

Organic Dissemination and Real-World Implementation of Patient Decision Aids for Left Ventricular Assist Device

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Abstract

Background. Although patient decision aids (PtDAs) have been shown to improve patient knowledge and satisfaction, they are infrequently used in the real world. We aimed to understand how our publicly available PtDAs developed for destination therapy left ventricular assist device (DT LVAD) were implemented in clinical practice and characterize factors influencing adoption. **Methods.** We contacted 39 people, 31 who had independently emailed inquiring about our DT LVAD PtDAs and 8 identified through snowball sampling. Thirty people from 23 programs participated in semistructured interviews, which were analyzed using normalization process theory. **Results.** Eleven programs currently use the PtDAs, 5 plan to use them but have not yet, and 7 do not currently use them nor have active plans to use them. Due to major tradeoffs and preference sensitivity of the DT LVAD decision, participants recognized a role for shared decision making and a need for significant information transfer. Due to a relative lack of resources, participants saw the PtDAs as a way to help facilitate a higher quality decision-making process. Limited time, lack of personnel, and perceived burden to implementing system-level change were cited as barriers to use. Initial implementation was accomplished by a champion of the PtDAs. Actual use of the PtDAs most commonly occurred through LVAD coordinators at the start of formal patient teaching sessions, where the PtDAs could be integrated into the existing LVAD consent and education structure. **Conclusion.** Interest in and implementation of PtDAs occurred independently at several LVAD programs due to a favorable decisional context, including a perceived role for shared decision making in the high-stakes decision around DT LVAD, unmet informational needs, preexisting education sessions, and invested clinical champions.

Keywords

heart failure, implementation, medical decision making, patient decision aids, ventricular assist device

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Patient decision aids (PtDAs) have been developed for decades as a tool to facilitate shared decision making for patients considering health screenings and treatments. PtDAs have been shown to 1) increase patient's knowledge of their treatment options and accurate risk perceptions, 2) lower decision conflict, 3) improve the likelihood of patients choosing an option congruent with their values, and 4) have a positive effect on patient-provider communication.¹ Complex, end-of-life decisions can particularly benefit from

PtDAs.² Despite their established efficacy, PtDAs are rarely implemented in the real-world setting. Logistical barriers exist for those PtDAs studied in routine care settings, including providers' concern with time needed to use the

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PtDAs, perceived disruption of established workflow, and lack of trust or agreement with the content of the PtDAs.^{3,4}

Advanced heart failure is an arena where shared decision making is being promoted as essential, including recommendations by the American College of Cardiology and American Heart Association.^{5,6} One of the more complex decisions in end-stage heart failure is the decision around implantation of a left ventricular assist device (LVAD), particularly for the destination therapy (DT) indication, where patients dying of heart failure who are ineligible for heart transplantation may choose to live the remainder of their lives dependent on a partial artificial heart. Chances of survival are markedly increased with the LVAD; however, complications with the device are also quite high.⁷ Additionally, considerable lifestyle changes and caregiver burden further complicate the decision, leading DT LVAD to be a truly preference-sensitive decision.⁸ Due to a perceived need for better patient decision support resources, our research group systematically developed an 8-page pamphlet and a 26-minute video PtDA for patients and their caregivers considering DT LVAD.⁹ We made them available online for free public use, registered and listed them on the Ottawa Hospital Research Institute's patient decision aid website, presented them at a number of US-based medical conferences, and published an article describing their development.⁹ The pamphlet was subsequently translated into French by a group in Canada. The implementation and effectiveness of the PtDAs are being tested in the DECIDE-LVAD trial, funded by the Patient-Centered Outcomes Research Institute, at six sites across the United States.¹⁰

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Beyond development and formal evaluation, we wanted the PtDAs to be used in real-world clinical encounters outside of the research setting. After making the PtDAs publicly available online, people began contacting our research group inquiring about the PtDAs and expressing an interest in potentially using them at their programs, providing an opportunity for us to study the dissemination and implementation of our materials. Thus, we aimed to 1) understand if and how the PtDAs were being organically disseminated in routine clinical practice and 2) evaluate the factors influencing real-world implementation.

Methods

Sampling and Recruitment

In January 2014, the pamphlet and video PtDAs were posted on our research group's website, patientdecisionaid.org, for free public access and use.¹¹ The PtDAs contained contact information for the lead researcher, and the website contained a "Contact Us" link. People contacted our research group through email, the website contact function, or in-person conversations in which group members followed-up with details through email. All email communications were systematically tracked and recorded.

Email invitations requesting an interview were sent directly to people who had contacted us about the PtDAs. If first email requests were not returned, up to three follow-up emails were sent. Subsequent snowball sampling occurred through the following: 1) invited participants suggesting a more appropriate or preferred person at their program to interview, 2) interviewees recommending other people to interview, or 3) word of mouth obtained in-person by research group members. This study was approved by the Colorado Multiple Institutional Review Board, and verbal consent was obtained from all participants.

Data Collection

In-depth telephone interviews were conducted using a semistructured interview guide by a member of the research team (JST) with no professional or personal relationships with any of the participants. Basic demographic information was obtained at the end of the interview. All interviews were audio recorded. While listening to the audio recordings of the interview, the interviewer wrote detailed summaries, transcribing verbatim exemplar quotations.

