

SUPPORTING EVIDENCE: DECISION AIDS FOR PATIENTS WITH SYMPTOMATIC AORTIC STENOSIS

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Introduction

In an effort to improve the patient-centered nature of decision making surrounding options for symptomatic aortic stenosis, and with support from the American College of Cardiology Foundation, we sought to create patient decision aids (PtDAs) which effectively portray treatment options available to groups of such patients. These treatments include traditional surgical aortic valve replacement (SAVR), a newer transcatheter aortic valve replacement procedure (TAVR), and medical symptom management (aligned with palliative care).

PtDAs have emerged as an effective intervention to improve patients' decision making.¹ A Cochrane review of 110 randomized trials demonstrated that PtDAs improve knowledge, satisfaction, involvement in decision making, patient/provider communication, and decisional conflict/regret reported by patients². This model is accordingly realized within the Ottawa Decision Support Framework (ODSF)³, which defines a "good" patient decision as one which is both informed and reflective of patient values. The primary goal of PtDAs are to help support the shared decision-making process.

We have developed two paper-based PtDAs (delineated according to whether the patient does or does not qualify for SAVR based on clinician-assessed surgical risk) and are in the process of developing accompanying video decision aids to assist patients decision-making process. These tools are designed to be supplemental information for patients to use in discussions with their clinicians throughout the decision-making process.

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Development Process

Clinical Background

Aortic stenosis (AS) is a common cardiovascular condition, affecting between 0.3 and 0.5% of the general population, but with up to 7% prevalence among older adults.⁴⁻⁵ While surgical aortic valve replacement (SAVR) has traditionally been the preferred method of treating AS, the high degree of surgical risk involved in this procedure has given rise to the popularity of TAVR, which can be conducted less invasively for patients whose health is too compromised for SAVR. TAVR thus extends a therapeutic option for aortic valve stenosis to patients that were previously of prohibitive or extremely high risk for surgical valve replacement.⁶⁻⁷ By 2012, the TAVR procedure had been conducted more than 50,000 times,⁶ a figure certain to increase with indications expanding to lower-risk patients.⁸

The vast majority of research effort in TAVR has been devoted to improving clinical approaches and devices, followed by efficacy and safety testing. To date, no decision aids are included in standard practice for TAVR. In a recent memo addressing local coverage determination (LCD) criteria for TAVR, however, the Centers for Medicare & Medicaid Services (CMS) required quality of life assessment both pre- and 1-year post-TAVR⁹. This determination was informed by a number of reviews of relevant efficacy data, which highlight a general lack of attention to defining patients who are poor candidates for TAVR rather than just for SAVR, and which fail to differentiate the lack of clinical gains in non-cardiac comorbidities at the patient level among older AS patients¹⁰. Patient decision aids represent an ideal format for including patient perspectives in the decision-making process, thereby addressing CMS concerns about TAVR patient selection.

This project aims to develop and test decision aids designed to improve TAVR decision making for patients. Each type of decision aid has advantages: a short, paper decision aid may be useful during an office visit with a clinician; a video may be better for patients with lower health literacy, fewer technical skills or greater level of acute illness. Developing two types of decision aids will allow us to inform a broader patient-centered research agenda. The development of different types of decision aids will provide a deeper understanding of how decision aids are best applied to particular populations in real-world settings. Development will be conducted in close collaboration with patients, caregivers and clinicians, allowing for full understanding of the decision context and maximizing future implementation and dissemination.

Decision Aid Development

Following the standard Colorado Model of DA Development and Alpha Testing (Figure), prototypes of the paper decisions aids were developed by the study team, based upon International Patient Decision Aid Standards (IPDAS)¹¹, examples of current decision aids previously developed by team members, and formal evidence of the types, rates, and severity of the range of potential risks, benefits, and burdens for TAVR, surgical AVR, or ongoing symptom management and/or hospice. The drafts of each paper decision aid underwent a process of iterative testing and revision to assure accuracy, readability and lack of bias including:

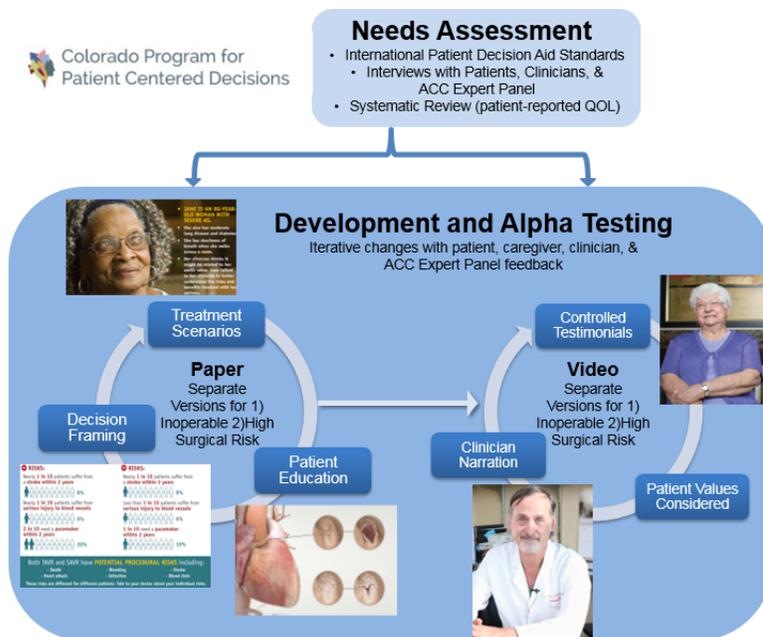
Interviews with Patients and Caregivers

Interviews with patients and caregivers were conducted. Patients were recruited from one facility and were interviewed about their experience in their decision making to accept or decline TAVR. They were also asked to review a draft of the paper decision aid and provide candid feedback along with suggestions for improvement.

Risk & Benefit Data Overview

Benefit: Quality of Life

Author (Year)	Registry	Measure	Duration (months)	Tx Arms	n	Results
Reynolds et al. (2011) ¹²	PARTNER	KCCQ, SF-12	12	TF-TAVR	179	In patients with inoperable aortic stenosis, TAVR showed significant improvements in health related quality of life relative to standard of care.
				Symptom Mgmt	179	



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Reynolds et al. (2012) ¹³	PARTNER	KCCQ, SF-12, EQ-5D	12	TF-TAVR	184	In high risk patients with severe AS, health status substantially improved with TAVR or AVR 1 year after baseline. TAVR via transfemoral approach only associated with short term advantage relative to surgery.
				Non-TF TAVR	76	
				AVR	218	
Arnold et al. (2015) ¹⁴	Corevalve US Pivot Trial	KCCQ, SF-12, EQ-5D	12	TF-TAVR	315	Health status improved substantially in surviving patients with increased surgical risk who were treated with either TAVR or AVR. TAVR via the TF route was associated with better early health status compared with AVR, but there was no early health status benefit with non-TF routes.
				Non-TF TAVR	61	
				AVR	333	
Arnold et al. (2017) ¹⁵	STS/ACC TVT	KCCQ	12	TAVR	701 4	Improvement in TAVR health status similar to results seen in clinical trials. 1 in 3 still had a poor health status outcome 1 year after TAVR, with other comorbidities having a significant impact on outcome.
Baron et al. (2017) ¹⁶	PARTNER 2	KCCQ, SF-12, EQ-5D	24	TF-TAVR	723	In intermediate-risk patients with severe AS, health status improved significantly with both TAVR and SAVR through 2 years of follow up. Early health status improvement was greater with patients treated with TF-TAVR only.
				Non-TF TAVR	227	

Lowered all-cause mortality at two years (inoperable risk)

Study	Year	Subjects	Duration (months)	Results		
				TAVR	UC	Confidence
Partner I ⁷	2012	N= 179	24	43.3%	68.0%	p<0.001

Mortality data summary - Patients presenting with inoperable surgical risk:

The PARTNER I trial remains the landmark US trial establishing a clear all-cause and cardiovascular mortality benefit among patients presenting with inoperable surgical risk. As such, we chose to report observed all-cause mortality verbatim (NEJM ref). While we considered including cardiovascular mortality, we chose all-cause to address the central question for patients with inoperable risk (frequently due to comorbidities which are themselves life-limiting), which is absolute survival over time.

