Ventricular assist device technology and fundamental causes of black-white disparities on the heart transplant wait list

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Abstract:

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Heart transplantation is the definitive treatment for end-stage heart failure. Left ventricular assist devices (LVADs) are a continually improving technology that extends life for candidates on the transplant waiting list. We use transplant registry data from the United Network for Organ Sharing (N=5,550) and fundamental cause theory to understand how type and timing of LVAD implantation are associated with differences in heart transplant wait list outcomes among black and white candidates. Consistent with fundamental cause theory, we found that although black and white candidates were equally likely to receive newer continuous flow LVADs, black candidates were more likely to undergo LVAD implantation after transplant listing (i.e., later in the disease course). This later timing of technological intervention contributed to poorer wait list outcomes among black transplant candidates, which included lower likelihood of receiving a heart transplant and greater likelihood of being removed from the wait list due to worsening health.

Ventricular assist device technology and fundamental causes of black-white disparities on the heart transplant wait list

Heart failure affects 5.7 million adults living in the United States, with approximately 915,000 new cases occurring each year (Mozaffarian et al. 2016). In cases progressing to end-stage heart failure, heart transplantation remains the gold standard for definitive treatment (Boilson et al. 2010). However, insufficient availability of donor hearts presents the challenges of keeping patients with end-stage heart failure alive until they can receive a transplant, as well as preventing their condition from deteriorating to the point where they would no longer be eligible to undergo transplantation (Merion et al. 2005). For many candidates, survival to transplant can be enhanced through the use of mechanical circulatory support (MCS) to supplement the function of the failing heart. The most commonly used MCS devices are left ventricular assistance devices (LVADs), which assist the heart in circulating oxygenated blood to other organs. Technological innovation has resulted in three generations of durable LVADs since the mid 1990s, each with successively better results for "bridging" patients to transplant (Gustafsson and Rogers 2017; Miller and Rogers 2018).

These technological improvements raise questions of equity in access to new LVAD technology, especially in light of the persistent racial disparities in heart failure diagnosis and heart transplant wait list survival (Morris et al. 2016; Mozaffarian et al. 2016). Building on Link and Phelan's (1995) classic work documenting that social conditions act as fundamental causes of disease, we use transplant registry data from the United Network for Organ Sharing (UNOS) to investigate how technological innovation in bridge-to-transplant (BTT) LVADs may have reproduced racial disparities in the outcomes of listing for heart transplantation. Particularly, we

draw attention to the *timing of a medical intervention* (LVAD implantation), vis-à-vis the disease course, as an under-theorized area where fundamental causes act to reproduce unequal health outcomes.

Drawing on fundamental cause theory, we analyze black-white disparities in the introduction of new LVAD technology for heart transplant candidates. Specifically, we evaluate racial differences in use of newer versus older generation LVADs, the timing of LVAD implantation relative to the timing of heart transplant wait listing, and racial disparities in wait list outcomes – either transplant, wait list mortality, or delisting due to worsening condition -- among candidates supported by LVADs. Our findings indicate that black patients requiring LVAD support were equally or more likely than white patients to receive newer generation LVADs. Nevertheless, black patients' access to this newer technology did not result in a narrowing of racial differences in waiting list outcomes. In part, this was due to race differences in the timing of medical intervention. Black candidates were disproportionately likely to undergo LVAD implantation after being listed for transplant rather than having an LVAD implanted before listing, when the device might have been more effective in arresting the progression of heart failure and the deterioration of a patient's condition (Gustafsson and Rogers 2017). As a result, even as new LVAD technologies were made available to black and white patients on the heart transplant wait list, black patients continued to experience a lower likelihood of receiving a heart transplant and a greater likelihood of delisting (being removed from the heart waiting list due to worsening condition). These findings demonstrate how delayed use of a new medical intervention, relative to the disease course, can reproduce social inequality in health outcomes even when dissemination of a new medical technology appears to reach all groups.

Theory and Background

Racial disparities in heart disease morbidity and mortality are well established. Evidence for racial disparities in morbidity and mortality emerged in the late 19th century, when W.E.B. Du Bois documented significant racial differences in heart disease and heart disease mortality between urban whites and urban African-Americans in Philadelphia (Du Bois 2007). More recent research has demonstrated the persistence of racial disparities in heart disease incidence and mortality (Graham 2015; Mozaffarian et al. 2016). For example, in 2014, age-adjusted heart disease mortality rates were 1.2 times higher for African-Americans when compared to Non-Hispanic whites (Kochanek et al. 2016). In addition, African-Americans have a higher incidence of heart failure relative to whites, and are more likely to experience early-onset heart disease (Bahrami et al. 2008; Husaini et al. 2016; Mozaffarian et al. 2016). Recent research estimates that the incidence rate of heart failure is approximately six times higher for African Americans ages 18-54, compared to Whites ages 18-54 (Husaini et al. 2016). Despite innovation in the treatment and management of heart failure, evidence suggests that racial disparities in heart failure mortality are persisting (Durstenfeld et al. 2016; Ni and Xu 2015).