Data Analysis

Detailed summaries were inductively coded and analyzed using the framework of normalization process theory

(NPT).^{12–15} NPT “provides a conceptual framework for understanding and evaluating the processes (implementation) by which new health technologies and other complex interventions are routinely operationalized in everyday work (embedding), and sustained in practice (integration).”¹⁶ NPT focuses on factors that affect implementation and integration of interventions into health care organizations, understanding what makes the task “normal” or “standard” for the workplace.^{14,15} NPT consists of 4 constructs: 1) coherence—how people understand the new practice and work that needs to be done to operationalize it; 2) cognitive participation—how and by whom people think the new practice will be conducted; (3) collective action—how the new practice is operationalized and managed; and (4) reflexive monitoring—what people think of the new practice and its worth.¹⁶ These constructs helped us understand how people thought of the PtDAs and the work needed to implement them (coherence, cognitive participation, and reflexive monitoring), and thus the factors contributing to their use, as well as how people used the PtDAs across programs (cognitive participation and collective action). We chose NPT for analysis as it is a theory that has been used in previous decision aid implementation evaluations and captures important clinical questions.^{14,17}

Analysis was an iterative, multidisciplinary team-based process, including those intimately familiar with how LVAD programs function and those with limited knowledge about LVADs overall. Two members of the research team, the interviewer (JST) and a qualitative expert who had no involvement in the PtDAs development (MAM), coded all data inductively, using data-derived codes. Codes were iteratively revised by the coders, with input from the other team members. Consensus coding was achieved, complete with team discussion and data re-immersion, to provide a descriptive and thematic summary of the data.

To ensure credibility and confirmability of the findings,^{18,19} we triangulated the data using a multidisciplinary study team, consisting of an advanced heart failure cardiologist (LAA) and nurse practitioner (CKM), a geriatrician and palliative care physician specializing in shared decision making (DDM), a health communication expert and heart failure research project manager (JST), and a qualitative expert (MAM). Throughout the data analysis, the team met to discuss the analytic process and emergent themes. Additionally, member checking with some of the participants was done to further ensure credibility, where the interviewer presented preliminary findings to some of the latter participants to confirm data resonated with members of the core audience.²⁰

The funding source had no role in the study.

Results

Organic Dissemination

From May 2014 to December 2016, 32 people from 26 different affiliations contacted us through email inquiring about the PtDAs. These included surgeons, cardiologists, LVAD coordinators (typically registered nurses, nurse practitioners, or physician assistants), other nurses, social workers, palliative care doctors, and market development managers; affiliations included LVAD programs, industry, and government. Of the 32 eligible, 31 were contacted for an interview; 1 was excluded due to the program’s involvement in the trial testing the effectiveness of the PtDAs. An additional 8 potential participants were contacted through snowball sampling (4 from already identified affiliations and 4 from additional affiliations).

Between June 2016 and January 2017, we conducted telephone interviews with 30 people from 26 different affiliations (23 hospital-based LVAD programs, 2 industry, and 1 government agency). Nonparticipation was due to nonresponse ($n = 3$), refusal due to change in employment ($n = 1$), and refusal in favor of another program team member being interviewed ($n = 5$); the refusals primarily came from LVAD programs’ surgical or medical directors; one nonparticipant was a marketing manager from industry (see Figure 1). Interview duration was between 9 and 50 minutes (mean = 24 minutes). Most interviews were with clinicians or members of the LVAD program involved in decision making. Five of the participants worked outside of the United States (three from Canada and two from France). Time between initial inquiry about the PtDAs and date of interview ranged from 2 weeks to 26 months (median = 12 months). Detailed participant characteristics are provided in Table 1.

Participants reported learning about the PtDAs through informal conversations ($n = 8$) or formal presentations ($n = 5$) at conferences or program visits, a colleague from program’s LVAD team ($n = 5$), published manuscript on the PtDAs’ development ($n = 4$), an Internet search or online message boards ($n = 4$), word of mouth ($n = 2$), or the PtDAs already being used when starting in the position of employment ($n = 2$).

Real-World Implementation

In order to further examine how direct implementation at the program-level occurred, we excluded the 3 nonprogram participants from the real-world implementation

