Informed consent in the context of left ventricular assist device use as destination therapy (LVAD-DT): A systematic review and ethical analysis

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This work is dedicated to my wife, Julie, and son, Noah.

Abstract

Background: The circumstances surrounding the informed consent process for accepting LVAD-DT are incredibly complex and discretely nuanced from individual to individual. Additionally, the population requiring this powerful technology continues to grow, and those receiving it are living much longer. The gaps between client experiences and expectations prior to LVAD-DT consideration and after LVAD-DT implantation, and the evolving legal and ethical underpinnings influencing clinicians and health care more generally indicate a critical need for review and assessment of the degree to which current practice conforms to the standard(s) of informed consent, and the level to which that application can be sustained. The primary aim of this proposed systematic review then is to identify and understand the standard(s) of informed consent applied in the context of LVAD-DT. A secondary aim is to determine the degree to which informed consent in this context conforms to the accepted standard(s). A third aim is to recommend guidelines for undertaking informed consent in a way that better addresses the needs and interests of individuals receiving LVAD-DT.

Methods: This report is a systematic review of the LVAD-DT and ethics literature, and ethical analysis of the application of informed consent in the context of LVAD-DT. Two related but distinct literature reviews will be undertaken.

Findings: Four important findings with regard to the practice of informed consent were identified: 1) the broadest perception of the purpose of informed consent is to inform the client, not foster and facilitate autonomy; 2) clinicians lack adequate understanding or insight about the amount and type of information required or preferred by the individual client, as well as how that information is preferred to be shared with them; 3) This lack of understanding or insight undermines the practice of informed consent and adversely affects care delivery and outcomes; 4) The quality of informed consent may be closely associated with the quality and depth of relationship between client and clinician.

Conclusions: Although all centers offering LVAD-DT comply with the currently accepted practice of informed consent, there are significant concerns about the usefulness of that model in this context. Joan Tronto's (2009) informed consent as a grant of authority is a model of empowered choice that is more conducive to the goal of fostering and facilitating client autonomy than the currently accepted practice of informed consent.

Key words: standards of informed consent, left ventricular assist device-destination therapy, LVAD-DT, and LVAD

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List of Abbreviations:

BTT: bridge to transplant

DT: destination therapy

IC: informed consent

INTERMACS: Interagency Registry for Mechanically Assisted Circulatory Support

LVAD: left ventricular assist device

LVAD-BTT: left ventricular assist device, bridge to transplant

LVAD-DT: left ventricular assist device, destination therapy

MCS: mechanical circulatory support

RPeS: reasonable person standard

RPrS: reasonable prescriber standard

SIC: standards of informed consent

SS: subjective standard

Introduction

In the late and end stages of heart failure, symptom and disease burdens become extreme, often leading to inability to work, enjoy hobbies, and care dependence. Often, these symptoms are refractory with minimal exertion, or even at rest (Kitko, Hupcey, Alonso, & Birriel, 2016; American Heart Association, 2017; Barg, Kellom, Ziv, Hull, Suhail-Sindhu, & Kirkpatrick, 2017). A left ventricular assist device (LVAD) may prolong life, improve life quality, or accomplish both for many of these individuals. (Jacques, Jensen, Schafer, Smith, Casey, Lotfi, 2013; Medicare Learning Network, 2014; Abshire, Prichard, Cahita, DiGiacomo, and Himmelfarb, 2016; Kirklin, Naftel, Pagani, Kormos, Stevenson, Blume, Myers, Miller, Baldwin, and Young, 2015; Kirklin, Cantor, Mohacsi, Gummert, De By, Hannan, Kormos, Schueler, Lund, Nakatani, Taylor & Lannon, 2016; Kormos, Cowger, Pagani, Teuteberg, Goldstein, Jacobs, Higgins, Stevenson, Stehlik, Atluri, Grady, Kirklin, 2019).

Originally, the LVAD was developed to provide a conduit to heart transplantation – bridge to transplant (BTT). Often, transplantation was not a viable opportunity due to rapidly progressing illness, or dying process, or a donor heart was not found while the window of opportunity was still open. To improve life quality for these individuals, destination therapy (DT) was initiated. LVAD-DT recipients will die with the device within them. In the early stage of development, LVAD-DT survivability was about 95% at one month, dropping to 61% at 12

months for the least critically ill (Kirklin, Naftel, Stevenson, Kormos, Pagani, Miller, Ulisney & Young, 2008). The most critically ill on the other hand were less likely to experience such success. For the most critically ill, average survivability at that time was about 84% at 1 month, and 42% at 12 months (Kirklin, et al., 2008).

Today, current trends in LVAD-DT indicate it is the majority treatment trajectory for those implanted with an LVAD (Kormos, et al., (2019); Friedman, 2020). For those clients electing to accept LVAD-DT, and those clients for whom BTT becomes unavailable after post implantation, improved life quality and perhaps longevity are largely achievable. (Medicare Learning Network, 2013; Kaufman, 2015; Kirklin, et al., 2016; Barg, et al., 2017; Kormos, et al., 2019). However, risk of death and adverse events such as major infections, sepsis, stroke, neurocognitive impairment, multiple organ dysfunction, hemorrhage, mechanical failure, and many psychosocial concerns remain significant. (Snipelisky, Stulak, Schettle, Sharma, Kushwaha, & Dunlay, 2015; Kirklin, et al., 2016; Abshire, et al., 2016; Barg, et al., 2017; Fedson, MacKenzie, Delgado, Abraham, Estep, Blumenthal-Barby, and Bruce, 2018). Although life quality is improved for most, the more profoundly ill LVAD-DT recipient tends to experience worse outcomes throughout their trajectory. (Ottenberg, Cook, Topazian, Mueller, Mueller, and Swetz, 2014; Kirklin, et al., 2016, Kormos, et al., 2019).

This realization of benefit must come also with the appreciation and acceptance of the significant and varied risks associated with LVAD-DT. Such a balance of information can only be achieved through the ethical informing of the LVAD-DT candidate client. The practice of informed consent (IC) in this population is especially critical because of the very nature of the therapy – life quality improving and life prolonging, but not curative. Discrete client expectations and hopes for individual outcomes make the practice of IC in this population most challenging with respect to the benefits and risks that could be realized.

Informed consent itself is a murky pool into which one is immersed if one is to seek or require any form of medical treatment (or to participate in research for that matter, although this is outside the scope of this thesis and shall not be explored further). The dichotomy of client hopes/expectations and actual individual outcomes identified above raises several concerns. These concerns include, but are not limited to: the variability between states and therefore the organizations offering LVAD-DT in terms of IC and the standards of informed consent (SIC) themselves (King & Moulton, 2006; Shah, Thornton, Turin & Hipskind,2020); the lack of a standardized guideline and approach for IC in this population (King & Moulton, 2006; Fedson, et al., 2018; Shah, Thornton, Turin & Hipskind, 2020); and the lack of understanding of the preferences and values of

candidates for this therapy, beyond the desire for life quality improvement and life prolongation (Friedman, 2020).

Background

Left Ventricular Assist Device – Destination Therapy (LVAD-DT)

Research findings across several studies suggest that LVAD-DT recipients often misunderstand the basic function and purpose of their LVAD, and that LVAD recipients report experiences for which they were not made aware, and for which they were scarcely prepared to manage (McIlvenan, Allen, Nowels, Brieke, Cleveland & Matlock, 2014; Bruce, Kostick, Delgado, Wilhelms, Volk, Smith, McCurdy, Loebe, Estep & Blumenthal-Barby, 2015; Magid, McIlvenan, Jones, Nowels, Allen, Thompson & Matlock, 2016; Barg, et al., 2017). For instance, a study undertaken by Kitko, and colleagues (2016) found that recipients often incorrectly believe that their LVAD will either reverse or fix their heart failure as exemplified by this participant's commentary: "*I thought when they put it in I was going to be fine and be able to do everything like I used to do…well that is not the way it is. When they put it in I had 20% function and I still have only 20% function." (Kitko, et al., 2016; Friedman, 2020).* The following participant comment from the same study is another example of this finding: *"They had me talk to someone who was skiing after his implant…I am nowhere near there…don't think I ever will be…this has not fixed my heart failure."* (Kitko, et al., 2016; Friedman, 2020).

In another case, a study revealed that this procedure brings recipients into a space of liminality (Barg, et al., 2016) where the LVAD recipient sees themselves as both sick and well, at the same time (Friedman, 2020). One participant of this study shared: *"I have a fear of being away from my doctors and my daughters, because I know they are always here for me. But when I go away – first of all you have to take so much stuff with you. It's almost not worth it to me."* (Barg, et al., 2016; Friedman, 2020). Another participant from this study stated: *"My view is that I'm always concerned about the tube, with the four wires in it, because they look fragile, the wires are very small, and it moves with the bag. See if anything happens to that wire, they've gotta open me up and the whole thing and that's scary. Particularly not knowing when it might happen." (Barg, et al., 2016; Friedman, 2020).*

These findings raise an important implication for clinicians engaging in the ethical practice of obtaining an informed consent from individuals who are candidates for LVAD-DT. Namely, that clients may not be as well served by the current and accepted practice of obtaining an informed consent as we would like to think. And if that is the case, then both the individual client, their autonomy, and their care are undermined.

The LVAD procedure presents a myriad of unique challenges and ethical questions for clinicians to consider. These challenges become more complex and personal with evolution of technology, and an expanding population of

candidate recipients confronted with their mortality and the decision to delay it, or not (Kormos, et al., 2019). Chief among these concerns is that of informed consent (Fedson, et al., 2019; Kitko, et al., 2016: Sonntag, 2019). Complex topics associated with the consent process for LVAD-DT ought to include the opportunity for pump replacement, deactivation preferences, and the influence of concomitant illnesses such as depression, and neurocognitive decline, as well as appropriate advance care planning in addition to information regarding risks and benefits of the procedure itself (Sonntag, 2019).

Informed Consent (IC)

Informed consent discussions are routinely undertaken for most invasive procedures. Informed consent is intended to garner a voluntary and informed authorization from the client allowing the healthcare clinician to engage a certain action on the client's behalf (Tronto, 2009).

The notion of meaningful informed consent can be traced back to the middle of the last century. Prior to that, the purview of medical decision-making rested with the physician. The prevailing attitude at that time was that physicians knew best and those in their charge should not or could not contribute meaningfully to the informing of their care or contribute to decisions regarding treatment (Murray, 1990). In its early history, informed consent was intended to reduce opportunity for harm in human subject research. Later, in the 1970's,

there was an expansion of purpose for informed consent to include the protection of autonomous choice. In addition, human subjects of research informed consent also came to include health care clients (Beauchamp & Childress, 2013). Today, relationships between healthcare clinicians and clients of health care are much more specifically circumscribed in terms of informed consent and the communication pertinent to informed consent.

The Joint Commission requires that all components of informed consent be memorialized in writing, or other form of documentation. That documentation should include a description or explanation of the expected procedure, treatment or action; the associated risks, and benefits; the other options available aside from the one being explained; and a sensing or appraisal of the client's understanding of all the preceding elements (Shah, et al., 2020).

The Statement on Principles (American College of Surgeons, 2016), however, expands informed consent to include not only information about the client's illness, the treatment options, the benefits of the treatments, the consequences of not accepting treatment, and the risks involved, but also to listen carefully to the questions asked by the client. Finally, all information should be presented in a fair, clear, accurate, and compassionate fashion. However, Beauchamp and Childress (2013), Kaufman (2015), and Tronto (2009) point out that in certain circumstances, not only may the client be unable to comprehend what is being shared, they can scarcely imagine what questions to ask since they are unable to

conceive of what life will be like after the action for which the provider seeks consent (LVAD-DT implantation, for instance).

Problem Statement & Study Aim

The circumstances surrounding the informed consent process for accepting LVAD-DT are incredibly complex and nuanced. Additionally, the population requiring this powerful technology continues to grow and those receiving it are living much longer. According to The Society of Thoracic Surgeons Intermacs database annual report (Kormos, et al., 2019), 18,539 persons have undergone LVAD support. Of these, 43.3% (8,027 individuals) are associated with destination therapy at the time of the report's publishing. The annual report also indicates a mean survival rate across LVAD-DT recipients is 95% at 1 month and 34% at 72 months. However, Kormos and colleagues (2019) indicate that "adverse events, especially neurological events continue to have a detrimental impact on success of CF LVAD support" (Kormos, et al., 2019, p. 115). Adverse events include, but are not limited to, neurological insult (19%) from such events as ischemic or hemorrhagic strokes, multi-organ system failure (15%) – occurring most frequently in the first 30 days post implant, but slowly increasing with time from implant, cardiac causes inclusive of non-right sided heart failure, and sudden cardiac death (12%), withdrawal of the device (11%), and 8% as a consequence of infection – although this cause is believed to be understated due to concomitant complications of which infection is a likely

component. Device malfunction and hemorrhage represent approximately 3% and 2% of deaths, respectively. Death is realized through other means besides those listed here including respiratory failure, right-sided heart failure (new manifestation of end-stage illness progression, or concomitant end-stage illness) and other adverse effects directly or indirectly arising from implantation (Kormos, et al.2019, p. 121-122).

