

ORIGINAL ARTICLE

Show Me the Money

Patients' Perspectives on a Decision Aid for Sacubitril/Valsartan Addressing Out-of-Pocket Cost

See Editorial by Warraich et al

BACKGROUND: Out-of-pocket medication costs for patients who have heart failure with reduced ejection fraction may be an important part of shared decision-making, but cost has generally been excluded from clinical discussions. This study reports patients' perspectives on a decision aid for sacubitril/valsartan that explicitly addresses out-of-pocket costs.

METHODS: Structured, in-depth interviews were conducted with 20 patients with heart failure with reduced ejection fraction from 2 medical centers to elicit their views on a publicly available decision aid for sacubitril/valsartan that explicitly incorporates considerations related to out-of-pocket costs. Qualitative descriptive analysis was conducted.

RESULTS: Key themes identified were general enthusiasm for decision aids for medication decisions, openness on the part of patients to incorporation of cost into decision-making and the decision aid, requests for greater specificity regarding patient-specific cost, and challenges communicating evidence of benefit in a way that allows patients to make cost-benefit analyses for themselves. Patients also raised questions regarding logistical challenges of incorporating a decision aid into the normal clinical and decision-making workflow.

CONCLUSIONS: Patients were receptive to the inclusion of out-of-pocket cost as relevant in a decision aid for sacubitril/valsartan. Key challenges to effective integration of cost in these decisions include developing mechanisms for acquiring reliable patient-specific cost estimates and addressing patients' difficulties (and sometimes skepticism) applying trial evidence to their own situation. In addition, implementation strategies are important to develop to facilitate decision aid integration for routine medical decisions into clinic workflow.

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WHAT IS KNOWN

- Out-of-pocket cost is not typically addressed in the context of clinical encounters but is relevant to decision-making regarding medications for heart failure.
- Patients' perspectives regarding decision aids that address out-of-pocket cost in this context have not been studied.

WHAT THE STUDY ADDS

- Patients are receptive to discussing out-of-pocket cost and to the inclusion of this information in decision aids.
- Important challenges to facilitating integration of this information include a lack of availability of patient-specific cost and difficulty communicating benefits in a way that helps patients to make cost-benefit tradeoffs based on their values.

Out-of-pocket costs are highly relevant to patient care. These costs can burden patients, leading to therapeutic nonadherence or financial toxicity.¹⁻⁴ Patients and clinicians may make different medical decisions when costs and value are infused into discussions of options. Yet, financial considerations are rarely included in clinical practice guidelines and are not explicitly mentioned in the International Patient Decision Aid Standards criteria.⁵ Moreover, available evidence suggests that cost discussions are infrequently included in clinical encounters and, when they happen, are often poorly executed.^{6,7} This inattention to cost may be due to a combination of ethical concerns, emotional discomfort, logistical considerations, and convention.⁸ However, cost has important implications for patients; integration of cost into shared decision-making and inclusion of financial considerations in decision aids is needed. This is especially critical in the context of the current financial downturn due to the coronavirus pandemic.

Members of this group recently developed a patient decision aid to support shared decision-making for sacubitril/valsartan to treat heart failure with reduced ejection fraction (HFrEF).⁹ Sacubitril/valsartan has been demonstrated to reduce mortality and morbidity in the HFrEF patient population compared with ACE (angiotensin-converting enzyme) inhibitor therapy.¹⁰ Sacubitril/valsartan has a class IB recommendation in the American Heart Association/American College of Cardiology/Heart Failure Society of America clinical practice guidelines.¹¹ However, out-of-pocket costs can be appreciable. Under Medicare Part D programs, the mean monthly out-of-pocket cost is ≈\$57.¹² Moreover, the decision to change to sacubitril/valsartan appears to be cost-sensitive for patients. In prior work, willing-

ness to take the medication in a hypothetical context decreased from 92% to 43% among patients eligible for the medication at a price of \$5 per month versus \$100 per month above their current medication costs.¹³

For all of these reasons, the final patient decision aid explicitly included information about cost as a relevant consideration. However, the process of creating a decision aid incorporating financial considerations was complex. In addition to having little precedent from which to work, diverse stakeholders involved in the development process expressed different perspectives on whether, and how, to include costs.⁹ Here, we report the results of a qualitative study to examine patients' perspectives of the resulting sacubitril/valsartan patient decision aid.