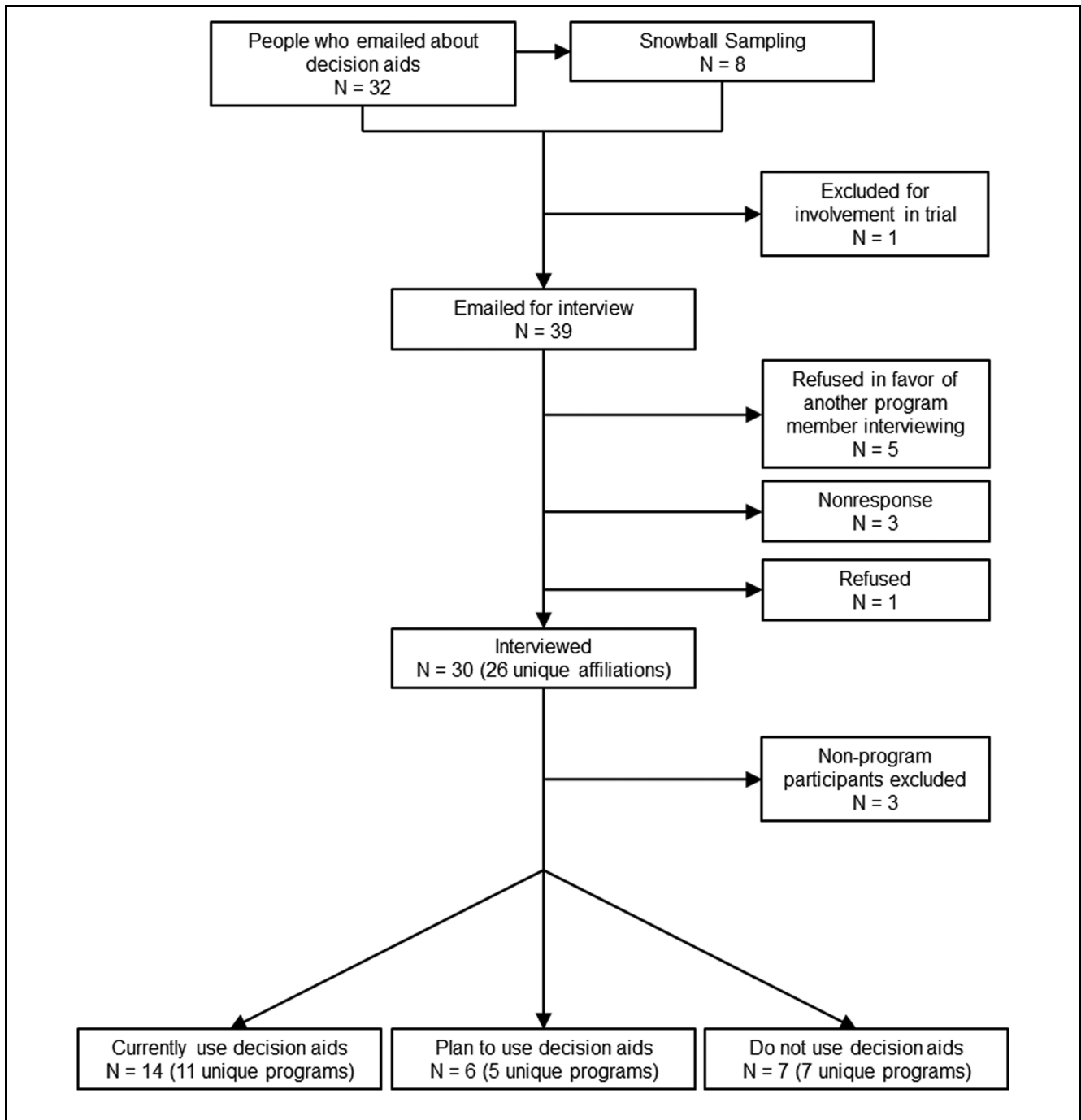


Figure 1 Methods of those contacted and interviewed; results of decision aid usage.

analysis. Several participants from the same institution were interviewed, for a total of 23 LVAD programs represented. Of those, 11 programs currently use the PtDAs, 5 plan to use the PtDAs in the near future, and

7 do not use nor have active plans to use the PtDAs. See Table 2 for details. Real-world implementation was conceptualized using the four constructs of NPT (see Table 3).

Table 1 Participant Characteristics

	Participants (<i>n</i> = 30)
Median age (range)	44 (29–60)
Gender, female	20
Highest academic degree	
Bachelor's	7
Master's	15
Doctorate	8
Current position	
LVAD coordinator	11
Cardiologist	6
Critical care nurse	3
Market development manager	2
Physician assistant	2
Social Worker	2
Government program coordinator	1
Patient care service director	1
Palliative care physician	1
Surgeon	1
Median years in position (range)	4.5 (1–17)
Median years at affiliation (range)	8 (0–32)
Type of affiliation	
LVAD program	27
Industry	2
Government agency	1
Location	
South, USA	9
Northeast, USA	6
Midwest, USA	5
West, USA	5
Canada	3
France	2
Median number of LVAD implants per year at program (range)	35 (1–90)

LVAD, left ventricular assist device.

Coherence: "Sense-Making Work"

Under coherence, three main themes emerged from the interviews: 1) clear recognition of a need for shared decision making, 2) perception that our PtDAs help meet the shared decision-making need, and 3) concern over implementation being a burdensome process.

Coherence Theme 1: Recognition of a Need for Shared Decision Making. Participants reported a clear and strong need for shared decision making. This theme encompassed several aspects, including participants acknowledging that this is a unique decision that warrants extra attention during education, as well as a sense of duty to ensure that patients knew what they were getting into with an LVAD.

The perceived need for shared decision making was driven by participants' recognition of how challenging education on this complex decision is for the sick patient

population and, having seen complications from LVAD, an understanding that patients need to make this decision for themselves.

We've struggled with people that we feel like we've promised the world to and then they haven't done as well after the surgery. So I think it's been eye opening to the medical team that we need to look at several angles when we talk about the therapy and what we can offer to people. (Participant 5, LVAD Coordinator, uses PtDAs)

Participants saw a need for as much information transfer as possible and saw it as their duty to help patients make an appropriate decision, whether by directly providing education (i.e., LVAD coordinator) or by knowing appropriate education was occurring at their program (i.e., cardiologist).

All of us are vested in the patient making good decisions for them. And we have all come across patients who have made decisions and accepted VAD therapy and it turned out to be the wrong decision for them. . . . The way we tend to parse out the decision process is us evaluating them, not them evaluating the decision, so we see a need, we see an unmet need. (Participant 20, LVAD Coordinator, uses PtDAs)

Well, I don't think we really do a good job in educating our patients up front. So any information we could provide them, I think would be helpful. (Participant 19, Cardiologist, does not use PtDAs)

Additionally, participants acknowledged a sense of bias inherent in clinicians and the process, which affects verbal communication about treatment and the decision, and would therefore benefit from objective shared decision making.

