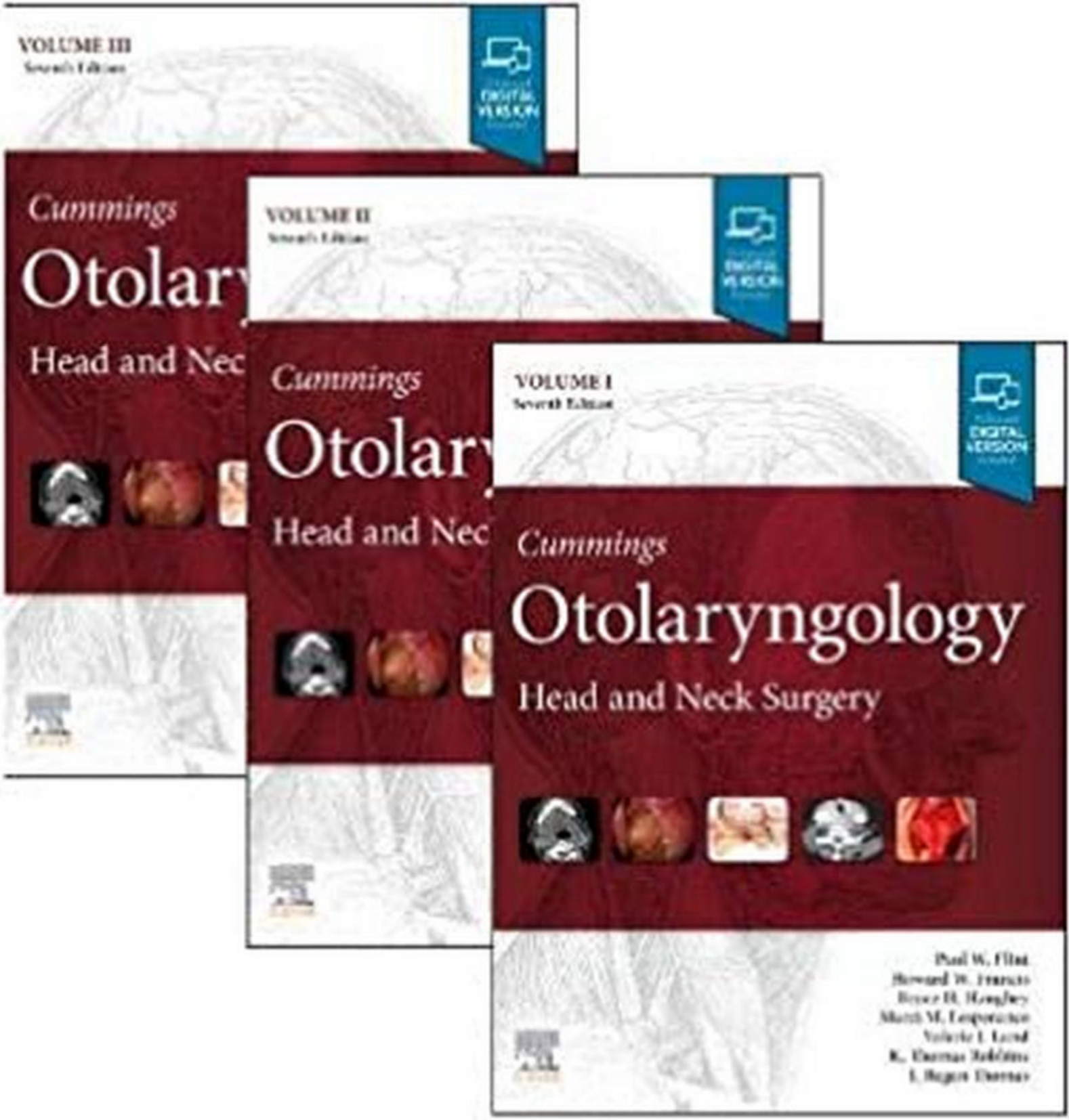
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Paul W. Flint, MD, FACS
Professor and Chair
Department of Otolaryngology–Head and Neck Surgery
Oregon Health & Science University
Portland, Oregon

Howard W. Francis, MD, MBA, FACS
Richard Hall Chaney Sr. Professor and Chair
Department of Head and Neck Surgery and Communication Sciences
Duke University School of Medicine
Durham, North Carolina

Bruce H. Haughey, MBChB, MD, FACS, FRACS
Medical Director, Oncology
Advent Health Celebration
Otolaryngology Head and Neck Surgery
Advent Health Medical Group
Orlando, Florida;
Collaborative Professor
Department of Otolaryngology–Head and Neck Surgery
Morsani School of Medicine
University of South Florida
Tampa, Florida;
Adjunct Professor
Department of Surgery
University of Auckland Faculty of Health Sciences
Auckland, New Zealand

Marci M. Lesperance, MD
Professor
Department of Otolaryngology–Head and Neck Surgery
Chief, Division of Pediatric Otolaryngology
University of Michigan Health System
Ann Arbor, Michigan

Valerie J. Lund, CBE, MBBS, MS, FRCS, FRCS(Ed), FACS(Hon)
Professor Emeritus
Rhinology and Anterior Skull Base Surgery
University College London and Royal National Throat, Nose, and Ear Hospital London, UCLH
London, United Kingdom

K. Thomas Robbins, MD
Professor Emeritus
Division of Otolaryngology–Head and Neck Surgery
Executive Director Emeritus
Simmons Cancer Institute at SIU
Simmons Endowed Chair of Excellence in Oncology
Southern Illinois University School of Medicine
Springfield, Illinois

