About This CME/CE Activity

RATIONALE AND PURPOSE

No matter how skillful and successful the transplant of a solid organ is performed, all the efforts expended by the transplant team before, during, and after surgery will be wasted if infections, hypertension, and other long-term transplant complications are not prevented or controlled or if the organ recipient fails to adhere to the immunosuppressive regimen prescribed.

This edition of *The Immunology Report* looks at these important issues facing the transplant community in its struggle to prevent acute and long-term rejection and graft loss. Based on selected clinical studies and other research presented at the 2013 American Transplant Congress, which was held May 18–22, 2013, in Seattle, Washington, the reports address the causes, recognition, and management of antibody-mediated rejection in kidney transplant recipients; the prevention and management of infections, hypertension, and other medical complications of transplantation; and current and emerging strategies for quantifying and improving patient adherence to prescribed immunosuppressive medications.

Among the many topics considered are the role of newer therapies that target specific components of the immune response, such as belatacept and eculizumab, and personalized treatment of liver transplant recipients; the reasons that patients do not adhere to their doctors' and nurses' recommendations for immunosuppressive therapy; the consequences of nonadherence; and strategies to improve adherence and thereby achieve optimal graft and patient outcomes. Other important topics include issues related to the use of modern immunosuppressants and their management, the development of new formulations of established medications to improve adherence, the risk factors for allograft failure, and methods to improve clinical outcomes by battling health illiteracy and using technology. Finally, this edition highlights laboratory research involving pathways of the immune response and clinical discoveries that provide new dimensions for everyday therapy and directions for future research.

The articles in this edition, written from the academic perspective of physicians in training, a pharmacist, and a transplant coordinator at leading medical centers, summarize the import of these new findings and place them into clinical context. This activity has been developed and approved by a planning committee of nationally recognized thought leaders to meet a perceived educational need to provide immunologists, transplant specialists, and other healthcare professionals with the latest knowledge and tools to help them perform their roles.

LEARNING OBJECTIVES

After studying this issue of *The Immunology Report,* participants in this educational activity should be able to:

- Describe the rationale for current immunosuppressive regimens and obstacles in the way of medication adherence.
- Summarize the basics of T- and B-cell regulation, antibody-mediated rejection, and other phenomena related to the immune response and graft survival.
- Explain how both humoral factors and behavioral obstacles may adversely affect graft and patient survival following organ transplant.
- Summarize the prevention and management of infections, hypertension, and other complications of transplantation.
- Review current and emerging strategies for improving patient education and adherence to immunosuppressive medication.

TARGET AUDIENCE

Immunologists and other physicians significantly involved in organ transplantation, transplant nurses, transplant coordinators, pharmacists, and transplant case managers should find participation in this educational activity valuable.

ACCREDITATION AND CREDIT DESIGNATION

Physicians: This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the University of Cincinnati and Direct One Communications, Inc. The University of Cincinnati is accredited by the ACCME to provide continuing medical education for physicians.

The University of Cincinnati designates this Enduring Material Activity for a maximum of 3.0 *AMA PRA Category 1 Credits*™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Transplant nurses and coordinators: The American Board for Transplant Certification (ABTC) has approved this educational offering for up to 3.0 Category I Continuing Education Points for Transplant Certification (CEPTCs). The ABTC approval number is 765.

Pharmacists: Northeastern University Bouvé College of Health Sciences School of Pharmacy is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. This activity is approved for 3.0 credit hours (0.30 CEU). The ACPE activity number is 0027-9999-13-067-H01-P, the initial release date is August 19, 2013, and the expiration date is August 19, 2016.

Case managers: This program has been pre-approved by the Commission for Case Manager Certification to provide continuing education credit to Certified Case Managers (CCMs). Expiration date: August 2, 2014.

CME/CNE CREDIT AVAILABILITY

Activity release date: August 19, 2013
Expiration date: August 20, 2014

METHOD OF PARTICIPATION

This Enduring Material Activity is available both in print and online at

www.ImmunologyReport.com and consists of an introduction, seven articles, a postactivity assessment, and an evaluation. Estimated time to complete the activity is 3.0 hours.

To receive credit, participants must read the CME/CE information on these two pages, including the learning objectives and disclosure statements, as well as the full content of this monograph, and then complete the post test and evaluation form online at www.ImmunologyReport.com. Upon successful completion of the post test (80% correct) and evaluation form, a CME/CE certificate of participation will be awarded automatically. The certificate may be printed directly from the Web site or e-mailed and printed later.

There are no fees for participating in or receiving credit for this activity.