METHODS

We conducted an exploratory, qualitative interview study enrolling patients with HFrEF. The primary objective was to gain insight and understanding about patients' views of the previously developed, publicly available decision aid comparing sacubitril/valsartan to angiotensin receptor blockers and ACE inhibitors.¹⁴ Patient input was solicited during development of the decision aid, but greater input on the current version, especially on cost-benefit information, was felt to be helpful to guide refinement and development of implementation strategies. Secondary objectives included exploring patients' views about discussing cost with clinicians in the context of medication decisions and what information patients find most valuable regarding medications in the context of heart failure.

The study was reviewed and approved by the Emory University Institutional Review Board and the Colorado Multiple Institutional Review Board. Data supporting the findings of this study are available from the corresponding author upon reasonable request for purposes of reproduction of results.

Study Population

Study participants were recruited from Emory Healthcare heart failure clinics and inpatient services and the University of Colorado Hospital Heart and Vascular Clinic from December 2018 through March 2019. Eligible participants were aged ≥18 years with a diagnosis of HFrEF and an absence of end-stage renal disease (rough eligibility for sacubitril/valsartan based on joint American Heart Association/American College of Cardiology/guidelines). While the decision aid was publicly available at the time of the study, this hypothetical context was chosen (as opposed to implementing the decision aid and interviewing patients afterward) to identify potential need for modification and to identify implementation strategies. At the time of the study, the decision aid was not yet routinely implemented in the clinical setting, and limited data were available regarding patients' views of the published tool or the cost component.

Patients were excluded if they had a history of heart transplant or LVAD, if they were currently receiving home inotropic medication, or if they were non-English-speaking. All

participants provided written informed consent. Participants were paid \$20 for participation.

Interview

A structured interview guide was developed by the research team (Appendix I in the [Data Supplement](#)) and built on investigators' prior work.^{9,13} The interview guide contained predominantly open-ended questions and probes, consistent with the qualitative goals of the study, and interviewers were trained to probe domains of interest. Major domains included the following: participants' views of the decision aid (including inclusion of cost information), views of the benefits of sacubitril/valsartan, perspectives on the cost of the drug, and views of clinician-patient cost discussion regarding medication. Patient characteristics including health status, health numeracy, health literacy, financial status, monthly medication costs, and basic demographics were also collected. The guide was cognitively pretested in 5 patients with HFrEF and refined by the authors.

The decision aid that participants were asked to review was developed by researchers at the University of Colorado at the request of the American College of Cardiology as part of their suite of CardioSmart decision aids.¹⁴ Participants were given a full-color copy of the decision aid and asked to review it before initiation of the interview questions. Interviews generally lasted 20 to 30 minutes and were conducted by trained interviewers at Emory (A.R.M.) and Colorado (G.E.V. and K.J.P.).

A planned sample size of 10 participants per site (total of 20) was chosen, consistent with the qualitative, exploratory nature of this study. There was a plan for further interviews if needed to achieve thematic saturation.

Data Management and Analysis

All interviews were audio-recorded, transcribed verbatim, corrected for errors, cleaned of identifiers, and imported into a qualitative data management software package (Dedoose; Los Angeles, CA) for coding. The analytic goal of the study was qualitative description, to provide rich description of the range of responses and views in the primary domains of interest. A template analytic strategy was used, in which a priori codes were created based on the primary domains of the interview guide, and the codebook was expanded and refined inductively. The codebook was further refined by the group of authors in the context of reviewing coded segments; the goal was to ensure that all codes represented coherent and distinct themes. Additional codes were created as necessary. All interviews were double coded. The lead interviewer (A.R.M.) coded all interviews; 2 additional team members (G.E.V. and G.S.) each coded half of the interviews. Any discrepancies were resolved by consensus. All interviews were coded using the final codebook.

