This timely new book, written by a transplant administrator with over sixteen years of experience, along with other expert contributors, covers the specifics of each aspect of transplant administration. Information is provided that will enable new administrators to quickly master essentials, help more seasoned administrators evaluate and improve their programs, and generally provide a knowledge base, focused on best-practices in light of regulatory requirements, for transplant surgeons, aspirant administrators and hospital administrators.

- Comprehensively covers all aspects of transplant program administration, including management, finance, staffing, quality improvement, patient intake, communication and collaboration with clinical staff, and more.
- Emphasizes practical application of best practices; uses bullet lists and other features to highlight essential information for each topic covered.
- Accompanying “Toolkit”, available via the book’s companion website, provides forms, a procedural manual, program assessment materials and more which buyers can use “out of the box” or adapt for use in their own program.

While the book and its supplemental materials have been created specifically with the US transplant community in mind, they still have considerable value for transplant administrators and related professionals outside the US. For instance, transplantation and health policy researchers, hospital management staff who are tasked with starting a transplant program from scratch and who need ready-made materials they can adapt to suit their own regulatory environment, and others.

This book is accompanied by a companion website: www.wiley.com/go/norris/transplantadmin

The website includes the online tools:
- Admin policies
- Clinical policies
- Kidney policies
- Other organ policies
- Web content forms

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Transplant Administration

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Transplantation as a field of medicine is a fairly new one with most of the major developments occurring within the past 40 years. As barriers to organ rejection were overcome with new immunosuppressive drugs, transplant programs began to form with surgeons, physicians, and nurses coming together to clinically manage patients.

Professional organizations and governmental regulation grew in parallel to the developing field of transplantation. With the regulatory and organizational complexity of the field expanding, administrative tasks became excessively burdensome for physicians and clinical staff. At this time, most transplant centers were within academic medical centers, therefore the surgery division managers took responsibility over all transplant administrative activity. The major tasks focused on billing, collections, budgeting, personnel management, and CMS program submissions. With the advent of managed care, increased regulatory scrutiny, and computerized medical records and data management, the scope of the division manager grew exponentially and the position of transplant administrator was created which encompassed both the cardiothoracic and abdominal transplant programs. A variety of other roles were created to support all the functions necessary to operate the program: financial coordinators, database administrators, financial analysts, contracting specialists, operations managers, and others. Managing this complexity combined with understanding the unique aspects of transplantation is integral to the success of any transplant program.

Transplant Administration is the first book to focus exclusively on the business aspects of transplantation. It is intended to be a resource for anyone wanting to gain an in-depth understanding of this complex field: senior hospital leaders, seasoned and/or novice transplant administrators, physicians, reimbursement professionals, managed care staff, or clinical staff. The goal of this book is to provide the reader with practical and detailed guidance in leading the transplant enterprise. The chapters outline the various business disciplines that are necessary to master with an emphasis on how they relate specifically to the field of transplantation. Content is based on experience, observation of successful transplant programs, and a survey.
of the published literature. Ideas, suggestions, examples, and tools are also provided that can be immediately put to use.

**Book Overview**

Chapter 1 focuses on the history of organ allocation, the creation of the United Network for Organ Sharing, and how transplant oversight and policy developed. The current state of organ allocation in the United States is explained detailing upcoming changes in allocation policy.

Chapter 2 describes the various organizational structures of transplant programs and their advantages and disadvantages with special emphasis on the growing trend of transplant institutes.

Chapter 3 concerns the management of transplant human resources from planning the workforce to recruitment and retention of these valuable and highly specialized personnel. A discussion of compensation and medical directorships is of particular interest.

Chapter 4 explores the various issues of the transplant clinical enterprise that affect the efficiency and profitability of the transplant program. These issues range from increasing the efficiency of evaluation to appropriate documentation and billing in transplant clinic.

Chapter 5 is a comprehensive review of the history and development of regulatory oversight of transplant programs and its current state. The emphasis of this chapter is on ensuring compliance within the program with an explanation of how a program can navigate the consequences of not achieving compliance.