CME REVIEWER

Rick Ricer, MD
Adjunct Professor of Family Medicine
University of Cincinnati
Cincinnati, Ohio

CME ACCREDITATION

Susan P. Tyler, MEd, CMP, CCMEP
Director, Continuing Medical Education
University of Cincinnati
Cincinnati, Ohio

CPE ACCREDITATION

Anita Young, EdD, RPh
Director, Continuing Pharmacy Education
Northeastern University Bouvé College of Health Sciences School of Pharmacy
Boston, Massachusetts

FACULTY DISCLOSURES

All faculty members (or anyone else in a position to control content, such as activity planners) are required to complete a Disclosure of Commercial Interest and Resolution form and to cooperate with identified methods for resolving conflict of interest prior to participating in the activity. The University of Cincinnati requires disclosure to the learners of all relevant financial relationships and adheres strictly to the ACCME Standards for Commercial Support.

Jorge D. Reyes, MD, is Roger K. Giesecke Distinguished Chair and Professor of Surgery and Chief of Transplant Surgery, University of Washington Medical Center, Seattle, Washington. He has nothing to disclose.

Malcolm P. MacConmara, MB, BCh, BAO, a Fellow in Transplant Surgery at Emory University Hospital, Emory University School of Medicine, Atlanta, Georgia, has nothing to disclose.

Shree Patel, PharmD, BCPS, a Solid Organ Transplant Pharmacy Resident and Clinical Instructor at the University of Illinois Hospital and Health Sciences System, Chicago, Illinois, has nothing to disclose.

Martin I. Montenovo, MD, an Abdominal Transplant Fellow at the University of Washington Medical Center, Seattle, Washington, has nothing to disclose.

Kasi R. McCune, MD, a Clinical Instructor and Abdominal Transplant Fellow in the Department of Surgery, Division of Transplantation, University of Wisconsin School of Medicine and Public Health, Madison, Wisconsin, has nothing to disclose.

Amit K. Mathur, MD, MS, a Clinical Lecturer/Multi-Organ Abdominal Transplant Fellow in the Department of Surgery, University of Michigan Hospital and Health System, Ann Arbor, Michigan, has nothing to disclose.

Victoria L. Shieck, RN, BSN, CCTN, a Clinical Care Coordinator at the University of Michigan Health System Transplant Center, Ann Arbor, Michigan, has nothing to disclose.

Joseph B. Lockridge, MD, a Clinical Lecturer and Fellow in Nephrology in the Department of Medicine, University of California, San Francisco, Medical Center, San Francisco, California, has nothing to disclose.

Rick Ricer, MD, has nothing to disclose.

Susan P. Tyler, MEd, CMP, CCMEP, has nothing to disclose.

Anita Young, EdD, RPh, has nothing to disclose.

Jacqueline Keenan and **Edwin S. Geffner**, of Direct One Communications, Inc., have nothing to disclose.

DISCLAIMER

This activity is an independent educational activity under the direction of the University of Cincinnati. The activity was planned and implemented in accordance with the Essential Areas and Policies of the ACCME, the Ethical Opinions/Guidelines of the American Medical Association, the US Food and Drug Administration, the Office of Inspector General of the US Department of Health and Human Services, and the Pharmaceutical Research and Manufacturers of America Code on Interactions With Healthcare Professionals, thus assuring the highest degree of independence, fair balance, scientific rigor, and objectivity.

However, the planning committee, faculty, University of Cincinnati, American Board for Transplant Certification, Northeastern University Bouvé College of Health Sciences School of Pharmacy, Astellas Pharma US, Inc., and Direct One Communications, Inc. shall in no way be liable for the currency of information or for any errors, omissions, or inaccuracies in this activity. Participants in this activity are encouraged to refer to primary references or full prescribing information resources.

The opinions and recommendations presented herein are those of the faculty and do not necessarily reflect the views of the provider, producer, or grantors.

DISCLOSURE OF UNAPPROVED/OFF-LABEL USE

Discussions concerning drugs, dosages, and procedures may reflect the clinical experience of the planning committee, may be derived from the professional literature or other sources, or may suggest uses that are investigational and not approved labeling or indications.

In this issue of *The Immunology Report,* Dr. Patel summarizes the results of clinical trials of several novel immunosuppressants, including ASKP1240, TOL101, voclosporin, belimumab, tocilizumab, and C1 esterase inhibitors, as well as the off-label use of intravenous immunoglobulin (IVIg), rituximab, bortezomib, and eculizumab, in preventing and managing antibody-mediated rejection (AMR); none of these drugs has been approved by the FDA for use in organ transplantation or for managing AMR.

CONTACT INFORMATION

We would like to hear your comments regarding this or other educational activities produced by Direct One Communications, Inc. In addition, suggestions for future activities are welcome. Contact us at:

Direct One Communications, Inc.
1424 Ridge Road
Syosset, NY 11791
Phone: 516-364-1020
Fax: 516-364-4217
Web: www.CMEdirect.net