Closed-ended questions and demographic data were entered into an Excel spreadsheet. Data entry was reviewed by an additional team member to ensure accuracy. Simple descriptive statistics were tabulated.

Results are presented according to major domains of the interview guide, which were created a priori based on prior work. Emerging themes within each domain are described.

RESULTS

Twenty patients were interviewed in total, 10 per site (Table 1). Mean age was 64 years; 9 patients were women, 6 were Black, and 2 were Hispanic. The group was relatively well-educated (15 having educational attainment higher than high school), 14 reported an annual income of \leq \$50 000, and 11 indicated the presence of some degree of financial constraint. Reported health literacy on a one-question screen was high, and answers to questions related to health numeracy were broadly distributed (Table I in the [Data Supplement](#)). Four reported having been unable to take a prescribed medication due to cost within the past year (Table 2). The median reported time living with heart failure was 7.5 years, 12 reported being hospitalized within the past year, and 10 reported their health status as fair or lower.

Attitudes Toward Sacubitril/Valsartan

After reading the decision aid, 12 participants stated that they would definitely or probably want to switch to sacubitril/valsartan if they were taking an ACE or angiotensin receptor blocker (Table 3). When asked what they would be willing to pay per month for the medication, the median response was \$50 (interquartile range, \$10–\$100).

Likely Use of the Decision Aid

Most participants had a generally positive impression of the decision aid, though they were not accustomed to seeing materials like this in the context of medication decisions. "I think overall this is good... they should do this with all of the medicines just coming out, especially these new ones you don't know nothing about (Emory 05)."

While no one stated that they would base a medication selection decision on the information in the decision aid alone, there were several ways in which they felt the decision aid might be useful. Some felt the decision aid would serve as a conversation starter if they received it before a clinician visit. "If I had the time, yeah, I could read it and then I could say, 'Hey, doc, you know, what have you heard about this drug?' (Emory 06)." Others stated the aid would provide a more informed conversation and decision with their clinician. "It jump starts the cardiologist in talking to me... So yes, it's helpful, but it isn't standing alone going to be the basis of a decision. It's background information (Colorado 16)." Still others stated that it might serve as a valuable resource to which they could refer later.

Participants also felt that their use of the decision aid may depend on how they receive it. They stated

Table 1. Participant Characteristics (n=20)

	n (%) or median (IQR)
Age, y	64 (58–70)
Women	9 (45)
Hispanic ethnicity	2 (10)
Race	
Black	6 (30)
White	13 (65)
Other (Cajun Indian)	1 (5)
Education	
High school or less	5 (25)
Some college	6 (30)
College or more	9 (45)
Income	
<\$25 000	7 (35)
\$25 000–\$50 000	7 (35)
\$50 000–\$100 000	1 (5)
\$100 000–\$200 000	1 (5)
>\$200 000	2 (10)
No answer	2 (10)
Financial situation	
After paying the bills, you still have enough money for special things that you want	9 (45)
You have enough to pay bills but little spare money to buy extra or special things	6 (30)
You have money to pay the bills but only because you have cut back on things	2 (10)
You are having difficulty paying bills, no matter what you do	3 (15)
Monthly medication costs (n=19)*	\$100 (\$30–\$200)
Years living with CHF	7.5 (3.25–15)
How many times have you had to be in hospital during the last 1 y?	1 (0–2)
In general, would you say your health is	
Excellent	0
Very good	1 (5)
Good	9 (45)
Fair	7 (35)
Poor	3 (15)

IQR indicates interquartile range.
 *One participant said they did not know their monthly cost.

they would be most likely to read it if it were handed to them in an appropriate clinical context. “Hand it to me, and at least try to explain to me what they’re handing me, then it’d probably keep my attention (Emory 04).” Participants varied in whether they felt they would likely take the time to read what they felt to be a lengthy decision aid carefully: “...time constraints, I don’t have time to really... look at all this. If you could condense it down to one, one and a half, two pages... then it would be good (Emory 07).”