Early explanations of racial disparities in health highlighted differences in social conditions (Du Bois 2007). Du Bois hypothesized that racial disparities in morbidity and mortality in urban Philadelphia were likely the result of relative differences in living conditions, access to nutritious foods, and employment opportunities (Du Bois 2007). More recently, fundamental cause theory has proposed that socioeconomic status (SES) fundamentally affects health status through a multiplicity of risk factors, notwithstanding improvements in medical technology and public health (Link and Phelan 1995, 1996; Phelan, Link, and Tehranifar 2010). In particular, SES encompasses important resources such as prestige, power, money, knowledge, and social connections that can

be mobilized to reduce exposure to risk factors and increase exposure to protective factors (Phelan et al. 2010).

The role of technological innovation in reproducing social disparities in health is a key component of fundamental cause theory (Phelan et al. 2010). According to fundamental cause theory, social disparities in health increase when new developments in medical technology and treatment become available, because those with higher SES are better positioned to mobilize their greater resources to gain early access to the benefits of new technology. This unequal diffusion of new technology reproduces disparities in health outcomes such as disease incidence, disease progression, and mortality. The technology diffusion hypothesis embedded in fundamental cause theory has been validated across multiple settings (Burdette et al. 2017; Chang and Lauderdale 2009; Clouston et al. 2017; Fenton et al. 2018; Korda, Clements, and Dixon 2011; Link et al. 1998; Lutfey and Freese 2005; Polonijo and Carpiano 2013; Rubin, Colen, and Link 2010; Wang et al. 2012). Unequal diffusion of new technology has been observed in the cases of human papillomavirus (HPV) vaccination (Burdette et al. 2017; Fenton et al. 2018; Polonijo and Carpiano 2013), use of statins for treating high cholesterol (Chang and Lauderdale 2009), cancer screening (Clouston et al. 2017; Link et al. 1998; Wang et al. 2012), coronary artery bypass grafting (Korda et al. 2011), diabetes education (Lutfey and Freese 2005), and antiretroviral therapy for HIV/AIDS (Rubin et al. 2010). In this research, social conditions were found to strongly influence and uptake of new medical advances, thereby reproducing or even widening health inequalities.

In current applications of fundamental cause theory, unequal diffusion of new technology is the principal way in which technology reproduces or exacerbates socioeconomic health inequalities. For diseases that cannot be prevented, socioeconomic differences in disease incidence and mortality are less pronounced (Masters, Link, and Phelan 2015; Rubin, Clouston, and Link

2014) . However, when new technology emerges that can help to detect, treat, or manage a disease, socially advantaged groups are able to deploy necessary resources to secure early or greater access to the technology at hand. For example, in the 1970s socioeconomically advantaged groups were likely to have higher cholesterol levels until the introduction of statin medications to lower cholesterol. Chang and Lauderdale (2009) show that early access to this new technology (statins) produced better health outcomes for people with more social and economic resources.

While a growing body of fundamental cause research has demonstrated emerging differences in access to new technology, such as cancer screening, HPV vaccines, and antiretroviral therapy, very little research has focused on how the timing of technological intervention, vis-à-vis the disease course, contributes to social disparities in health. In their work describing the role of medical advances in shaping racial/ethnic disparities in cancer survival, Tehranifar et al (2009: 2702) discussed how medical interventions might facilitate "1) earlier detection of the cancer, or 2) increased success of treatment due to earlier detection, timely or effective treatment options." However, recent research has emphasized social disparities in early detection of disease (Henry, Sherman, and Roche 2009; Kim, Dolecek, and Davis 2010; Tehranifar et al. 2016), as opposed to disparities in the timing of treatment relative to disease progression. With many diseases being progressive in nature, disparities in the timing of a technological intervention with respect to the onset of disease may strongly influence health outcomes, even when technological interventions are made equally available to all social groups. In some cases, such as end-stage heart failure, technological intervention occurring too late in the disease course would be markedly less effective, meaning that social differences in the timing of treatment could be a prime mechanism by which social inequality in health outcomes is maintained.

Although much of the fundamental cause literature focuses on aspects of social class such as income, education, and occupational prestige and their roles in maintaining health inequalities, the role of structural racism in creating and maintaining health inequalities can also be viewed through a fundamental cause lens (Phelan and Link 2015). Structural racism (also see Bailey et al. 2017 for definitions and a review) affects Black Americans' job prospects, social networks, access to housing, education, health care experiences and coverage, and many other factors cited in the fundamental cause literature as processes through which health inequalities are maintained. Further, "there is evidence that racism, largely via inequalities in power, prestige, freedom, neighborhood context, and health care, also has a fundamental association with health independent of SES" (Phelan and Link 2015:311). As such, we posit that fundamental cause is a valuable theory for understanding race inequalities in LVAD implantation and transplant outcomes.

