Original Study

ANNALS OF SURGERY OPEN

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The Public Health Service "Increased Risk" 2020 Policy Change Has not Improved Organ Utilization in the United States

A Nationwide Cohort Study

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Objective: To assess the effects of the 2020 United States Public Health Service (PHS) "Increased Risk" Guidelines update.

Background: Donors labeled as "Increased Risk" for transmission of infectious diseases have been found to have decreased organ utilization rates despite no significant impact on recipient survival. Recently, the PHS provided an updated guideline focused on "Increased Risk" organ donors, which included the removal of the "Increased Risk" label and the elimination of the separate informed consent form, although the actual increased risk status of donors is still ultimately transmitted to transplant physicians. We sought to analyze the effect of this update on organ utilization rates.

Methods: This was a retrospective analysis of the Organ Procurement and Transplantation Network database which compared donor organ utilization in the 2 years before the June 2020 PHS Guideline update for increased-risk donor organs (June 2018–May 2020) versus the 2 years after the update (August 2020–July 2022). The organ utilization rate for each donor was determined by dividing the number of organs transplanted by the total number of organs available for procurement. Student *t* test and multivariable logistic regression models were used for analysis.

Results: There were 17,272 donors in the preupdate cohort and 17,922 donors in the postupdate cohort; of these, 4,977 (28.8%) and 3,893 (21.7%) donors were considered "Increased Risk", respectively. There was a 2% decrease in overall organ utilization rates after the update, driven by a 3% decrease in liver utilization rates and a 2% decrease in lung utilization rates. After multivariable adjustment, donors in the postupdate cohort had 10% decreased odds of having all organs transplanted.

Conclusions: The 2020 PHS "Increased Risk" Donor Guideline update was not associated with an increase in organ utilization rates in the first 2 years after its implementation, despite a decrease in the proportion of donors considered to be at higher risk. Further efforts to educate the community on the safe usage of high-risk organs are needed and may increase organ utilization.

Keywords: donor organ utilization, increased risk organ donor, organ transplantation

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Disclosure: The authors declare that they have nothing to disclose.

DCP and SBW's research fellowships are funded in part by philanthropic contributions by the Martignetti and Corrigan Minehan families

The datasets generated during and/or analyzed during the current study are publicly available.

All authors have contributed significantly as defined by the Annals of Surgery and are deserving of authorship of this paper. D.C.P.: conception, design, data acquisition, analysis, interpretation, drafting, revising, approval. S.B.W.: conception, design, interpretation, revising, approval. D.G.: conception, design, drafting, revising, approval. S.N.T., L.A.D., N.E., S.A.R., E.M., D.A.D.: interpretation, revising, approval. A.A.O.: conception, design, interpretation, drafting, revising, approval.

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Annals of Surgery Open (2024) 1:e368

Received: 16 May 2023; Accepted 20 November 2023

Published online 8 January 2024

DOI: 10.1097/AS9.0000000000000368

INTRODUCTION

The number of patients awaiting organ transplantation continues to increase and outpace the supply of donor organs.[1,2] Novel methods to increase the supply of organs available for transplantation including donation after circulatory death,[3,4] machine perfusion of organs, and xenotransplantation[5] are being used to close this gap. Another option that has recently been introduced to increase the number of donor organs is the transplantation of organs from hepatitis C virus (HCV)-positive donors. Due to our improved ability to prevent, detect, and treat this disease, outcomes for these donor organs have been found to be comparable to HCV-negative donors.[6,7] Despite the accumulating evidence, HCV-positive donor organ utilization rates are still low.[8] Similarly, donors labeled as "Increased Risk", by the United States Public Health Service (PHS) for transmission of HIV, hepatitis B virus (HBV), or HCV have been found to have decreased organ utilization rates despite no significant impact on recipient survival.[9,10] In addition, patients who refuse to consent to a donor organ based on its "Increased Risk" status have been found to have decreased transplant rates and an increased risk of death on the waiting list.[11]

In response to the accumulating evidence that "Increased Risk" donor organs are safe to transplant and the increasing organ supply/demand mismatch, the United States PHS released a donor management guideline update in 2020, which removed the "Increased Risk" label from donors in

addition to several other changes involving this population in an effort to increase donor organ utilization.[12] The additional changes included the elimination of a separate "Increased Risk" donor informed consent form and process, a shortened timeframe during which high-risk criteria were considered (from 12 months preceding donation to just 1 month before donation), and the removal of several high-risk criteria, including women who had sex with a man who had sex with another man, newly diagnosed or treated syphilis, gonorrhea, chlamydia, or genital ulcers, hemodialysis, and hemodilution of the blood sample used for infectious disease testing.[12] By decreasing the number of individuals classified as "Increased Risk", it was believed that overall organ utilization might consequently increase. We hypothesized that there would be an increase in organ utilization 2 years after the 2020 PHS Guideline update.