All-cause mortality at two years (high/intermediate risk)

Study	Year	Subjects	Duration (months)	Results		
				TAVR	SAVR	Confidence
Partner II ⁸	2016	N= 1011	24	16.7%	18%	p=0.45
SURTA VI ¹⁷	2017	N=864	24	11.4%	11.6%	95%CI=(-3.8-3.3)

Mortality data summary - Patients presenting with high/intermediate surgical risk:

As both the PARTNER II and SURTA VI trials were designed to test the relative risk and benefits of TAVR when compared to surgical AVR among patients with high and intermediate surgical risk, it was expected that neither established a comparative mortality benefit. As such, mortality is reported in each DA without a comparative context, as the “gist” knowledge to be portrayed is that both procedures illustrate similar all-cause mortality at two years. We chose to report rounded arithmetic averages of mortality between trials to manage any history or unmeasured variance effects which may account for differences in mortality between cohorts.

Note: We chose not to report rates of stroke, vascular injury and need for a pacemaker in the inoperable risk decision aid. Our team felt that the inoperative risk tool was less about these individual rates and more about the overall death rate. Also, the presentation of the risks was difficult to balance. For example, pacemaker may be much higher in the TAVR group but that is because of the very high mortality rate in the group that chooses against TAVR. Thus, showing the risks for the TAVR could inadvertently make the tool biased against TAVR and hurt the overall balance.

Risk: Stroke at two years (high/intermediate risk)

Study	Year	Subjects	Duration (months)	Results		
				TAVR	SAVR	Confidence
Partner II ⁸	2016	N=1011	24	9.5%	8.9%	p=0.67
SURTA VI ¹⁷	2017	N=864	24	6.2%	8.4%	95%CI=(-5.0-0.4)

Stroke data summary - Patients presenting with high/intermediate surgical risk:

Similar to what was observed with respect to mortality risk. Neither PARTNER II nor SURTAVI established TAVR as having a different rate of stroke (of all etiologies) when compared to SAVR. As such, both are reported as approximately 8% and interpreted as “nearly one in ten”.

Risk: Vascular complications at two years (high/intermediate risk)

Study	Year	Subjects	Duration (months)	Results		
				TAVR	SAVR	Confidence
Partner II ⁸	2016	N=1011	24	8.6%	5.5%	p=0.006
SURTAVI ¹⁷	2017	N=864	1	6.0%	1.1%	95%CI=(3.2-6.7)

Vascular complications data summary- Patients presenting with intermediate/high surgical risk:

TAVR logically presents with an increased risk of vascular injury, owing to the amount of vasculature involved in the (most common) transfemoral access route. This is reflected in both the PARTNER II and SURTAVI trials. We elected to report the moderately higher risks reported in PARTNER II to maintain a consistent 2-year follow-up period in each risk category.

Risk: Need for a pacemaker implanted at two years (high/intermediate risk)

Study	Year	Subjects	Duration (months)	Results		
				TAVR	SAVR	Confidence
Partner II ⁸	2016	N=1011	24	11.8%	10.3%	p=0.29
SURTAVI ¹⁷	2017	N=864	1	25.9%	6.6%	95%CI=(15.9-22.7)

Pacemaker data summary- Patients presenting with intermediate/high surgical risk:

Perhaps the starkest difference in results between the PARTNER II and SURTAVI trials was the risk of permanent pacemaker placement associated with TAVR (which increased from 11.8% at 24 months to 25.9% at one month post-procedure). Upon publication of SURTAVI results, we consulted with both local experts (Drs. Valle and Carroll) and the ACC in an effort to report a risk rate that was acceptable to clinical audiences. The elevated risk observed in SURTAVI, according to these experts, was consistent with their anecdotal experience. We therefore elected to report a 2-year risk of permanent pacemaker placement following TAVR as 20% (or “two in ten”), honoring both the elevated results from SURTAVI and the lower rate observed in the earlier (but larger) PARTNER II trial.

References

1. O'Connor AM, Wennberg JE, Legare F, Llewellyn-Thomas HA, Moulton BW, Sepucha KR, Sodano AG, King JS. Toward the 'tipping point': Decision aids and informed patient choice. *Health Aff (Millwood)*. 2007;26:716-725
2. Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, Holmes-Rovner M, Llewellyn-Thomas H, Lyddiatt A, Thomson R, Trevena L. Decision aids for people facing health treatment or screening decisions. *Cochrane Database of Systematic Reviews* 2017, Issue 4. Art. No.: CD001431. DOI: 10.1002/14651858.CD001431.pub5.
3. Ottawa Decision Support Framework. University of Ottawa. 2010.
4. Nkomo VT, Gardin JM. Burden of valvular heart diseases: A population-based study. *Lancet*. 2006;368:1005-1011.
5. Vahanian A, Alfieri O, Andreotti F, et al. Guidelines on the management of valvular heart disease. *Eur Heart J*. 2012;33:2451-2496.
6. Leon MB. Transcatheter aortic valve replacement: a breakthrough medical therapy. The 20-year odyssey, and now, a 10-year anniversary. *Arch Cardiovasc Dis*. 2012;105(3):145–52.
7. Mack MJ, Leon MB, Smith CR, Miller DC, Moses JW, Tuzcu EM, Webb JG, Douglas PS, Anderson WN, Blackstone EH, Kodali SK. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet*. 2015;385(9986):2477-84.
8. Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, Thourani VH, Tuzcu EM, Miller DC, Herrmann HC, Doshi D. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *New Eng J of Med*. 2016;374(17):1609-20.
9. [https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=257&ver=4&NcaName=Transcatheter+Aortic+Valve+Replacement+\(TAVR\)&bc=ACAAAAAAIAAA&](https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=257&ver=4&NcaName=Transcatheter+Aortic+Valve+Replacement+(TAVR)&bc=ACAAAAAAIAAA&)
10. Neyt M, Van Brabandt H. Health technology assessment. Transcatheter aortic valve implantation (TAVI): a health technology assessment update. *Health*

Technology Assessment (HTA) Brussels: Belgian Health Care Knowledge Centre (KCE). *KCE Reports*. 2011;163C. D/2011/10.273/48