Racial disparities in health outcomes persist across all levels of SES (Braveman et al. 2010; Williams and Sternthal 2010). Mortality rates of heart disease in blacks and whites show that at every educational level, a race gap persists (Jemal et al. 2008). Further, all indicators of SES, including access to economic resources, education level, and wealth, are patterned by race (Williams, Priest, and Anderson 2016). While race and SES are related, they each "reflect distinct processes of stratification" (Williams, Priest and Anderson 2016:410). The persistent impact of race and racism on health outcomes (Phelan and Link 2015), as well as an organ transplant screening process that tends to exclude the most socioeconomically disadvantaged candidates (Dew et al. 2018), supports our claim that that race is the most important social characteristic to consider when understanding heart failure, LVAD implantation, and transplant wait listing.

In this paper, we explore implications of race as a fundamental cause of health inequalities in a setting where both access to new technology and the timing of technological intervention

profoundly influence health outcomes. Among candidates for heart transplantation requiring LVAD implantation, we investigate whether there are race differences in access to technological advances in LVADs, whether there are race differences in the timing of device implantation relative to timing of listing on the transplant wait list, and how these differences shape racial disparities in transplant wait list outcomes. In doing this, we present this as a case study where the timing of medical intervention is the operative mechanism of fundamental cause theory linking social conditions to health outcomes.

LVADs in Cardiac Transplantation

Due to the limited number of donor hearts available, patients with heart failure are at risk of dying before undergoing transplantation, or of being removed from the waiting list due to deteriorating condition (Ward et al. 2017). Durable LVADs, which support the failing heart by pumping oxygenated blood into the aorta, can be used as a bridge to transplant (BTT), improving a patient's chances of surviving until a suitable donor heart becomes available. Briefly, durable LVAD technology evolved from pulsatile flow (PF) devices in the 1990s, to continuous flow (CF) devices in the 2000s, to centrifugal flow devices in the present decade (Holley, Harvey, and John 2014). With each generation of LVADs, the aim has been to increase device durability; reduce complications associated with implantation; improve patients' functional status; and make LVAD therapy available to a broader range of patients with heart failure. In this study, we begin our observation during the period in which pulsatile flow LVADs reached widespread use for BTT under the current donor heart allocation system, in January 1999 (Wever-Pinzon et al. 2013). Our study period includes the beginning of CF-LVAD clinical trials (Frazier et al. 1995) and subsequent FDA approval for CF-LVAD to be used for BTT (April 2008). We censor the study period when the latest-generation centrifugal flow LVADs began clinical trials in September 2014,

and therefore we describe a period in which an old medical technology (PF-LVAD) was gradually but almost completely superseded by a new technology (CF-LVAD).

LVAD advances, particularly the well-documented improvements of CF devices over PF devices (Loor and Gonzalez-Stawinski 2012; McIlvennan et al. 2014), presented a challenge of equitably distributing the new technology to patients who would benefit from LVAD BTT. Available evidence and clinical consensus suggest that patients with CF-LVADs have better health outcomes compared to those with older, PF technology to assist failing heart function (Cai et al. 2017). Furthermore, CF-LVADs have made this therapy available to a wider range of heart failure patients (due to a wider range of body sizes in which CF-LVADs can be implanted), with improved outcomes and fewer device failures or complications (Miller et al. 2007). However, patient factors associated with limited access to LVAD technology have been described as older age, female sex, and African American race (Joyce et al. 2009).

Benefits of LVAD therapy depend not only on having the device implanted, but also on the timing of device implantation relative to progression of heart failure. The current clinical consensus is that delayed implantation of LVADs leads to worse outcomes (Gustafsson and Rogers 2017; Kitada et al. 2016). However, there are discrepancies in when a patient receives an assisted device, either before or after being placed on the transplant list by a physician. Most transplant candidates requiring LVAD support have the device implanted before listing. Yet some clinical trials of CF-LVAD required that the patient already be listed for heart transplantation to be considered eligible to receive the new device type (Aaronson et al. 2012). In addition, public insurance programs governed by the Centers for Medicare and Medicaid Services require individuals to be listed for heart transplant before costs associated with BTT LVADs are covered. Related to this requirement, recent clinical literature suggests that differences in wait list survival

between privately insured individuals and Medicaid insured individuals may be due to differences in the timing of LVAD implantation (Emani et al. 2017). In sum, the timing of device implantation is related to both clinical factors as well as socioeconomic factors associated with insurance coverage and referral for LVAD therapy.