I think sometimes it's also easy for us to just assume that people would want it, because who would want to die? . . . We don't necessarily dig deep into, well, "what if you had a pretty decent chance of having a stroke and would you really want to live like that?" So it's just such a high stakes decision, and I think it's hard to be totally objective about something like this. So having something, an outside source to sort of do the dirty work and take some subjectivity out of this sort of life and death situation, it eases the burden of the clinicians, to sort of take that off. (Participant 16, Cardiologist, uses PtDAs)

Sometimes I've observed in my own viewings of the providers and patients, that a lot of times, patients just have complete trust in what their heart failure doctor is telling them, and that's enough to make their decision. So I think some of it has to do with just the traditional relationship with their

Table 2 Decision Aid Usage and Characteristics, Reason for Lack of Use

<i>Programs currently using the decision aids, n = 11</i>	
Decision aids used	
Pamphlet and video (English-language version)	5
Pamphlet only (English-language version)	5
French-language pamphlet	1
Patients decision aids used with	
BTT and DT patients	9
DT patients only	2
Decision aids delivered to patients by	
LVAD coordinator	7
Social worker	2
LVAD coordinator and social worker	1
Physician assistant	1
Primary location of decision aid delivery	
Inpatient	4
Outpatient	1
Equally inpatient and outpatient	6
How decision aids used	
Gone through with patient as part of teaching	7
Just given to patient as resource to view on their own	4
Standardization of use	
Used as standard part of education	7
Not yet standard but plans to protocolize it	4
Length of decision aid use	
6 months or less	6
Over 1 year	5
<i>Programs that plan to use the decision aids in near future, n = 5</i>	
Site's plan for decision aid use	
Started implementation process post interview	2
Once program-specific modifications to decision aid are finished	1
Once program begins implanting again	1
Once in new position	1
<i>Programs that do not use decision aids nor have plans to use, n = 7</i>	
Primary reason for not using decision aids	
Lack of time or personnel to implement	5
BTT-only center/desire for BTT-specific materials	2

BTT, bridge-to-transplant; DT, destination therapy; LVAD, left ventricular assist device.

provider, that they just trust their word. (Participant 26, Critical Care Nurse, does not use PtDAs)

To combat this inherent bias, participants described a need for standardized materials that not only could help present the decision in an objective way but could also help move the conversation forward in the busy, real-world clinical encounters.

I think everyone recognizes that we as physicians and extenders and team members don't have the time to really spend to help patients make decisions that are good for them. We are very good at giving information, but we're not good at

walking them through that. And that getting the patients to think about it would prevent potentially, you know, buyer's remorse. (Participant 23, Surgeon, plans to use PtDAs)

Coherence Theme 2: Perception That the PtDAs Help Meet the Shared Decision-Making Need. Participants reported a clear lack of existing resources. Our PtDAs were seen as a way to fill the current gap in objective, standardized materials that could help facilitate this complex, often challenging process. Participants expressed a desire to use the materials with patients in the hopes of better education and shared decision making. For some, the PtDAs were sought out and seen as missing from their current practice; those who "couldn't wait" to start using the PtDAs and saw implementation as being minimal effort.

There was nothing else out there, was the first thing, I couldn't find anything that I thought was appropriate for our patient population. The second thing is that . . . I think it's super important some of the questions that you pose for patients to think about, like is this congruent with quality of life. I've been there at the eleventh hour and people have to make decisions about what they want and don't want, and my hope is for them to have a decision aid going into this. (Participant 24, Critical Care Nurse, uses PtDAs)

Despite its patient and caregiver focus, the PtDAs also helped some clinicians see their own biases, which they found as enlightening and valuable.

My initial thoughts were that I thought it was, I wouldn't say anti-VAD, but wasn't as pro-VAD as I had hoped, let's say it like that. And then on further reflection, I thought it presented the information in a very fair way. . . . And I had to come to realize that my view was not unbiased. . . . It also helped me recognize my own inherent biases in the way that I present information to my patients. (Participant 23, Surgeon, plans to use PtDAs)

Coherence Theme 3: Concern Over Implementation Being a Burdensome Process. For those participants who had not implemented the PtDAs into their program, many saw the time and effort to implement the materials as burdensome or that making any change in the health care system as too difficult. These participants acknowledged the importance of additional education resources and reported an interest in the PtDAs, but did not see them as a necessary element of their routine or had simply not gotten around to implementing yet. Others mentioned a personal interest in the PtDAs, but a perception that certain clinicians would not be willing to use them.

Table 3 Normalization Process Theory Constructs and Main Study Findings

Construct	Description ¹⁶	Main Study Findings
Coherence	The sense-making work people do to understand a new practice and the work that needs to be done to operationalize it—Understanding of the aims, objectives, importance, expected benefits, and responsibilities	<ul style="list-style-type: none"> • Clear recognition of need for shared decision making in LVAD decision • Decision aids can meet the need for an unbiased, standard resource • Implementation can be seen as burdensome
Cognitive Participation	The relational work people do to operationalize a new practice—The individual and group thought on how the new practice will be conducted and by whom	<ul style="list-style-type: none"> • Team consensus is necessary for implementation • A champion to advocate for the decision aids' use helps facilitate implementation
Collective Action	The operational work people do to enact a new practice—How the practice is operationalized and managed, including the division of labor	<ul style="list-style-type: none"> • Use varied depending on program's existing structure for formal teaching • Typically incorporated in the existing teaching session done by LVAD coordinators • Used either as a central part of teaching or provided in existing packet of educational materials
Reflexive Monitoring	The appraisal work people do to assess the effects of a new practice—What people think of the work around the new materials, their effect, and evaluation of their worth	<ul style="list-style-type: none"> • Seen as helpful for clinicians' educating patient and in patients' decision making • Helpful to some patients, but some already have made a decision prior to formal teaching

LVAD, left ventricular assist device.