Chapter 6 covers the financial aspects of transplantation which are unique within healthcare due to the way Medicare reimburses pre-transplant activity through the Medicare cost report. The steps to ensure accurate and complete capture of all costs are explained in detail, as well as monitoring financial performance and profitability.

Chapter 7 offers practical explanation and advice on transplant managed care contracting. The reader is taken through the steps of this process, how managed care organizations (MCO) operate, contracting basics, and the strategies that lead to a successful partnership between the MCO and the transplant program.

Chapter 8 is focused on quality and performance improvement of transplant programs and how this has become a focal point for regulatory agencies. The chapter explains how to form a quality and performance improvement program, what the regulators are looking for and how to manage any real or potential adverse events.

Chapter 9 deals with the data requirements of a transplant program and how they are developed and managed. The history of the Scientific
Preface

Registry of Transplant Recipients is discussed along with how data requirements shape the operations and viability of programs.

Chapter 10 examines the importance of establishing strategic direction for the transplant enterprise and how that influences organizational structure, marketing, profitability, and future success.

Chapter 11 presents an overview of leading and managing a transplant program, the difference between the two, and the leadership skill sets that must be mastered. Also covered is succession planning and why it is important for a thriving transplant enterprise.

Online tools are also provided with this book which can be found at www.wiley.com/go/norris/transplantadmin

Lisa Norris
Acknowledgments

I have recognized the need for a book on the business of transplantation for many years and hoped that one of my colleagues would take on the task. However, with the field of transplantation in such flux and change, I realized that a book should be published now more than ever. As I started on this journey, I received much encouragement and support from my business colleague, Frank Greaney. I am grateful for his insight and patience. Many thanks to my friends at the Cleveland Clinic and to Art Thomson for his enormous help with this project and his review of the drafts of this manuscript.

Of course, I want to acknowledge my contributors who have spent countless hours writing and editing their work for this book: Kenneth Andreoni, Ciara Samana, Mindy Scharlin, Marguerite Brown, and Lauren E. Kearns. I greatly appreciate their wisdom and expertise—without their contributions, this book would not be complete.

I also want to thank the publishing professionals at Wiley Blackwell, particularly my Editor, Thomas Hartman, who adeptly guided me through the publishing process with sage advice and assistance, and Julie Elliott, my Development Editor.

Last, but not least, I want to thank the many transplant professionals with whom I have had the privilege to work with and know during the past 20 years. The learning and knowledge that I have gained as a result of this network of professional colleagues cannot be measured.
About the Companion Website

This book is accompanied by a companion website:

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- Kidney policies
- Other organ policies
- Web content forms
CHAPTER 1
Organ Allocation: NOTA, the OPTN, and Policy Development

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The history: why did deceased donor allocation begin?

Successful kidney transplantation began in 1954 between identical twin brothers at Peter Bent Brigham Hospital. In 1958, immunosuppression was successfully used for renal transplants in fraternal twins. Non-twin siblings were transplanted in 1960 and then non-siblings in 1961. The year 1962 saw the first successful transplant using a deceased donor kidney allograft with the introduction of azathioprine. The Uniform Anatomical Gift Act allowed those aged 18 and over to donate their organs upon death in 1968. The year 1972 saw the discovery of cyclosporine, with its introduction to patient use in 1983. With the introduction of cyclosporine, the early success due to improved acute rejection rates in deceased donor transplantation was dramatic, and the modern era of solid organ transplantation began and expanded to other extra-renal organs.