The lack of client understanding about their illness and the LVAD-DT purpose and function, and the unexpected challenges realized post implant suggest a meaningful assessment of the practice of informed consent in this context is warranted. The topic of decision-making in the LVAD literature is ubiquitous. Many investigative teams suggest improvement of informing and decision-making can be achieved by considering an individual's emotional state, as well as technology needs for informing, and addressing the specter of death or death postponement with LVAD-DT candidates (Ottenberg, et al., 2014; McIlvennan, et al.; 2014, Magid, et al., 2016; Kitko, et al. 2016). Several others, however, call outright for the review and perhaps remodeling of current informed consent practices in pursuit of the same objective (Bruce, et al., 2015; Fedson, et al., 2019; Sonntag, 2019; Kormos, et al., 2019). This recommendation is especially meaningful in the cases of those refusing LVAD-DT therapy (Bruce, et al., 2015), and those individuals deciding to withdraw LVAD-DT support – those choosing to die after implant (Kormos, et al., 2019). In all cases, insights critical

to the best understanding and support of individuals seeking this powerful technology are sought.

The primary aim of this systematic review then is to: 1) identify and understand the purpose and standard(s) of informed consent in the context of LVAD-DT; 2) determine the degree to which the act of obtaining informed consent in this context conforms to the identified standard(s); and, to 3) recommend framework for undertaking informed consent in a way that better addresses the needs, preferences and interests of individuals receiving LVAD-DT, if indicated.

Methodology

This study is a systematic review of the literature and ethical analysis of the standard(s) which underpin the obtaining of informed consent in the context of LVAD-DT. Two related but distinct literature reviews will be undertaken. The first is to identify and understand the standards of informed consent from the ethics literature. The second is to identify what is written about the application of those standards identified in the ethics literature in relation to the obtaining of informed consent in the context of LVAD-DT in the evidence-based healthcare practice literature.

Search

These reviews will employ the following search engines: CINAHL, EthicsShare, Google Scholar, Ovid Medline, Philosophers Index, and PubMed.

Search terms for both searches will include standards of informed consent, left ventricular assist device-destination therapy, LVAD-DT, and LVAD. The literature searches will be limited to literature published in English, and results having full text access. The resulting hits from this exploratory phase of these literature searches will be further limited through application of discreet selection and exclusion criteria. (*See table 1)*

Selection

To have been considered for review, search results from the ethics literature must have specifically addressed the standards under which informed consent applies. Results from a search of the literature germane to LVAD-DT and relevant clinical care must have addressed standard(s) of informed consent (SIC), and directly refer to left ventricular assist device, destination therapy (LVAD-DT).

Articles were screened iteratively through several stages of vetting for review. First, results were screened by title, then again by abstract, and then again by full text screening. Articles not conforming to the inclusion criteria at each progressive screening stage were excluded from further review.

Table 1 Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Free full access.	No free full access.
Published in English.	Not published in English.
Peer Reviewed.	Not Peer Reviewed.

SIC specific.	Not SIC specific.
Germane to LVAD-DT.	Not Germane to LVAD-DT.
Specific to clinical Practice	Not specific to clinical practice.
If empirical study, then subjects are human adults.	If empirical study, then subjects not human, adult, or human and adult.

Data Collection

The final articles for review were then iteratively read and reviewed for qualitative data. This information was then extracted from the articles using a data extraction table (Garrard, 2017). The data extracted includes specific details about reviewed items. These details include: article title, year of publication, article type, author; author aim(s) or objective(s); SIC discussed within the article; author's perception of the purpose of IC; sample, method and finding, if an empirical study; author recommendations, if any were offered; and author essential messages as understood or interpreted by the reviewer/investigator.

Analysis

LVAD Literature

Since no results germane to SIC within the LVAD-DT literature search were found, no analysis could be undertaken. Insights from the LVAD-DT literature will be explored in the discussion section of this report.

Ethics Literature

Data was extracted from respective review articles using the matrix method (Garrard, 2017) for literature review and synthesis as guidance. Information from the reviewed studies was then concatenated within four separate but related contexts: reviewed article characteristics, reviewed article identified themes, high-level critical appraisal of article quality, and granular critical appraisal of article quality.

Critical Appraisal of Reviewed Articles

This systemic review of the ethical literature was guided by the work of De Grazia and Beauchamp, (2001); McCullough, Coverdale, and Chervenak, (2004); and, Jansen and Ellerton, (2018). To judge appropriateness of the arguments or bases for arguments brought forward, the investigator applied the five basic appeals identified as ubiquitous within the medical body of literature by De Grazia and Beauchamp (2001), and one additional appeal from the ethical literature brought forward by McCullough and colleagues (2004). Finally, the investigator minimally modified the ethics critical appraisal worksheet developed by Jansen and Ellerton, (2018), based upon the work of McCullough and colleagues, and then applied that tool to the critical appraisal and review of the qualified articles. Three iterative critical appraisals of the reviewed studies were undertaken to ascertain the overall strength and credibility of information, knowledge, and methodology presented in each, as appropriate. The first of which was a higher-level review simply determining whether the reviewed article

met the five general critical appraisal criteria. (See Table 2) Next, the investigator reviewed in greater detail each article applying more granular criteria under each of the five higher level categories of review. (See Appendix D). Finally, the author then went back to the first, general review and made fine adjustments as to the quality, strength and credibility of the specific article under review by applying the more detailed findings elicited by the probative statements related to each general appraisal criteria (Jansen & Ellerton, 2018). In this way, the investigator was able to maintain rigor in the evaluation of these studies and thus appraise the quality of the evidence presented.

Synthesis of Reviewed Articles

A hermeneutic synthesis framework was used to refine and synthesize the data extracted from each article (Boell and Cezec-Kecmanovic, 2014; Kroeze and van Zyl, 2015). The analyzed data from the ethics literature was synthesized into discrete characteristics and descriptors. Ultimately, this knowledge is related to that which is known about the experiences of LVAD-DT recipients. Once concatenated into tables, findings amongst cells within tables, and across tables one to another, the investigator reconciled findings to assure rigor and fidelity to reviewed article author voice. For example, reviewed study author recommendations and/or essential messaging were reconciled with reviewed study author identified implications. Once reconciled, the investigator further synthesized reviewed study findings, relating them to pertinent intersections with

the LVAD-DT literature with deference to preserving human participant voice. Next, to maximize internal and external validity, the investigator reconciled the more general critical appraisal findings with those of the granular critical appraisal findings, including a more exacting review of reflecting points between the messaging of the reviewed articles from the ethics literature, and the often reported findings from the LVAD-DT literature, inclusive of participant voice in most cases.

Ethical Analysis

An ethical analysis of the application of informed consent in the context of LVAD-DT was then undertaken, applying Joan Tronto's conception of consent as a grant of authority (Tronto, 2009).

Peer Review

One peer reviewer (JL) was engaged to maintain rigor with study protocol as described herein. Differences were vetted to consensus. The process, and project entire was then examined by three individuals with specific expertise germane to the substance and/or methodology of this work: JL – expertise in ethics, the social construction of health and illness bioethics expertise, and qualitative study expertise; CP – end of life issues in critical care, qualitative research methods, and systematic reviews; and, DD – background and distinction in the areas of bioethics, health policy and philosophy. Differences in opinion or interpretation were vetted to consensus.

Results

Search

Both the LVAD and ethics bodies of literature were culled for suitable items for review using the following search engines: CINAHL, EthicsShare, Google Scholar, Ovid Medline, Philosophers Index, and PubMed. Search terms for both searches included: standards of informed consent, left ventricular assist device-destination therapy, LVAD-DT, and LVAD. The literature searches were limited to literature published in English, and results having full text access. The resulting hits numbered 552 items: 78 from the LVAD body of literature, and 474 items from the ethics body of literature. (See figure 1) No duplicates were found. Of these items, all 552 were screened using specific inclusion criteria. Those criteria are that the discrete items for review must be free full access, published in English, peer reviewed, standards of informed consent specific and focused, germane to LVAD-DT if within the LVAD or ethics literature, specific to clinical practice, and if an empirical study, then subjects are human adults. Articles were excluded if they did not meet one or more of the inclusion criteria.

Applying the afore mentioned criteria for inclusion (and exclusion), a total of 400 items were excluded at the title screening stage; 57 items were excluded from the LVAD literature, and 343 items were excluded from the ethics literature. A total of 91 more items were excluded at the abstract screening stage; 20 from the LVAD literature, and 71 from the ethics literature. Items disqualified for

further review from the LVAD literature were as follows: one item was not peer reviewed; 19 items were not SIC focused or specific. Items disqualified from further review from the ethics literature were as follows: 24 items were not SIC focused or specific; 34 items were not pertinent to clinical practice; 11 were specifically pertinent to a clinical practice other than cardiology or LVAD-DT; and, 2 items were not pertinent to adult human participants (pediatric clients).

A total of 61 articles were assessed for eligibility. Forty-four items were ultimately disqualified from further review as follows: one article from the LVAD literature as it was not SIC focused or specific. Forty-three articles from the ethics literature were disqualified from further review as follows: 38 articles were not SIC focused or specific; and, five articles were not pertinent to clinical practice. A total of 17 items were ultimately qualified for this systematic review: zero from the LVAD body of literature, and 17 from the ethics body of literature.

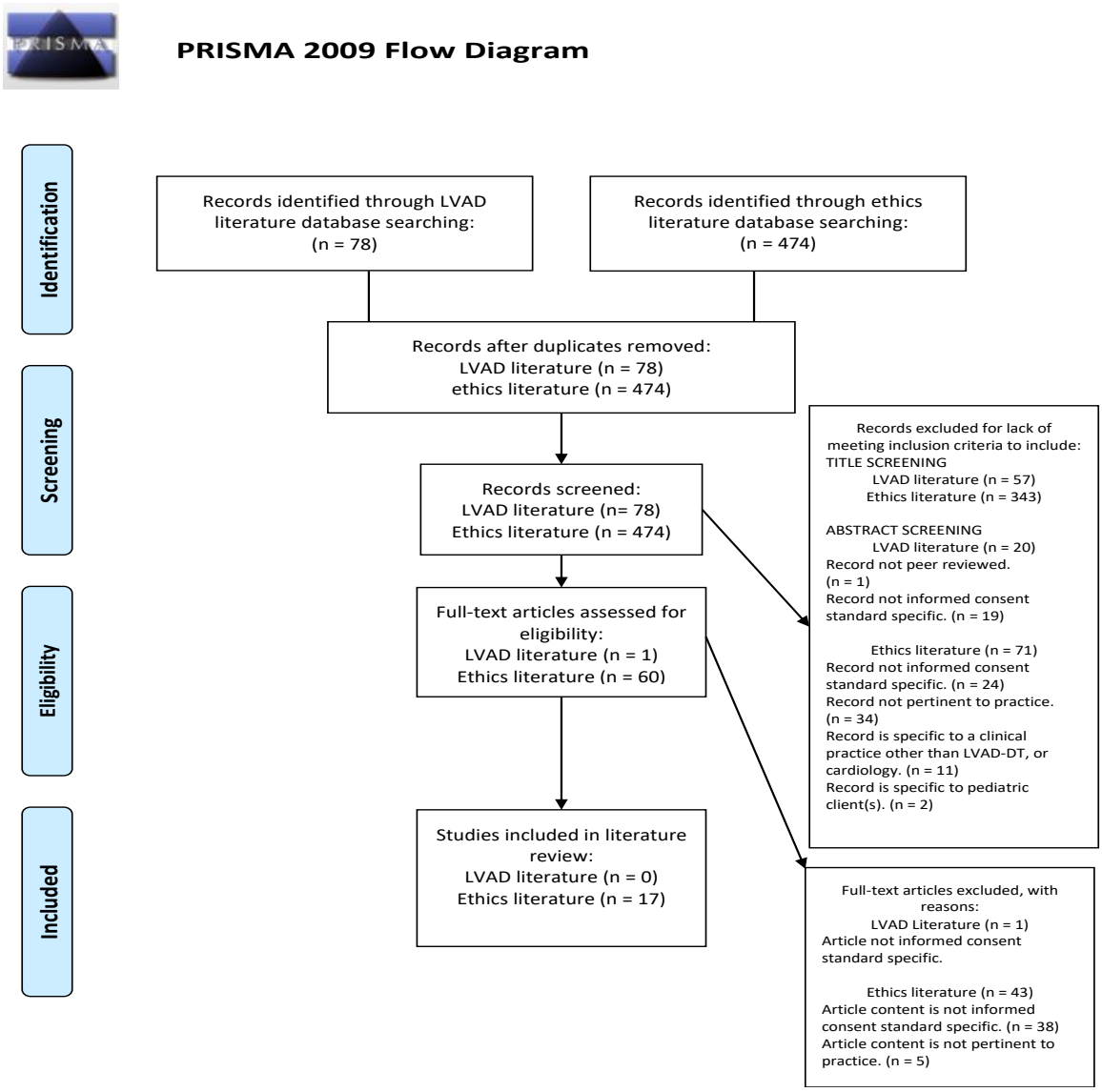


Figure 1 (Moher, Liberati, Tetzlaff, Altman, The PRISMA Group, (2009).