Table 2. Experiences With Cost Discussions and Cost Issues (n=20)

	n (%)
In the past 12 mo, how often did a doctor or a nurse ask you about your medication costs?	
Never	9 (45)
Rarely	3 (15)
Occasionally	3 (15)
Frequently	4 (20)
Very frequently	1 (5)
In the past 12 mo, how often have you been unable to take medications as prescribed due to their cost?	
Never	9 (45)
Rarely	3 (15)
Occasionally	4 (20)
Frequently	0
Very frequently	0
Missing	4 (20)

Receptiveness to Cost Information

Most patients were receptive to inclusion of cost in the decision aid. Primary concerns were not about the concept but rather about the availability of specific cost information in real time to guide decision-making. Because of the variability between health insurance plans and even the variability within plans for out-of-pocket medication costs by month, the patient decision aid describes a range of scenarios and provides information regarding how patients can find out out-of-pocket costs. Patients reported that clinicians often did not know the exact prices of the drugs they prescribe. Some patients reported that, in their experience, clinicians sometimes mentioned cost qualitatively but rarely discussed it in any detail. “The doctors just know it’s expensive. They don’t know the exact cost (Colorado 15).” The majority of patients reported getting specific prices of their medications only when obtaining medicines at the pharmacy. “No, normally they [clinicians] write the prescription, they send it down, you go to pick it up, and that’s when the surprise comes (Colorado 13).” In this context, participants questioned how useful the cost discussion in the decision aid would be, as no patient-specific costs can be included in a universal tool, only estimated averages and ranges.

Perceived Benefit of the Drug

The decision aid incorporates a pictograph demonstrating the ≈3% absolute reduction in mortality observed in PARADIGM-HF.¹⁰ There is an additional statement that hospitalizations for HF were reduced by a similar magnitude. In general, participants found this benefit to be modest. “I don’t think it’s that big of a benefit. Three people (Emory 01).” “Yeah, the death rate was somewhat – just a little bit lower. What was it, 3% or

Table 3. Questions About Decision Aid (n=20)

Questions	n (%) or median (IQR)
Based on what you read, if you were taking an ACE inhibitor or ARB (like lisinopril or valsartan), would you want to change to an ARNI (sacubitril-valsartan)?	
Definitely yes	1 (5)
Probably yes	11 (55)
Do not know	3 (15)
Probably no	3 (15)
Definitely no	1 (5)
Missing	1 (5)
Would you expect your doctor to recommend this medicine to you based on what you read?	
Yes	9 (45)
No	1 (5)
Do not know	9 (45)
Missing	1 (5)
What is the most money you think you would be willing to pay per month for this medicine? (n=17)*	\$50 (10–100)

ACE indicates angiotensin-converting enzyme; ARB, angiotensin receptor blocker; ARNI, angiotensin receptor neprilysin inhibitor; and IQR, interquartile range.

*Three participants did not respond.

something? (Colorado 18).” Others suggested that the benefits were less significant: “to me, three people isn’t much (Colorado 15),” or “the numbers aren’t impressive... it’s not making me jump over there (Emory 06).” No participant indicated they felt this benefit was particularly substantial.

While there was heterogeneity regarding participants’ assessment of the value or meaning of the described benefits associated with sacubitril/valsartan, there was little evidence of frank misunderstanding of the numeric data presented. One participant did confuse a 3% absolute reduction in mortality with living 3 more years, but this was atypical.

Views of Study Data and Personal Applicability

Distinct from their assessments of the meaning or magnitude of the presented benefit, some participants raised questions about the study data that were presented in the decision aid. First, there were participants who questioned the study design or validity. “What was the quality of that study? Was it peer reviewed? (Colorado 16)” or “You know, your five-year expectancy - I haven’t seen two-year expectancies much, you know? They usually do five (Colorado 19).” Second, there were questions raised about trustworthiness; one questioned the researchers. “I don’t know who wrote this. I mean, and you may’ve gone to a bum down on the corner...(Colorado 16).”