In the early and mid-1960s, as individual transplant centers originated and developed their associated hospital-centered organ procurement organizations (OPOs), there was a very high rate of early severe rejection and graft loss in deceased donor kidney transplants. The early transplant pioneers in this pre-cyclosporine era understood that they could not easily overcome the immunological barriers of greatly mismatched organs. The odds of finding well-matched organs for their small patient lists with their few local donors were scant. They saw success with better genetically or HLA (human leukocyte antigen)-matched living donor organs and attempted to extend this to deceased donor transplantation by joining together with other transplant centers and their local OPOs to better the odds of their patients finding well-matched deceased donor organs. David Hume and Bernard Amos began the effort as SEROPP, the South-Eastern Regional Organ Procurement Program. This effort expanded to eight
transplant centers in the Southeast and became SEOPF, the Southeastern Organ Procurement Foundation. Soon, other adjacent centers sought membership in SEOPF, and this membership organization began to grow. SEOPF developed the Kidney Center that assisted with deceased donor kidney matching 24 hours a day. Eventually, this was renamed the United Network for Organ Sharing, UNOS. As government regulation became formal through the development of the National Organ Transplant Act (NOTA), UNOS separated from SEOPF as a not-for-profit organization; so it could apply for the Organ Procurement Transplantation Network (OPTN) and Scientific Registry for Transplant Recipients (SRTR) contracts created in NOTA and administered by the Health Resources and Services Administration (HRSA) of the US Department of Health and Human Services (HHS). UNOS remains a membership organization consisting of transplant centers, OPOs, donor families, organ recipients and candidates, prior living donors, and others interested in organ transplantation. The Kidney Center celebrated 30 years of continuous operation in 2012 [1].

Organ allocation

Organ allocation in the United States is governed by a complex, multifaceted set of policies. These policies are used to program the national allocation system by which candidates are identified and prioritized for organ offers. There are many players in the field of organ transplantation, and the field is highly regulated at multiple levels. At the federal level, NOTA and OPTN Final Rule set the requirements for policy development. These requirements are executed by the OPTN Board of Directors and its 20 committees (Figure 1.1) in the development of policies. Policies are developed collaboratively within the committee and Board structure, with input and comment provided by the transplant community, general public, and HRSA representation. The regulatory requirements,

- Ad hoc Disease Transmission Advisory
- Ad hoc International Relations
- Ethics
- Executive
- Finance
- Histocompatibility
- Kidney Transplantation
- Liver and Intestinal Organ Transplantation
- Living Donor
- Membership and Professional Standards
- Minority Affairs
- Operations and Safety
- OPO
- Pancreas Transplantation
- Patient Affairs
- Pediatric Transplantation
- Policy Oversight
- Thoracic Organ Transplantation
- Transplant Administrators
- Transplant Coordinators

Figure 1.1 OPTN/UNOS Committees.
Organ allocation for kidney, pancreas, and liver grafts has traditionally followed the concept of “local, then regional, then national” allocation. The local unit of allocation generally involves the center(s) served by an individual OPO. The country has traditionally been divided into 11 regions as seen in Figure 1.2. The regions are based mainly from historic sharing arrangements. Heart and lung allocation has transitioned to a concentric circle model centered on the location of the donor hospital. The zones include the transplant hospitals that are 500, 1000, 1500, and 2500 nautical miles from the donor hospital. The remaining chapter discusses the regulatory and ethical frameworks that guide the development of organ allocation policies.

**Regulations governing organ transplantation**

**National Organ Transplant Act (NOTA)**

The NOTA was passed in 1984 when the Congress recognized the need for a transplantation network. NOTA is the regulation that established the OPTN and the SRTR. NOTA called for the OPTN and SRTR contracts to be operated by a private, non-profit organization(s) under federal contract.

The OPTN is a unique public–private partnership that links all of the professionals involved in the donation and transplantation system. The primary goals of the OPTN are to

- increase the effectiveness and efficiency of organ sharing and equity in the national system of organ allocation;
- increase the supply of donated organs available for transplantation.
The UNOS, based in Richmond, Virginia, administers the OPTN contract. The SRTR contract is administered by the Chronic Disease Research Group of the Minneapolis Medical Research Foundation. The HRSA of the US Department of HHS is the issuing agency for both contracts.

The OPTN acts through its Board of Directors. The current UNOS Board also presently serves as the OPTN Board of Directors, with the addition of HRSA representatives to complete the OPTN Board. Board members, chosen through an open, comprehensive nomination process, bring a wealth of commitment and technical knowledge to guide the OPTN in establishing and maintaining policies and procedures for the field of transplantation [2].

Organ Procurement and Transplantation Network (OPTN) Final Rule
Effective March 16, 2000, the Department of HHS implemented a Final Rule establishing a regulatory framework for the structure and operations of the OPTN. Under the terms of the Final Rule, policies intended to be binding upon OPTN members are developed through the OPTN Committees and Board of Directors and then submitted to the Secretary of HHS for final approval.