J. Regan Thomas, MD
Professor, Facial Plastic Surgery
Department of Otolaryngology–Head and Neck Surgery
Northwestern University Feinberg School of Medicine
Chicago, Illinois

ELSEVIER

1600 John F. Kennedy Blvd.
Ste. 1600
Philadelphia, PA 19103-2899

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Contributors

Dunia Abdul-Aziz, MD
Instructor
Department of Otolaryngology
Harvard Medical School
Massachusetts Eye and Ear
Boston, Massachusetts

Waleed M. Abuzeid, MD
Clinical Instructor
Department of Otolaryngology–Head and Neck Surgery
Stanford Sinus Center
Palo Alto, California

Meredith E. Adams, MD, MS
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
University of Minnesota
Minneapolis, Minnesota

Peter A. Adamson, OOnt, MD, FRCS(C), FACS
Professor, Division of Facial Plastic and Reconstructive Surgery
Department of Otolaryngology–Head and Neck Surgery
University of Toronto Faculty of Medicine
Toronto, Ontario, Canada

Edem S. Agamah, MD, MS
Associate Professor of Clinical Medicine
Division of Hematology and Oncology
Department of Internal Medicine
Southern Illinois School of Medicine
Springfield, Illinois

Yuri Agrawal, MD
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Johns Hopkins University School of Medicine
Baltimore, Maryland

Faisal I. Ahmad, MD
Fellow
Head and Neck Surgery
University of Texas MD Anderson Cancer Center
Houston, Texas

Mostafa M. Ahmed, MD
Assistant Professor
Carl R Darnall Army Medical Center
Fort Hood, Texas

Seth A. Akst, MD, MBA
Anesthesiologist and Critical Care Physician
TeamHealth Anesthesia
Department of Anesthesiology
Sibley Memorial Hospital
Johns Hopkins Medicine
Washington, DC

W. Greer Albergotti, MD
Assistant Professor, Head and Neck Surgery
Medical College of Georgia
Augusta University
Augusta, Georgia

Sheri L. Albers, DO, FAOCR
Director
Radiology Research and Consultation
Sacramento, California

Clint T. Allen, MD
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Johns Hopkins University
Baltimore, Maryland

Abdulmalik S. Alsaied, MD
Otolaryngologist
Department of Otolaryngology–Head and Neck Surgery
Medical College of Georgia
Augusta University
Augusta, Georgia;
King Fahd University Hospital
Khobar, Saudi Arabia

Mohamedkazim Alwani, MD
Resident Surgeon
Department of Otolaryngology–Head and Neck Surgery
Indiana University School of Medicine
Indianapolis, Indiana

Jennifer Christy Alyono, MD
Clinical Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
Stanford University School of Medicine
Stanford, California

Carryn Anderson, MD
Clinical Associate Professor
Department of Radiation Oncology
University of Iowa Hospitals and Clinics
Iowa City, Iowa

William B. Armstrong, MD
Professor and Chair
Department of Otolaryngology–Head and Neck Surgery
University of California, Irvine
Irvine, California

Michelle G. Arnold, MD
Staff Otolaryngologist
Naval Medical Center
San Diego, California

Moises A. Arriaga, MD, MBA
Clinical Professor and Director of Otology and Neurotology
Department of Otolaryngology and Neurosurgery
Louisiana State University Health Sciences Center
Medical Director
CNC Hearing and Balance Center
Culicchia Neurological Clinic
Medical Director
Cochlear Implant Program
Children's Hospital
New Orleans, Louisiana;
Medical Director
LSU–Our Lady of the Lake Hearing and Balance Center
Our Lady of the Lake Regional Medical Center
Baton Rouge, Louisiana

H. Alexander Arts, MD, FASCS
Professor
Departments of Otolaryngology and Neurosurgery
University of Michigan School of Medicine
Ann Arbor, Michigan

Joan C. Arvedson, PhD
Clinical Professor
Department of Pediatrics
Medical College of Wisconsin
Program Coordinator, Feeding and Swallowing Services
Departments of Speech Pathology and Audiology
Children's Hospital of Wisconsin
Milwaukee, Wisconsin

Yasmine A. Ashram, MD
Professor
Department of Physiology
Consultant, Intraoperative Neurophysiologist
Faculty of Medicine
Alexandria, University
Alexandria, Egypt

Nafi Aygun, MD
Associate Professor
Russel H. Morgan Department of Radiology
Johns Hopkins University School of Medicine
Baltimore, Maryland

Douglas D. Backous, MD, FACS
Medical Director
Center for Hearing and Skull Base Surgery
Swedish Neuroscience Institute
Swedish Medical Center
Seattle, Washington

Shan R. Baker, MD
Professor Emeritus
Facial Plastic and Reconstructive Surgery
Department of Otolaryngology–Head and Neck Surgery
University of Michigan
Ann Arbor, Michigan

Thomas J. Balkany, MD, FACS, FAAP
Hotchkiss Professor and Chairman Emeritus
Department of Otolaryngology
University of Miami Miller School of Medicine
President, Institute for Cochlear Implant Training
Miami, Florida

Leonardo Balsalobre, MD, PhD
Staff of Rhinology Division
Sao Paulo ENT Center
Edmundo Vasconcelos Hospital
Sao Paulo, Brazil

Fuad M. Baroody, MD, FACS
Professor of Surgery
Section of Otolaryngology–Head and Neck Surgery
Professor of Pediatrics
Director, Otolaryngology Residency Program
Director of Pediatric Otolaryngology
The University of Chicago Medicine and The Comer Children's Hospital
Chicago, Illinois

Robert W. Bastian, MD
Founder and Director
Bastian Voice Institute
Downers Grove, Illinois