We propose that the timing of LVAD implementation may vary across race over and above class for several reasons relating directly to structural racism as described in fundamental cause theory (Phelan and Link 2015). The unequal experiences of black patients in access to healthcare, health provider bias, and health care policies are well established and likely contribute to race differences in the timing of LVAD implantation. Racial disparities in insurance status are well known (National Center for Health Statistics 2016) and may contribute to disparities in the timing of LVAD implementation due to African Americans' disproportionate likelihood to report public insurance (see Kirby and Kaneda 2010). Medicare and Medicaid policy requirements for LVAD cost reimbursement may delay LVAD implantation until a patient is placed on the heart transplant wait list, which could contribute to greater risk of waitlist mortality or delisting. Reduced access to specialists who may recommend LVAD implantation, or inconsistent access to care may also impede access to LVAD technology prior to going on the waitlist (see Daw 2012 for an explanation of this process with regard to kidney transplant wait listing). Racial disparities in the timing of LVAD implantation may also vary across race due to provider bias, as racial biases held by medical providers may influence the behavior and advice they offer to their patients. For example, studies have shown evidence of racial disparities in provider recommendations for individuals to receive HPV vaccines (Burdette et al. 2017).

Current study

The rapid evolution of LVAD technology from pulsatile to continuous flow, and the significance of LVAD implantation timing for heart transplant candidacy outcomes create a unique setting in which to test key aspects of fundamental cause theory. Specifically, due to the continual and significant role of race, separate from SES, in heart disease incidence and mortality, we expect that racial disparities in transplant wait list outcomes (survival to transplant; wait list mortality; delisting), will persist over the study period notwithstanding the technological innovation described. We explore several potential explanations for this expected finding that are derived from fundamental cause theory. First, White candidates could have been more likely to receive CF rather than PF-LVAD, as compared to black candidates, in the period when CF-LVADs were first introduced. Second, White candidates could have received CF-LVADs earlier in the disease course than black candidates (i.e., before heart transplant wait list registration), possibly avoiding further decline in clinical status before undergoing transplantation. Third, black patients may experience different outcomes even when receiving the same types of medical interventions, consistent with the fundamental cause tenet that social inequalities persist even as technologies improve and are disseminated to more disadvantaged groups.

Overall, we test whether racial disparities in waitlist outcomes can be driven by two factors – LVAD type and timing of implantation. We also examine whether race disparities persist even among patients receiving similar medical interventions. Specifically, we hypothesize the following:

H1a: Black patients will be less likely to receive a continuous flow (CF) versus pulsatile flow (PF) LVAD compared with white patients.

H1b: Black patients will be more likely receive LVADs later in the disease course – specifically, after being listed for transplant compared with reporting an LVAD prior to listing – compared with white peers.

H2: Controlling for LVAD type (PF versus CF), timing of device implantation (prior to listing or after listing), and clinical status at the time of wait listing (the highest priority Status 1A versus all others), black patients will experience worse transplant outcomes, including greater likelihood of delisting or waitlist mortality, and lower likelihood of transplant, compared with white candidates.

Methods

Data and sample

The UNOS STAR files contain information on all transplant candidates, transplant recipients, and deceased and living donors in the United States from the late 1980s through today (Organ Procurement & Transplantation Network 2017). Transplant professionals enter candidates' social, clinical, and geographic data into UNet, a database maintained by the Organ Procurement and Transplantation Network (OPTN). Candidate data are collected when a patient is first placed on the wait list, upon transplantation or waitlist removal, and during scheduled post-transplant follow-ups, if a transplant occurs. Our data are primarily taken from the heart transplant candidate registration forms, which are collected for all heart transplant candidates in the US when they are first registered on the heart waiting list.

We first limit our sample to the 6,284 black or white adult heart transplant candidates using LVADs upon wait listing, or who have an LVAD implanted within 30 days of being waitlisted between January 1999 (cf. Wever-Pinzon et al. 2013, including the early period where PF-LVADs were still in common use) and September 2014 (the beginning of clinical trials for the current,

third-generation LVAD devices). For a few patients with multiple device implantations reported, we focus on the most recent device implanted. Next, we exclude 319 candidates with temporary, bedside, or extracorporeal circulatory support devices, and 254 candidates for whom the specific device type was not reported. Finally, we use listwise deletion to exclude 161 candidates missing clinical or social variables at registration. Our final sample includes 5,550 black or white adult heart transplant candidates who entered the waiting list between January 1999-September 2014.

Measures

Waiting list outcome. Wait list outcomes are coded from the reasons given for wait list removal for each registered transplant candidate. Removal codes used to test our hypotheses include (1) transplant, (2) death while waitlisted, and (3) delisting due to worsening of condition. Those removed for improved condition or recovery are treated as censored. Candidates whose status was changed to inactive or who were still waitlisted at the time the most recent data were collected are also treated as censored.