Participants also asked questions about the applicability of the study findings to themselves. “Now what you don’t have on here is you don’t have the age ranges of the people... what are the age ranges of the people who died, what are the age ranges of the people who lived who started taking it, so that information’s kind of skewed there, so we need that (Emory 07).” The same respondent stated, “What are the demographics of this study here...That’s important, because you know, as African-Americans versus other cultures, you know, we have different problems (Emory 07).” Some people also wanted more information on the specific cause of death saying, “It could have been the drug or something else wrong with them (Emory 05)” or “3 out of 100, doesn’t say how those 3 died, so I don’t know if they got hit by a car, the dog might have bit them or anything, you know (Colorado 18).” Notably, the presence of skeptical views of the presented evidence was not typically accompanied by a generally negative or nihilistic attitude toward either clinicians or the value of medical care during the interview.

Framing of Information/Perception of Balance

One of the key issues explored during these interviews was participants’ perspectives of whether the decision aid was balanced or had the right valence. Several participants noted that the decision aid felt promotional. For example, “Well, it’s a good piece of advertisement, the way it looks (Emory 01).” “It looks a little bit like promotional materials... trying to convince you that most of the time the ARNI is going to possibly be more expensive but better for you... (Colorado 15).” Others explicitly stated they felt it should be more positive regarding the benefits of the drug “...maybe stressing more on the positive side, you know, what are the positive benefits (Colorado 12).” One of the novel features of this decision aid was the specific inclusion of a contextualizing or gist statement. Next to the figure displaying the observed mortality benefits, there is a box stating that the observed benefit is “actually a pretty big benefit.” There were no strong reactions among participants about this statement being heavy-handed or overemphasizing the drug’s benefits or value.

Views on Informational Content in the Decision Aid

While acknowledging that the length (4 pages) of the decision aid was substantial, most participants felt that the information contained was important and did not have concrete suggestions regarding what information should be removed to shorten it. Participants reported the most critical pieces of information to them were the survival

data/survival data graphic and the comparisons of the different commonly used drugs including having both the brand and the generic names for each. Several participants did mention more information about benefits beyond survival would be helpful. Specifically, they requested information about quality of life. "...it didn't talk about quality of life (Colorado 19)." "Is it going to cause me to live three years of a rotten quality life? (Colorado 16)."

Some participants also suggested the inclusion of more detailed information regarding potential side effects, including less common side effects, and information on potential interactions with other commonly prescribed medications.

DISCUSSION

The decision about initiation of sacubitril/valsartan for patients with HFrEF, which specifically involves out-of-pocket costs, illustrates the context-sensitivity of shared decision-making and raises interesting challenges regarding the content and role of a patient decision aid in guiding prescribing decisions. Specifically, this medication has a class IB guideline level of recommendation due to demonstrated benefits in health outcomes over existing alternatives (including mortality) with similar side effects.¹¹ The decision is only preference-sensitive due to the high out-of-pocket costs for many patients. Any decision aid thus must help patients to weigh demonstrated benefits of the drug against potential costs.

Although the prospect of including cost and directly addressing the fact that a decision about this medication represents a tradeoff between mortality risk and money was controversial in development of the decision aid, it did not seem to be a concern among patients.⁹ No patient described this as irrelevant or inappropriate; this finding coheres with other work that has demonstrated patients' recognition of out-of-pocket cost as an important issue. The primary concerns expressed about the inclusion of cost in the decision aid related to the fact that the decision aid could only provide generic cost information. Given that out-of-pocket costs for this drug can range from nothing to over \$400 a month, there was a clear desire for real-time cost information to make a price-sensitive decision and to avoid the commonly reported experience of sticker shock at the pharmacy. This finding makes it clear that a primary challenge of including cost in decision aids, at least from these patients' perspective, is not conceptual but practical and must be addressed by the health system more generally. In this respect, these data provide additional support for efforts to make patient-specific out-of-pocket cost available in real time and to study the impact of these efforts on decision-making and other important outcomes such as medication adherence.

