelines for TAVR

<table>
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<th>Condition of implementation</th>
<th>Guidelines</th>
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| 1. The TAVR application of the relevant hospital can be approved after all requirements for human resources, equipment, and facilities have been satisfied. | 1) > 10 AVRs, > 10 aortic stent graft or aorto-iliac stent grafts, > 100 PCIs  
2) > 2 Cardiac surgeons with more than 5 years of cardiac surgery experience  
3) > 2 Cardiac interventionists with more than 5 years of cardiac intervention experience  
4) Hospital should install fluoroscopic devices that are amenable to TEE and emergency cardiac surgery conversion |
| 2. TAVR should be done after an evaluation by the heart team. The heart team should decide whether a patient is a suitable candidate for TAVR. | 1) Heart team: > 2 cardiologists including 1 echocardiographer, > 2 cardiac surgeons, > 1 anesthesiologist and radiologist. Their opinions can be replaced by consultation replies if they are not available for heart team meetings.  
2) The recommendation for TAVR should be based on the indications, contraindications, risks, and benefits of TAVR after all members of the heart team have agreed to the implementation of TAVR. |

Indications for TAVR

Symptomatic severe aortic stenosis with high or inoperable surgical risk

1. Cardiac symptoms: NYHA functional class > 2
2. Grade of severity
   1) Mean pressure gradient of AV $\geq$ 40 mm Hg or peak jet velocity $\geq$ 4 m/sec
   2) Initial echo-derived AVA $< 1.0 \text{ cm}^2$ or AVA index $\leq 0.6 \text{ cm}^2/\text{m}^2$
   3) High surgical risk: predicted risk of operative mortality $\geq 15\%$, STS score $\geq 8$

Contraindications for TAVR

1. Absolute contraindications
   1) Clinical
      (1) Life expectancy $\leq 1$ yr
      (2) No expectation of quality of life improvement due to severity of comorbidities
      (3) Presence of concomitant major valvular disease amenable to surgical treatment only
   2) Anatomic
      (1) Aortic annular diameter ($< 18 \text{ mm}$, $> 29 \text{ mm}$)
      (2) LV thrombus
      (3) Active IE
      (4) High risk of coronary OS obstruction (asymmetric valve calcification, short coronary OS and annular distance, small aortic sinus)
      (5) Mobile thrombotic plaques in ascending aorta and aortic arch
      (6) Poor transfemoral and transsubclavian access due to size, presence of calcification, and extreme tortuosity
   2. Relative contraindications
      1) Bicuspid or non-calcified AV
      2) CAD requiring coronary intervention or surgery
      3) Hemodynamically unstable condition or LV EF $< 20\%$
   4) Contraindication for transapical route: severe lung disease or otherwise not accessible through the transapical route

Heart team documentation

1. Documentation of heart team records should include the time and location of the heart team meeting, the name and signature of the participating doctors, treatment plan, and the reasons for the decisions regarding TAVR, which should also be recorded in the medical records.
2. A heart-lung machine or ECMO, as well as a cardiac surgeon, anesthesiologist, and perfusionists, should be on standby in case of an emergency operation during TAVR. Names of on-call staff should be recorded in the medical records.

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Appendix 1. Continued

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<th>Variable</th>
<th>Guidelines</th>
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<td>3. The relevant hospitals should submit clinical records including the reason for conducting TAVR, pre- and post-TAVR patient status, any complications after TAVR, and whether TAVR was successful within 30 days of TAVR.</td>
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<td>1) Submission time: before discharge, between 30 days and 6 months, 1 year, 2 years, and 3 years after TAVR.</td>
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<td>2) The hospital should submit a statement of the reasons if follow-up clinical data collection was not done or if the data are unavailable.</td>
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<td>4. The chairman of HIRA should monitor clinical data relating to TAVR by the relevant hospitals that grant TAVR approval and report the data to the Minister of Health and Welfare.</td>
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TAVR, transcatheter aortic valve replacement; AVR, aortic valve replacement; PCI, percutaneous coronary intervention; TEE, transesophageal echocardiography; NYHA, New York Heart Association; AV, aortic valve; AVA, aortic valve area; STS, Society of Thoracic Surgeons; LV, left ventricle; IE, infective endocarditis; OS, ostium; CAD, coronary artery disease; EF, ejection fraction; ECMO, extracorporeal membrane oxygenation; HIRA, Health Insurance Review and Assessment Service.