Device type. We exclude candidates with extracorporeal, bedside, or temporary mechanical circulatory support devices rather than durable implanted LVADs. Durable CF-LVADs available during this period included the Heartmate II, the Jarvik 2000, the Heartware HVAD, the MicroMed DeBakey, and the Ventracor VentrAssist (Wever-Pinzon et al. 2013). Durable PF-LVADs during the same period included the Heartmate IP, Heartmate VE, Heartmate XVE, Thoratec IVAD, and Toyobo (Wever-Pinzon et al. 2013).

Late-implanted device. Devices that are implanted after the date of wait list registration, but within a month of registration, were considered late-implanted devices. In patients with end-stage heart-failure, early implantation of LVADs, relative to the disease course, can prevent clinical deterioration and improve survival to transplant (Gustafsson and Rogers 2017). By

contrast, later device implantation can represent a delayed intervention for patients expected to benefit from LVAD support; while device exchange (explanting an existing LVAD and replacing with a new LVAD) can be associated with device complications such as infection and clotting (Gustafsson and Rogers 2017). We excluded patients undergoing device implantation >30 days after wait listing to limit the possibility that late device implantation was associated with acute deterioration in clinical status, which was unforeseen at the time the patient was initially listed for transplant.

Control and explanatory variables. Clinical and social control variables were selected to be consistent with prior studies on heart transplant candidates with LVADs (see Wever-Pinzon et al. 2013) and include candidate age at wait listing, race-ethnicity, gender, primary diagnosis (ischemic cardiomyopathy, non-ischemic cardiomyopathy, or other diagnosis), type of insurance (public, private, other), whether the candidate is a smoker, diabetic, or has had prior cardiac surgery, whether the candidate is on life support or dialysis, UNOS wait list status (Status 1A, indicating greatest priority for donor organs, versus all others), use of inotropes, most recent serum creatinine level, blood type, and estimated body surface area (BSA), using the Mosteller formula (Mosteller 1987). Controlling for BSA is important when comparing the 2 generations of LVAD devices, as the smaller CF-LVAD devices could be implanted in a wider range of body sizes than the larger PF-LVADs.

Analytical strategy

Cross-tabulations are used to evaluate unadjusted differences across race in LVAD type, timing of implant, and wait list outcomes. Logistic regression is used to evaluate race differences in receiving a PF versus CF LVAD, as well as timing of LVAD implantation. Competing-risks

event history models are used to compare wait list outcomes, including mortality, receiving a transplant, and delisting (Tong et al. 2015; Wehbe et al. 2016).

Results

Race differences in device type and timing of implantation

Table 1 includes descriptive statistics by race and chi-square and t-tests for whether bivariate race differences are statistically significant. Prior to adjusting for clinical characteristics, we see that black transplant candidates are more likely to receive a continuous flow LVAD than their white peers; this difference is significant (p=.013). Black candidates are also more likely to receive a late-implanted device (24% versus 19%; p<.001). Many other clinical and social indicators also differ by race, and show that on average, white and black patients differ in diagnosis, age, timing of wait list registration, and primary form of payment, with black patients more reliant on government-funded health care. However, clinical variables do not show a consistent difference in disease severity between groups. Black candidates have higher serum creatinine (indicating impaired kidney function), and are more likely to be using inotropic medications (medications increasing muscle contractility to increase cardiac output), although white candidates are slightly more likely to have been diagnosed with diabetes, and are more likely to have undergone previous heart surgery. Notably, black and white candidates did not differ in the likelihood of being assigned Status 1A at listing, indicating similar priority for donor organs on the transplant wait list.

Table 2 is a logistic regression predicting LVAD type using Table 1 variables (excluding wait list outcome) as predictors. Model 1 of Table 2 indicates that adjusting for gender, age, and year added to waiting list, black and white heart transplant candidates needing left ventricular support were equally likely to receive a CF-LVAD. The equitable use of CF-LVADs persists after

adjusting for clinical and social variables in Model 2. Variables significantly associated with LVAD type were female sex, year registered on the waiting list, BSA, smoking status, dialysis, inotropic support, and waiting list status. This initial evidence points to equal allocation of this new technology, failing to support Hypothesis 1a. Because we observed no race differences in receipt of a CF-LVAD, we fitted a separate logistic regression model (not shown) predicting late-implanted CF-LVAD versus having a CF-LVAD implanted prior to wait list registration, testing Hypothesis 1b among only those with the newer, CF-LVADs. Adjusting only for age, year added to wait list, and gender, we found that black candidates were more likely to receive a late-implanted LVAD (OR = 1.25, p = .003). However, when controlling for inotrope use at wait listing in addition to the previously mentioned variables (results not shown), the race difference in CF-LVAD implant timing became non-significant (OR = 1.18, p = .051). Effectively, the black-white difference in delayed CF-LVAD implantation is associated with black patients being more likely than white patients to experience a change from medical management of low cardiac output (using inotropic medications to increase delivery of oxygenated blood to the body) to surgical management (LVAD implantation) soon after a candidate is listed for transplant. This result is consistent with our assumption that delayed CF-LVAD implantation within 30 days of waitlisting primarily represents a change in the treatment of an existing problem (low cardiac output), rather than treatment of an unforeseen deterioration in health status.