Among other items, the OPTN Final Rule addresses the organization of the OPTN, membership, policies, listing requirements, organ procurement, identification of recipients, allocation of organs, designated transplant program requirements, and reporting requirements.

With regard to allocation of organs, the Final Rule has requirements for policy development. Allocation policies shall
- be based on sound medical judgment;
- preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient . . . ;
- be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;
- be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;
- be reviewed periodically and revised as appropriate;
- include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program’s application of the policies to patients listed or proposed to be listed at the program;
- not be based on the candidate’s place of residence or place of listing, except to the extent required [by points 1–5 above]” [3].
Responsibilities of OPTN

The OPTN helps ensure the success and efficiency of the US organ transplant system. OPTN responsibilities include

- facilitating the organ matching and placement process through the use of the computer system and a fully staffed Organ Center operating 24 hours a day;
- developing consensus-based policies and procedures for organ recovery, distribution (allocation), and transportation;
- collecting and managing scientific data about organ donation and transplantation;
- providing data to the government, the public, students, researchers, and the Scientific Registry of Transplant Recipients, for use in the ongoing quest for improvement in the field of solid organ allocation and transplantation;
- developing and maintaining a secure Web-based computer system, which maintains the nation’s organ transplant waiting list and recipient/donor organ characteristics (UNETSM and DonorNetSM);
- providing professional and public education about donation and transplantation, the activities of the OPTN, and the critical need for donation [4].

Under federal law, all US transplant centers and OPOs must be members of the OPTN to receive any funds through Medicare. Other members of the OPTN include independent histocompatibility laboratories involved in organ transplantation; relevant medical, scientific, and professional organizations; relevant voluntary health and patient advocacy organizations; and members of the general public with a particular interest in donation and/or transplantation.

Responsibilities of the Scientific Registry of Transplant Recipients

The Scientific Registry of Transplant Recipients is a national database of statistics related to solid organ transplantation—kidney, liver, pancreas, intestine, heart, and lung. The SRTR contract was administered by UNOS until 2000, then the Arbor Research Collaborative for Health with the University of Michigan until 2010, and currently by Chronic Disease Research Group of the Minneapolis Medical Research Foundation.

The registry covers the full range of transplant activity, from organ donation and waiting list candidates to transplant recipients and survival statistics. Its purpose is to
- support the development of sound policy;
- encourage research on issues of importance to the transplant community;
- facilitate responsible analysis of transplant programs and OPOs.

Data in the registry are collected by the OPTN from transplant hospitals and OPOs across the country. The SRTR supplements this information by using the Social Security Master Death Data Base and Medicare database for potential re-initiation of renal replacement therapy via dialysis [5]. SRTR data will be discussed further in Chapter 9.

**Ethical frameworks used in organ allocation policy development**

In 1994, the OPTN/UNOS Board of Directors approved a set of guidelines for creating equitable organ allocation policies. The statement describes how organ allocation policies should balance the principles of utility (i.e., the net medical benefit to all transplant patients as a group) and justice (i.e., equity and distribution of the benefits and burdens among all transplant patients) [6].

The OPTN policy for equitable organ allocation *strikes a balance* among the following principles. The policy must

1. enhance the overall availability of transplantable organs;
2. allocate organs based on medical criteria, striving to give equal consideration to medical utility (i.e., *net* medical benefit to all transplant patients as a group) and justice (i.e., equity in distribution of the benefits and burdens among all transplant patients);
3. provide transplant candidates reasonable opportunities to be considered for organ offers within comparable time periods, taking into consideration similarities and dissimilarities in medical circumstances as well as technical and logistical factors in organ distribution;
4. respect autonomy of persons.

The goal of the OPTN organ allocation system is to achieve, *in balance with one another*, the following objectives:

1. Maximize the availability of transplantable organs by
   a. promoting consent for donation;
   b. enhancing procurement efficiency;
   c. minimizing organ discards;
   d. promoting efficiency in organ distribution and allocation.
2. Maximize patient and graft survival.
3. Minimize disparities in consistently measured waiting times until an offer of an organ for transplantation is made among patients with similar or comparable medical/demographic characteristics. (At the