Systematic Review

Characteristics of Reviewed Articles.

Variables of interest for the reviewed articles included the year of publication, author(s), article type; author identified aim or objective for the work; the standards of informed consent identified and discussed within the work; the purpose of informed consent as interpreted or explained by the author(s); sample, method and findings as appropriate; and, author recommendations and essential message conveyed. (See Appendix C)

Critical Appraisal of Reviewed Articles

The reviewed articles represent a mélange of expert opinion, investigation, and practice across four knowledge and expertise domains: academia (2), medicine (3), ethical/philosophical (6), and legal (8). Due to several articles being authored by groups of individuals, one particular article or another may represent evidentiary findings from more than one discrete context. The seventeen reviewed articles represented include individual qualitative or descriptive studies (one literature search, one qualitative/quantitative mixed-methods, and one hermeneutic interpretative qualitative study), and fourteen expert commentaries. All reviewed studies were found to largely satisfy De Grazia's and Beauchamp's five basic appeal perspectives (tradition & current practice standards; ethical principles; general ethical theory; casuistry; and, reflective equilibrium) (2004), as well as McCullough's, Coverdale's and Chervenak's additional appeal perspective (virtue-based), (2018). Accordingly, all 17 articles represent well the continuum of those perspectives which can be

considered to be normative within the bodies of ethical and medical literature (inclusive of the LVAD body of literature).

A high-level critical appraisal of the reviewed articles indicated that 11 of 17 (65%) met all five of the criteria outlined in Jansen's and Ellerton's tool for the critical appraisal of ethical scientific reports (2018); four of 17 (23%) met all but one of the criteria, and two of the 17 (12%) articles met all but two of the criteria. (See Table 2)

Table 2 Ethics Literature Critical Evaluation; General Criteria

M=Criteria Met, U=Criteria Unmet, Blank=Does Not Apply	**The point(s) at issue is/are apparent.**	**Author has defined all terms used.**	**Premises or conclusions clearly asserted.**	**Relevant counter arguments addressed.**	**Presented argument(s) is/are applicable to practice.**
Coleman/Abernathy (1973)	M	U	M	U	M
Hoyt (1983)	M	M	M	U	M
Cust (1991)	M	M	M	M	M
Dunn (1994)	M	M	M	M	M
Stewart (1995)	M	M	M	M	M
Gore (2001)	M	U	M	M	M
Skene/Smallwood (2002)	M	M	M	M	M
Gert (2002)	M	M	U	M	M
Doyal (2002)	M	M	M	M	M
Brenner, et al., (2009)	M	M	M	U	M
Leclerg et al. (2010)	M	M	M	M	M
Cheng (2013)	M	M	M	M	M
Chima (2013)	M	M	M	M	M
Moulton, et al. (2013)	M	M	M	M	M
Malik/Foster (2014)	M	M	M	M	M
Weinmeyer (2014	M	M	U	U	M
Subramani (2017)	M	M	M	M	M

Applying Jansen's and Ellerton's (2018) more exacting evaluative criteria within the discrete contexts of the five more general concepts, revealed further departures for some of the reviewed articles. (See Appendix D) Of the 11 reviewed articles meeting all five general critical appraisal criteria, seven (64%) of them also met all of the more specific critical appraisal criteria within those discrete general contexts. Of the remaining reviewed articles, only four (24%) departed significantly enough from the more critical criteria to warrant a threat to the strength or credibility of the reviewed report. The impediments to meeting criteria were lack of clarity in writing or the conveying of perspective (2), and/or the incomplete addressing or discussion of all perspectives/arguments relevant at the time of the writing of the report reviewed (3).

Hermeneutic Synthesis

A hermeneutic synthesis framework was utilized to review the ethics literature (Boell & Cezec-Kecmanovic, 2014; Kroeze & van Zyl, 2015). (See Appendix B) The authors across the reviewed articles regardless of their various perspectives and associations agree that the practice of informed consent is a moral good, and ought to protect and respect the autonomous choices of the medical client when at a decision point relevant to a particular action – a treatment or procedure. Three distinct concepts of purpose for informed consent were identified. The most widely held perception of purpose for informed consent coalesce around the concept of informing (13 of 17 reviewed articles).

Additional perspectives on purpose include respect and protection of autonomy (four of 17 reviewed articles), and legal protection for the prescriber and their associations (identified in three of 17 reviewed articles).

Three distinct commonalities across the articles were identified: 1) all authors characterized main points or problems germane to informed consent and its practice; 2) all discussed implications; 3) seven made recommendations for moving forward. Six shared concerns across the ethics and LVAD literature are identified. The first of which is the concern that a lack of understanding exists for healthcare clinicians about what is important to the individual healthcare client in terms of individual client values, preferences, and what equates with a good life to that individual, according to individual healthcare clients. The second concern is that a lack of understanding exists for healthcare clinicians about what information and how much of it the individual health care client wants or requires. The third concern in common was that these unique needs and expectations of individual health care clients confound the achieving of informed consent. A fourth concern is that “informed” consent may not be generally achievable. The fifth concern is that consent that is not informed, as guided by client preference, and/or need, negatively impacts client care and client outcomes. And a final shared concern is that relationships between health care client and healthcare clinicians that are characterized by the act of obtaining informed consent, rather than a context of mutuality in which power and standing are shared, undermine

respect for client autonomy, or more precisely, the voluntariness of the client's decision-making. (See Appendix E)

The overarching implication across the reviewed articles is that the practice of informed consent as is generally understood (informing, understanding, competence, voluntariness, and consent), will continue to undermine healthcare client autonomy, and limit healthcare client outcomes. All articles contained concepts of what needed to change to address the identified challenges, with seven authors or groups of authors offering specific recommendations for addressing their concerns. These recommendations are represented by two concepts. First, that informed consent discussions ought to be healthcare client-centered, guided by the individual healthcare client's informational preferences and requirements. Second, that such discussions should unfold between healthcare clinician and healthcare client shared understandings within the context of a therapeutic relationship informed by client values and guided by ethical and empathetic medical practice.

Ethical Analysis

Although a standard definition for informed consent is not shared, the accepted practice of informed consent by healthcare clinicians and the institution of medicine revolve around the disclosure of specific information from the healthcare clinician to the healthcare client. This information includes what the procedure involves and its purpose, the inherent risks, the benefits, and any

alternative treatments, including no treatment. This informing is often considered the first of several elements of informed consent: a disclosure, or sharing of all information with the healthcare client; the client's comprehension of the information shared; the client's voluntary consent must not be uncoerced; the healthcare client has decisional capacity and is capable of giving consent; and finally, the consent of the healthcare client, if that is obtained.

The main purpose of the practice of informed consent is widely seen as the respect and/or protection of the healthcare client's autonomy vis-à-vie this sharing of information by the healthcare clinician. These basic concepts are consistent across the ethics and LVAD-DT literature.

Here is the problem, however: the current practice of informed consent is heavily invested in, and girded by, the full weight and influence of legal and institutional policy which focuses on the primacy of disclosing certain required information, rather than making the client's needs and preferences for information the primary focus (Miller, 1981; Faden & Beauchamp, 1986; King & Moulton, 2006: Tronto, 2009). This is problematic because under this construct, informed consent fails to adequately achieve its purpose: the fostering and facilitation of autonomous choice (Miller, 1981; Faden & Beauchamp, 1986; King & Moulton, 2006: Tronto, 2009). This sobering realization is critically important because it goes to the very heart of what our society wants to think of autonomy. Or, more specifically what society wants to believe about an one's control over

one's actions. (Miller, 1981; Faden & Beauchamp, 1986; King & Moulton, 2006: Tronto, 2009). In other words, under what condition does a client give consent? Is it to express an intentional and authentic authorization for another to perform a specific act on their behalf (Faden & Beauchamp, 1986)? Or, is it simply a routine step in an institutional process (Faden & Beauchamp, 1986)? However, seeing the practice of informed consent as a "this or that" dichotomy misses the point. Rather, the situation is one of "this *and* that" – a practice of informed consent such that client values drive the discussion, facilitated by the ethical tenets of medical practice in this regard (Tronto, 2009). What is of concern is that what ought to be an autonomous action by the client is reduced such that a client becomes a mere object to be acted upon through the routine of institutional authority (acknowledgement that at least a discussion occurred, and the client consented) (Tronto, 2009). In the end, information is merely a commodity; the value of which depends upon one's unique perspective and understanding of that information.

To correct this misalignment of the practice of informed consent, it's purpose: the fostering and facilitating of healthcare client autonomy, and reconceptualize the practice of obtaining informed consent as currently understood and practiced, needs to be reconsidered. When consent is reduced to little more than the routine delivery of information for a tacit acknowledgment, the act of consent itself is the antithesis of autonomy. (Tronto, 2009). We must

realize consent can only arise from a relational context involving conscious thought and engagement on the part of both client and clinician, in a shared common goal with a shared common interest achieved through the ethical framework of informing - *not the informing itself.* (Faden & Beauchamp, 1986; Tronto, 2009).

To better appreciate the difference between the current and an alternative approach to obtaining consent, one must understand the context in which such a transaction between client and clinician occurs. Discussions for the purpose of sharing information and obtaining consent occur expressly for the more invasive procedures encountered by health care clients. Things like examinations, lab work, and similar non or less invasive practices occur without an express informing and consenting occurring as one's arrival at the clinic, hospital or other health care venue is considered an implied consent. Fundamental to non-invasive, minimally invasive, and maximally invasive procedures is the fact that the treatment or procedure in question is necessary, and that care cannot be undertaken by the client themself. In such cases, a power imbalance is created between client and clinician (Tronto, 2009). Additionally, the straightforward perception of autonomous choice diminishes the more voluminous and detailed the information being shared becomes, making it less likely the client is able to apply what is shared to their own set of circumstances, and how that may impact their lives (Miller, 1981; Faden & Beauchamp, 1986; Tronto, 2009; Kaufman,

2015). Also, while consent discussions occur prior to a recommended procedure or treatment, this discourse does not occur at the beginning or early within treatment trajectories, rather it occurs near the crescendo – the brink or scheduling of the procedure or treatment. Much can be missed on the part of the clinician without a knowing of the client, and undue influence can arise for the client at such a pivotal point. These factors substantively put the client at considerable disadvantage to which the client typically surrenders rather than consents.

Thinking of and obtaining informed consent as a grant of authority rather than as autonomy neutralizes this power imbalance. In the context of consent as a grant of authority, power is shared, stemming from the client/clinician relationship directed by a common end. In this way then, expression of trust and beneficence are enjoined with respect for autonomy. Furthermore, such a fiduciary and therapeutic relationship raises up responsibilities to the client rather than duties of the clinician, reducing the opportunity for a tipping of the power gradient out of level.