Race differences in wait list outcomes

We next examine the roles of race-ethnicity, LVAD type, and timing of implantation for wait list outcomes from 1999-2014 using multivariate competing risks event history models. We initially consider the independent associations of each factor with mortality, delisting, and transplantation.

Waiting list mortality

Models 1-3 of Table 3 show no race disparities in waiting list mortality. In Model 1, only age and year added to the waiting list are associated with mortality. In Model 2, we see that race is not associated with waiting list mortality, but a late implanted CF-LVAD increases the risk of waiting list mortality by 91%. Controlling for clinical and social indicators in Model 3, black candidates are equally likely to die waiting for a transplant as whites. However, in this model, female sex, year registered on the waiting list, late CF-LVAD implantation (more common among black patients), BSA, and clinical indicators were associated with mortality.

Delisting

Removal from the waitlist due to a worsening of condition is more common for black candidates, adjusting for LVAD type and timing. Model 1 of Table 4 shows that controlling for age, sex, LVAD type, and year registered on the wait list, black candidates are 27% more likely than whites to be delisted. Age, sex, and year added to wait list are also associated with delisting. Model 2 shows that both black candidates and candidates with late-implanted CF-LVADs are significantly more likely to be delisted than white candidates and candidates with devices listed at registration. In Model 3 of Table 4, adjusting for social and clinical factors reduces the black-white difference to nonsignificance, but candidates with late-implanted CF-LVADs, who were disproportionately black, were more than twice as likely to be delisted as candidates with CF-LVAD present at listing. Those with public insurance – which is more common among black candidates and is also associated with late CF-LVAD implantation – were 40% more likely to be delisted.

Transplant

Completion of a heart transplant is less common for black candidates. Controlling for age, sex, year added to wait list, and LVAD type, black candidates were 16% less likely to experience a heart transplant while waitlisted. In Model 2, black candidates remain less likely to receive a transplant. Those with late implanted CF-LVADs were significantly less likely to receive a transplant, but those with older PF devices were more likely to receive a transplant (possibly due to few candidates in this group still being on the wait list at the time of censoring in our analysis). In Model 3, we see that controlling for social and clinical characteristics, black candidates remain 11% less likely to receive a heart transplant relative to white candidates.

Supplemental analyses

We performed several supplemental analyses to add to our interpretation of the results described above. First, interactions between race and year of listing indicate that all estimated black-white differences presented in Tables 2-5 are constant over time. The race differences (or lack thereof) do not narrow for candidates wait listed in more recent years, notwithstanding the evolution and dissemination of new LVAD technology. We also fit models that controlled for patient educational attainment, but this was not a significant predictor of wait list outcomes, likely because of candidate selection criteria that tends to exclude the most socioeconomically disadvantaged candidates from the transplant waiting list (Dew et al. 2018). Finally, we tested interactions between race and the type and timing of LVAD, to determine whether late-implanted CF-LVADs or older style PF-LVADs were equally associated with waiting list outcomes for black and white patients alike. These interactions were not significant for waiting list mortality and delisting, indicating that black and white candidates experience equal risks related to late CF-LVAD implantation. For transplant, the interaction was significant: the negative impact of late CF-

LVAD implantation was slightly attenuated for black candidates (subhazard ratio of late vs. pre-listing CF-LVAD implantation = 0.61 x 1.20 = 0.73), but remained statistically significant ($p < .001$).

Discussion

As fundamental causes of disease, race and class stratify patients' access to health knowledge, financial resources, social support, and advanced medical technologies. In applying fundamental cause theory to LVAD technological advances, we found that black candidates' poorer outcomes on the transplant wait list persist despite equal access to new technologies. Specifically, in an era where PF-LVADs were replaced by superior CF technology, black candidates were more likely or as likely to receive a CF-LVAD as whites (H1a), but were less likely to receive this technology early in the disease course (H1b). Controlling for LVAD type and timing of implantation, we still found that black candidates were less likely to undergo a transplant and were more likely to be delisted due to a worsening condition (H2). These results point to continued racial disparities among heart failure patients that are not entirely related to evolution of mechanical circulatory support technology.

We also find some evidence of differences in treatment type by race in the period prior to or immediately following waitlisting. Black candidates were more likely to receive late-implanted CF-LVADs, but were also more likely to report inotrope use at listing. The greater likelihood of black patients to receive a pharmaceutical intervention for low cardiac output prior to receiving durable implanted LVAD support highlights the important role of intervention timing in shaping disease outcomes. Further attention should be given to the reasons for these treatment differences by race.