Just adapt in practice, or you know, as a team we haven't come to a complete consensus that we're going to implement it, because it's kind of a change in workflow, and that just hasn't really been discussed or adapted. I really just think it comes down to like a system level change and how hospitals or health care systems, how they're used to implementing change, and it's hard for big organizations to implement change. And that just in it of itself is a barrier. (Participant 26, Critical Care Nurse, does not use PtDAs)

Cognitive Participation: "Relational Work"

Under cognitive participation, we identified 2 main themes: 1) the need for team consensus and 2) the importance of opinion leaders to champion the implementation.

Cognitive Participation Theme 1: The Need for Team Consensus. To implement the PtDAs into routine practice, there was a clear team consensus that needed to take place. Among those who were using or planned to use the PtDAs, all referenced bringing the PtDAs to their LVAD team for discussion and approval; for those who did not use the PtDAs, they stated a need to introduce the PtDAs to their team first and obtain a consensus.

I know that one provider thought things like that [PtDA] can get misinterpreted if you just hand the patient that and just walk off. He wasn't really someone in favor of it.

Another provider thought, the more information we give these guys, the better, no matter what the format. So it was kind of a mixed consensus. (Participant 11, Clinical Nurse Specialist, does not use PtDAs)

Participants using the PtDAs reported that the introduction of the PtDAs was well received by their teams and there was minimal resistance to the PtDAs' use at their program. Some participants reported being surprised that certain team members, such as the surgeons, were accepting of the materials' use.

There was zero resistance . . . everyone universally thought it would be a good thing to use. There was not a single person who said, "Oh, we can't show them this, this is terrible." Everyone was on board with using it, from the surgeons to the cardiologist to the nurses. (Participant 16, Cardiologist, uses PtDAs)

Cognitive Participation Theme 2: The Importance of Opinion Leaders to Champion the Implementation. Introduction and implementation of the PtDAs to the team was universally led by a champion. This champion was either a cardiologist or medical/surgical director who told the team to use the materials (top-down), or was an LVAD coordinator or social worker who worked to push the implementation forward and obtain permission to use the PtDAs themselves (bottom-up). Regardless of

champion type, it was often the LVAD coordinator, physician assistant, or social worker who took the time and initiative to get PtDAs implemented, embedded, and integrated into the existing clinical structure.

I know [surgical director] feels pretty strongly that it's a good tool and was the one who pushed the initial use of it . . . he says to us "make sure you're using this." (Participant 6, Physician Assistant, uses PtDAs)

In the cases where the PtDAs had not been implemented, there was a clear lack of a champion; participants reported that there was an absence of personnel or personnel time to push the PtDAs' use forward and get them implemented within their program. In a few cases, personnel had recently left the institution, either leaving the existing staff with little time to take on something new or the program without the point person who would have taken on this change. Lack of time and personnel was the most commonly reported reason for lack of PtDA use.

I think it just comes down to process, and having someone willing to champion the process. It's not something I would ever say, "No, my patient can't do that," but getting it to be a well-greased system. . . . It just takes that person who really believes in the idea and who would put in the time to implement it. (Participant 4, Cardiologist, does not use PtDAs)

Collective Action: "Operational Work"

Under collective action, we found that programs were using the PtDAs as intended (to augment or replace the current materials used during patient education in order to improve shared decision making) with anticipated adaptations to fit their program's existing structure, while unanticipated adaptations to PtDAs were occurring at some programs. See Figure 2 for a typical LVAD evaluation/education workflow and where the PtDAs fit.

Collective Action Theme 1: Fidelity to PtDA Intended Use and Anticipated Adaptations. Most often, LVAD coordinators provided the PtDAs to patients and their families during the scheduled initial education session that takes place early during the LVAD evaluation process. The timing and location of delivery varied depending on how the initial teaching was conducted at the program, but most aimed to provide the materials as early on in the process as possible. In some cases, the PtDAs were used primarily as early education prior to evaluation, and in a few cases by the social worker during the standard psychosocial evaluation.

Participants reported using the PtDAs in one of three ways: 1) as a central part of teaching, where the PtDAs

acted as a structure or guide for the teaching session; 2) highlighting certain sections during teaching or for patients to view on their own, such as the visual portions to illustrate main concepts; or 3) provided in the packet of education materials that was already being given to patients for independent viewing, where the PtDAs were either added to the existing literature or used to replace less favorable materials (such as industry pamphlets or high-level articles).

As part of my psycho-social assessment, I'm using the brochure as a speaking tool, as an exploration, as a way to discuss more issues around the VAD. (Participant 1, Social Worker, uses PtDAs)

Collective Action Theme 2: Unanticipated Adaptations. While the intent was for both pamphlet and video PtDAs to be used as a resource, the video PtDA was used much less than the pamphlet, primarily for logistical reasons. Participants reported difficulty in finding ways to show the video in the clinical setting, due to a lack of DVD players in the hospital rooms, limited patient access to computers, and challenges with getting outside videos incorporated on the in-hospital education channel. Some worked around, providing patients with the link to the video to view on their own time, playing it on patients' own mobile devices in clinic or hospital, or playing it on clinic computers. Few had access to tablet devices, which, when available, were cited as a convenient way to show the pamphlet and video during teaching.