11. http://ipdas.ohri.ca/IPDAS_checklist.pdf
12. Reynolds MR, Magnuson EA, Lei Y, Leon MB, Smith CR, Svensson LG, Webb JG, Babaliaros VC, Bowers BS, Fearon WF, Herrmann HC. Health-related quality of life after transcatheter aortic valve replacement in inoperable patients with severe aortic stenosis. *Circ*. 2011 Jan 1:CIRCULATIONAHA-111.
13. Reynolds MR, Magnuson EA, Wang K, Thourani VH, Williams M, Zajarias A, Rihal CS, Brown DL, Smith CR, Leon MB, Cohen DJ. Health-related quality of life after transcatheter or surgical aortic valve replacement in high-risk patients with severe aortic stenosis: results from the PARTNER (Placement of AoRTic TraNscathetER Valve) Trial (Cohort A). *JACC*. 2012 Aug 7;60(6):548-58.
14. Arnold SV, Reynolds MR, Wang K, Magnuson EA, Baron SJ, Chinnakondepalli KM, Reardon MJ, Tadros PN, Zorn GL, Maini B, Mumtaz MA. Health status after transcatheter or surgical aortic valve replacement in patients with severe aortic stenosis at increased surgical risk: results from the CoreValve US Pivotal Trial. *JACC: Card Interv*. 2015 Aug 17;8(9):1207-17.
15. Arnold SV, Spertus JA, Vemulapalli S, Li Z, Matsouaka RA, Baron SJ, Vora AN, Mack MJ, Reynolds MR, Rumsfeld JS, Cohen DJ. Quality-of-life outcomes after transcatheter aortic valve replacement in an unselected population: a report from the STS/ACC Transcatheter Valve Therapy Registry. *JAMA Card*. 2017 Apr 1;2(4):409-16.
16. Baron SJ, Arnold SV, Wang K, Magnuson EA, Chinnakondepali K, Makkar R, Herrmann HC, Kodali S, Thourani VH, Kapadia S, Svensson L. Health Status Benefits of Transcatheter vs Surgical Aortic Valve Replacement in Patients With Severe Aortic Stenosis at Intermediate Surgical Risk: Results From the PARTNER 2 Randomized Clinical Trial. *JAMA Card*. 2017 Aug 1;2(8):837-45.
17. Reardon MJ, Van Mieghem NM, Popma JJ, Kleiman NS, Søndergaard L, Mumtaz M, Adams DH, Deeb GM, Maini B, Gada H, Chetcuti S. Surgical or transcatheter aortic-valve replacement in intermediate-risk patients. *New Eng J of Med*. 2017 Apr 6;376(14):1321-31.

Appendices: Feedback by Source

Appendix 1: American College of Cardiology Expert Review Panel

Comments/Suggestions	Author Response	Text Changes
Paper Decision Aid: Intermediate/High Surgical Risk		
Page 2: “to pump blood out” instead of “to do its job”	We kept wording as is to keep literacy low.	No change.
Page 5: This reference does not appear to be the correct reference. The NEJM paper for inoperable cohort was published in 2010 and for high-risk in 2016. Please double check the data for death alone which is 17 TAVR and 18 SAVR (19 and 21 is for death or disabling stroke).	This is correct, we will change to reflect the correct data.	Typos for references corrected, data for death was corrected.
Overall these are very good. It may make sense to include [both decision aids] as one document and perhaps shorten them up a little more. They are quite comprehensive and I could see giving these out to patients to read more about. The cases at the end are good but could be appendices or online available to save space.	We originally had the two decision aids as one document addressing the three options- however through our feedback process realized that the patient scenarios are very different and the DAs became too complicated. Will consider adding appendices for online versions.	No changes.
A lot of people also want to know the minor side effects i.e. “pump head” or later cognitive dysfunction from open-heart surgery, what to do when they have concomitant CAD, and recovery times, etc... Recovery time is a key one.	We agree to add information about recovery times for TAVR and SAVR	Recovery time information, including average hospital stay and at-home recovery time, were added to page 3.
Page 2: The Wait and See section is very misleading. I think in this section you need to incorporate the ACC/AHA guidelines. Recommend rewriting this section.	Agree that this section is confusing. We will rewrite to make it more straightforward.	Removed “Wait and See” heading on page 2; kept information about why a patient may not have surgery or TAVR right away.
Page 3: TAVR is available by more routes than through the leg or upper chest. If you are hoping to have this as a widespread document the section should be more inclusive.	Agree that the goal is to balance inclusivity with representativeness. Given that >90% of procedures use transfemoral or transapic access, we elected to soften language with “typically”	Changed the language to say “typically in the upper chest or leg”

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Page 4: Risk list is not inclusive. May want to state “potential risks include”	Agree to focus on major risks, while acknowledging that others may be possible.	Added “potential” the risk language.
Page 4: Two year study was with XT? Would recommend using more up to date data.	We are conducting a systematic literature review and will update risk statistics when we have the data.	No change
Page 5: Heart box on the bottom of page 4 and the box in the middle of page 5 say the same thing. Would keep the heart box.	Agree to keep thematic consistency.	Kept the “heart box” theme for consistency.
Page 5: Benefits seems like they should go first, as it is why you would even start the discussion. Move to the top of page 4?	Agree – will reorder.	Switched order presentation of benefits and risks to show benefits first.
Page 4: need a reference; Is this from the Leon paper listed on slide 5? Why such an old slide? The recent data suggests fewer strokes with TAVR. These numbers are only for high-risk patients. The intermediate risk paper shows different results, as does the CoreValve study. Need to revise.	This reference has a typo and is actually the publication from 2016, so the data used is very recent. We double-checked the data from the randomized trial (Leon 2016), and verified that overall stroke rate within 2 years for TAVR is slightly higher than that of SAVR. Will keep data as is.	Added reference to page 4; corrected reference typo on page 5.
Page 4: For benefits of SAVR, need to add something about the availability of information about valve durability	Agree to add information about valve durability. The question of availability of evidence of valve durability was a consistent theme of feedback from a few clinician sources. Others, however, were concerned about unnecessary bias against TAVR if this were reported, due both to a lack of theoretic rationale predicting differences in bioprosthetic valve durability between TAVR and SAVR and no apparent emerging data supporting such a theory either from Europe or with the newest generation of valves. To address the issue of valve durability between mechanical valves and bioprosthetic valves In TAVR, we elected to portray the opportunity to use more durable mechanical valves as a benefit of SAVR.	Small section on valve durability added to page 3.
I like the tools, but I think for the patients at intermediate risk we need to put a little more about one options versus the other. In clinical	Continually adapting the risk/benefit discussions for patients choosing between TAVR/SAVR.	Added note concerning the possible need for additional testing on page 2.