METHODS

Study Population

This was a retrospective analysis of the Organ Procurement and Transplantation Network database comparing the organ utilization rates of deceased donors 2 years before and after the PHS Guideline update on June 26, 2020. This study was approved by the Mass General Brigham Institutional Review Board. A 1-month "washout" period was observed immediately before and after the update. In addition to donors who had missing data for organ disposition (n = 353), donation after circulatory death donors were excluded from analysis due to the changing overall rate of donation after circulatory death procurements, unpredictable patterns of expiration, variability in acceptance of organs based on warm ischemic time, and variability in procurement methods (n = 13,102).

Statistical Methods

We divided the study cohort into preupdate and postupdate cohorts. The overall organ utilization rate for each donor was determined by dividing the number of organs transplanted by the total number of organs available for procurement (1 heart, 2 lungs, 1 liver, and 2 kidneys for a maximum of 6/6). Organ-specific utilization rates were also calculated in a similar fashion by dividing the number of organs transplanted by the total number of organs available for procurement. For the heart and liver utilization rates, the denominator was 1 and therefore the possibilities for each donor were 0/1 (if not transplanted) or 1/1 (if transplanted). Split livers could not be excluded from the United Network for Organ Sharing deceased donor dataset, but upon query of the United Network for Organ Sharing liver dataset, there was no difference in the proportion of split liver transplants between preupdate (7.51%) and postupdate groups (7.83%, $P = 0.27$). For lungs and kidneys, the denominator was assumed to be 2, and therefore the possibilities for each donor were 0/2 (if neither lung was transplanted), 1/2 (if only 1 lung was transplanted), or 2/2 (if both lungs were transplanted). The utilization rates were considered as continuous data and analyzed using the student *t* test. A multivariable logistic regression model was fit to assess the odds of having all organs procured after the update. The same analysis was also performed with only donors identified as "increased risk" in the Organ Procurement and Transplantation Network database. A sensitivity analysis to assess for the delayed response to the update was performed by comparing the organ utilization rates during the second year of the update to the preupdate cohort. A two-sided P value < 0.05 was considered statistically significant. Data analysis was performed using *Stata Statistical Software: Release 17*. College Station, TX: StataCorp LLC.

RESULTS

All Donors

There were 17,272 donors in the preupdate cohort and 17,922 donors in the postupdate cohort. Table 1 displays donor characteristics; there were no clinically meaningful differences between the two groups despite their statistically significant differences due to increased power given the large cohort sizes. Figure 1 demonstrates the organ utilization rates before and after the 2020 PHS update. There was a 2% decrease in the overall donor organ utilization rate after the update (53% before *vs* 51% after, $P < 0.001$). By organ, liver utilization rate decreased by 3%, followed by lungs at 2%, and heart and kidney utilization both decreased by 1%. After adjusting for donor age, gender, HIV status, HCV status, and ABO blood type, donors in the postupdate cohort had a 10% decreased odds of having all organs transplanted compared to the preupdate cohort (OR, 0.90; 95% CI, 0.84–0.96; $P = 0.002$).

Increased Risk Donors

There were 4,977 (28.8%) and 3,893 (21.7%) increased risk donors in the preupdate and postupdate cohorts, respectively ($P < 0.001$). Figure 2 displays the "Increased Risk" donor organ utilization rates before and after the update. There was

TABLE 1.

Donor Baseline Characteristics

Characteristics	Pre-Update (n = 17,272)	Post-Update (n = 17,922)	P value
Age	41.2 ± 17.4	41.6 ± 16.8	0.02
Female	6,976 (40.4%)	6,998 (39.0%)	0.01
Increased Risk donor	4,977 (28.8%)	3,893 (21.7%)	<0.01
HIV positive	55 (0.3%)	70 (0.4%)	0.28
HBV core antibody	1,008 (5.8%)	1,108 (6.2%)	0.18
HCV antibody	1,852 (10.7%)	1,902 (10.6%)	0.74
HCV NAT +	1,172 (6.8%)	1,089 (6.1%)	<0.01
Intravenous drug use	2,393 (13.9%)	2,316 (12.9%)	0.01
ABO blood type			0.07
O	8,175 (47.3%)	8,737 (48.8%)	
A	6,384 (37.0%)	6,441 (35.9%)	
B	2,110 (12.2%)	2,135 (11.9%)	
AB	602 (3.5%)	609 (3.4%)	

HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; NAT, nucleic acid amplification test.