Additionally, programs reported adapting the intended use of the PtDAs (DT-specific materials) to use with both bridge-to-transplant (patient getting a device temporarily until transplant is available) and DT patients, an "off-label" use of the materials. Participants saw a value in using the PtDAs with even those who were not DT because much of the educational content is the same and indication is not always certain. Participants reported augmenting the PtDAs for bridge-to-transplant candidates with verbal qualifiers or additional information on transplant (see Figure 3).

Reflexive Monitoring: "Appraisal Work"

Most programs were early in implementation and had not experienced much reflexive monitoring yet, although some notable patterns emerged from the interviews. Those who used the PtDAs reported the materials were useful tools complementary to their current processes. Participants specifically referenced the visual portions, clarity and conciseness, portability and accessibility, and the tangible nature of the PtDAs as being most helpful.

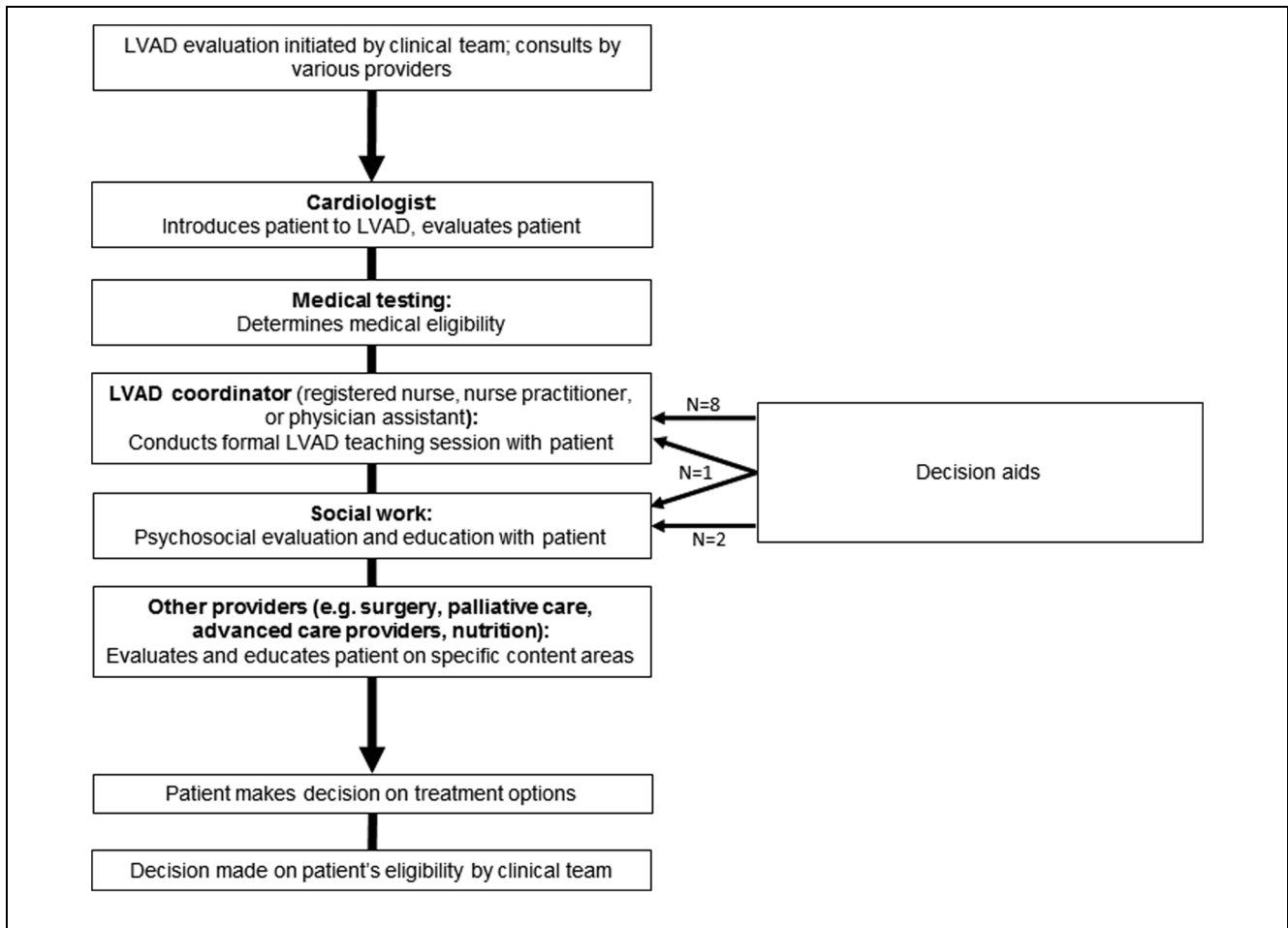


Figure 2 Evaluation and education workflow and decision aid usage. LVAD, left ventricular assist device.

Many participants mentioned the unbiased and objective nature of the PtDAs, and that they can be used to help counteract the implicit biases of clinicians. Some reported the PtDAs as being a guide for “these difficult conversations”; an aid for patients to better assess risks and benefits and feel they have more control in the decision.