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<p>practice this is based on some special consideration which we use to counsel patients and I am happy to outline them for you but I am not sure how you want them incorporated into the document. I think we need to include that even though TAVR is less invasive, some patients might be more appropriate for surgery and that evaluation by a surgeon and a cardiologist is important to decide which options might be best. As you outlined, patients who are younger, and more active might be more appropriate for surgery as opposed to TAVR in the intermediate group. We should also include what is intermediate risk—that means a calculated risk of death between 4 and 8%—patients usually think it is a lot higher when you say intermediate risk. For patients in this group, it is important to see if they have other problems which can also be fixed during an operation—such as atrial fibrillation, or coronary artery disease. Perhaps adding other scenarios to illustrate these points might be helpful. Patients who are older (in their 80s), are not in very good physical shape, have had a prior cardiac operation and are intermediate risk might be best served by TAVR. Patients who are younger, more active, or have additional things that might need to be fixed, might be more appropriate for SAVR.</p>	<p>While clinical variability is often difficult to capture in paper decision aids, the comment is well received. Since the focus is to set up conversations with healthcare providers, we will add notes highlighting that additional testing for candidacy and appropriateness may be necessary.</p>	
<p>There are two risks that should be listed in the TAVR group for completeness—paravalvular leak and pacemaker. These are more common with TAVR and data has so far suggested that paravalvular leak is not a good thing—this should be included in the decision aid for intermediate risk patients. There is also concern about the durability of the TAVR valves compared to the surgical valves, simply because we have had the surgical valves for a long time. Still, these are the kinds of things I</p>	<p>After some discussion we decided not to include paravalvular leak. Potential need for a pacemaker is included in risks for intermediate surgical risks.</p> <p>Agree to add information about valve durability.</p>	<p>Small section on valve durability added to page 3.</p>

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discuss with my patients when I try to outline the options for TAVR vs SAVR in intermediate risk.		
Many people are misinformed about the sternotomy (getting one's chest cracked open) and want to avoid that at all cost, which in reality patients who do have surgery tolerate it quite well and the pain is manageable.	Patients often underestimate their ability to manage and/or recover from illness/disability/surgery. However, we elected to focus on quantitative estimates of recovery time, eschewing discussion of the subjective experience of recovery from SAVR.	No change
Not all SAVR is done via sternotomy, so the incision statement isn't correct	Agree and will reword to include "typical".	Added "incision typically made along the breastbone" to make the statement more generalizable.
Page 2: under "Wait and See: 1"- what educational level is "deconditioning"? May be too difficult of a word	Agree, will change wording.	Changed "deconditioning" to "being out of shape"
Page 4: under TAVR risks "Need for Permanent Pacemaker"- " <i>within 2 years</i> " instead of two years later	Agree and will clarify phrasing.	Changed wording to "within 2 years"
Page 1: Should label the tools as Intermediate or High surgical risk at the top for usability- will allow providers to quickly determine which tool to give to patient	We agree that it is important to make these tools easy to use for clinicians; we will incorporate some kind of label on the front page.	Added section for clinicians to indicate surgical risk for decision aid.
Page 2: A lot of patients do not understand what a heart valve is. Potentially introduce what SAVR and TAVR stand for on this page	We are continuing to weight the trade-offs between detail and making that page too long. A constant challenge.	No changes made to paper decision aid for readability purposes and space issues; however description of aortic valve was added to both videos.
Page 3: Recovery time for TAVR: up and walking in three hours, ready to go home the next day, recovery time 1-2 weeks	Agree	We will fix the typo to clarify recovery time for TAVR is 1-2 weeks
Page 3: Under SAVR: valve is actually replaced, big difference between SAVR and TAVR	Agree	Added wording to state that the valve is actually replaced during SAVR
Page 3: Take out age; just keep "those without other severe health problems are good candidates"	Agree, as we want to maintain focus on the assessment of other health conditions which will not ameliorate with AVR.	Removed "age" from description of who might be appropriate for SAVR
Page 3: Take risks off this page.	We will consider moving risks to page 4. d	Risks added to page 4; removed from page 3.
Page 4: Add information about durability: there is uncertainty about how long TAVR valves last, whereas SAVR can last 9-15 years	The degree of uncertainty surrounding the durability of TAVR valves is controversial. In the interest of minimizing the chance of	Added information about valve durability and what types of valves are used for each procedure on page 3.

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	alienating clinicians, we sought to balance the presentation of estimated durability (mechanical valves, bioprosthetic valves used in SAVR) with theoretic durability (bioprosthetic valves in TAVR) and the possibility of future valve-in-valve (which only exists in TAVR).	
Page 4: Risk data; recommend using 30 day outcomes rather than 2 year outcomes as this is often what clinicians present to their patients	We recognize the importance of the 30-day risk information and certainly do not want to contradict what providers are telling their patients. However, we feel that ultimately patients are concerned with long-term outcomes; therefore we will keep the data at the 2 year outcomes. Also, from a decision science perspective, it is important to balance the time frames used in the risk and benefit discussions.	No changes made.
Things that are missing: what it takes to get a final decision, i.e. CT scans and cardiac catheterization	Agree, to highlight candidacy determination process	Added sentence “You may need additional testing so your doctor has a better understanding of what your treatment options are” to page 2.
Paper Decision Aid: TAVR vs. Symptom Management		
The high risk decision aid should in fact be labeled as INOPERABLE risk where TAVR and medical therapy are the only treatment options.	We thought the term “inoperable” was too high literacy, however we want to address on the first page that the choices are TAVR vs. Medical Management because the reader cannot have open-heart surgery	Added sentence to page 1: “This booklet is specifically for patients who cannot have open-heart surgery.”
Page 2: “to pump blood out” instead of “to do its job”	We kept wording as is to keep patient literacy in mind.	No change.
Page 1: stenosis spelled incorrectly		Fixed typo.
Page 1: Consider changing physician to provider		Changed “physician” to “clinician”.
Page 2: consider adding fatigue/tiredness to symptoms	“Feeling tired or dizzy” is already included under symptoms on page 2.	No changes made.
Page 3: document is patient friendly- not sure if patient will understand ‘catheter’.	Agree to improve literacy	Added descriptor for catheter on page 3: “place in the heart through a wire (called a catheter).”

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Page 3: TAVR is available for patients who are moderate, high, or inoperable. Please include this group. Many patients come in who are told by their provider that they are “not good candidates for surgery”	Agree to improve acceptability	Changed language to make it clear that TAVR is available to Intermediate, High, and Prohibitive Risk patients.
Page 3: Under medical management add medications can help to control symptoms of AS	We debated listing medications under medical management, but decided against it due to the variations of medications used for each patient.	No change.
Page 4: Under TAVR, change vascular to damage to the blood vessels	Agree to improve literacy	Changed description to “injury to the blood vessels”
Page 4: add on medical management ongoing and potential progression of symptoms	Agree	Changed language on page 4 to “ongoing symptoms that may get worse”
Page 4: hospice care focuses on comfort over cure of disease	We considered this feedback, however we feel that our description incorporates the idea of comfort over cure. Additionally, we are basing this description off of feedback we have received in the past on other decision aids.	No change.
Page 5: 25 people lived longer with TAVR than without TAVR	Agree	Fixed typo.
Page 6: Jane is a 78 year old woman (spelling incorrect on form)		Fixed typo.
Page 7: caution about stating TAVR is not too invasive	Agree as “invasive” is entirely subjective	Removed “TAVR is not too invasive” on page 7.
Page 7: would avoid stating repair his valve since this is typically not an option with AS	Agree – mischaracterizes AVR options	Removed “repairing” on page 7.
Page 8: take out biggest. Any questions are appreciated.	Agree – benefits are subjective	Removed “biggest” and rephrased the questions on page 8.
Information about QOL outcomes – magnitude of benefit and who benefits? Not everyone benefits due to completing risk of symptoms from COPD, etc. Flip side is those who benefit are really better.	We agree with feedback about quality of life and will explore options on how to best convey this.	None at this time
Pg 3. The word fixing has two ii’s, and there is no space between ‘thesymptoms’ and ‘thegroin’	Agree	Fixed typos.
Pg 3. The picture of medication being given suggests there is a pill to fix it. A picture or graphic of a doctor putting hand on shoulder of patient, to imply no abandonment but tries as symptom alleviation might be more reflective of the approach in a high risk patient.	We agree with this graphic idea and will explore ways to incorporate this.	Image changed to photo of health care provider and patient holding hands.