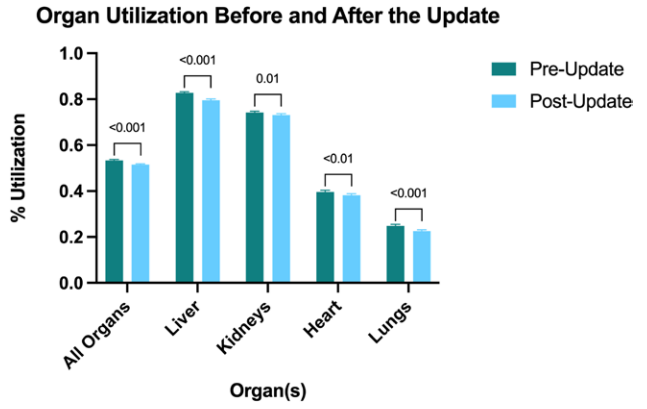

FIGURE 1. Organ utilization rates by organ. *P* values produced by Student *t* test.

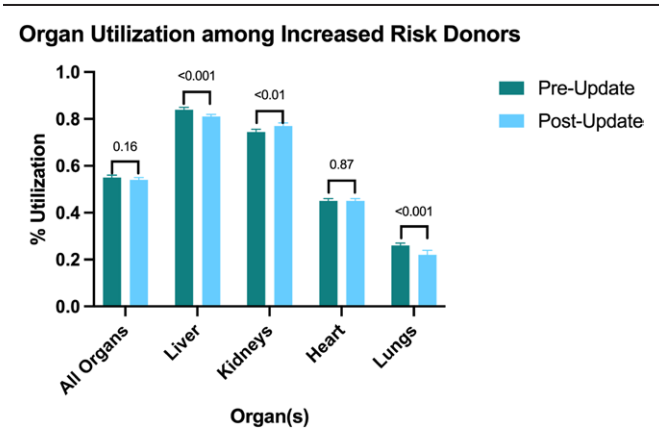

FIGURE 2. Organ utilization rates by organ in Increased Risk Donors only. *P* values produced by Student *t* test.

no difference in the overall IRS organ utilization rates before and after the update (55% preupdate *vs* 54% postupdate; $P = 0.16$). By organ, there was no difference in heart utilization (45% preupdate *vs* 45% postupdate; $P = 0.88$); however, there was a 4% decrease in lung utilization (26% preupdate *vs* 22% postupdate; $P < 0.001$), a 3% decrease in liver utilization (84% preupdate *vs* 81% postupdate; $P < 0.001$), and a 2% increase in kidney utilization (75% preupdate *vs* 77% postupdate; $P = 0.002$). After adjusting for donor age, gender, HIV and HCV serology, and ABO blood type, there was no difference in the odds of donors having all organs transplanted in the postupdate cohort compared to the preupdate cohort (OR, 0.94; 95% CI, 0.83–1.08; $P = 0.39$).

Sensitivity Analysis

To assess whether there was a delayed response in organ utilization increase following the update, we assessed whether there was an increase in organ utilization among those donors whose organ procurement occurred 1 year after the update (June 2021) through the remainder of the dataset (July 2022) compared to the organ utilization rates 2 years before the update. For the overall organ utilization rate, there was a decrease of 2% from 53% preupdate to 51% postupdate ($P < 0.001$). Similarly, by organ, there were 3% decreases in liver, kidney, and lung utilization ($P < 0.001$ for all 3), while there was no difference in heart utilization (39% preupdate *vs* 38% postupdate, $P = 0.51$).

COMMENT

As the organ transplant waiting list continues to grow, it is critical that we optimize the utilization of donor organs, including those who are considered "Increased Risk" to transmit infectious diseases such as HIV, HBV, or HCV. This study found donor organ utilization decreased by 2% following the 2020 United States PHS Guideline update, despite a significant decrease in the proportion of donors considered "Increased Risk". This decrease in organ utilization was observed across donor livers, kidneys, hearts, and lungs, and was confirmed with a sensitivity analysis, which also helps to account for secular changes that occurred with the onset of the pandemic. A subgroup analysis of "Increased Risk" donors found no difference in overall organ utilization before and after the update.