Gregory J. Basura, MD, PhD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of Michigan
Ann Arbor, Michigan

Pete S. Batra, MD, FACS
Stanton A. Friedberg MD Chair in Otolaryngology
Professor and Chairman
Section Head, Rhinology, Sinus Surgery, and Skull Base Surgery
Co-Director, Rush Center for Skull Base and Pituitary Surgery
Secretary, American Rhinologic Society
Department of Otorhinolaryngology–Head and Neck Surgery
Rush University Medical Center
Chicago, Illinois

Beth M. Beadle, MD, PhD
Associate Professor
Department of Radiation Oncology
Stanford University
Stanford, California

Nicholas A. Beckmann, DO
Resident
Department of Otolaryngology–Head and Neck Surgery
University of Tennessee Health Science Center
Memphis, Tennessee

James R. Bekeny, MD
Surgeon
Department of Otorhinolaryngology–Head and Neck Surgery
Advent Health
Celebration, Florida

Diana M. Bell
Associate Professor
Department of Pathology
The University of Texas MD Anderson Cancer Center
Houston, Texas

Elizabeth Bradford Bell, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of Nebraska Medical Center
Omaha, Nebraska

Michael S. Benninger, MD
Professor of Surgery
Lerner College of Medicine of Case Western Reserve University
Chairman, Head and Neck Institute
Cleveland Clinic
Cleveland, Ohio

Heidi J. Bernknopf, AuD, BS
Audiologist
Department of Speech and Hearing
Robert Wood Johnson University Hospital
New Brunswick, New Jersey

Daniel M. Beswick, MD
Assistant Professor
Department of Otolaryngology
University of Colorado
Aurora, Colorado

Mukul Bhattarai, MD, FACP
Assistant Professor
Department of Internal Medicine
Southern Illinois University
Springfield, Illinois

Benjamin S. Bleier, MD
Associate Professor
Director of Otolaryngology Translational Research
Director of Endoscopic Skull Base Surgery
Co-Director of Center for Thyroid Disease and Orbital Surgery
Department of Otolaryngology–Head and Neck Surgery
Harvard Medical School
Massachusetts Eye and Ear
Boston, Massachusetts

Nikolas H. Blevins, MD
Larry and Sharon Malcolmson Professor
Department of Otolaryngology–Head and Neck Surgery
Stanford University School of Medicine
Stanford, California

Andrew Blitzer, MD, DDS
Professor Emeritus of Otolaryngology–Head and Neck Surgery
Columbia University College of Physicians and Surgeons
Adjunct Professor of Neurology
Icahn School of Medicine at Mt. Sinai
Director, NY Center for Voice and Swallowing Disorders
Co-Founder and Director of Research, ADN International
New York, New York

Kofi Boahene, MD
Professor
Department of Otolaryngology–Head and Neck Surgery
Johns Hopkins University School of Medicine
Baltimore, Maryland

Lauren A. Bohm, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of Michigan
Ann Arbor, Michigan

Michael M. Bottros, MD
Associate Professor
Associate Chief of Pain Management
Department of Anesthesiology and Pain Medicine
Director, Acute Pain Service
Washington University School of Medicine in St. Louis
St. Louis, Missouri

Derald E. Brackmann, MD
Clinical Professor of Otolaryngology
Head and Neck Surgery
University of California School of Medicine
Associate, House Ear Clinic
Los Angeles, California

Carol R. Bradford, MD
Executive Vice Dean for Academic Affairs and Professor
Department of Otolaryngology–Head and Neck Surgery
University of Michigan Medical School
Ann Arbor, Michigan

Gregory H. Branham, MD
Professor and Chief, Facial Plastic and Reconstructive Surgery
Department of Otolaryngology–Head and Neck Surgery
Washington University School of Medicine in St. Louis
St. Louis, Missouri

Barton F. Branstetter IV, MD, FACR
Chief of Neuroradiology
Department of Radiology
University of Pittsburgh Medical Center
Professor
Departments of Radiology, Otolaryngology, and Biomedical Informatics
University of Pittsburgh
Pittsburgh, Pennsylvania

Jason A. Brant, MD
Assistant Professor
Department of Otorhinolaryngology–Head and Neck Surgery
Hospital of the University of Pennsylvania
Philadelphia, Pennsylvania

Scott E. Brietzke, MD, MPH
Affiliate Professor of Surgery
Charles E. Schmidt College of Medicine
Florida Atlantic University
Boca Raton, Florida;
Joe DiMaggio Children's Hospital at Memorial
Hollywood, Florida

Jennifer Brinkmeier, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
Division of Pediatric Otolaryngology
Saint Louis University
St. Louis, Missouri

Hilary A. Brodie, MD, PhD
Professor
Department of Otolaryngology–Head and Neck Surgery
University of California Davis Medical Center
Sacramento, California

Bena Brown, BSpPath, PhD
Health Research Fellow
Centre for Functioning and Health Research
Metro South Hospital and Health Service
Department of Speech Pathology
Princess Alexandra Hospital
Senior Lecturer
School of Health and Rehabilitation Sciences
University of Queensland
Brisbane, Queensland, Australia

Cameron L. Budenz, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
Department of Neurosurgery
New York Medical College
Valhalla, New York;
ENT and Allergy Associates, LLP
Sleepy Hollow, New York

Clare Burns, PhD, BSpPath
Advanced Speech Pathologist
Department of Speech Pathology and Audiology
Royal Brisbane and Women's Hospital
Clinician Research Fellow
Metro North Hospital and Health Service
Lecturer
School of Health and Rehabilitation Sciences
University of Queensland
Brisbane, Queensland, Australia