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May be good to list surgical AVR as well, but with notation about the patient being at high risk	We appreciate this note as patients may know or otherwise be aware of SAVR. Will highlight that this DA is for patients who are not eligible for SAVR.	Added sentence to page 1: "This booklet is specifically for patients who cannot have open-heart surgery." Typos addressed.
Page 5: Reference is wrong - Makkar; Also this reference doesn't include patients that didn't receive TAVR. I think you need a second reference for the medical therapy arm. -unclear what the lower panel on this page is showing. What are the numbers?		We corrected the reference.
Page 6 and 7: Would add reasons for why each decision was made to the yellow box — slide 6 because TAVR would alleviate most of her symptoms and prolong life and patient preference, slide 7 no because the he would have a lot of persistent symptoms even after TAVR and/or patient preference	We agree to add reasoning to the decisions for the patient scenarios.	Sections have been added to each patient scenario
I think page #5 has too much emphasis on death. Anyone who has been diagnosed with a heart condition is keenly aware of the possibility of death. What they really want is hope that they can live through the procedure and manage their condition. It is clear in the charts that death is a possibility without actually quoting the number of patients who did not survive.	This is an excellent comment. We still feel it is important to talk about the data as is, however we are going to incorporate language to address the emotional components of talking about death, preparing patients/families for what is often a difficult conversation.	Added "It can be scary to think about life and death. However, many people in your position also feel it is important to have information about how likely it is for TAVR to help patients live longer" to page 5
Page 2: labels on valve graphic difficult to read	Agree to improve image clarity	Quality of image improved so that it is clearer.
Page 2 Talk with your doctor...- delete last sentence. This could be extremely confusing to elderly patients and/or the extremely ill	Agree	We rephrased this sentence.
Major comment: there is no discussion that SAVR is not an option for the pt using this DA. That should be included in the introduction. The use of TAVR on the first page without definition is confusing.	We will change the language on the first page to address this issue.	Added sentence on page 1 to specify that this decision aid is for individuals who <i>cannot</i> have open-heart surgery.
Page 2: under symptoms, dizziness and passing out is missing. Also, edema is not a	We will separate symptoms with bullets to make this more clear that dizziness and	Changed format of symptoms to bullet point list.

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symptom of AS. Shortness of breath is and other HF symptoms are, but edema alone is not.	passing out is included. We will leave swelling of legs as is for now.	
Page 4: 'palliative focused plan of care' is not defined and above the reading level of this DA.	We agree with this feedback, we will rephrase to make more reader friendly.	Took out "palliative focused plan of care" and added "care focused on comfort".
Page 3 under Medical Management "How": do patients typically use the word "impact"	Agree	Removed the word "impact"
The only other thought is one from prior work with some decision aids. Many times, with other tools, we have posed questions to the patients like "Yes/No: I would like to avoid a long incision". or "Yes/No: I would like to avoid taking a blood thinner like Plavix for 3 months". At that point, you are acquiring patient preferences and can then help the patient line up the preferences and see which makes the best sense for them.	We gave seen these types of decision aids too, however we have not designed our own decision aids in this interactive way in the past. Will continue to consider this option.	No change.
The other issue is the statement: "Not everyone has the same treatment options available". I think exceptions to the rule perhaps should be outlined. For instance: if you have a blocked coronary artery, you may opt for surgery where the artery could be bypassed, etc.	Agree and will remove.	We took "not everyone has the same options available" out of both decision aids.
There is a tendency for patients to cop out on the issue of "perhaps my shortness of breath isn't from my aortic stenosis. If someone has a valve area of 0.5, having them think that it is possible that the AS isn't the cause of their symptoms allows them to cop out on the discussion.	We think the underlying assumption is that people are going to choose TAVR and we really want them to consider whether symptoms really are from their AS.	No change.
Video Decision Aid: Intermediate/High Risk		
I note that an interventionalist is narrating the intermediate to high risk group. Is the intent to present TAVR as the clear choice? I agree with this for prohibitive risk, and still feel it worthwhile for surgical voice in the intermediate risk option.	We are considering adding a surgical narrator to some parts of the Intermediate/High Risk Video.	Filmed C.T. Surgeon for explanation on surgical aortic valve replacement in an effort to provide conceptual balance between TAVR and SAVR.
The one risk not mentioned that patients care about is the risk of new atrial fibrillation. This	We reviewed this comment with our team, and we believe that the existing evidence on this	Afib not added as a risk.

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<p>carries long term medical consequences, including potential need for long term blood thinners. There is a significant difference between SAVR and TAVR in this regard. In our decision aid work, we modeled that risk like this: The risk was 6-12% in the transcatheter arms and 16-31% in the surgical arms of the SAPIEN and Corevalve trials.</p>	<p>issue is too inconclusive as to 1) the direction of the relationship between Afib and valve replacement, as there is the inherent risk for Afib with or without a procedure due to structural abnormalities of the heart. And 2) difference in persistence of Afib between TAVR and SAVR. Thus, this information potentially complicates the decision aid unnecessarily.</p>	
<p>My only concern: Is this for patients who have already been through the screening process and have a surgical disposition? If not, would likely add a note that not everyone is appropriate for TAVR and the patient should undergo a full workup by the Heart Team to explore options for treatment of their aortic valve disease.</p>	<p>We try to address this with a disclaimer in both the paper and video decision aids “You may need additional testing so your doctor can best understand what options are available to you.”</p>	<p>No change.</p>
<p>This is very patient centered and would be good to see the final video with the pictures/graphs, etc. I agree the Afib risk is important to discuss.</p>	<p>See above response for Afib comment.</p>	<p>No change.</p>
<p>I would agree the surgeon might be the one to introduce the high risk one and explain that when the risk gets too high, this limits the options available.</p>	<p>We are considering adding a surgical narrator to balance the video.</p>	<p>Filmed C.T. Surgeon for explanation on surgical aortic valve replacement, including why it is not appropriate for all patients.</p>
<p>It would be nice to emphasize the heart team approach and have a surgeon and a cardiologists speak during the video. This is especially true for the surgical portion which should include that surgery remains a well-tolerated procedure in patients who are intermediate risk.</p>	<p>Agree, this will add balance to the presentation of TAVR/SAVR.</p>	<p>Filmed C.T. Surgeon for explanation on surgical aortic valve replacement.</p>
<p>In the section on injury to blood vessels, it should say most of these occurs at the time of the TAVR, not surgery. Also, rather than saying less than 1 in 10 have blood vessel injury with SAVR, it should day that injury to blood vessels is extremely uncommon with SAVR.</p>	<p>Agree to remove references to “surgery”. Will also emphasize that vascular injury is rare in SAVR.</p>	