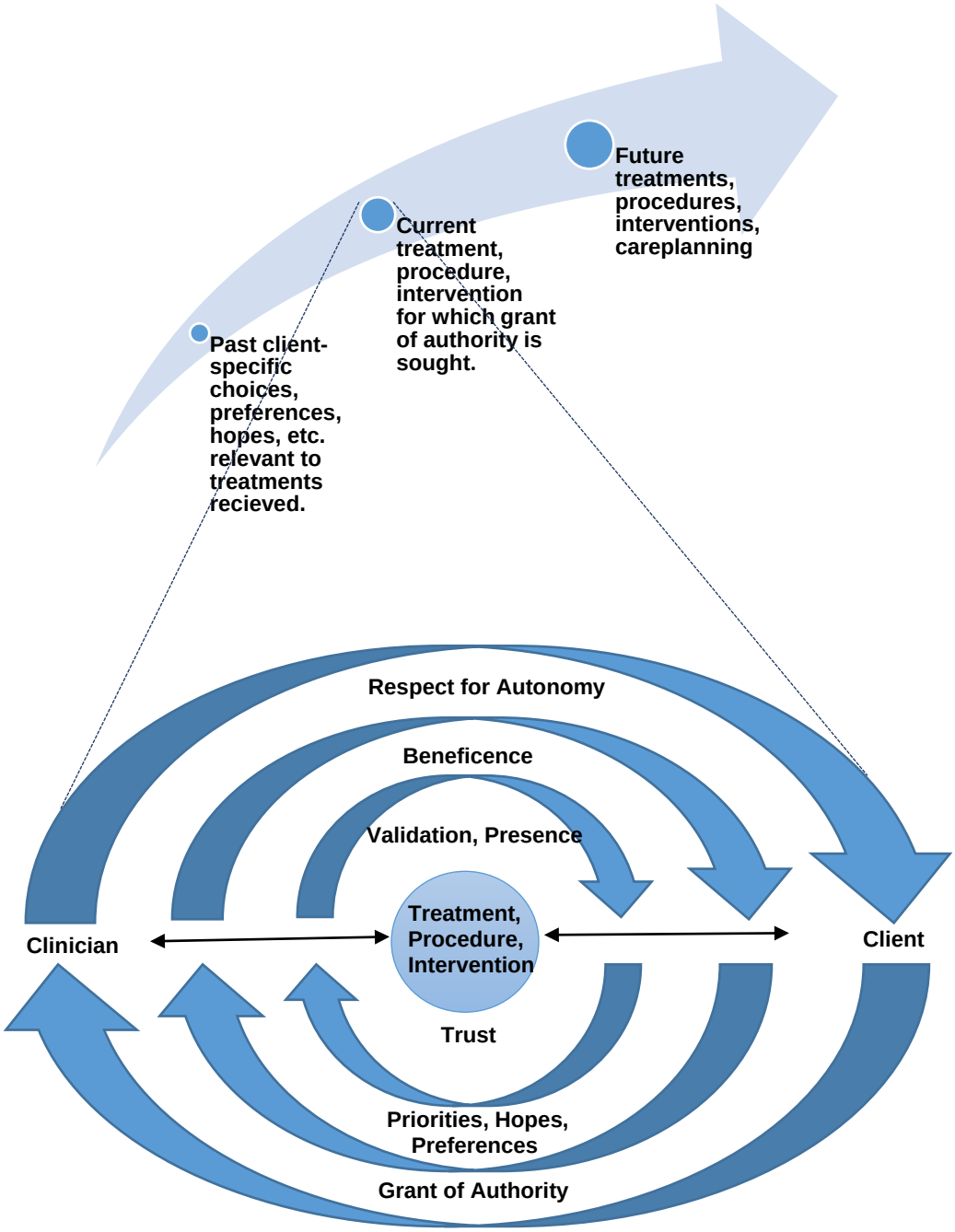
Conceiving of this interaction between client and clinician as something other than a protection of client autonomy vis-à-vie the informed consent process as currently accepted and practiced is best appreciated through Joan Tronto's "consent as a grant of authority" (Tronto, 2009, p. 184). Consent as a grant of authority as described by Tronto (2009) is the tightly integrated expression of

trust, beneficence and respect for client autonomy founded in and propelled forward through the client/clinician relationship. Optimally, this relationship is grounded in and guided by a knowing of the client such that the clinician has empathetic insight into discrete client preferences, values, hopes and wishes about what is to be gained from the procedure – in this case, LVAD-DT. Additionally, such insight on the part of the clinician is helpful in developing and nurturing both trust and rapport between individual client's and the clinician(s) involved (Tronto, 2009). The benefit therein, is the ability to carry forward lessons learned at this juncture, in furtherance of relationship as may be necessary for ongoing and future treatment and relevant requests for grants of authority (Tronto, 2009). (See figure 2)

Consent as a grant of authority then, as described by Tronto (2009), is a nexus of closely related components that when integrated into a whole, empower the client's autonomous choice as well as elevates the realization of professional and ethical responsibility on the part of the clinician. Seeing, and obtaining consent in this way conveys a shared trust across client, caregivers, and clinicians to accomplish a common goal or outcome. Granting authority to act under such an understanding connotes a bona fide exercise of control rather than a surrendering of it (Faden & Beauchamp, 1986; Tronto, 2009). This fiduciary relationship through which a grant of authority can be given and obtained can also be seen as therapeutic, bringing with it responsibilities from

one participant to the other, in the service of the common goal – the improvement of life quality and life quantity through LVAD implantation (Faden & Beauchamp, 1986; Tronto, 2009).

Figure 2: Author's conceptualization of grant of authority within client/clinician relationship.



Discussion

A rigorous systematic review of the ethics literature revealed several important findings with regard to the practice of informed consent. First, the broadest perception of the purpose of informed consent is to inform the client (not foster and facilitate autonomy). Second, clinicians lack adequate understanding or insight about the amount and type of information required or preferred by the individual client, as well as how that information is preferred to be shared with them. Third, this lack of understanding or insight undermines the practice of informed consent and adversely affects care delivery and outcomes. And finally, the quality of informed consent may be strongly associated with the quality and depth of relationship between client and clinician.

If we consider informed consent in the context of the bigger picture of respecting autonomy, then these findings suggest that autonomy stems from the information shared, and manifests as the act of consent (Tronto, 2019). Rather, it is realized through the fiduciary and therapeutic relationship shared by client and clinician to achieve a commonly held goal, in service of the client's preferences and interests as a bona fide grant of authority (Tronto, 2019). Therefore, the relationship ought to be recognized and operationalized as the conduit for autonomy, not the provision of information.

The majority of the articles reviewed discussed the informing as a primary focus, function, or purpose of informed consent, mostly for transparency with regard to risk (Coleman & Abernathy, 1973; Hoyt, 1983; Dunn, 1994; Gore, 2001; Skene & Smallwood, 2002; Gert, 2002; Chima, 2013; Malik & Foster, 2014). This perspective has been preeminent in the literature over the last half century. At the same time, the reasonable physician standard of informed consent has been the prevailing standard although three standards coexist across the United States. The reasonable physician standard holds that a clinician need only provide the information they deem appropriate considering the procedure for which consent is sought, and in line with the informing practices of other clinicians for that same procedure (King & Moulton, 2006, Shah, Thornton, Turrin & Hipskind, 2020). A second and next most frequently followed standard in the United States is the reasonable patient standard which holds the physician responsible for providing information to the client that any reasonable client would want in order to make a treatment decision (King & Moulton, 2006; Shah, Thornton, Turrin & Hipskind, 2020). Finally, a third alternative standard of informed consent is the subjective standard which indicates a discrete informing of a particular client based upon that client's information needs in order to arrive

at a treatment decision (Shah, Thornton, Turrin & Hipskind, 2020). As you can see, all three standards allude to information sharing as the genesis of the decision to consent (or decline).

By the time we get to the late 1990's and well into the 2000's we are seeing a shift from informing predominantly about risk (as a protection against malpractice), to the transparent informing of client decision making (Stewart, 1995; Gert, 2002; Brenner, et al., 2009; Leclerq, et al., 2010; Chima, 2013; Weinmeyer, 2014), to the respect and protection of autonomy (Doyal, 2002; Cheng, 2013, Malik & Foster, 2014), and finally to the purposeful protection of the client's autonomous *choice* - an action (Subramani, 2017). Skene and Smallwood (2002); King and Moulton, (2006); Brenner and colleagues (2009); Moutlon, et al., (2013); and, Malik and Foster (2014) and Friedman (2020) suggest that changes in healthcare delivery in response to a more sophisticated health care client base has challenged the usefulness of the two dominating standards of informed consent.

The concerns evident throughout the reviewed articles and the findings from this study are highly reflective of the well summarized assertions by King and Moulton (2006). These are: 1) that complex procedures and treatments ought to be guided by the values and preferences of the client rather than treatment and practice norms of clinicians given the range of unique circumstances and outcomes associated with them; 2) this is especially the case

when the treatment is particularly invasive and life altering since clinicians are not in the best position for making insightful determinations of information needs in these cases; and, 3) client variability from one to another in terms of disclosure need or preference is such that applying a reasonable client standard, is certain to prevent sufficient informing of some, while overwhelming others, thereby neutralizing the notion of an informed consent.

These concerns regarding the usefulness of informed consent as currently practiced and understood are echoed in the LVAD-DT literature (Kitko, et al., 2016; Fedson, et al., 2018; Friedman, 2020). A recent mapping of the informed consent process across 19 LVAD programs across the United States was revealing. Fedson and colleagues (2018) found a number of concerning shortcomings related to the practice of informing during the process of obtaining consent. One example is the lack of discussion around the specifics of alternative treatments, including hospice care, palliative care, and advance care planning. This is important because LVAD-DT recipients and candidates personify the lifespan - they range from younger than 5 years, to older than 85 years. Another example would be the discussion about what is expected from LVAD-DT. Fedson and colleagues (2018) found that although a higher level of what can be realized is shared (improved life quality and perhaps longevity), exactly how that impacts that client's living post-implant is absented from the discussion. This is important for LVAD-DT clients to discern because not all

clients are satisfied with the tradeoff made, or the impact on their lives in order to breath better, walk farther, live longer. Fedson and colleagues (2018) as well as others worry that in some cases, LVAD-DT clients who have not been informed according to their discrete needs and preferences may opt to deactivate their LVAD because these clients had different perceptions of what returning to their life as they knew it would mean for them post-implant (McIlvennan, Magid, Ambardekar, Thompson, Matlock, & Allen, 2014; Kirklin, et al,, 2015).

Furthermore, the discrete information needs from one LVAD-DT client to another are variable with some being more reflective or reasoned in their decision making, and others more automatic or instinctive (McIlvennan, et al., 2014; Magid, et al., 2016; Kitko, et al., 2016). Once again, the standards of informed consent currently applied are ill-suited to the disparate approaches to deciding in the context of LVAD-DT, not to mention the overarching perception of lacking choice generally due to the fact of impending death and overbearing symptom burden (Ottenberg, et al., 2014; McIlvennan, et al., 2014).

Finally, all of these points are embedded in a specific LVAD-DT context in that it is the routinization of the process of obtaining a consent that threatens to compel (and sometimes does) a consent rather than facilitate an autonomous choice (McIlvennan, et al, 2014; Kaufman, 2015; Barg et al., 2017).

Recommendations for Practice and Further Study

In order to address the concerns raised in the literature, It is necessary to shift the basic understanding of informed consent as a routinized practice of disclosing information from the clinician to the client to one of understanding informed consent as a granting of authority by the client to the clinician. To that end, Two recommendations are offered: one, grants of authority for LVAD-DT ought to be client-centered and guided by the individual client's informational preferences and requirements, commensurate with the ethical mandates for the practice of medicine. And two, such grants of authority ought to stem from ongoing holistic engagement with the client and cumulative insights from earlier points of consent or grants of authority, between clinician(s) and client working in partnership to achieve shared understandings in service of the particular client's values, preferences, and best interests.

Further investigation of the status of the practice of informed consent in the context of LVAD-DT needs to be undertaken to fully understand the areas of need and to identify optimal points of intervention. Additionally further exploratory work needs to be done to better understand how such an evolution should function and could be sustained. Finally, such a framework will need to be tested and implemented with refinements over time.

Strengths and Limitations

This systematic review expands the knowledge base on the review topic revealing concerns about the usefulness of the current and accepted practice of

informed consent in the context of LVAD-DT. A second strength of this work is that the findings support the need for changing the current practice of informed consent for those considered candidates for LVAD-DT. A third strength is that the knowledge gathered here could extend to other contexts of the practice of informed consent. A fourth strength is that this report contributes to and aligns with the body of findings of past research initiatives in this healthcare client population. A final strength is that this work opens the discussion on the topic in both the ethical and LVAD-DT literature.

The major limitation of this study reflects that of both the ethics and the LVAD-DT literature; no discussion of the standards of informed consent is evident in the LVAD-DT literature, and no direct insight into the practice of informed consent in the context of LVAD-DT is evident in the ethics literature. A second limitation is that although directed and rigorous, this systematic review cannot be thought of as comprehensive as it is not all-encompassing and does not contemplate the entirety of implications stemming from all of the literature available exploring these topics, due to limits of time and resource.

Conclusion

The aims of this study were to identify and understand the purpose, and standard(s) of informed consent in the context of LVAD-DT. The second aim was to determine the degree to which obtaining informed consent in this context conforms to the identified standard(s). The third aim was to recommend an

alternative framework for undertaking informed consent in a way that better addresses the needs, preferences, and interests of individuals receiving LVAD-DT. It was found that across the U.S., 25 states apply the Reasonable Physician Standard, while 23 states apply the Reasonable Patient Standard. One state applies a hybrid of all three standards, and the District of Columbia applies the Reasonable Person Standard. No states apply the Subjective Standard (King & Moulton, 2006; Weinmeyer, 2014). All but 10 states (Alaska, Hawaii, Idaho, Montana, New Hampshire, North Dakota, Rhode Island, South Dakota, Vermont & Wyoming) have healthcare centers that meet CMS criteria to undertake LVAD-DT; there are 183 LVAD-DT centers across the remaining forty states (Centers for Medicare and Medicaid Services, 2016).