It just really lays out for them what life is like with a VAD and what it's like without a VAD, and I think it clearly lays out what the risks are and what the benefits might be. So it's very balanced and I think it does help the patients kind of mentally walk through that decision. And it makes them recognize that it is a decision, that they're not just being pushed into doing this. (Participant 2, Social Worker, uses PtDAs)

While some participants saw the value in the PtDAs, they also commented that for patients who have made up their mind already on the treatment decision, these materials are not likely to make much difference.

I definitely think for the patients who are really conflicted about whether they want a VAD or not, I think that pamphlet is incredibly helpful. I think, by far, the majority of patients are just like, “When am I going to get it, and when can I get it, and are you going to give it to me.” And for the patients like that, I don't know, and I haven't ever gotten feedback to say, “Boy, I really wanted one but now I'm changing my mind because I read about a lot of stuff in here.” (Participant 8, Physician Assistant, uses PtDAs)

Discussion

This study examined the real-world approach to implementation for early adopters of DT LVAD PtDAs in order to better understand how this is done in a non-research setting. According to the Centers for Medicare and Medicaid Services, there are currently 162 certified DT LVAD implanting centers in the United States.²¹ Twenty-three programs interested in the PtDAs

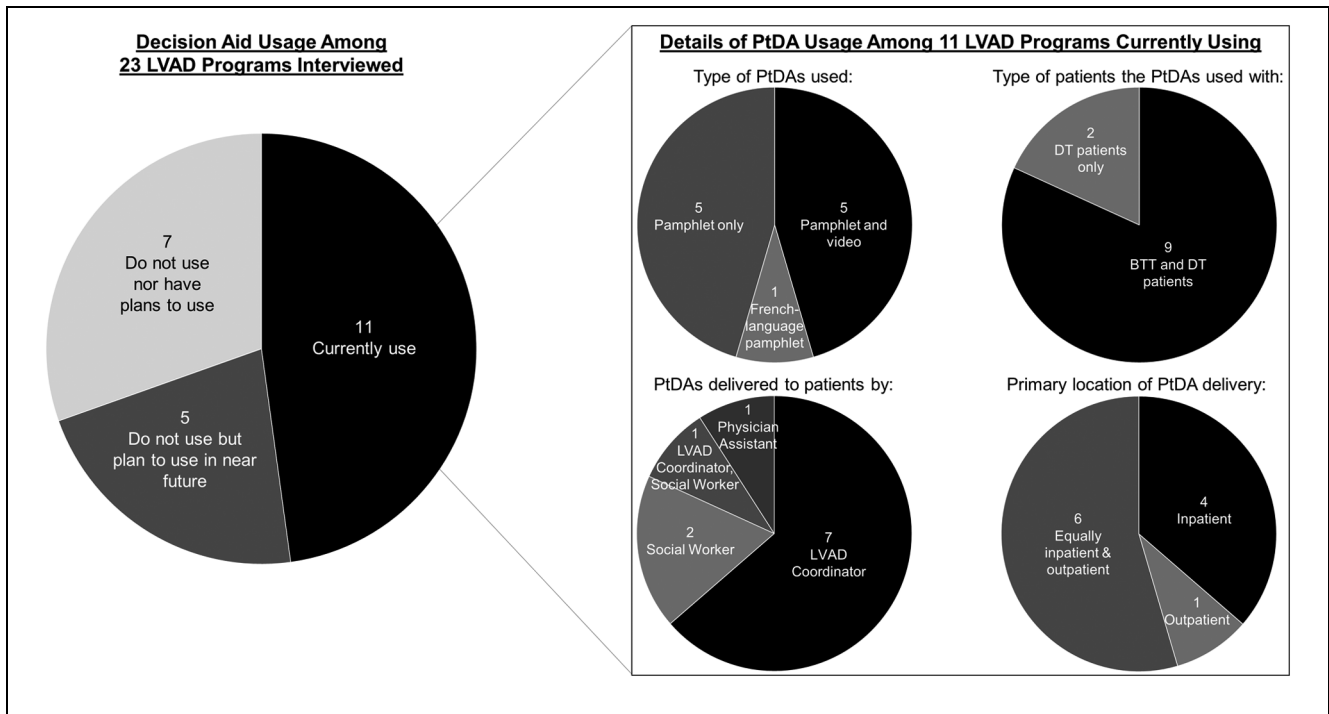


Figure 3 Details of decision aid usage. BTT, bridge-to-transplant; DT, destination therapy; LVAD, left ventricular assist device; PtDA, patient decision aid.

contacted our group (as well as personnel from LVAD companies and government agencies). More than half of those programs are using or plan to use the PtDAs in their routine clinical practice. The interest in and implementation of these PtDAs is particularly interesting, largely because it occurred in a setting that required minimal efforts to encourage active implementation. The findings herein suggest that such organic dissemination and implementation occurred because of a perceived role for shared decision making in the high-stakes decision around DT LVAD, unmet informational needs in part resulting from a prior reliance on industry materials, and preexisting consent and education sessions that provided a formal structure for using the PtDAs. Understanding the natural factors associated with this adoption and implementation are important to inform learning for both LVAD decision making in particular and broader PtDA usage in general.