Effective integration of cost into shared decision-making is not limited to merely providing cost information. It requires communication of the relevant benefits of the drug in a way that helps patients to translate their values and financial state into a decision. Communication of objective, probabilistic information from a large clinical trial is a common challenge. This decision aid used a common pictographic format to do this, but it also included an innovative gist or contextualizing statement that was intended to avoid patients' dismissing the $\approx 3\%$ absolute risk reduction as insignificant. Although some may believe that a statement like this represents a significant nudge toward taking the medication, no patients had a strong view of the statement, and most patients had what many physicians might consider to be a relatively dismissive view of the demonstrated benefit. This raises questions about the impact of such statements and how best to frame the information. More generally, patients had a range of views about the valence or directionality of the decision aid. While some felt it seemed promotional, others expressed that it should be more positive toward the medication. These findings are interesting and suggest a need to carefully study the impact of specific types of framing on decisions that patients make.

Also related to the presentation of trial data, we observed what appeared to be a high rate of understanding of the probabilistic benefit of sacubitril/valsartan; however, there was an appreciable degree of skepticism on several grounds. There are many reasons why people may not believe data with which they are presented,¹⁵ and our findings illustrate that the challenge of communicating trial data to facilitate shared decision-making extends beyond understanding the numbers; it extends to promotion of trust and belief in data as well. Furthermore, while patients seemed to understand the survival benefit in absolute numerical terms, they did not seem to share the medical community's general view of the relative value of a 3% survival benefit.¹¹ The presence of significant heterogeneity in assessment of the significance of medical risk and the disconnect between these assessments by the public and the medical establishment are not unique to this context. These phenomena have been visible in cancer, other forms of heart disease, and in the ongoing COVID-19 pandemic.¹⁶⁻¹⁸

A final set of findings relates to the general creation and use of a decision aid for a routine medication like this in the clinical context. Patients did have questions about how the decision aid would be administered in the normal clinic workflow, and many doubted that they would have time to read it before having to make a choice about the drug if that choice was introduced during a clinic visit. The longer decision aid reviewed here may be useful to patients considering this medication while at home. For example, a clinician could introduce the medication during one visit and plan to readdresses a decision about

initiation at a subsequent visit after the patient has a chance to review the decision aid and to seek cost information. However, more streamlined materials focused on key financial and medical benefit-risk information could be designed to serve as a real-time supplement within clinical encounters. Of course, all challenges related to implementation are made more difficult by the lack of cost transparency within health care as noted above. The latter issue is more a criticism of the current health care system rather than a true limitation of decision aids or clinicians. However, the overarching theme is that any tool created to aid decisions must be implementable in the context in which it will be delivered.

There are important limitations to this study. The sample size was small; however, the sample was diverse socioeconomically and demographically. While this was appropriate for a qualitative project, data with larger samples will provide more meaningful evidence of the reception of the decision aid within the broader population of patients with HFREF. Similarly, the reported views of these respondents regarding willingness to pay for sacubitril-valsartan should not be taken as an indication of the prevalence of particular views on cost or value in the broader population. Finally, this study was hypothetical in design. Most respondents met criteria for sacubitril/valsartan, but none of these interviews was conducted as patients were actually making a decision about whether to take this medication.

CONCLUSIONS

Patients were highly receptive to the inclusion of out-of-pocket cost within a decision aid for sacubitril/valsartan. Key challenges to effective integration of cost in these decisions include developing mechanisms for acquiring reliable patient-specific cost estimates, addressing patients' difficulties (and sometimes skepticism) applying clinical trial evidence to their own situation, and understanding the real impact of various approaches to framing of information. In addition, implementation strategies are important to develop to facilitate decision aid integration for such routine medical decisions into clinic workflow.

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