Based on the results and findings herein, it is determined that although all centers offering LVAD-DT comply with the currently accepted practice of informed consent, there are significant concerns about the usefulness of that model in this context, and perhaps other contexts. As such, an alternative process was identified for further consideration and study.

Joan Tronto's (2009) informed consent as a grant of authority is a model of empowered choice that is more conducive to the goal of fostering and facilitating client autonomy than the currently accepted practice of informed consent. Another benefit is that such an approach expands the expression of beneficence.

Additionally, recommendations for practice and further research are offered.

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Appendix A

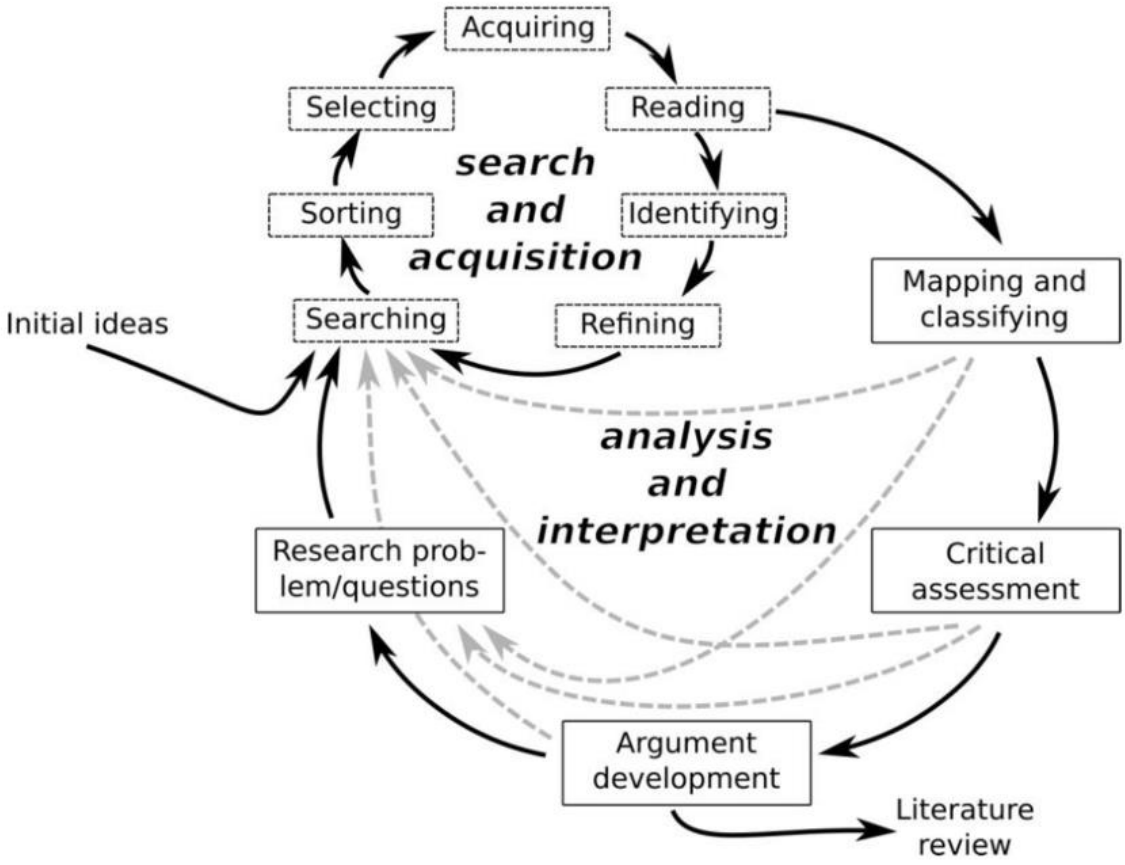
Ethics critical appraisal worksheet

How to read an ethics paper: a resource for healthcare practitioners This worksheet is to be used in conjunction with the paper 'How to read an ethics paper' (reference)		
Can you find this information in the paper?	Is the way this was approached a problem?	Does this threaten the strength or credibility of the paper?
1. What is the point at issue?	Does the author conflate different points at issue? Does the author fail to adequately address the points raised?	Is the purpose of the paper so unclear that it is not useful? Is a conclusion clearly linked to a defined problem or point?
2. Has the author defined all of the terms they use?	Are the key terms well-defined? Are the definitions correct/reasonable?	If there are no clear definitions, what ambiguity does this give rise to? If the definitions are wrong or unreasonable, what impact does this have in this case?
3. Dissect the argument: (a) What are the premises of the author's argument? (b) What are the author's conclusions?	Are the premises true? What evidence/reasons does the author give to support their premises? Does the conclusion follow on logically from the premises? If not, where are the errors of reasoning? Are there any hidden assumptions?	If the premises are untrue or unreasonable, how does this impact the overall argument? If the argument is invalid, what implications does this have for the author's overall position?
4. Does the author address all relevant counterarguments?	Do the authors address relevant counterarguments? Do they do so convincingly? (based on standards from all the previous steps?) Can you think of any other significant counterarguments?	If not, does this affect the overall credibility of the author's position? What key arguments or ideas has the author missed and what implications does this have for their position?
5. Is the argument or exploration of the issue relevant to your practice?	Is the problem framed in a way that is useful to practitioners?	Overall, is the paper useful? Does the author provide

How to read an ethics paper: a resource for healthcare practitioners This worksheet is to be used in conjunction with the paper ‘How to read an ethics paper’ (reference)		
Can you find this information in the paper?	Is the way this was approached a problem?	Does this threaten the strength or credibility of the paper?
	Is the paper directed towards practical outcomes? Does the paper help to clarify or organize your thinking?	valuable insights into a difficult topic? Are the conclusions relevant to the population you are interested in?

Jansen & Ellerton, (2018)

Appendix B



Hermeneutic Framework (Kroeze and van Zyl, 2018; Boell and Cezec-Kecmanovic, 2014).

APPENDIX C

Review Article Characteristics

Year of Publication, Author(s), Title, Article Type	Aim/Objective/Purpose	Standards of Informed Consent (SIC) Identified	Purpose of IC as interpreted or explained by author(s)	Sample, Method, Findings, or N/A	Recommendations and Essential Messaging
(1973) Coleman & Abernathy; Informed consent: Legal vs. medical standards; Expert Commentary: legal	Specific SIC are not identified by author. However, the bases for the Reasonable Prescriber Standard and Subjective Standard are present	None identified by authors	Adequate informing of the client about a given procedure and the related risks	N/A	Discuss major risks involved with any medical procedure and document the discussion/*The law in the context of informed consent is unclear. It is important to discuss major risks involved in any medical procedure and to document that discussion.*
(1983) Hoyt; Mandatory disclosure standards or informed consent - Texas style; Expert Commentary: legal	Not identified by author.	Reasonable Person, Reasonable Prescriber, Subjective	The informing of the client by the prescriber of certain risks inherent to a particular treatment or procedure.	N/A	None offered by author/*The law of informed consent is still evolving.*

(1991) Cust; Hypothetical contractarianism and the disclosure requirement problem in informed consent; Expert commentary: philosophical, ethical	To reason what fully informed and fully rational agents would agree to under the hypothetical conditions of Rawl's Theory of Justice and Gauthier's Morals by Agreement, asking to what their respective hypothetical contractors would agree with respect to selection of a discrete standard of disclosure to guide the practice of informed consent.	Reasonable Person, Reasonable Prescriber, Subjective	To inform a client with the right type and amount of information necessary to make a free and informed decision regarding consent.	N/A	None offered by author/*Though human ideals and values vary and even clash, all essentially desire to live well, however each conceives of that. To do so, within the context of medical intervention, the sharing of information deemed necessary by the client must necessarily be provided by the prescriber.*

(1994) Dunn; The law's 3 standards of informed consent; Expert Commentary: legal	Not identified by author.	Reasonable Person, Reasonable Prescriber, Subjective	Encourage prudent medical practice through proper informing of risks affiliated with a particular treatment or procedure, reducing, or eliminating risk of malpractice as a result of insufficient informing of risks to the health care client.	N/A	1) Do not delegate the task of informed consent (IC). 2) Tell the healthcare client what the you (the provider) or your (the provider's) spouse would want to know if you or they were the healthcare client/ *Understanding SIC for the state in which the prescriber practices will help navigate the legal realities in the context of informed consent.*

(1995) Stewart; Informed consent: Texas standards and duty; Expert Commentary: legal	Address history of informed consent and standards, including Texas statutory and case law standards; to identify who has obligation to inform the healthcare client; short review of informed consent in the area of investigational (experimental) devices and drugs, and experimental procedures is included.	Reasonable Person, Reasonable Prescriber, Subjective	The provision of information to a client for the purpose of intelligent decision making regarding medical treatment.	N/A	1) Disclose and discuss all risks and hazards that might influence decision-making. 2) Have healthcare client sign documentation in presence of a witness. 3) Document all such discussions and signatures in the medical record. 4) If emergent circumstances, clearly document such circumstances. 5) In the case of research/experimental interventions, contact institution's IRB in advance/*The standards of informed consent and the laws germane to them continue to evolve.*

(2001) Gore; Ethical, professional, and legal obligations in clinical practice: A series of discussion topics for postgraduate medical education. Education and topic 1: informed consent; Expert Commentary: academic	Not identified by author.	Reasonable Prescriber	The provision of an adequate amount and type of information to achieve a client's understanding, regarding a treatment or procedure and the related risks.	N/A	None offered by author/*Consent is rarely fully informed despite sufficient information given patient limits on their understanding of the illness, the treatment or procedure, or both.*
(2002) Doyal; Good clinical practice and informed consent are inseparable; Expert Commentary: ethical	Not identified by author.	Reasonable Person, Reasonable Prescriber	The providing of information to a client sufficient in amount and type to respect that client's autonomy.	N/A	None offered by author/*Morally oriented clinical relationships enable the healthcare client to make decisions about their health and wellness that optimize their interests and autonomy. Lack of respect and priority for proper informed consent is evident through insufficient time and resources to train clinicians to communicate more meaningfully and successfully with their clients.*

(2002) Skene & Smallwood; Informed consent: Lessons from Australia; Expert Commentary: legal and medical	Not identified by author.	Reasonable Person, Reasonable Prescriber, Subjective	Though not discretely stated as such in the article, the informing of risk is specifically discussed as a purpose for delivering informed consent	N/A	None offered by author/*In both Australia and the United Kingdom, courts have placed more emphasis on client needs as part of a wider social movement to give more weight to individual rights. Prescribers failing to heed this social movement towards granting greater weight to client rights are likely to experience greater risk of liability and may in fact compromise client care. It is suggested that much remedial work needs to be done to reduce future litigation and to promote optimal client care and outcomes.*

(2002) Gert; Avoiding surprises: A model for informing patients; Expert commentary: philosophical	1) Introduce a model for thinking about the general information that prescribers are morally obligated to give their clients. 2) Provoke discussion of this topic, in hopes of stimulation of alternative models for exploration.	Reasonable Person, Principle of Avoiding Surprises, Transparency Model, General Moral Theory	Provision of an adequate amount and type of information sufficient for a client to make an informed decision about accepting a given treatment or procedure.	N/A	No discrete recommendations offered/*Share enough information not only to inform, but also to prevent surprises or surprise outcomes.*

(2009) Brenner, Brenner, & Horowitz; Beyond informed consent: Educating the patient; Expert Commentary: legal, medical	Propose and evidence support for a change to an educational model of informing.	Reasonable Person	Conceived as a basis for allowing patients to meaningfully participate in the decision-making process; evolving into a formal document equating with a waiver of liability.	N/A	1) informed consent discussions must occur. 2) informed consent forms ought to be designed to be understandable; the purpose of the discussion ought to be educational. 3) Uncertainty ought to be used as a foundation for forming a therapeutic alliance, in support of the relationship between provider and receiver of care. 4) The educated receiver of care ought to be participatory in the informed consent discussion(s) and processes important to decision-making. 5) The discussion(s) and processes of informed consent ought to be evident in the medical record through a clear and understandable note/*Informed consent is seen and applied largely as a release of liability protecting the prescriber rather than a point of education and relationship*

					building to support the client.

(2010) Leclerq, Keulers, Scheltinga, Spauwen & van der Wilt; A review of surgical informed consent: Past, present, and future. A quest to help patients make better decisions; Original Research: literature search	To describe the pertinent literature concerning surgical informed consent and to provide suggestions to improve the surgical informed consent process in daily practice.	Reasonable Person, Reasonable Prescriber	to evidence voluntary authorization by a healthcare client, obtained with sufficient information to assure comprehension, for diagnostic or investigative procedures and for medical and surgical treatment.	71 articles met inclusion criteria; Literature search; Meta-analysis was not possible because the studies identified differed in design, tests used, and outcome measurement.	12 specific recommendations are made across 5 areas of concern: General, Competence, Information, Consent, and Research.