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Not sure that the number 1 in 10 gets pacemaker with SAVR is accurate. Where did this number come from?	Original estimates were abstracted from PARTNER II data. Updated at release of SURTAVI to reflect higher risk of PM.	Risk of PM updated
It would be best to move the recovery paragraph under the comparison section.	Decline – would complicate the DA and would be addressed in clinic	No change
In this video, we might want to mention something about patients with bicuspid valves. Many if these fall into the intermediate risk category and most agree that these patients should go for surgery at this time secondary to less optimal technical outcomes with TAVR in these patients.		
Also, clarification regarding the afib risk: the risk of afib with SAVR is higher, roughly 30%, but it is a temporary event usually going away by 3 months. This may necessitate coumadin for 3 months but the guidelines still recommend coumadin for 3 months for tissue valves anyway. With TAVR, the risk of afib is much less but it does put the patient at risk for need for triple therapy because they are already on aspirin and plavix for the TAVR. The afib issue might be too much to discuss in this video.	Similar to note above: we believe that the existing evidence on this issue is inconclusive as to 1) the direction of the relationship between Afib and valve replacement, as there is the inherent risk for Afib with or without a procedure due to structural abnormalities of the heart. And 2) difference in persistence of Afib between TAVR and SAVR. Thus, this information potentially complicates the decision aid unnecessarily.	No change
There is no mention of paravalvular leak. This might need to be included in this video.	Decline, we elected not to include paravalvular leak in the paper DA and wish to mirror presentation	No change.
Video Decision Aid: Prohibitive Risk		
We should include that in some patients, even though TAVR might be a technical option, it might not be recommended (i.e. Cohort C). This is regardless of patient decision. In those patients, palliative care is the only option.	In both paper and video decision aids, we add the caveat “You may need additional understanding for your doctor to better understand your treatment options” to indicate that the decision may not be up to preference alone. Additionally, in implementation we hope that patients who are not candidates for TAVR will not be shown the video.	No change

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Appendix 2: University of Colorado Denver Internal Review

Comments	Author Response	Text Changes
Paper Decision Aid: Intermediate/High Risk		
<p>Reading this one, I got hung up on the 2-year death pictographs. I'm not sure how much you want to go there, as it actually becomes distracting to the main point for a few reasons:</p> <ol style="list-style-type: none"> 1. Is 79 versus 81 significantly different? I assume that you purposely chose not to show the 2 "saves" for TAVR in a different color (as you do in PARTNER 1 and other PtDAs) because you don't want to highlight the 2% difference as meaningful. SAVR early death may be a touch higher, but long-term could be better (we don't really know yet). 2. That got me thinking, if the survival is the same, then the figures actually make a patient say, "whoa, I have a 20% chance of death in the next year". That is probably quite variable based on a number of factors. Usually we have found it to be fine to "brush stroke" the outcome rates – but when the difference is so small, then I went to the overall, and that's not really the point here, is it? <p>So maybe the pictographs need to NOT show death (which is similar and shouldn't really drive the decision), but all the other factors that are potentially different.</p>	<p>We will look into changes in how the risks/benefits data is presented.</p>	<p>Pictographs designed to highlight similarities (e.g. mortality, stroke) and differences (pacemaker).</p>

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<p>RE: valve durability issue I like the clause about durability-- or maybe it can be raised as a question:</p> <p>“Will my valve have to be replaced again?”</p> <p>“While we believe SAVR and TAVR valve replacements are durable, no valve can ever work as well as the valves you were born with. Eventually your valve may need to be replaced. The timing of this can be different for every patient, and unfortunately we cannot accurately predict when or if your valve will need to be replaced again. We currently know more about the durability of surgically placed valves than we do about TAVR valves, but more information is coming. Talk to your clinician about any concerns you have about how long your valve might last, and what your options might be if your new valve needed to be replaced.”</p> <p>The majority of these patients are >70, and many are in their 80s. The post-TAVR mortality is high enough that even bioprosthesis degeneration is unlikely to even play a role, based on comorbidities and age. TAVR degeneration is unclear, because we just don’t know.</p>	<p>Valve durability as it pertains to the decisional calculus of a younger, theoretically healthier AVR candidate, has been a consistent area of focus. TO avoid potentially alienating clinicians, we elected to balance known estimates of durability (for bioprosthetic and mechanical valves in TAVR) with theoretical durability (bioprosthetic in TAVR) and the possibility of future valve-in-valve.</p>	<p>No change.</p>
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<p>Do we need to specify the difference between bioprosthetic and mechanical valves at all? Maybe this could be the left out, or a more general statement could be made guiding the patient toward discussion with their Cardiologist. See my statement below....I reworded from Javier's a little.</p> <p>“While bioprosthetic and mechanical valve replacements are durable, no valve can ever work as well as the valves you were born with. Eventually your valve may need to be replaced. The timing of this can be different for every patient, and unfortunately we cannot accurately predict when or if your valve will need to be replaced again. Talk to your clinician about any concerns you have about how long your valve might last, and what your options might be if your new valve needed to be replaced.”</p> <p>My thoughts are to still try to keep it simple, with the direction to be toward facilitating patient discussion with their provider/physician. I do agree that if I were going to make a decision about TAVR v SAVR or bioSAVR v mechSAVR; I would want to know pros/cons of each. Would providing</p>	<p>After substantial consideration, and in light of patient feedback, we elected to highlight the relative durability of mechanical valves, which would be weighed against the recovery experience and the possibility of future AVR.</p>	<p>Lengthened discussion of valve durability within the context of “Benefits”</p>
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<p>small bullet points with pros/cons of each be something we could add to DA?</p> <p>Also, if we are talking specifically about durability, do we need to bring up the possibility of valve in valve via TAVR down the road (currently only an option for bioprosthetic and not mechanical)? This may be something that patients would consider when making a decision, and we do bring this up to the patients in clinic when talking about choices and durability. Again, this might be over complicating things.</p>		
<p>I think the decision for most AS is TAVR v BioSAVR v MechSAVR. I don't think you can just say first decision is TAVR/SAVR for everyone, and then for those who say SAVR decide which valve – part of how I would decide about TAVR is what my comparator options are.</p> <p>Specifically, if one assumes that I want SAVR because of durability (especially for younger patients), that is likely true for mechanical but not so much for bio. So “durability” of SAVR necessitates anticoagulation. Perhaps I am overcomplicating this unnecessarily.</p>	<p>Agree</p>	<p>Each valve/procedure option is now discussed in parallel format.</p>
<p>First--we need to classify the decision aids into two categories: high/intermediate risk and prohibitive risk</p>	<p>Agree to classify decision aids to high/intermediate and prohibitive risk</p>	<p>Changed decision aids from “Intermediate Risk” and “High Risk” to</p>