J. Kenneth Byrd, MD
Associate Professor
Department of Otolaryngology
Medical College of Georgia at Augusta University
Augusta, Georgia

Patrick Byrne, MD
Director
Division of Facial Plastic and Reconstructive Surgery
Johns Hopkins University School of Medicine
Baltimore, Maryland

Yi Cai, MD
Resident Physician
Department of Otolaryngology–Head and Neck Surgery
University of California, San Francisco
San Francisco, California

Hollin Calloway, MD
Otolaryngologist, Facial Plastic and Reconstructive Surgeon
ENT and Allergy Associates, LLP
Hoboken, New Jersey

Paolo Campisi, MD, MSc, FRCS(C)
Professor and Vice Chair, Education
Department of Otolaryngology–Head and Neck Surgery
University of Toronto
Staff Otolaryngologist
Department of Otolaryngology–Head and Neck Surgery
Hospital for Sick Children
Toronto, Ontario, Canada

John P. Carey, MD
Professor and Division Chief for Otology, Neurotology, and Skull Base Surgery
Department of Otolaryngology–Head and Neck Surgery
Johns Hopkins University School of Medicine
Baltimore, Maryland

Eric T. Carniol, MD, MBA
Division Chief
Department of Otolaryngology–Head and Neck Surgery
Milford Regional Medical Center
Director, Facial Plastic Surgery
etc aesthetic surgery
Milford, Massachusetts

Simon D. Carr, MD, FRCS (ORL-HNS)
Clinical Fellow
Department of Otolaryngology–Head and Neck Surgery
Hospital for Sick Children
Toronto, Ontario, Canada

Geoffrey C. Casazza, MD
Resident Physician
Division of Otolaryngology–Head and Neck Surgery
University of Utah
Salt Lake City, Utah

Keith Casper, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of Michigan
Ann Arbor, Michigan

Paolo Castelnuovo, MD, FRCS(Ed), FACS
Professor and Head of Otorhinolaryngology
Department of Biotechnology and Life Science (DBSV)
University of Insubria
Director, Head and Neck Surgery and Forensic Dissection Research Center
Director, Surgical Specialties
Circolo-Varese Hospital
Varese, Lombardy, Italy

Ivette Cejas, PhD
Associate Professor
Director, Family Support Services
Department of Otolaryngology
University of Miami
Miami, Florida

Kay W. Chang, MD
Professor
Department of Otolaryngology
Stanford University
Palo Alto, California

Burke E. Chegar, MD
Medical Director
Chegar Facial Plastic Surgery
Carmel, Indiana

Alan G. Cheng, MD
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Stanford University
Stanford, California

Alan T.L. Cheng, MD, FRACS
Clinical Associate Professor
Discipline of Child and Adolescent Health
University of Sydney
Sydney, NSW, Australia;
Department of Paediatric ENT
The Children's Hospital at Westmead
Westmead, NSW, Australia

Douglas B. Chepeha, MD, MSPH
Professor
Department of Otolaryngology–Head and Neck Surgery
University of Toronto
Toronto, Ontario, Canada;
Adjunct Professor
Department of Otolaryngology–Head and Neck Surgery
University of Michigan
Ann Arbor, Michigan

Wade W. Chien, MD
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Johns Hopkins University School of Medicine
Baltimore, Maryland;
Staff Clinician
National Institute On Deafness and Other Communication Disorders
National Institutes of Health
Bethesda, Maryland

Oliver Y. Chin, MD
Resident Physician
Department of Otolaryngology–Head and Neck Surgery
University of California Davis Medical Center
Sacramento, California

Sukgi S. Choi, MD, MBA
Attending Physician
Otolaryngology and Communication Enhancement
Boston Children's Hospital
Senior Lecturer
Department of Otolaryngology
Harvard Medical School
Boston, Massachusetts

Richard A. Chole, MD, PhD
Professor
Department of Otolaryngology
Washington University School of Medicine in St. Louis
St. Louis, Missouri

Baishakhi Choudhury, MD
Assistant Professor
Otology/Neurotology and Lateral Skull Base Surgery
Department of Otolaryngology–Head and Neck Surgery
Loma Linda University Healthcare
Loma Linda, California

James M. Christian, DDS, MBA, FACS
Professor
Department of Oral and Maxillofacial Surgery
University of Tennessee Health Science Center
Memphis, Tennessee

Robert H. Chun, MD
Associate Professor
Department of Pediatric Otolaryngology
Medical College of Wisconsin
Milwaukee, Wisconsin

Martin J. Citardi, MD
Professor and Chair
Department of Otorhinolaryngology–Head and Neck Surgery
University of Texas Health Science Center at Houston
Chief of Otorhinolaryngology
Memorial Hermann–Texas Medical Center
Houston, Texas

Andrew Michael Compton, MD
[Ch 17]
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Oakland University William Beaumont School of Medicine
Royal Oak, Michigan;
Physician-Owner
Oakland ENT, LLC
West Bloomfield, Michigan

Maura K. Cosetti, MD
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Icahn School of Medicine
New York Eye and Ear Infirmary of Mount Sinai
New York, New York

M. Laurin Council, MD
Associate Professor
Departments of Internal Medicine and Dermatology
Washington University School of Medicine in St. Louis
St. Louis, Missouri

Mark S. Courey, MD
Professor
Department of Otolaryngology–Head and Neck Surgery
Chief, Division of Laryngology
Director, Grabscheid Voice and Swallowing Center
Vice Chair of Quality
Department of Otolaryngology–Head and Neck Surgery
Mount Sinai Health System
New York, New York

Renee Cover, BSN, RN, CPHRM
Risk Manager
Johns Hopkins Hospital
Baltimore, Maryland