(2013) Cheng; What does respect for the patient's autonomy require? Expert commentary: ethical, philosophical	Explore how the identified problems (irrational decisions based upon lack of information about their disease or treatments; irrational decisions based upon irrational beliefs or desires; and, irrational decisions arising from an incomplete understanding of one's disease or treatments that have nothing to do with lack of information) may arise and how to overcome them.	Reasonable Prescriber (Professional), Reasonable Person (Objective), Subjective	The protection of and respect for client autonomy.	N/A	No recommendations offered/*Through greater investment of time and effort, the provision of thorough medical information, good arguments, and the presentation/availability of information in different perspectives is achievable.*

(2013) Chima; Evaluating the quality of informed consent and contemporary clinical practices by medical doctors in South Africa: An empirical study; Original Research: qualitative/quantitative mixed methods	To evaluate whether the quality of informed consent obtained by doctors practicing in South Africa is consistent with international ethical standards and local regulations.	Reasonable Person, Reasonable Prescriber	The precise informing of a healthcare client as to the risks and benefits of their decision about consenting to a diagnostic or therapeutic procedure.	956 out of 1118 possible participants (85%); Qualitative/quantitative mixed methods; 1) Doctors practicing in South Africa while generally knowledgeable about some aspects of informed consent, many are not compliant with local or international standards or guidelines. 2) Several barriers challenge the proper practice or achievement of informed consent. 3) Doctors felt more time needs to be spent with individuals, obtaining informed, 4) more doctors espouse reasonable provider standard than prudent individual standard and the disclosure of all material risks, 5) there is evidence of overuse of implied and presumed consent by doctors with implications for medical paternalism and	1) Recruit and train a group of interpreters as a part of medical teams in South African hospitals. 2) Modify current hospital consent forms. 3) Production of patient information pamphlets in local languages. 4) Offer continuing education for doctors and other healthcare professionals in ethics and medical law/*There is scant research in the area of Informed Consent process in the country of South Africa. And that this study offers similar findings as other studies in developed and developing countries, demonstrating a need for further research, education, and health service improvement in the area of informed consent.*

				lack of voluntariness in consent.	

(2013) Moulton, Collins, Burns-Cox & Coulter; From informed consent to informed request: do we need a new gold standard? Expert Commentary: legal, medical, academic, research,	Not identified by author.	Reasonable Person, Reasonable Prescriber	The legal and ethical informing of a health care client to obtain permission to proceed with an invasive or risky treatment.	N/A	None offered by author/*development of a standard for informed consent that balances beneficence and respect for autonomy, informed by the principles of shared decision-making, employing where possible evidence-based decision support aides.*
(2014) Malik & Foster; From informed consent to informed request: Strengthening shared decision-making; Expert Commentary: philosophical, ethical	Not identified by author.	Reasonable Person, Reasonable Prescriber	Respect for autonomy through the Informing one of risks and benefits of a medical intervention .	N/A	None offered by author/*Summarizes and support the argument advanced by Moulton, Collins, Burns-Cox & Coulter - informed request rather than informed consent through shared decision-making in order to respect patient autonomy more meaningfully.*

(2014) Weinmeyer; Lack of standardized informed consent practices and medical malpractice; Expert commentary: legal, philosophical	Not identified by author.	Reasonable Person, reasonable Prescriber	A sharing of information between prescriber and healthcare client that shapes the former's decision to consent to undergo a procedure.	N/A	None offered by author/*Identifies variability of informed consent standards as problematic, and advocates for Moulton's and King's (and likewise, Moulton's, Collins', Burns-Cox's & Coulter's) perspective on a form of informed consent convergent with shared decision-making.*
(2017) Subramani; Patient autonomy within real or valid consent: Samira Kohli's case; Original Research: Qualitative/Hermeneutic interpretation	Reflect on the underlying ethical and legal principles of the doctrine of real or valid consent in the Indian context using the Samira Kohli case as exemplar.	Real and valid consent (Reasonable Prescriber), Informed consent (Reasonable Person)	The protection of autonomous choices.	Sample is 1 case study; Qualitative hermeneutic interpretation; 1) The real or valid consent doctrine has been a tool to protect the client's bodily integrity and physical well-being. 2) Bolam test applied and professional standards used in consideration of the real or valid consent concept and the standard of information disclosure. 3) The importance of client choice was undermined by giving precedence to the application of the professional standard of disclosure.	None offered by author/*Putting strong emphasis on the ethical and legal principle of duty to disclose material information on prescribers and applying client preferences for disclosure of information protects and respects client choice (autonomy).*

APPENDIX D

Ethical Literature Critical Appraisal; Granular Criteria

Article	General Critical Appraisal Criteria(GCAC)	GCAC (M)et/ (U)nmet	Specific Critical Appraisal Criteria(SCAC)	SCAC (M)et/ (U)nmet	If U, how so?	Credibility threatened? (Y)es/(N)o	If threatened, how so?	Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest (SIC in LVAD-DT)(Friedman, 2020)
COLEMAN & ABERNATHY	**The point(s) at issue is/are apparent.**	M	*Author clearly state(s) at issue.*	M				
			Raised points adequately addressed.	M				
			Purpose of paper is clear.	M				
			Conclusion clearly linked to the point identified.	M				
	Author has defined all terms used.	U	*Key terms clearly defined.*	U	Only RPrS is directly discussed. RPeS and SS are vaguely characterized through legal recommendation as protecti	N		

					on against malpractice.			
			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	M	*Premises are true/reasonable.*	M				
			Evidence supports premises.	M				
			Conclusions follow logically.	M				
	Relevant counterarguments addressed.	U	All Counterarguments are clearly identified and reported	U	As noted above.	Y	Specific recommendation is made to defend against malpractice through the sharing of risks to the "particular" client, (p.181), thus subjective standard is alluded to, but neither defined nor addressed.	

		U	*Counterarguments are reasonable and convincing.*	M				
			Counterarguments are clear and concise.	M				
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers?*	M				
			Article is directed towards practical outcomes.	M				
			Article clarifies/organizes thinking of the reader.	M				
			Overall, article is useful.	M				
			Valuable insights are provided.	M				
			Conclusions are relevant to population/phenomenon of interest (SIC in LVAD-DT).	M				historical underpinnings of SS are identified.
Article	**General Critical Appraisal Criteria(GCAC)**	**GCAC (M)et/ (U)nmet**	**Specific Critical Appraisal Criteria(SCAC)**	**SCAC (M)et/ (U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened, how so?**	**Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest**

								(SIC in LVAD-DT)
HOYT	**The point(s) at issue is/are apparent.**	M	*Author clearly states issue(s).*	M				
			Raised points adequately addressed.	M				
			Purpose of paper is clear.	M				
			Conclusion clearly linked to the point identified.	M				
	Author has defined all terms used.	M	*Key terms clearly defined.*	M				
			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	M	*Premises are true/reasonable.*	M				
			Evidence supports premises.	M				
			Conclusions follow logically.	M				
	Relevant counterarguments addressed.	U	All Counterarguments are clearly identified and reported	U	RPrS and RPeS directly discussed; SS is outside of the context of the discussion, despite discret	N		

					e materiality of information curtailed to the individual.			
			Counterarguments are reasonable and convincing.	M				
			Counterarguments are clear and concise.	M				
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers.*	M				
			Article is directed towards practical outcomes.	M				
			Article clarifies/organizes thinking of the reader.	M				
			Overall, article is useful.	M				
			Valuable insights are provided.	M				.

			Conclusions are relevant to population/ phenomenon of interest (SIC in LVAD-DT).	M				Consideration of current practice of IC in light of current practice LVAD-DT is evident in LVAD-DT literature.
Article	**General Critical Appraisal Criteria(GCAC)**	**GCAC (M)et/ (U)nmet**	**Specific Critical Appraisal Criteria(SCAC)**	**SCAC (M)et/ (U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened, how so?**	**Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest (SIC in LVAD-DT)**
CUST	**The point(s) at issue is/are apparent.**	M	*Author clearly states issue(s).*	M				
			Raised points adequately addressed.	M				
			Purpose of paper is clear.	M				
			Conclusion clearly linked to the point identified.	M				
	Author has defined all terms used.	M	*Key terms clearly defined.*	M				
			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	M	*Premises are true/reasonable.*	M				
			Evidence supports premises.	M				

			Conclusions follow logically.	M				
	Relevant counterarguments addressed.	M	All Counterarguments are clearly identified and reported	M				
			Counterarguments are reasonable and convincing.	M				
			Counterarguments are clear and concise.	M				
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers.*	U	The arguments are presented from an ethics stance, rather than a practical stance, although the author very nicely addresses practical issues in their conclusion.	N		
			Article is directed towards practical outcomes.	M				
			Article clarifies/or	M				

			ganizes thinking of the reader.					
			Overall, article is useful.	M				
			Valuable insights are provided.	M				
			Conclusions are relevant to population/ phenomenon of interest (SIC in LVAD-DT).	M				The considering of ideal or theoretically circumscribed arguments are moot given the lack of application to real world realities within the context of LVAD-DT.
Article	**General Critical Appraisal Criteria(GCAC)**	**GCAC (M)et/ (U)nmet**	**Specific Critical Appraisal Criteria(SCAC)**	**SCAC (M)et/ (U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened, how so?**	**Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest (SIC in LVAD-DT)**
DUNN	**The point(s) at issue is/are apparent.**	M	*Author clearly states issue(s).*	M				
			Raised points adequately addressed.	M				
			Purpose of paper is clear.	M				
			Conclusion clearly	M				

			linked to the point identified.					
	Author has defined all terms used.	M	*Key terms clearly defined.*	M				
			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	M	*Premises are true/reasonable.*	M				
			Evidence supports premises.	M				
			Conclusions follow logically.	M				
	Relevant counterarguments addressed.	M	All Counterarguments are clearly identified and reported	M				
			Counterarguments are reasonable and convincing.	M				
			Counterarguments are clear and concise.	M				
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers.*	M				
			Article is directed towards practical outcomes.	M				
			Article clarifies/organizes	M				

			thinking of the reader.					
			Overall, article is useful.	M				
			Valuable insights are provided.	M				
			Conclusions are relevant to population/ phenomenon of interest (SIC in LVAD-DT).	M				Given complexity of LVAD-DT, Info quantity/quality may be affected.
Article	**General Critical Appraisal Criteria(GCAC)**	**GCAC (M)et/ (U)nmet**	**Specific Critical Appraisal Criteria(SCAC)**	**SCAC (M)et/ (U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened, how so?**	**Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest (SIC in LVAD-DT)**
STEWART	**The point(s) at issue is/are apparent.**	M	*Author clearly states issue(s).*	M				
			Raised points adequately addressed.	M				
			Purpose of paper is clear.	M				
			Conclusion clearly linked to the point identified.	M				
	Author has defined all terms used.	M	*Key terms clearly defined.*	M				
			Definitions are correct/reasonable	M				

	Premises/conclusions clearly asserted.	M	*Premises are true/reasonable.*	M				
			Evidence supports premises.	M				
			Conclusions follow logically.	M				
	Relevant counterarguments addressed.	M	All Counterarguments are clearly identified and reported	M				
			Counterarguments are reasonable and convincing.	M				
			Counterarguments are clear and concise.	M				
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers.*	M				
			Article is directed towards practical outcomes.	M				
			Article clarifies/organizes thinking of the reader.	M				
			Overall, article is useful.	M				
			Valuable insights are provided.	M				

			Conclusions are relevant to population/ phenomenon of interest (SIC in LVAD-DT).	M				Author's first recommendation is for the informing of all information (risks and hazards) that may influence the client's decision to proceed or not. This is a consistent expectation and preference voiced by LVAD-DT recipient respondents participating in LVAD-DT research.
Article	**General Critical Appraisal Criteria(GCAC)**	**GCAC (M)et/ (U)nmet**	**Specific Critical Appraisal Criteria(SCAC)**	**SCAC (M)et/ (U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened, how so?**	**Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest (SIC in LVAD-DT)**
GORE	**The point(s) at issue is/are apparent.**	M	*Author clearly states issue(s).*	M				

			Raised points adequately addressed.	U	Author identifies lack of consensus on how much information to provide, and the level of comprehension by the client as a point of debate. The author fails to address these assertions in a direct and cohesive fashion.	Y	Bias seems to be present as evidenced by the authors notion of the obvious: clients of surgeons are unlikely to hold as clear of a picture of the procedure as they, therefore the client is likely incapable of receiving IC despite receiving abundant information.	
			Purpose of paper is clear.	M				
			Conclusion clearly linked to the point identified.	M				