Racial disparities in heart failure may in fact be wider than what we show in our study. Some of the racial disparities related to heart failure mortality and eligibility for a heart transplant may not be reflected in these analyses because black patients may be disproportionately screened out of transplant eligibility. A recent review by Dew and colleagues (2018) describes consensus recommendations for patient screening procedures when determining eligibility for MCS implantation and heart transplant listing. The recommendations list several criteria that may disproportionately exclude black candidates from MCS devices and transplant candidacy. For example, treatment and medication non-adherence are seen as risk factors that may compromise eligibility for MCS devices or transplant, and black patients are far more likely than white patients to be reported by providers as nonadherent (Gerber et al. 2010; Zhang and Baik 2014). In addition, "social history", defined by lower educational attainment, poor literacy and health literacy, and receipt of public insurance, are also far more likely to exclude black as opposed to white candidates. By reducing the pool of eligible MCS and transplant recipients using seemingly colorblind yet highly racially stratified criteria, racial disparities among patients who receive LVADs can appear to be unrelated to racial bias, because this bias occurs earlier during the screening process for MCS implantation and transplant wait listing.

We add to the fundamental cause literature in several ways. First, our findings show that the issue of equal access to new medical technology is nuanced. It is not sufficient to simply measure whether groups are equally likely to receive a new intervention, technology, or treatment. We find that evidence that suggests while black and white individuals are equally as likely to ultimately receive LVAD technology, black heart transplant candidates are more likely to receive this intervention later in the disease course. This finding highlights the need for fundamental cause scholars to take into consideration the timing of intervention relative to disease progression,

particularly for social groups that are more likely to delay medical care. The context of heart transplantation also provides an example how public policy (e.g., CMS regulations for LVAD reimbursement) may inadvertently create differences in timing of medical intervention for groups more reliant on public health insurance.

Our findings also add greater insight into the argument that race and SES are "distinct processes of stratification" (see Williams et al. 2016: 410). Transplant waiting lists are a unique setting in which to demonstrate the complex role of race inequalities in health outcomes. In the particular case of heart transplant waitlists and access to technology, those with the greatest socioeconomic disadvantage are largely screened out of transplant eligibility, and may be unable to access MCS technology even when insured. Because patients considered eligible for transplant are pre-screened for financial and psychosocial stability, our analysis shows the persistence of racial inequalities even among a highly selective group of patients. We urge others to continue to explore the unique ways in which race acts as a fundamental cause of health inequalities by increasing focus on the social and cultural dimensions of health, including patient and provider interactions, health education, and network capital.

Limitations and conclusions

Our study has a few limitations worth noting. One limitation of the UNOS transplant data is limited information of the social support available to patients, their psychological health, labor force participation, and cognitive ability. These variables, however, are used as screening criteria to facilitate better transplant outcomes (see Dew et al. 2018). Second, we did not extend our analysis to the relatively new third generation (centrifugal flow) LVADs, which could have provided another timely perspective on outcomes of timing of delayed LVAD implantation. Despite these limitations, we add to fundamental cause and medical sociology literatures by

showing the role of race and structural racism in unequal transplant wait list outcomes, and encourage further research to eliminate these disparities among heart failure patients.

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Table 1: Descriptive statistics of variables across race, January 1999-September 2014

	Black	White	P for difference
Continuous-flow LVAD	90%	88%	**.013**
Female	29%	19%	**.000**
Age at registration (SD)	50 (13)	55 (12)	**.019**
Year registered on wait list (SD)	2011.1 (2.5)	2010.9 (2.6)	**.002**
Primary diagnosis			
Ischemic cardiomyopathy	19%	46%	
Non-ischemic cardiomyopathy	78%	45%	**.000**
Other diagnosis	4%	9%	
Device implanted after registration	24%	19%	**.000**
Body Surface Area (BSA) (SD)	2.08 (.28)	2.06 (.25)	**.017**
Most recent serum creatinine at registration (SD)	1.41 (.78)	1.26 (.62)	**.002**
Type O blood	51%	46%	**.001**
Current or former smoker	47%	57%	**.000**
Diabetes	30%	33%	**.036**
Ventilator life support	4%	4%	.986
Dialysis	2%	2%	**.039**
Inotropes at registration	25%	20%	**.000**
Prior cardiac surgery	49%	57%	**.000**
Wait list status at registration			
Status 1A	30%	31%	**.**384
Primary payment			
Private	40%	55%	
Government	59%	43%	**.000**
Other	1%	1%	
Wait list outcomes			
Transplant	63%	69%	
Mortality	9%	9%	
Delisted (too ill)	11%	9%	**.000**
Recovered (censored)	1%	2%	
Remains waitlisted (censored)	10%	6%	
Inactive (censored)	6%	5%	
Total (N)	1,562	3,988	5,550