Daniel R. Cox, MD
Fellow in Rhinology
Department of Otolaryngology–Head and Neck Surgery
Emory University School of Medicine
Atlanta, Georgia

Benjamin T. Crane, MD, PhD
Professor
Departments of Otolaryngology, Bioengineering, and Neuroscience
University of Rochester
Rochester, New York

Francis X. Creighton Jr, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
Division of Otology, Neurotology, and Skull Base Surgery
Johns Hopkins University School of Medicine
Baltimore, Maryland

Matthew G. Crowson, MD, MPA, FRCSC
Clinical Fellow, Neurotology
Department of Otolaryngology–Head and Neck Surgery
Sunnybrook Health Sciences Center
University of Toronto
Toronto, Canada

Frank Culicchia, MD
David G. Kline Professor and Chairman
Department of Neurosurgery
Louisiana State University School of Medicine
New Orleans, Louisiana

Charles W. Cummings, MD
Distinguished Service Professor
Department of Otolaryngology–Head and Neck Surgery
Johns Hopkins Medical Institutions
Baltimore, Maryland

Calhoun D. Cunningham III, MD
Associate Professor
Co-Director, Duke Raleigh Skull Base and Cerebrovascular Center
Department of Head and Neck Surgery and Communication Sciences
Duke University Medical Center
Durham, North Carolina

Sharon L. Cushing, MD, MSc, FRCS(C)
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
University of Toronto
Staff Physician
Department of Otolaryngology–Head and Neck Surgery
Archie's Cochlear Implant Laboratory
Hospital for Sick Children
Toronto, Ontario, Canada

Brian C. Dahlin, MD
Associate Professor
Department of Radiology
University of California, Davis
Sacramento, California

Sam J. Daniel, MD, CM, FRCS(C)
Hugh Hallward Chair
Department of Pediatric Surgery
McGill University
Director, Pediatric Otolaryngology–Head and Neck Surgery
Montreal Children's Hospital
Montreal, Quebec, Canada

Camila Soares Dassi, MD
Otolaryngology-Rhinology and Skull Base Surgery
Sao Paulo ENT Center
Edmundo Vasconcelos Hospital
Sao Paulo, Brazil

Terry A. Day, MD
Professor
Director, Head and Neck Tumor Center
Medical University of South Carolina
Charleston, South Carolina

Kavita Dedhia, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of Pennsylvania Perelman School of Medicine
Division of Otolaryngology
Children's Hospital of Philadelphia
Philadelphia, Pennsylvania

Matthew M. Dedmon, MD, PhD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of North Carolina at Chapel Hill School of Medicine
Chapel Hill, North Carolina

Nicholas L. Deep, MD
Fellow in Neurotology
Department of Otolaryngology
NYU Langone Health
New York, New York

Charles C. Della Santina, PhD, MD
Professor
Departments of Otolaryngology–Head and Neck Surgery and Biomedical Engineering
Johns Hopkins University School of Medicine
Baltimore, Maryland

Joshua C. Demke, MD
Associate Professor
Facial Plastic and Reconstructive Surgery
Department of Otolaryngology
Texas Tech Health Sciences Center
Lubbock, Texas

Craig S. Derkay, MD
Professor and Vice-Chairman
Department of Otolaryngology–Head and Neck Surgery
Eastern Virginia Medical School
Director
Pediatric Otolaryngology
Children's Hospital of the King's Daughters
Norfolk, Virginia

Nicholas A. Dewyer, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of Arizona College of Medicine
Tucson, Arizona

Rodney C. Diaz, MD
Professor
Department of Otolaryngology–Head and Neck Surgery
University of California Davis Medical Center
Sacramento, California

Amanda E. Dilger, MD
Fellow
Facial Plastic and Reconstructive Surgery
Beverly Hills/Roseville, California

Lynn E. Driver, MS, CCC-SLP
Pediatric Speech-Language Pathology
Department of Pediatric Otolaryngology
University of Michigan, Michigan Medicine
Ann Arbor, Michigan

Alison B. Durham, MD
Assistant Professor
Department of Dermatology
University of Michigan
Ann Arbor, Michigan

Avraham Eisbruch, MD
Professor
Department of Radiation Oncology
University of Michigan
Attending Physician
Hospital of the University of Michigan
Ann Arbor, Michigan

David W. Eisele, MD, FACS
Andelot Professor and Director
Department of Otolaryngology–Head and Neck Surgery
Johns Hopkins University School of Medicine
Baltimore, Maryland

Laurie Eisenberg, PhD
Professor of Research Otolaryngology
Tina and Rick Caruso Department of Otolaryngology–Head and Neck Surgery
University of Southern California Keck School of Medicine
Los Angeles, California

Mark El-Deiry, MD, FACS
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Emory University School of Medicine
Atlanta, Georgia

Edward El Rassi, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of Oklahoma Health Sciences Center
Oklahoma City, Oklahoma

Hussam K. El-Kashlan, MD
Professor and Associate Chair
Department of Otolaryngology–Head and Neck Surgery
Director, Division of Otology and Neurotology
University of Michigan
Ann Arbor, Michigan

Anila B. Elliott, MD
Assistant Professor
University of Michigan
Department of Anesthesiology
CS Mott Children's Hospital
Ann Arbor, Michigan

Ravindhra G. Elluru, MD, PhD
Professor and Chair
Department of Otolaryngology
Wright State Boonshoft School of Medicine
Director, Division of Pediatric Otolaryngology
Dayton Children's Hospital
Dayton, Ohio