<p>Our patient examples should be a little more clearly guided toward a specific treatment. It would be important to steer the patient examples based on the heart team evaluation. So example: Elroy has been evaluated by the Heart Team, and based on his risks, he has the option of SAVR v TAVR...then talk about Elroy's specific decision. He thinks that the Heart Team recommendations are important, because, in example, sometimes a patient may think they have an option for SAVR but really SAVR is off the table for them based on their risks. So knowing that they only have an option for TAVR v palliative care/medical mgt; this may help them start to make their decision.</p> <p>Regarding durability, this might need to be a different decision aid.... It's a complex decision that should be discussed with the clinician (obviously), and it might be too hard to narrow down in a few sentences. He was talking about the durability of SAVR valves is not entirely known because the surveillance of these valves has not been standardized for all aged patients as compared to TAVR. He does think it's important to note that the 5 year data suggests TAVR is durable for at least 5</p>		<p>“Intermediate/High Risk” and “Prohibitive Risk”.</p>
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<p>years, but we won't know more about longevity until the low risk trial is complete.</p>		
<p>Paper Decision Aid: Prohibitive Risk</p>		
<p>When it switches from “aortic stenosis” to AS on the second page is odd. Either commit early to acronym or don’t. Can spell out AS again once of second page.</p> <p>I don’t particularly love the way to two cases are written. Particularly the second declining TAVR case should be more about going a hospice-type route - he has severe AS and multimorbidity, he’s dying - maybe he should be moderately demented in a nursing home and family is like “enough is enough / AS-death would be a blessing” - that is a much more likely scenario for folks who are actually going to turn down TAVR, yes? I think conceptually the contrasting cases are good, so would just modify what you have. Would they be better side-by-side?</p>	<p>We agree that the differences between the two vignettes are too finite.</p>	<p>Will introduce AS acronym on first page and switch to AS for rest of tool.</p> <p>Changed “symptom management” vignette to emphasize deteriorating health, likelihood of comorbidity, and increasing use of health services.</p>
<p>Video Decision Aid: Intermediate/High Risk</p>		
<p>Description of SAVR and TAVR seems unbalanced</p>	<p>We will try to balance SAVR information better with the TAVR information.</p>	<p>Added description of SAVR, including narrative from CT surgeon.</p>
<p>Valve durability information isn’t correct, suggest adding caveat that “every patient is different”, some averages are that mechanical valves typically last longer.</p>	<p>We will discuss the issues with valve durability with our TAVR team to address the best way to present this information.</p>	<p>Valve durability description includes multiple statements highlighting variability, encouraging patients to discuss with their HCPs.</p>

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<p>There are average life spans but there is variability among everybody.</p>		
<p>Take out the “pig valve” comment unless we have a patient saying it.</p>	<p>Agree</p>	<p>Removed “pig valve” from script.</p>
<p>I’m not sure these are polished enough for ACC. For example: “Nearly 1 in 10 patients will suffer from serious injury to blood vessels, such as a tear or puncture, within two years after TAVR.” Since procedural complications really only occur early, that kind of feels like the equivalent of a typo. The blood vessel description is also not tied to the access site issues as well and I think it should be. So it’s unnecessarily and confusing as written.</p>	<p>We will add some contextual information for why there would be injury to the blood vessels. To keep the DA balanced, we will keep the 2 year data, however we will point out that the majority of blood vessel injuries occur around the time of the procedure.</p>	<p>Description of how vascular injury occurs has been added.</p>
<p>At times your health literacy level seems off. “Durable”, “incision”, etc. There are terms you need to use, like “mechanical and bioprosthetic”, that would really benefit from more context.</p>	<p>We agree that we do not want the health literacy to be too high- will explore other options for words that can be replaced without losing meaning.</p>	<p>No changes</p>
<p>You skip over options to give details that I think would be really helpful. I think these DAs should be a little longer and more developed in places:</p> <ul style="list-style-type: none"> - Recovery is really vague for both TAVR and SAVR - Complications are not particularly well developed - You talk about durability and replacement, but then give zero 	<p>We want to avoid overcomplicating information about recovery in the DA’s, however we will add some context that SAVR is more long and complicated of a recovery than TAVR. Will also address that every patient recovers differently.</p>	<p>Recovery now emphasizes time in hospital.</p>

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<p>quantitative data (I like the ballpark 15 years estimate for bioAVR)</p> <ul style="list-style-type: none"> - You say “ask your doctor about future replacement options” but then don’t even hint at the implications- most cardiologists would not pick up on the missed opportunity for valve-in-valve TAVR is mechanical SAVR is chosen 		
<p>The SAVR mechanical valve option seems underdeveloped and kind of left hanging. Anything you learned from the Belgian CIRC:CQO mech. V. bio paper/DA that you’d want to incorporate?</p>	<p>We do not want to overcomplicated information about valve options and durability, so we will leave information about mechanical as is.</p>	<p>No change.</p>
<p>Page 2- a catheter is not a wire</p>	<p>Agree</p>	<p>Changed description of catheter from “wire” to “small tube”.</p>
<p>Seems like you should say what a mechanical valve is made of.</p>	<p>Will add brief description of what mechanical valve is made of.</p>	<p>Changed description of mechanical valve to add that it is “typically made of metal”.</p>
<p>After watching this video, we don’t know why someone would choose SAVR. Seems to favor TAVR. Flipping the order of how each procedure is presented might slightly help with bias towards TAVR (present SAVR first).</p>	<p>We agree that it is important to present the two options in a balanced way; this has especially been a challenge for us because, for many people, TAVR just sounds better as an intervention that is less invasive and has similar results to surgical AVR.</p>	<p>We flipped the order of presentation in the videos so that surgical AVR is discussed first, and TAVR is discussed second.</p>
<p>Give more context for the decisions; why would someone choose TAVR or SAVR and vice versa</p> <ul style="list-style-type: none"> - Say “surgery is the only way to implant a mechanical valve” 	<p>Agree as this clarifies the contours of each option and their relative benefits.</p>	<p>Added a sentence to say that “open-heart surgery is the only option for patients who want a mechanical valve”</p> <p>Added a sentence to say “Even though it seems like TAVR and open-heart surgery</p>

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- “Even though it seems like they are very similar, there are nuances. These are things you will discuss when you have a meeting with your doctor.”		are very similar, there are distinct differences”
Say “standard of care for more than 50 years” for SAVR	Agree	We changed the language to say “standard of care for more than 50 years” instead of “SAVR has been around for over 50 years”.
Repeat full names of TAVR and SAVR to give viewer a chance to understand the acronyms	Agree	Added additional repetitions saying the full name instead of the abbreviations of SAVR and TAVR.
Change “SAVR” to “open-heart surgery” or a term that lay people will better understand.	Agree	Changed abbreviation of “SAVR” to open-heart surgery throughout the video
Figure out a more understandable way to present data for vascular injury- the way it is presented now makes it seem like there is not much of a difference.	Agree	Added more context to why vascular injury might occur, and that this is more common in TAVR than in open-heart surgery.
Provide more context for the risk of a pacemaker- why would that come up	Agree – especially as it pertains to why pacemaker need might be considered a risk	Provided more of a description of what a pacemaker is and what getting one would involve.
Don’t say “AS” in the video, say aortic stenosis every time	Agree	Changed all abbreviations of “AS” to “aortic stenosis”
Video Decision Aid: Prohibitive Risk		
Flow/order at times seemed a little off. There are a couple of places where transitions may benefit from a little massaging.		
Recovery time and experience of TAVR did not seem to have enough detail. There are some simple things you could add to make	Agree	Added estimates of definable recovery times for both TAVR and SAVR, based on