Appendix 2. Administrative decree for the approval of TAVR in relevant hospitals

<table>
<thead>
<tr>
<th>No.</th>
<th>June 2015</th>
<th>February 2016 revision</th>
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<tbody>
<tr>
<td>1</td>
<td>The objective of this administrative decree is to define the necessary procedures for pre-approval of the relevant hospital and clinical data submission.</td>
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<td>2</td>
<td>The hospital should submit the documents relating to TAVR application to the chairman of HIRA.</td>
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<td>3</td>
<td>1) The special advisory board should report the results of the evaluation of the relevant hospitals for the TAVR application to the Minister of Health and Welfare within 45 days upon receipt of the application.</td>
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<td>2) The chairman of HIRA can ask the relevant hospital to submit all data necessary to make a decision regarding the approval of TAVR.</td>
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<td>3) The chairman of HIRA can ask HIRA staff to check the conditions of the hospital, if doing so is necessary for the decision to approve TAVR according to 3.1).</td>
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<td>4) Hospitals confirmed by the Minister of Health and Welfare should report any change in the standards of TAVR applications to the chairman of HIRA without delay.</td>
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<td>4</td>
<td>① The chairman of HIRA can reject a TAVR application after consultation with the special advisory board, for the following reasons:</td>
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<td>1) The relevant hospital does not submit TAVR application data by 3.2) within the required period.</td>
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<td>2) The hospital submits false data or data based on false information.</td>
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<td>① The chairman of HIRA should report the rejection to the Minister of Health and Welfare without delay if the rejection is confirmed by the special advisory board according to 4.①.</td>
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<th>No.</th>
<th>June 2015</th>
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| 5   | ① The relevant hospital should submit clinical pre-discharge data of TAVR within the required period. The data should be submitted together with medical care expenses if medical care expenses are claimed before discharge or within 30 days after discharge.  
② Hospital should submit follow-up data of TAVR within the following periods:  
- Between 30 days and 6 months after TAVR  
- 1 Year after TAVR  
- 2 Years after TAVR  
- 3 Years after TAVR  
③ The chairman of HIRA can ask the hospital to submit associated data to verify whether the conditions for the TAVR application have been satisfied.  
④ The chairman of HIRA can routinely verify items associated with clinical data for the approval of TAVR application. |  |
| 6   | ① The chairman of HIRA may allow the special advisory board to investigate a hospital to decide whether they should restrict TAVR based on the items below:  
1. The hospital does not meet the requirements for TAVR approval by 3.4).  
2. The hospital does not submit data or submits falsified data, by 5.①–③.  
3. The hospital denies or avoids the investigation of the requirements for approval by 5.④.  
4. The hospital does not meet the requirements for approval of TAVR after investigation by 5.③,④.  
② The chairman of HIRA should inform the Minister of Health and Welfare of the results of the investigation promptly by 6.①. | ① The hospital should submit the data for the requirements for approval of TAVR without delay when they have been requested.  
② The Minister of Health and Welfare can cancel a TAVR application after review by the special advisory board if the hospital does not meet the requirements for approval or does not follow the required conditions.  
5. The hospital does not meet the requirements for a TAVR application. |
| 7   | ① The chairman of HIRA should permit medical care expenses of TAVR approved by the Minister of Health and Welfare after investigation by the special advisory board.  
② The chairman of HIRA should suspend medical care expenses of TAVR cancelled by the Minister of Health and Welfare after investigation by the special advisory board. | |

TAVR, transcatheter aortic valve replacement; HIRA, Health Insurance Review and Assessment Service.