Susan D. Emmett, MD, MPH
Assistant Professor of Surgery and Global Health
Department of Head and Neck Surgery and Communication Sciences
Duke University School of Medicine
Duke Global Health Institute
Durham, North Carolina

Donovan Eu, MBBS, MMed, FAMS
Associate Consultant
Department of Otolaryngology–Head and Neck Surgery
National University Hospital
Singapore

Samer Fakhri, MD
Professor and Chair
Department of Otorhinolaryngology
American University of Beirut
Beirut, Lebanon

Carole Fakhry, MD, MPH
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Johns Hopkins University School of Medicine
Baltimore, Maryland

Edward H. Farrior, MD
Affiliate Associate Professor, Voluntary Faculty
Department of Otolaryngology–Head and Neck Surgery
University of South Florida
Tampa, Florida;
Visiting Clinical Associate Professor
Department of Otolaryngology–Head and Neck Surgery
University of Virginia
Charlottesville, Virginia

David Feller-Kopman, MD, FACP
Director, Bronchoscopy and Interventional Pulmonology
Division of Pulmonary and Critical Care Medicine
Professor of Medicine, Anesthesiology, Otolaryngology–Head and Neck Surgery
Johns Hopkins Hospital
Baltimore, Maryland

Charles B. Felts, DDS
Former Chief Resident
Department of Oral and Maxillofacial Surgery
University of Tennessee Health Science Center
Memphis, Tennessee

Daniel S. Fink, MD
Assistant Professor, Laryngology and Voice Disorders
Department of Otolaryngology–Head and Neck Surgery
University of Colorado School of Medicine
Aurora, Colorado

Kenneth C. Fletcher Jr, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
Vanderbilt University
Nashville, Tennessee

Paul W. Flint, MD, FACS
Professor and Chair
Department of Otolaryngology–Head and Neck Surgery
Oregon Health and Science University
Portland, Oregon

Elizabeth M. Floyd, MD
Assistant Professor
Department of Otolaryngology
Northwell Health
Great Neck, New York

Wytske J. Fokkens, MD, PhD
Department of Otorhinolaryngology
Amsterdam University Medical Centres
Amsterdam, The Netherlands

Howard W. Francis, MD, MBA, FACS
Richard Hall Chaney Sr. Professor and Chair
Department of Head and Neck Surgery and Communication Sciences
Duke University School of Medicine
Durham, North Carolina

David R. Friedland, MD, PhD
Professor and Vice-Chair
Chief, Division of Otology and Neuro-otologic Skull Base Surgery
Otolaryngology and Communication Sciences
Medical College of Wisconsin
Milwaukee, Wisconsin

Oren Friedman, MD
Associate Professor
Director, Facial Plastic Surgery
Otorhinolaryngology
University of Pennsylvania
Philadelphia, Pennsylvania

Rick A. Friedman, MD, PhD
Vice Chief of Otolaryngology–Head and Neck Surgery
Professor of Surgery
Director of University of California San Diego Acoustic Neuroma Program
University of San Diego
San Diego, California

John L. Frodel Jr, MD
Atlanta Medispa and Surgicenter, LLC
Atlanta, Georgia;
Geisinger Center for Aesthetics and Cosmetic Surgery
Danville, Pennsylvania

Ian Ganly, MD, PhD, MSc
Professor
Head and Neck Surgery
Memorial Sloan Kettering Cancer Center
Professor
Otolaryngology–Head and Neck Surgery
Weill Cornell Medical College
New York, New York

Andres Gantous, MD, FRCS(C), FACS
Associate Professor and Head
Division of Facial Plastic and Reconstructive Surgery
Department of Otolaryngology–Head and Neck Surgery
University of Toronto
Toronto, Ontario, Canada

Bruce J. Gantz, MD
Professor and Chair
Department of Otolaryngology–Head and Neck Surgery
University of Iowa
Iowa City, Iowa

C. Gaelyn Garrett, MD, MMHC
Professor and Vice Chair
Department of Otolaryngology
Guy M. Maness Chair in Laryngology and Voice
Vanderbilt University
Medical Director
Vanderbilt Voice Center
Nashville, Tennessee

M. Boyd Gillespie, MD, MSc
Professor and Chair
Department of Otolaryngology–Head and Neck Surgery
University of Tennessee Health Science Center
Memphis, Tennessee

Douglas A. Girod, MD, FACS
Professor
Department of Otolaryngology–Head and Neck Surgery
University of Kansas School of Medicine
Kansas City, Kansas;
Chancellor
University of Kansas
Lawrence, Kansas

Hannah Glick, AuD, PhD, CCC-A
Department of Speech, Language, and Hearing Science
Institute of Cognitive Science
Center for Neuroscience
University of Colorado
Boulder, Colorado

John C. Goddard, MD
Division Head of Otology and Neurotology
Physician Director of Audiology
Department of Head and Neck Surgery
Northwest Permanente, PC
Portland, Oregon

George S. Goding Jr, MD
Professor
Department of Otolaryngology
University of Minnesota Medical School
Faculty, Department of Otolaryngology
Hennepin County Medical Center
Minneapolis, Minnesota

Andrew N. Goldberg, MD, MSCE, FACS
Professor and Director, Division of Rhinology and Sinus Surgery
Department of Otolaryngology–Head and Neck Surgery
University of California, San Francisco
San Francisco, California

David Goldenberg, MD, FACS
Steven and Sharon Baron Professor and Chair
Department of Otolaryngology–Head and Neck Surgery
Pennsylvania State University College of Medicine
Hershey, Pennsylvania

Nira A. Goldstein, MD, MPH
Professor, Attending Physician
Department of Otolaryngology
State University of New York
Downstate Medical Center
Attending Physician
Department of Otolaryngology
Kings County Hospital Center
Brooklyn, New York