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<p>it more palpable (e.g. average hospital stay, percent of patients who have a complication, etc.)</p>		<p>experience and feedback from local IC experts.</p>
<p>Choice of medical management is off to me. In my mind, as TAVR has become easier to do, the main reason that a person would decline TAVR is less because they singularly want to avoid a procedure and more because they are ready to die, usually because they have a lot of medical problems (not just AS) and so allowing the AS to progress is a way “out”. The testimonials will help, but I think you should be a little more direct/explicit.</p>	<p>Agree, as both patient and clinician feedback are highlighting that a person who declines TAVR is really expressing a desire to alter their philosophical goals of care (toward more explicitly palliative options).</p>	<p>Included more direct descriptions highlighting that medical management (now “symptom management”) is not likely to lengthen life. This description is now accompanied by definitions of palliative care and hospice to highlight what symptom management entails.</p>
<p>Consider calling it something other than “medical management”; focus on symptoms <ul style="list-style-type: none"> - Potentially outline the options as “TAVR” or “Not TAVR” </p>	<p>Agree</p>	<p>Changed “medical management” to “symptom management” in both the video and paper version of Prohibitive Risk</p>
<p>Don’t like illustration of hand with pill bottle</p>	<p>Agree</p>	<p>Changed image to an image of patient and doctor holding hands.</p>
<p>How did patients end up in this risk class? Then the rest of the video is “for patients like you”</p>	<p>Agree, as an improved description of risk will aid both patient understanding and reduce clinician burden (in selecting the correct brochure for a patient, etc.)</p>	<p>An explanation was added to the introduction of the video explaining why someone might be considered prohibitive risk or inoperable.</p>
<p>May not even introduce non-operable. Consider introducing the concept of operable vs. non-operable early.</p>	<p>Agree</p>	<p>An explanation was added to the introduction of the video explaining why someone might be considered prohibitive risk or inoperable.</p>

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<p>When asking viewers to think about their goals throughout the video, provide some examples of what people’s goals might be. Is it living longer? Having a better quality of life? Staying out of the hospital?</p>	<p>Agree</p>	<p>Cardiologist narrator (Dr. Khazanie) now highlights each of these in her descriptions of options and considerations.</p>
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Appendix III: Patient and Caregiver Participant Review

Comments/Suggestions	Author Response	Text Changes
Paper Decision Aid: Intermediate/High Surgical Risk		
<p>When you say younger adults, you know, I think somebody who, you know, is 65 – I’m not sure that they would consider themselves a younger adult. I think I would just say adults without severe health problems.</p>	<p>Agree</p>	<p>“Younger adults” removed from description.</p>
<p>I think it wouldn’t hurt to acknowledge the anxiety that the patients are experiencing</p>	<p>We appreciate and completely agree with this feedback. Emotions are an important piece of a person’s health care experience and are certainly a part of their decision making process. We attempt to address the emotions throughout the decision aid.</p>	<p>No change.</p>
<p>Make information about recovery times a little more descriptive- what are typical hospital stays? When can you start driving?</p>	<p>Estimates of specific benchmarks of recovery (walking, driving, working, etc) are highly variable at the patient level, and risk overcomplicating the description of TAVR (as the recovery process is more highly controlled in SAVR).</p>	<p>No change.</p>

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The risks aren't informative- are they rare or are they common risks?	Agree	Added numerical data for risks from Partner I and II trials, as well as from SURTAVI data.
The information was kind of light- I like to know more about after the surgery, percentages, etc.	Agree	Added numerical data for risks from Partner I and II trials, as well as from SURTAVI data.
I wasn't impressed with the drawing, it was more like a comic book drawing rather than an actual photograph which would be more realistic.	Agree, although these early pictures were placeholders during content development	Images for the patient scenarios were changed to stock photographs of real people.
Because medical management does not fix aortic stenosis, it might be misleading for it to be presented as an equal option alongside TAVR and SAVR	Agree, and medical management is not an equitable option for lower risk patients.	Divided paper decision aids into two separate booklets: Intermediate/High Surgical Risk and Prohibitive Risk.
Include more in depth experiences of patient examples; how it helped them or didn't help them and so-on.	In order to provide a balanced and unbiased decision aid, we like to avoid outcome narratives and focus more on peoples' processes in their decision making.	Added more context to the decision making process in the patient scenarios, but did not add information about the outcome of their procedures.
More details about what open-heart surgery entails and what time of recovery is like for TAVR.	Agree	Added description of procedures and information about recovery time for both TAVR and SAVR.
More information about different valves and how long each might last.	We agree that this is important and through the developmental process, we have consistently debated how much or little detail on valve durability to provide.	Small section on valve durability added to page 3.
The patient examples have people that are much older, which is alienating for younger patients in their 40s, 50s, 60s	Agree, however, the majority of participants in relevant clinical trials (including those in the most influential trials both in the US and Europe) were age >70.	No change.

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The aortic stenosis acronym “AS” reads like the word “as”	Agree	Removed nearly all instances of “AS” in favor of “aortic stenosis”, recognizing that literacy will be a challenge for some patients.
More specific information about valve longevity; what percentage of valves last however long, etc. And what that looks like among age groups.	We agree that this is important and through the developmental process, we have consistently debated how much or little detail on valve durability to provide.	Small section on valve durability added to page 3.
Seeing “SAVR” and “TAVR” side by side is confusing, it’s hard to differentiate which one is being talked about. “Open-heart” surgery would make more sense for SAVR	Agree	Removed most instances of “SAVR” in favor of the more familiar “open heart surgery”
Make information about life of the valve more clear and provide context so people have an idea of why people would choose a valve with SAVR over TAVR	We agree that this is important and through the developmental process, we have consistently debated how much or little detail on valve durability to provide.	Small section on valve durability added to page 3.
Vascular injury risk statistics are hard to understand	Agree	Clarified the definition of vascular injury and presented risk statistics in format identical to those addressing mortality, stroke, pacemaker need, etc.
“SAVR” is less scary wording than “open heart surgery”	Agree, but in light of other feedback which described both a need to visually discriminate from “TAVR” and to improve accessibility of information, we elected to refer to the surgical option as “open heart surgery”	Removed most instances of “SAVR” in favor of the more familiar “open heart surgery”
More context about pacemaker and what the procedure would entail.	Agree	Improved description of why pacemaker risk occurs and that this risk entails the possibility of another procedure.
Page 2: It’s hard to see the valve differences- too small	Agree	Changed quality of graphic to make the image clearer.

Supporting Evidence: Decision Aids for Patients with Symptomatic Aortic Stenosis

Explain what SAVR is on the first page, not knowing what it stands for when you first read it is confusing.	Agree	Explained surgical option at first instance.
It's not clear what "SAVR" is when it is mentioned- "open-heart surgery" would be easier to follow.	Agree	Removed most instances of "SAVR" in favor of the more familiar "open heart surgery"
Page 3: Organize it as "Who/What/When/Where/Why" as this is a more familiar information pattern for people in general.	This is great feedback, and yet we feel the order we present it in is the most logical flow for information regarding these two treatment options.	No changes made
Paper Decision Aid: Prohibitive Risk		
More details about what the aortic valve is and what the procedure involves.	Agree to a point. Clinician feedback was consistently positive regarding the paper description of AS. The video version of the DA may include expanded description	No additional information added to the paper decision aid; however a more detailed description of what the aortic valve is and what the TAVR procedure entails were added to the Prohibitive Risk video (using the metaphor of a "door" between the heart and the rest of the body).
Use the word "doctor" and not "clinician".	Agree, that doctor is better for people with lower literacy. However, the term was unacceptable to many non-physician health care professionals.	No changes
The information about mortality and the potential of TAVR not fixing your valve is very negative.	We appreciate the emotional weight of reading statistics about life and death and the impact that may have on the patient; however we feel it is important to provide helpful information about how likely a procedure might help someone feel better and live longer. We have added the "warning shot" prior to the graphic with	No changes made.

	statistics to validate the emotions one might feel while thinking about mortality information.	
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