	Author has defined all terms used.	U	*Key terms clearly defined.*	U	Terms explanation or definition are less than clear and transparent with regard to applied SIC	N		
			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	M	*Premises are true/reasonable.*	M				
			Evidence supports premises.	M				
			Conclusions follow logically.	M				
	Relevant counterarguments addressed.	M	All Counterarguments are clearly identified and reported	M				
			Counterarguments are reasonable and convincing.	M				
			Counterarguments are clear and concise.	M				
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to*	M				

			prescribers.					
			Article is directed towards practical outcomes.	M				
			Article clarifies/organizes thinking of the reader.	M				
			Overall, article is useful.	M				
			Valuable insights are provided.	M				
			Conclusions are relevant to population/phenomenon of interest (SIC in LVAD-DT).	M				The notion of sharing information that is discretely relevant to the realities and expectations of the specific individual, is reflected in the LVAD-DT literature.
Article	**General Critical Appraisal Criteria(GCAC)**	**GCAC (M)et/ (U)nmet**	**Specific Critical Appraisal Criteria(SCAC)**	**SCAC (M)et/ (U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened, how so?**	**Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest (SIC in LVAD-DT)**
SKENE & SMALLWOOD	**The point(s) at issue is/are apparent.**	M	*Author clearly states issue(s).*	M				
			Raised points adequately	M				

			addressed .					
			Purpose of paper is clear.	M				
			Conclusion clearly linked to the point identified.	M				
	Author has defined all terms used.	M	*Key terms clearly defined.*	M				
			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	M	*Premises are true/reasonable.*	M				
			Evidence supports premises.	M				
			Conclusions follow logically.	M				
	Relevant counterarguments addressed.	M	All Counterarguments are clearly identified and reported	M				
			Counterarguments are reasonable and convincing .	M				
			Counterarguments are clear and concise.	M				
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers.*	M				

			Article is directed towards practical outcomes.	M				
			Article clarifies/organizes thinking of the reader.	M				
			Overall, article is useful.	M				
			Valuable insights are provided.	M				
			Conclusions are relevant to population/ phenomenon of interest (SIC in LVAD-DT).	M				Current LVAD-DT literature echoes several important considerations raised by authors, through client voice and investigator recommendation.
Article	**General Critical Appraisal Criteria(GCAC)**	**GCAC (M)et/ (U)nmet**	**Specific Critical Appraisal Criteria(SCAC)**	**SCAC (M)et/ (U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened, how so?**	**Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest (SIC in LVAD-DT)**

GERT	**The point(s) at issue is/are apparent.**	M	*Author clearly states issue(s).*	U	Author's use of metaphor to relate or explain her perspective is confusing, as is the writing style of the author, generally.	Y	Lack of author clarity can lead to one's discounting of the message conveyed by the author, or the importance of the work itself.	
			Raised points adequately addressed.	M				
			Purpose of paper is clear.	M				
			Conclusion clearly linked to the point identified.	M				
	Author has defined all terms used.	M	*Key terms clearly defined.*	M				
			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	U	*Premises are true/reasonable.*	M				
			Evidence supports premises.	U	As noted above.	Y	As noted above.	
			Conclusions follow logically.	U				
	Relevant counterarg	M	All Counterarguments	M				

	uments addressed.		are clearly identified and reported					
			Counterarguments are reasonable and convincing.	M				
			Counterarguments are clear and concise.	M				
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers.*	U	As noted above.	Y	As noted above.	
			Article is directed towards practical outcomes.	M				
			Article clarifies/organizes thinking of the reader.	U	As noted above.	Y	As noted above.	
			Overall, article is useful.	M				
			Valuable insights are provided.	M				
			Conclusions are relevant to population/phenomenon of interest (SIC in LVAD-DT).	M				Findings across LVAD-DT literature indicate that there is a gap between what is desired or received by clients in terms of information and what

								providers believe is provided. Furthermore, evidence of marginalized dignity concerns as well as the undermining of trust are also apparent.
Article	**General Critical Appraisal Criteria(GCAC)**	**GCAC (M)et/ (U)nmet**	**Specific Critical Appraisal Criteria(SCAC)**	**SCAC (M)et/ (U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened, how so?**	**Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest (SIC in LVAD-DT)**
DOYAL	**The point(s) at issue is/are apparent.**	M	*Author clearly states issue(s).*	M				
			Raised points adequately addressed.	M				
			Purpose of paper is clear.	U	Author does not clearly state their purpose.	N		
			Conclusion clearly linked to the point identified.	M				
	Author has defined all terms used.	M	*Key terms clearly defined.*	U	Terms are explained, but not clearly defined.	N		

			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	M	*Premises are true/reasonable.*	M				
			Evidence supports premises.	M				
			Conclusions follow logically.	M				
	Relevant counterarguments addressed.	M	All Counterarguments are clearly identified and reported	M				
			Counterarguments are reasonable and convincing.	M				
			Counterarguments are clear and concise.	M				
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers.*	M				
			Article is directed towards practical outcomes.	M				
			Article clarifies/organizes thinking of the reader.	M				
			Overall, article is useful.	M				
			Valuable insights	M				

			are provided.					
			Conclusions are relevant to population/ phenomenon of interest (SIC in LVAD-DT).	M				Current LVAD-DT literature investigator recommendations based upon client voice and independent study findings are relatable to author's assertions of benefits stemming from morally rigorous clinical practice inclusive of optimally obtained IC.
Article	**General Critical Appraisal Criteria(GCAC)**	**GCAC (M)et/ (U)nmet**	**Specific Critical Appraisal Criteria(SCAC)**	**SCAC (M)et/ (U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened, how so?**	**Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest (SIC in LVAD-DT)**
BRENNER, ET AL.	**The point(s) at issue is/are apparent.**	M	*Author clearly states issue(s).*	M				
			Raised points adequately addressed.	M				
			Purpose of paper is clear.	M				
			Conclusion clearly linked to the point identified.	M				

	Author has defined all terms used.	M	*Key terms clearly defined.*	M				
			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	M	*Premises are true/reasonable.*	M				
			Evidence supports premises.	M				
			Conclusions follow logically.	M				
	Relevant counterarguments addressed.	U	All Counterarguments are clearly identified and reported	U	The argument is not presented in contrast to other perspectives.	N		
			Counterarguments are reasonable and convincing.	U	As noted above.	N		
			Counterarguments are clear and concise.	U	As noted above.	N		
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers.*	M				
			Article is directed towards practical outcomes.	M				
			Article clarifies/or	M				

			ganizes thinking of the reader.					
			Overall, article is useful.	M				
			Valuable insights are provided.	M				
			Conclusions are relevant to population/ phenomenon of interest (SIC in LVAD-DT).	M				Authors' conclusions and recommendations are widely reflected across the LVAD-DT literature in response to concerns and preferences raised by study participants voiced through qualitative findings.
Article	**General Critical Appraisal Criteria(GCAC)**	**GCAC (M)et/ (U)nmet**	**Specific Critical Appraisal Criteria(SCAC)**	**SCAC (M)et/ (U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened, how so?**	**Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest (SIC in LVAD-DT)**
LECLERQ, ET AL.	**The point(s) at issue is/are apparent.**	M	*Author clearly states issue(s).*	M				
			Raised points adequately addressed.	M				
			Purpose of paper is clear.	M				

			Conclusion clearly linked to the point identified.	M				
	Author has defined all terms used.	M	*Key terms clearly defined.*	M				
			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	M	*Premises are true/reasonable.*	M				
			Evidence supports premises.	M				
			Conclusions follow logically.	M				
	Relevant counterarguments addressed.	M	All Counterarguments are clearly identified and reported	M				
			Counterarguments are reasonable and convincing.	M				
			Counterarguments are clear and concise.	M				
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers.*	M				
			Article is directed towards practical outcomes.	M				

			Article clarifies/organizes thinking of the reader.	M				
			Overall, article is useful.	M				
			Valuable insights are provided.	M				
			Conclusions are relevant to population/phenomenon of interest (SIC in LVAD-DT).	M				LVAD-DT literature prescriber implications and process recommendations are reflective of those identified here.
Article	**General Critical Appraisal Criteria(GCAC)**	**GCAC (M)et/ (U)nmet**	**Specific Critical Appraisal Criteria(SCAC)**	**SCAC (M)et/ (U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened, how so?**	**Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest (SIC in LVAD-DT)**
CHENG	**The point(s) at issue is/are apparent.**	M	*Author clearly states issue(s).*	M				
			Raised points adequately addressed.	M				
			Purpose of paper is clear.	M				
			Conclusion clearly linked to the point identified.	M				
	Author has defined all terms used.	M	*Key terms clearly defined.*	M				

			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	M	*Premises are true/reasonable.*	M				
			Evidence supports premises.	M				
			Conclusions follow logically.	M				
	Relevant counterarguments addressed.	M	All Counterarguments are clearly identified and reported	M				
			Counterarguments are reasonable and convincing.	M				
			Counterarguments are clear and concise.	M				
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers.*	M				
			Article is directed towards practical outcomes.	M				
			Article clarifies/organizes thinking of the reader.	M				
			Overall, article is useful.	M				
			Valuable insights	M				

			are provided.					
			Conclusions are relevant to population/ phenomenon of interest (SIC in LVAD-DT).	M				Barriers to meaningful IC noted in LVAD-DT literature are reflective of threats to autonomy explored here.
Article	**General Critical Appraisal Criteria(GCAC)**	**GCAC (M)et/ (U)nmet**	**Specific Critical Appraisal Criteria(SCAC)**	**SCAC (M)et/ (U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened, how so?**	**Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest (SIC in LVAD-DT)**
CHIMA	**The point(s) at issue is/are apparent.**	M	*Author clearly states issue(s).*	M				
			Raised points adequately addressed.	M				
			Purpose of paper is clear.	M				
			Conclusion clearly linked to the point identified.	M				
	Author has defined all terms used.	M	*Key terms clearly defined.*	M				
			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	M	*Premises are true/reasonable.*	M				

			Evidence supports premises.	M				
			Conclusions follow logically.	M				
	Relevant counterarguments addressed.	M	All Counterarguments are clearly identified and reported	M				
			Counterarguments are reasonable and convincing.	M				
			Counterarguments are clear and concise.	M				
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers.*	M				
			Article is directed towards practical outcomes.	M				
			Article clarifies/organizes thinking of the reader.	M				
			Overall, article is useful.	M				
			Valuable insights are provided.	M				
			Conclusions are relevant to population/phenomenon of	M				Barriers to meaningful IC noted in LVAD-DT literature are

			interest (SIC in LVAD-DT).					reflective of threats to autonomy explored here.
Article	**General Critical Appraisal Criteria(GCAC)**	**GCAC (M)et/ (U)nmet**	**Specific Critical Appraisal Criteria(SCAC)**	**SCAC (M)et/ (U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened, how so?**	**Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest (SIC in LVAD-DT)**
MOULTON, ET AL.	**The point(s) at issue is/are apparent.**	M	*Author clearly states issue(s).*	M				
			Raised points adequately addressed.	M				
			Purpose of paper is clear.	M				
			Conclusion clearly linked to the point identified.	M				
	Author has defined all terms used.	M	*Key terms clearly defined.*	M				
			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	M	*Premises are true/reasonable.*	M				
			Evidence supports premises.	M				
			Conclusions follow logically.	M				
	Relevant counterarg	M	All Counterarguments	M				

	uments addressed.		are clearly identified and reported					
			Counterarguments are reasonable and convincing.	M				
			Counterarguments are clear and concise.	M				
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers.*	M				
			Article is directed towards practical outcomes.	M				
			Article clarifies/organizes thinking of the reader.	M				
			Overall, article is useful.	M				
			Valuable insights are provided.	M				
			Conclusions are relevant to population/phenomenon of interest (SIC in LVAD-DT).	M				LVAD-DT literature prescriber implications and process recommendations are reflective of those identified here.
Article	**General Critical Appraisal**	**GCAC(M)et/(U)nmet**	**Specific Critical Appraisal**	**SCAC(M)et/(U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened,**	**Reviewer's Perceived Contemporary Value**

	Criteria(GCAC)		**Criteria(SCAC)**				**how so?**	**of Article to Phenomenon of Interest (SIC in LVAD-DT)**
MALIK & FOSTER	**The point(s) at issue is/are apparent.**	M	*Author clearly states issue(s).*	M				
			Raised points adequately addressed.	M				
			Purpose of paper is clear.	M				
			Conclusion clearly linked to the point identified.	M				
	Author has defined all terms used.	M	*Key terms clearly defined.*	M				
			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	M	*Premises are true/reasonable.*	M				
			Evidence supports premises.	M				
			Conclusions follow logically.	M				
	Relevant counterarguments addressed.	M	All Counterarguments are clearly identified and reported	M				
			Counterarguments are reasonable and	M				

			convincing .					
			Counterarguments are clear and concise.	M				
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers.*	M				
			Article is directed towards practical outcomes.	M				
			Article clarifies/organizes thinking of the reader.	M				
			Overall, article is useful.	M				
			Valuable insights are provided.	M				
			Conclusions are relevant to population/phenomenon of interest (SIC in LVAD-DT).	M				LVAD-DT literature prescriber implications and process recommendations are reflective of those identified here.
Article	**General Critical Appraisal Criteria(GCAC)**	**GCAC (M)et/ (U)nmet**	**Specific Critical Appraisal Criteria(SCAC)**	**SCAC (M)et/ (U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened, how so?**	**Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest (SIC in LVAD-DT)**
Weinmeyer	**The point(s) at**	M	*Author clearly*	M				

	issue is/are apparent.		*states issue(s).*					
			Raised points adequately addressed .	M				
			Purpose of paper is clear.	M				
			Conclusion clearly linked to the point identified.	M				
	Author has defined all terms used.	M	*Key terms clearly defined.*	M				
			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	U	*Premises are true/reasonable.*	M				
			Evidence supports premises.	M				
			Conclusions follow logically.	U	Given absence of alternatives to standards stated, although premises are reasonable, conclusions are not entirely Informed.	Y	In lack of all perspectives, conclusions may be skewed or biased.	