Nathan J. Gonik, MD, MHSA
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
Wayne State University
Assistant Professor
Department of Pediatric Otolaryngology
Children's Hospital of Michigan
Detroit, Michigan

Debra Gonzalez, MD
Assistant Professor
Department of Otolaryngology
Washington University School of Medicine in St. Louis
St. Louis, Missouri

Christine G. Gourin, MD, MPH, FACS
Professor
Department of Otolaryngology–Head and Neck Surgery
Johns Hopkins University School of Medicine
Baltimore, Maryland

M. Elise Graham, MD, FRCS(C)
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
London Health Sciences Centre and Western University
London, Ontario, Canada

Glenn E. Green, MD
Professor
Department of Otolaryngology–Head and Neck Surgery
University of Michigan
Ann Arbor, Michigan

Stephen T. Green, MD
Resident Physician
Department of Otolaryngology–Head and Neck Surgery
Louisiana State University School of Medicine
New Orleans, Louisiana

Vincent Grégoire, MD, PhD, FRCR
Professor
Department of Radiation Oncology
Centre Léon Bérard
Lyon, France

J. Fredrik Grimmer, MD
Professor
Division of Otolaryngology–Head and Neck Surgery
University of Utah
Director of the Vascular Anomalies Center
Primary Children's Hospital
Salt Lake City, Utah

Catherine A. Gruffi, MD
Clinical Lecturer
University of Michigan
Department of Pediatric Anesthesiology
CS Mott Children's Hospital
Ann Arbor, Michigan

Samuel P. Gubbels, MD, FACS
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
University of Colorado School of Medicine
Director, UCHealth Hearing and Balance Clinics
Aurora, Colorado

Piyush Gupta, MBBS, MS
Research Fellow
Head and Neck Surgery, Department of Surgery
Memorial Sloan Kettering Cancer Center
New York, New York

Richard K. Gurgel, MD
Associate Professor
Division of Otolaryngology–Head and Neck Surgery
University of Utah
Salt Lake City, Utah

Jose G. Gurrola II, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of California, San Francisco
San Francisco, California

Jennifer F. Ha, MBBS (Hons), FRACS
Pediatric Otolaryngologist
Pediatric Otolaryngology–Head and Neck Surgery
Perth Children's Hospital
Otolaryngologist
Murdoch ENT
St. John of God Murdoch Hospital
Pediatric Otolaryngologist
Department of Surgery
University of Western Australia
Nedlands, Western Australia

Patrick K. Ha, MD
Irwin Mark Jacobs and Joan Klein Jacobs Distinguished Professor
Chief, Division of Head and Neck Surgical Oncology
Department of Otolaryngology–Head and Neck Surgery
University of California, San Francisco
San Francisco, California

Natalia M. Hajnas, MD
Department of Otolaryngology–Head and Neck Surgery
University of Illinois at Chicago
Chicago, Illinois

Bronwyn E. Hamilton, MD
Professor and Director of Head and Neck Radiology
Department of Radiology
Oregon Health and Science University
Portland, Oregon

Grant S. Hamilton III, MD
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Mayo Clinic
Rochester, Minnesota

Marc Hamoir, MD
Professor and Head
Department of Head and Neck Surgery
Université Catholique de Louvain,
Louvain-la-Neuve, Belgium;
Chairman of the Executive Board
King Albert II Cancer Institute
St Luc University Hospital
Brussels, Belgium

Ehab Y. Hanna, MD, FACS
Professor and Director of Skull Base Surgery
Vice Chairman
Department of Head and Neck Surgery
University of Texas MD Anderson Cancer Center
Houston, Texas

Jeffrey J. Harmon Jr, MD
Graduated Resident
Department of Otolaryngology–Head and Neck Surgery
University of Cincinnati College of Medicine
Cincinnati, Ohio

Ulrich Harréus, MD
Professor and Chair
Department of Otolaryngology–Head and Neck Surgery
EVK Duesseldorf Academic Hospital of Heinrich-Heine University
Duesseldorf, Germany

Renee Banakis Hartl, MD, AuD
Resident Physician
Department of Otolaryngology
University of Colorado
Aurora, Colorado

Richard Harvey, MD, PhD, FRACS
Professor and Program Head
Rhinology and Skull Base Research Group
University of New South Wales
Professor
Faculty of Medicine and Health Sciences
Macquarie University
Sydney, NSW, Australia

Bruce H. Haughey, MBChB, MD, FACS, FRACS
Medical Director, Oncology
Advent Health Celebration
Otolaryngology Head and Neck Surgery
Advent Health Medical Group
Orlando, Florida;
Collaborative Professor
Department of Otolaryngology–Head and Neck Surgery
Morsani School of Medicine
University of South Florida
Tampa, Florida;
Adjunct Professor
Department of Surgery
University of Auckland Faculty of Health Sciences
Auckland, New Zealand

Peter Hawkins, MD
Radiation Oncology
University of Michigan
Ann Arbor, Michigan

Peter Hellings, MD, PhD
Clinic Head
Department of Otorhinolaryngology
University Hospitals Leuven
Leuven, Belgium

John W. Hellstein, DDS, MS
Professor and Head
Department of Oral Pathology
University of Iowa
Iowa City, Iowa

Kurt Herzer, MD, PhD
Director
Population Health
Oscar Health
New York, New York

Frans J.M. Hilgers, MD, PhD
Chairman Emeritus
Department of Head and Neck Oncology and Surgery
The Netherlands Cancer Institute–Antoni van Leeuwenhoek
Professor Emeritus for Oncology-Related Voice and Speech Disorders
Amsterdam Center for Language and Communication
University of Amsterdam
Amsterdam, The Netherlands

