Decade-Long Trends in Liver Transplant Waitlist Removal Due to Illness Severity: The Impact of Centers for Medicare and Medicaid Services Policy

Natasha H Dolgin, PhD, Babak Movahedi, MD, PhD, Paulo NA Martins, MD, PhD, Robert Goldberg, PhD, Kate L Lapane, PhD, MS, Frederick A Anderson, PhD, Adel Bozorgzadeh, MD, FACS

BACKGROUND: The central tenet of liver transplant organ allocation is to prioritize the sickest patients first. However, a 2007 Centers for Medicare and Medicaid Services regulatory policy, Conditions of Participation (COP), which mandates publically reported transplant center performance assessment and outcomes-based auditing, critically altered waitlist management and clinical decision making. We examine the extent to which COP implementation is associated with increased removal of the "sickest" patients from the liver transplant waitlist.

STUDY DESIGN: This study included 90,765 adult (aged 18 years and older) deceased donor liver transplant candidates listed at 102 transplant centers from April 2002 through December 2012 (Scientific Registry of Transplant Recipients). We quantified the effect of COP implementation on trends in waitlist removal due to illness severity and 1-year post-transplant mortality using interrupted time series segmented Poisson regression analysis.

RESULTS: We observed increasing trends in delisting due to illness severity in the setting of comparable demographic and clinical characteristics. Delisting abruptly increased by 16% at the time of COP implementation, and likelihood of being delisted continued to increase by 3% per quarter thereafter, without attenuation ($p < 0.001$). Results remained consistent after stratifying on key variables (ie, Model for End-Stage Liver Disease and age). The COP did not significantly impact 1-year post-transplant mortality ($p = 0.38$).

CONCLUSIONS: Although the 2007 Centers for Medicare and Medicaid Services COP policy was a quality initiative designed to improve patient outcomes, in reality, it failed to show beneficial effects in the liver transplant population. Patients who could potentially benefit from transplantation are increasingly being denied this lifesaving procedure while transplant mortality rates remain unaffected. Policy makers and clinicians should strive to balance candidate and recipient needs from a population-benefit perspective when designing performance metrics and during clinical decision making for patients on the waitlist. (J Am Coll Surg 2016; 222:1054–1065. © 2016 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

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From the Department of Surgery, Division of Organ Transplantation, UMass Memorial Medical Center (Dolgin, Movahedi, Martins, Bozorgzadeh), Department of Quantitative Health Sciences, Clinical and Population Health Research (Dolgin, Goldberg, Lapane), and Department of Surgery, Center for Outcomes Research, University of Massachusetts Medical School (Dolgin, Anderson), University of Massachusetts, Worcester, MA.

Correspondence address: Natasha H Dolgin, PhD, Department of Quantitative Health Sciences, University of Massachusetts Medical School, Albert Sherman Center, 8th Floor, 55 Lake Ave, Worcester, MA 01655. email: natasha.dolgin@umassmed.edu

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Abbreviations and Acronyms
CMS = Centers for Medicare and Medicaid Services
COP = Conditions of Participation
MELD = Model for End-Stage Liver Disease
SRTR = Scientific Registry of Transplant Recipients

The current Model for End-Stage Liver Disease (MELD)-based liver allocation system was introduced in 2002 in response to rising waitlist mortality in the setting of increasingly limited resources (ie, organs) relative to rising demand. The system is based on the fundamental principle that scarce resources should be allocated to those most in need ("sickest first"). Although waitlist mortality has stabilized since its introduction, removal of patients "too sick to transplant" has been on the rise.[1-8] This clinical decision invariably results in patient death without a transplant; an estimated 80% will die within 2 weeks of waitlist removal.[7]

The MELD score, calculated using 3 laboratory values (ie, creatinine, international normalized ratio, and bilirubin), is used to rank candidates within transplant centers' waiting lists. It allows the local or regional organ bank to easily and objectively sort potential recipients of a new organ offer. However, the composition of waiting lists and decisions on whether to accept or reject an organ once offered are made at the level of the transplant center. These decisions take into account not only the risk status of the patient and organ, but are also affected by institution-level financial pressures and potential regulatory consequences of high-risk transplantation.[9-11]

In 2007, the Centers for Medicaid and Medicare Services (CMS) implemented the Conditions of Participation (COP) policy.[12,13] This regulatory policy uses Scientific Registry of Transplant Recipient (SRTR)-generated transplant program-specific performance reports to audit and publically report "underperforming" transplant centers. This puts centers at risk for losing contracts with CMS and exclusion from private insurance "Centers of Excellence" networks, among other consequences.[14,15] However, the policy only evaluates post-transplant survival. Without the consideration of waitlist outcomes, COP has led to unintended consequences for patients. Centers that have been flagged as "underperforming" have been shown to exhibit risk aversion with respect to candidate and donor selection,[9,10,14,16-24] decreased waitlist and transplant volume,[20,25] and prolonged waiting times.[26,27] These changes ultimately result in reduced access to essential resources for patients, changing definitions of transplant "futility" toward conservatism, and conflict with the central tenet of modern transplant allocation: to prioritize the sickest patients first.

The purpose of this study was to evaluate whether known effects of COP flagging at the transplant center level translate to meaningful changes in waitlist dynamics at the national level. Specifically, we use more than a decade of comprehensive national data to describe and quantify the extent to which trends in candidate waitlist removal for being "too sick to transplant" were altered in the short- and long-term after implementation of the COP policy. In addition, we will examine whether COP implementation resulted in worse overall (waitlist and post-transplant) population survival.

METHODS

Study population

This study used data from the Scientific Registry of Transplant Recipients (SRTR). The SRTR data system includes data on all donors, wait-listed candidates, and transplant recipients in the United States, submitted by the members of the Organ Procurement and Transplantation Network (OPTN). The Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services provides oversight to the activities of the OPTN and SRTR contractors.

This quasi-experimental (retrospective) study included adults (aged 18 years and older) on US deceased donor liver transplant waitlists for first liver transplant between April 1, 2002 and December 31, 2012, inclusive (Fig. 1). Patients listed with hepatocellular carcinoma were excluded because, for this indication, waitlist removal due to condition deterioration is primarily based on objective measures of tumor progression (Milan criteria) and these patients are removed by mandate rather than clinical judgment. In addition, allocation policies changed multiple times during the course of the study period for these patients.[28,29]

Patients listed at transplant centers with very small or fluctuating waitlist volumes, as defined in earlier literature,[30] where each quarter that a candidate was on the waiting list was counted as a unique observation, were excluded (Fig. 1). For patients listed at multiple centers, one record was chosen at random using a computer-generated randomization schema.

Comparison groups

The key intervention of interest was implementation of CMS COP on June 28, 2007.[16] Our intervention group consisted of observations occurring after COP implementation (July 1, 2007 through December 31, 2012).

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