The 2020 US PHS Guideline update was associated with a 25% relative decrease in the proportion of donors considered "Increased Risk" to transmit HIV, HBV, or HCV, from 28.8% of all donors preupdate to 21.7% of donors postupdate. This finding alone should be considered a success of the update, especially considering the increasing temporal trend of drug intoxication-related death and organ donation.[13] However, a major supposition of this policy change was that a decrease in donors classified as "Increased Risk" would lead to an increase in organ utilization rates. At 2 years after the update, there was a 2% decrease in overall organ utilization rates compared to preupdate utilization rates, driven largely by decreases in liver (3%) and lung (2%) utilization. Among only "Increased Risk" donors, there was no difference in overall organ utilization rates; however, there was a 2% increase in the kidney utilization rate which, taken in the context of a decrease in utilization rates among all donors, may be a positive finding and suggest that "Increased Risk" donor organs are becoming less stigmatized as the evidence in favor of transplanting these organs continues to propagate. However, this was not observed for the other organs and thus continued research and education is needed.

These findings strengthen those from a study that found no difference in the utilization rate of donor hearts at 1 year after the 2020 PHS update by increasing the study period to 2 years after the update and extending the findings to include liver, kidney, and lung utilization.[14] While the authors recognize the PHS Guideline update is not responsible for the decrease in organ utilization rates, it is important to assess the effects of guideline updates to determine whether they achieved their intended objective, and if the update did not achieve its objective, to determine the potential causes and possible solutions. There are a number of possible explanations why donor organ utilization did not increase following the update. The first is that our analysis overlaps with the COVID-19 pandemic given the guideline implementation date of June 26, 2020; however, while there certainly was a decrease in the rate of organ transplantation in the United States associated with the COVID-19 pandemic,[15] the largest decrease in organ transplantation in the United States occurred between March 2020 and May 2020. By June 2020, the month during which the guideline update was implemented, organ transplantation in the United States had rebounded to prepandemic levels.[16] This finding suggests the pandemic may not be entirely to blame for the decrease in donor organ utilization rates after the update, although the trajectory of utilization may have been ultimately impacted. In addition, there were updates to the liver (April 2020) and kidney (March 2021) allocation policies which could have contributed to the study findings. However, these have both been found to have increased the number of transplants in postpolicy analyses, which would have supported an increase in organ utilization in the postupdate cohort though this was not observed.[17,18] Organ utilization rate, as opposed to the raw number of transplants (which continues to increase yearly), is a useful metric to highlight potential inefficiencies.[19]

Second, it is possible that barriers to accepting and transplanting "Increased Risk" donors still exist despite the update. The 2 major stakeholders in determining if an "Increased Risk" donor organ is utilized are the potential recipient and the physician. Likely, the removal of (1) the "Increased Risk" label that was previously used during the conversation with a potential recipient and (2) the separate "Increased Risk" informed consent for recipients has increased the number of recipients who consented to receive an organ but previously would have rejected an organ based on its "Increased Risk" designation. However, with regard to the physician, the actual increased risk status of donors is still ultimately transmitted to transplant physicians who decide to accept or reject the donor offer. Given the accumulating evidence of the benefit of transplanting "Increased Risk" donor organs,[10,11,20,21] it is essential that transplant professionals are educated of these benefits, given they have the authority to accept or decline an offer. Additionally, further studies, including surveys of transplant

physicians should be performed to assess for additional barriers to transplanting these organs. Finally, improving the dissemination of guideline updates to transplant physicians may be necessary. Given the limited donor pool and growing waitlist, it is critical that we maximize our opportunities to utilize donor organs.

Limitations

Our study is not without limitations which include its retrospective nature and inability to account for unmeasured confounding; however, we used multivariable logistic regression models to adjust for important known variables. Our study does not assess the outcomes of the recipients of Increased Risk donor organs; however, prior research has demonstrated that "Increased Risk" donor classification has no significant impact on adult heart transplant recipient survival probability.[10] We are unable to know how quickly this guideline was implemented at US transplant centers, which may affect the results, which is why we incorporated a 1-month "washout" period before and after the guideline date to attempt to account for a delay in guideline uptake by transplant centers and performed a sensitivity analysis 1 year after the update was implemented. The study period overlapped with the COVID-19 pandemic and allocation changes for kidney and liver, which may have impacted the results; however, the rates of organ transplantation in the United States had rebounded to prepandemic levels before the guideline implementation date, and therefore it is unlikely that the lower utilization rates of the postupdate cohort can be solely explained by the pandemic. Finally, this study only assesses donors considered for procurement by the organ procurement organizations.

Conclusions

The 2020 US PHS Guideline update related to increased risk designation and stratification decreased the number of individuals considered to be "Increased Risk" donors; however, this did not result in a subsequent increase in the organ utilization rate 2 years after its implementation. The utilization of "Increased Risk" donor organs continues to be low, and given the known benefit of transplanting these organs, barriers to "Increased Risk" donor organ transplantation should be further examined.

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