	Relevant counterarguments addressed.	U	All Counterarguments are clearly identified and reported	U	SS not addressed. Nor are other hybrid perspectives by at least 2 states, although 24 states using RPeS addressed directly.	Y	Absenting SS or other forms of IC which may address the author's concern does not present a fully informed picture of the state of IC at the time the article was written.	
			Counterarguments are reasonable and convincing.	M (those discussed)				
			Counterarguments are clear and concise.	M (those discussed)				
	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers.*	M				
			Article is directed towards practical outcomes.	M				
			Article clarifies/or	M				

			ganizes thinking of the reader.					
			Overall, article is useful.	M				
			Valuable insights are provided.	M				
			Conclusions are relevant to population/ phenomenon of interest (SIC in LVAD-DT).	M				Based upon what is evident in the LVAD-DT body of literature, this work raises several existential questions with regard to the development of a standardized form of IC: can it be achieved? If so, should it be achieved? If not, then what?
Article	**General Critical Appraisal Criteria(GCAC)**	**GCAC (M)et/ (U)nmet**	**Specific Critical Appraisal Criteria(SCAC)**	**SCAC (M)et/ (U)nmet**	**If U, how so?**	**Credibility threatened? (Y)es/(N)o**	**If threatened, how so?**	**Reviewer's Perceived Contemporary Value of Article to Phenomenon of Interest (SIC in LVAD-DT)**
Subramani	**The point(s) at issue is/are apparent.**	M	*Author clearly states issue(s).*	U	Writing style is an impediment to clarity of message.	N		

			Raised points adequately addressed.	M				
			Purpose of paper is clear.	M				
			Conclusion clearly linked to the point identified.	M				
	Author has defined all terms used.	M	*Key terms clearly defined.*	M				
			Definitions are correct/reasonable	M				
	Premises/conclusions clearly asserted.	M	*Premises are true/reasonable.*	M				
			Evidence supports premises.	M				
			Conclusions follow logically.	M				
	Relevant counterarguments addressed.	M	All Counterarguments are clearly identified and reported	M				
			Counterarguments are reasonable and convincing.	M				
			Counterarguments are clear and concise.	U	Writing style is an impediment to clarity of message.	N		

	Presented argument(s) is/are applicable to practice.	M	*Point or problem is framed in a way that is useful to prescribers.*	M				
			Article is directed towards practical outcomes.	M				
			Article clarifies/organizes thinking of the reader.					
			Overall, article is useful.	M				
			Valuable insights are provided.	M				
			Conclusions are relevant to population/phenomenon of interest (SIC in LVAD-DT).	M				Barriers to meaningful IC noted in LVAD-DT literature echo the implications discussed.

APPENDIX E

Ethics Literature Synthesis Classifications

Author, Year of Publishing; Perspective Context (Ethical/Philosophical, Legal, Medical)	Problem/Point	Implication	Recommendation(s)	Intersection with LVAD-DT (Friedman, 2020)
Coleman & Abernathy, (1973); L	IC is a concept that is difficult to apply. SIC are likely to change in response to evolving actions and perspectives of prescribers and their clients.	Because of the variability of client information need/preference, and varying prescriber beliefs of what to share in terms of risk, it is likely gaps will present themselves between these two perspectives.	Engage in informative discussions about treatments and procedures in the obtaining of IC and document those discussions and authorizations.	The underpinnings of differences between LVAD-DT client expectations and realized outcomes and/or lack of IC standard approach and/or variability from state to state are identified.
Hoyt, (1983); L	Disclosure of information (risk) is shifting from Reasonable Prescriber Standard to Reasonable Person Standard.	Prescribers then are likely to experience a high bar in assuring clients are capable of and do understand well the risks associated with a given procedure, to the degree the client requires.	No recommendations offered.	IC and optimal understanding of the procedure and its effects are lacking according to the report of many LVAD-DT recipients Therefore accountability of the prescriber, and vulnerability of the client are amplified within the context of LVAD-DT.

Cust, (1991); EP	Identifying the justification for the practice of informed consent. Identifying a standard for the nature and quantity of information to disclose for IC to occur.	There may be benefit from the engagement of more than one SIC.	No recommendations offered.	Cust asserts the fact that human ideals and values are often discordant, that what one wants is to live "the good life", that humans experiencing actual decisions that affect their ability to live the good life, and that the sharing of information which might affect their ability to achieve the good life as they conceive of it is just; LVAD-DT literature is reflective of these ideas.
Dunn, (1994); L	How much information and explanation are sufficient for the conveyance of IC depends upon in which state a complainant/medical client resides and provider treats.	Prescribers need to be aware of the SIC practiced in their state and abide by it.	1) Physician ought to personally inform patient and obtain IC. 2) Share with the patient that which the physician themselves (or their spouse) would want to know.	LVAD-DT literature similarly mirrors implication and recommendations offered, in terms of sympathetic/empathetic engagement.
Stewart, (1995); L	Health care clients are entitled to disclosure. Some procedures require written IC while others do not. Those requiring signed IC governed by state body, by definition, others not defined, by RPeS. Obligation to obtain IC is that of the Physician,	Physicians retain the obligation for the obtaining of IC, and IC must meticulously informed and abide by statute and policy.	1) Discuss all material information that may influence client's decision. 2) Document such informing. 3) Client and witness sign said documentation. 4) Maintain record of IC in health record. 5) if emergent deviation from IC, document circumstances. 6) Experimental procedures require specific approval from IRB.	Author's first recommendation is for the informing of all information (risks and hazards) that may influence the client's decision to proceed or not. This is a consistent expectation and preference voiced by LVAD-DT recipient respondents participating in LVAD-DT research.

Gore, (2001); L, M, EP	How much information about a procedure and its consequences is enough, and to what extent the client understands that information? Despite abundant sharing of information, clients are not likely to have as clear of an understanding as a physician experienced in that procedure.	Truly IC may not be typically given or obtained.	No recommendations offered.	Authors assertion that IC is "hardly ever fully informed" and the notion that the client will never "have as complete a picture as the physician familiar and experienced" with the intervention are both relevant to the experiences of giving and obtaining IC in the context of LVAD-DT.
Skene & Smallwood, (2002); L, M	Trend towards RPeS from RPrS validated, and argument is suggested is that prescribers have not yet caught up with this evolution even as judges have.	Evolution towards Reasonable Person implies the prescriber is accountable for greater knowledge and understanding of client's wishes and their client's information sharing preferences. Falling short of said bar for IC practices may negatively impact client care.	No recommendations offered.	The authors highlight the ideas that relevant factors such as the more complex the procedure, the more information ought be shared, client's preferences for more information ought be heeded, and the temperament/health of the client ought to be considered in the provision or more detailed information, or more time to process information fully (p.40). Current LVAD-DT literature echoes these same important considerations, through client voice.

Gert, (2002); M, EP	A significant gap exists between the information a typical client wants and the information that a reasonable person standard requires prescribers to provide.	Failure to disclose material risk that the client would have accepted, but deserved to know may marginalize client dignity, negatively affect prescriber/client trust the client, undermining client outcomes.	Share enough information not only to inform necessarily, but also widely enough to prevent surprises or surprise outcomes.	Findings from a growing number of LVAD-DT studies indicate that a gap exists between what prescribers explain and what clients expect as well as marginalization of dignity and trust.
Doyal, (2002); EP	The ethical duty of clinicians now is widely understood to include properly obtained IC as a key component of good clinical practice. Properly obtained IC through respect for individual client autonomy is the moral imperative to such practice.	Morally oriented prescriber/client relationships support ethically and properly informed IC, thereby respecting and even optimizing client autonomy and interests.	No recommendations offered.	The author's assertions of what is gained through ethically rigorous care and appropriately informed consent is reflected in current LVAD-DT literature vis a vie investigator recommendations based upon client voice and independent study findings.
Brenner, et al., (2009); M	IC purpose has drifted from a point of empowerment of the client joint decision-making to a waiver of liability sought be physicians. A return to an informing relational model is likely to improve client empowerment and outcomes thereby reducing risk of clinician liability.	Prescribers aims of self-protection may be more likely to be achieved through relational efforts such as empathetic validation and client education rather than transactional efforts such as promises and risk/benefit analyses.	A therapeutic and beneficent relationship must be enjoined by both parties to suborn a properly obtained IC. And that process must be memorialized within the medical record.	Authors' assertions of IC issues and subsequent recommendations are widely reflected across the LVAD-DT literature in response to concerns and preferences raised by study participants voiced through qualitative findings.

Leclerq, et al, (2010); M	Current IC practice (Surgical IC, specifically) is not in step with current need	IC must be client-centered, educational, and standardized. Prescribers then must be comfortable with a relational process rather than a transactional one if meaningful and appropriate IC is to be obtained.	12 specific recommendations are made across 5 areas of concern: General, Competence, Information, Consent, and Research.	LVAD-DT literature prescriber implications and process recommendations are reflective of those identified here as well as the inherent gap identified by Leclerq and colleagues.
Cheng, (2013); EP	A client's autonomy is at risk to three threats (insufficient information, irrationality of belief or desire, and the influence of situation). Therefore, IC is likewise threatened.	Respect for client autonomy is supported through thorough informing and the provision of strong reasoning through aligned and varied sources. Such attention to detail requires more time and effort than current medical practice values or allows for.	No recommendations offered.	Barriers to meaningful IC as well as benefits of respect for client autonomy noted in LVAD-DT literature are reflective of threats to autonomy explored here.
Chima, (2013); EP, M	Prescribers encounter many challenges in obtaining legal and ethical IC.	Remedying of the situation is likely to include systemic and educational improvements to facilitate improved IC practice and overall quality	Address language barriers through interpreter personnel and revision of written documents, address shortcomings of clinicians through ethics continuing education.	Barriers to meaningful IC and implications for practice are noted in LVAD-DT literature are reflective of threats to autonomy explored here.

		of healthcare delivery.		
Moulton, et al., (2013); EP, M	In UK, IC processes are not standardized across or amongst organizations; nor confirmation of client understanding compelled; finally, little research into IC practice. Use of high-quality client decision aids encouraged in USA to augment IC.	Evidence suggests that maintenance of status quo perpetuates incongruity between procedures consented to, and procedures actually desired by clients (consent); Shared decision-making via client decision aids may balance the disparity between autonomy and beneficence.	No recommendations offered.	LVAD-DT literature prescriber implications and process improvements suggested are reflective of those identified here.
Malik & Foster, (2014); M, EP	Both RPrS and RPeS fall short of their purpose (hold prescribers to account) since both are undermined by wide variation in practice and preference.	Without meaningful change, respect for autonomy and beneficent practice continue to be undermined.	No recommendations offered.	LVAD-DT literature prescriber implications and process improvements suggested are reflective of those identified here.

Weinmeyer, (2014); L	Variation in standard care, and variation in application of SIC, make the determining of what is fair and just by courts in malpractice cases challenging.	Given the robust evolution of healthcare and the measured evolution of the law, a standardized approach to obtaining IC is likely to remain elusive, if not impossible for the time being.	No recommendations offered.	Based upon what is evident through participant voice or investigator recommendation in the LVAD-DT body of literature, this work raises several existential questions with regard to the development of a standardized or unified form of IC: can it be achieved? If so, should it be achieved? If not, then what?
Subramani, (2017); EP	In essence, respect for autonomy (client's right to information/RPeS) is usurped through the pursuit of perceived beneficence (protection of physical well-being/RPrS).	True ability to convey consent or authorization is impotent if respect for client autonomy is subordinate to prescriber preference for client physical well-being.	No recommendations offered.	Barriers to meaningful IC noted in LVAD-DT literature echo the implications discussed.