Much of the previous work on shared decision-making implementation has focused on barriers and facilitators to implementation.^{3,4,22,23} In this decision context, many of the same findings emerged, such as reported lack of time and distraction by other duties, as contributing factors for inhibiting implementation.^{3,4} As

found in previous work, “motivation of the health professional” was a large contributor to successful implementation of our PtDAs.³ Having a champion of the PtDAs led to a seamless implementation, whereas a lack of a champion who would “devote time” to pushing the PtDAs forward often led to the PtDAs being of interest but ultimately “just not used” at certain programs. As with any new initiative, having enough interest and care in the new practice is crucial to its implementation.

While lack of time and motivation were barriers to implementation, once implemented, the PtDAs were generally felt to be efficient and seamlessly integrated. This is likely unique to this decision context, as LVAD programs have designated clinicians involved in formal evaluation, education, and informed consent prior to implantation of a durable LVAD. This structural anomaly that is absent in many other medical contexts seems to allow for relatively easy incorporation of the PtDAs into routine practice for patients considering LVADs. In many cases, the PtDAs can easily be integrated into the formal teaching session done by the LVAD coordinators, and often replace or augment materials deemed less helpful (industry pamphlets or complex, lengthy consent forms). In contrast to contexts like primary care and

other studies which report clinicians feeling a lack of time to use PtDAs or difficulty integrating in their usual care,^{3,4} the existing structure found in the LVAD setting does not require physicians or surgeons to take on additional work to use the PtDAs directly. For most programs, the LVAD coordinators are designated to provide education to the patient and are therefore the natural entities to distribute the PtDAs.

While the structure of the LVAD teaching session helps with implementation, the logistical aspects of the clinical setting appeared to limit the use of the video PtDA. Participants reported liking the video as much or more than the pamphlet, but less than half used it in routine teaching. The ease of use of the 8-page pamphlet, with the ability to print and distribute on site, allowed for greater overall implementation; in contrast, lack of resources for DVD usage hindered its regular use. This is a consideration for future work in implementation, where utilization of newer mediums would be of value, such as hospital-owned tablet devices or communal laptops. With the growing ownership of smartphones and tablets, utilizing a website address on patients' own mobile devices may improve dissemination and implementation of non-static tools. Another nuance that should be explored further is the international aspect from the French and Canadian participants. The differences in culture, laws, systems, and clinical practice led to varied reasons for and perspectives on PtDA use. French law bans patient materials that contain product names, which resulted in no previously available LVAD educational materials in French. Our French-language pamphlet met this need. On the other hand, with Canada's health care structure and limits on the number of total implants, there was a challenge to use the materials, both in terms of discrepancies regarding indications for LVAD implantation and restraints within the systems' ability to promote their use.

A strength of this study is the use of NPT to examine the processes and culture in which the new practice of using the PtDAs became routine work.¹⁵ Elwyn and colleagues have used NPT to understand adoption and implementation of shared decision-making tools,¹⁷ providing an alternative view to the more narrow "facilitators and barriers" approach.^{3,4} They found that many providers resisted shared decision making and use of PtDAs due to their existing normalized patterns within clinical encounters, which were reinforced by medical training and the expectations of traditional medical practice.¹⁷ We did not find that this was the case for LVAD decision making, although we do recognize that all participants in our study had proactively sought out the PtDAs on their own and thus were self-selected for their

interest in shared decision making. These primed participants felt that shared decision making was crucial for the DT LVAD decision-making process, which led them to seek out and potentially pursue the LVAD PtDA. Resistance to change from the traditional medical encounter model, as seen in Elwyn's PtDA work, was not present with participants of this study due to the perceived need for more education and better decision making for LVAD. This was often fostered by clinicians witnessing first-hand both the complications associated with the therapy and the results when patients do not make value-concordant decisions. Our study suggests that LVAD is perhaps a unique clinical case that encourages PtDA use because of both the lack of currently available objective materials and the perceived need for as much education and knowledge transfer as possible; this is compounded by clinicians' recognition that DT LVAD is a complex, challenging, and preference-sensitive decision that should not be taken lightly. In short, the decision context around LVADs fosters the use of PtDAs.¹⁷

Limitations

A limitation of this study is that the sample was derived passively, and there may have been people or programs using the PtDAs or with negative opinions of the PtDAs that we did not sample. However, we systematically sent interview requests to every person who had contacted us about the PtDAs, followed up with nonresponses, used existing relationships to solicit responses, and enhanced interviews through snowball sampling. Another limitation is that NPT provides a focused lens for evaluating relevant themes regarding implementation; however, NPT has been used frequently in shared decision making and implementation work and was an appropriate way to frame and structure the data from these interviews.^{15,17} Last, we acknowledge that the developers of the PtDAs are also the authors of this article, which creates potential bias. However, due to our explicit awareness of this concern, we were careful to use rigorous methods in both the conduct of the study and analysis of the data to ensure credibility and confirmability of the results.

Conclusion

While PtDA usage in general continues to be low and implementation difficult, this study examined how organic uptake of PtDAs can successfully occur in the right decision context. This is facilitated by a major decision with big tradeoffs, evidence of unmet informational

needs, invested clinical champions, and positive experiences with the PtDAs. LVAD is a unique clinical decision where clinicians recognize the importance and need for shared decision making and where an existing structure makes use of PtDAs fit easily into routine care. With a local champion of the materials, and once buy-in by the LVAD team is obtained, implementation can be relatively straightforward and successfully achieved in the real-world setting. Examining both implementation in the LVAD setting and the PtDAs' effect on the routine practice is helpful in understanding how we can continue to improve LVAD decision making and grow implementation of decision support resources.

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