Table 2. Logistic regression predicting continuous flow LVAD (reference = pulsatile flow LVAD) from January 1999-September 2014, Odds Ratios (N=5,550)

	Model 1		Model 2	
Black	.99		.94	
Age	1.00		1.00	
Female	2.60	***	2.02	***
Year registered on waitlist (centered at 2004)	2.61	***	2.68	***
Primary diagnosis (ref = ischemic cardiomyopathy)				
-Nonischemic CMP			1.16	
-Other			.83	
Body Surface Area			.38	***
Serum creatinine			1.06	
Type O blood			.91	
Current or former smoker			1.30	*
Diabetes			.89	
Ventilator life support			.89	
Dialysis			.29	**
Inotropic support			2.09	***
Prior cardiac surgery			.81	
Status 1A			.71	*
Primary payment (ref = private insurance)			1.05	
-public insurance			1.07	
-other payment			.91	

Note: + p<.10, *p<.05, **p<.01, ***p<.001, two-tailed tests.

Table 3. Competing risks event history models predicting wait list mortality by race, timing of implant, and LVAD type from January 1999-September 2014, Odds Ratios (N=5,550)

	Model 1		Model 2		Model 3	
Black	1.01		.98		.94	
Age	1.01	*	1.01	*	1.01	
Female	1.23	+	1.22	+	1.57	***
Continuous-flow LVAD	.78					
Year registered on wait list (centered at 2004)	.93	**	.92	***	.95	*
Type and timing of LVAD implant (ref = CF LVAD at listing)						
-CF-LVAD, late implant			1.91	***	1.47	**
-PF-LVAD at listing			1.24		1.21	
Primary diagnosis (ref = ischemic cardiomyopathy)						
-Nonischemic CMP					1.75	*
-Other					1.30	
Body Surface Area					1.21	*
Serum creatinine					.99	***
Type O blood					1.04	*
Current or former smoker					1.87	
Diabetes					1.13	
Ventilator life support					1.82	***
Dialysis					.89	
Inotropic support					1.04	***
Prior cardiac surgery					1.75	
Status 1A					1.30	
Primary payment (ref = private insurance)						
-public insurance					.99	
-other payment					1.13	

Note: + p<.10, *p<.05, **p<.01, ***p<.001, two-tailed tests.

Table 4. Competing risks event history models predicting delisting by race, timing of implant, and LVAD type from January 1999-September 2014, Odds Ratios (N=5,550)

	Model 1		Model 2		Model 4	
Black	1.27	*	1.23	*	1.17	
Age	1.02	***	1.02	***	1.02	**
Female	1.46	***	1.44	***	1.81	***
Continuous-flow LVAD	1.00					
Year registered on wait list (centered at 2004)	1.06	*	1.05	*	1.07	**
Type and timing of LVAD implant (ref = CF LVAD at listing)						
-CF-LVAD, late implant			1.93	***	2.11	***
-PF-LVAD at listing			.94		.88	
Primary diagnosis (ref = ischemic cardiomyopathy)						
-Nonischemic CMP					.71	**
-Other					.94	
Body Surface Area					1.57	*
Serum creatinine					1.17	**
Type O blood					1.33	**
Current or former smoker					1.10	
Diabetes					1.13	
Ventilator life support					2.65	***
Dialysis					1.59	
Inotropic support					.90	
Prior cardiac surgery					1.01	
Status 1A					1.00	
Primary payment (ref = private insurance)						
-public insurance					1.40	***
-other payment					1.48	

Note: + p<.10, *p<.05, **p<.01, ***p<.001, two-tailed tests.

Table 5. Competing risks event history models predicting transplant by race, timing of implant, and LVAD type from January 1999-September 2014, Odds Ratios (N=5,549)

	Model 1		Model 2		Model 3	
Black	.84	***	.85	**	.89	**
Age	1.00		1.00		1.00	
Female	.82	***	.84	***	.66	***
Continuous-flow LVAD	.65	***				
Late-implanted device						
Year registered on wait list (centered at 2004)	.98		.99		.98	*
Type and timing of LVAD implant (ref = CF LVAD at listing)						
-CF-LVAD, late implant			.61	***	.64	***
-PF-LVAD at listing			1.43	***	1.49	***
Primary diagnosis (ref = ischemic cardiomyopathy)						
-Nonischemic CMP					.52	***
-Other					.87	***
Body Surface Area					.64	***
Serum creatinine					.97	***
Type O blood					1.00	***
Current or former smoker					.42	
Diabetes					.89	
Ventilator life support					.83	***
Dialysis					1.13	
Inotropic support					1.52	***
Prior cardiac surgery					.52	**
Status 1A					.87	***
Primary payment (ref = private insurance)						
-public insurance					.95	
-other payment					.72	

Note: + p<.10, *p<.05, **p<.01, ***p<.001, two-tailed tests.