Justin D. Hill, MD
ENT Specialists
Salt Lake City, Utah

Alexander T. Hillel, MD
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Anesthesia and Critical Care Medicine
Johns Hopkins University School of Medicine
Baltimore, Maryland

Michael L. Hinni, MD
Professor
Department of Otolaryngology–Head and Neck Surgery
Mayo Clinic College of Medicine
Consultant
Department of Otolaryngology–Head and Neck Surgery
Mayo Clinic Arizona
Phoenix, Arizona

Kellie J. Hirce, AuD
Clinical Audiologist
Speech and Hearing
Robert Wood Johnson University Hospital
New Brunswick, New Jersey

Henry T. Hoffman, MD, FACS
Professor
Department of Otolaryngology
University of Iowa
Iowa City, Iowa

Ashlee E. Holman, MD
Assistant Professor
University of Michigan
Department of Anesthesiology
CS Mott Children's Hospital
Ann Arbor, Michigan

David B. Hom, MD, FACS
Professor of Surgery
Co-Director, Facial Plastic and Reconstructive Surgery
Head and Neck Surgery
University of California San Diego School of Medicine
San Diego, California

Claire Hopkins, BMBCh, MA(Oxon), FRCS(ORL-HNS), DM
Professor of Rhinology
ENT Department
Guy's Hospital
London, United Kingdom

Jeffrey J. Houlton, MD
Associate Professor
Department of Otolaryngology
University of Washington
Seattle, Washington

John W. House, MD
Clinical Professor
Department of Otolaryngology–Head and Neck Surgery
University of Southern California
Clinical Professor
Department of Otolaryngology–Head and Neck Surgery
University of California, Los Angeles
Los Angeles, California

Timothy E. Hullar, MD
Professor
Departments of Otolaryngology–Head and Neck Surgery and Neurology
Oregon Health and Science University
Portland, Oregon

Thomas Hummel, MD
Professor
Smell and Taste Clinic
Department of Otorhinolaryngology
Technische Universität Dresden
Dresden, Germany

Joseph O. Humtsoe, PhD
Assistant, Professional Research
Department of Otolaryngology–Head and Neck Surgery
University of California, San Francisco
San Francisco, California

Peter H. Hwang, MD
Professor
Department of Otolaryngology–Head and Neck Surgery
Stanford University
Stanford, California

Stacey L. Ishman, MD, MPH
Professor
Department of Otolaryngology–Head and Neck Surgery
University of Cincinnati
Surgical Director, Upper Airway Center
Divisions of Otolaryngology and Pulmonary Medicine
Cincinnati Children's Hospital Medical Center
Cincinnati, Ohio

Jad Jabbour, MD, MPH
Pediatric Otolaryngology
Charlotte Eye Ear Nose and Throat Associates, PA
Charlotte, North Carolina;
Lecturer, Department of Otolaryngology
Harvard Medical School
Associate Scientific Research Staff
Department of Otolaryngology
Boston Children's Hospital
Boston, Massachusetts

Robert K. Jackler, MD
Chair
Department of Otolaryngology–Head and Neck Surgery
Stanford University
Stanford, California

Neal M. Jackson, MD
Resident Physician
Lousiana State University Health Sciences Center
New Orleans, Louisiana

Adrian L. James, DM, FRCS(ORL-HNS)
Professor
Department of Otolaryngology–Head and Neck Surgery
University of Toronto
Pediatric Otolaryngologist
Hospital for Sick Children
Toronto, Ontario, Canada

Brian Jameson, MD
Department of Endocrinology
Geisinger Health System
Geisinger Wyoming Valley Medical Center
Wilkes-Barre, Pennsylvania

Taha A. Jan, MD
Fellow
Department of Otolaryngology–Head and Neck Surgery
Stanford University
Stanford, California

Herman A. Jenkins, MD
Professor and Chair
Department of Otolaryngology–Head and Neck Surgery
University of Colorado School of Medicine
Aurora, Colorado

Nicole T. Jiam, MD
Resident Physician
Department of Otolaryngology–Head and Neck Surgery
University of California, San Francisco
San Francisco, California

Hong-Ryul Jin, MD, PhD
Director
Otorhinolaryngology
Dr. Jin's Premium Nose Clinic
Seoul, Republic of Korea

Christopher M. Johnson, MD
Staff Surgeon
Department of Otolaryngology
Naval Medical Center
San Diego, California;
Assistant Professor
Department of Surgery
Uniformed Services University of the Health Sciences
Bethesda, Maryland

Timothy M. Johnson, MD
Professor
Departments of Dermatology, Otolaryngology, and Surgery
University of Michigan
Ann Arbor, Michigan

Dipti Kamani, MD
Research Director
Division of Thyroid and Parathyroid Surgery
Massachusetts Eye and Ear
Boston, Massachusetts

William E. Karle, MD
Clinical Instructor
Department of Otolaryngology–Head and Neck Surgery
Oregon Health and Science University
Portland, Oregon

Robert T. Kavitt, MD, MPH
Associate Professor of Medicine
Director, Center for Esophageal Diseases
Section of Gastroenterology, Hepatology, and Nutrition
University of Chicago
Chicago, Illinois

David M. Kaylie, MD
Professor of Surgery
Department of Head and Neck Surgery and Communication Sciences
Duke University Medical Center
Durham, North Carolina

Robert M. Kellman, MD, FACS
Professor and Chair Emeritus
Department of Otolaryngology and Communication Sciences
SUNY Upstate Medical University
Staff Physician
St. Joseph's Health
Syracuse, New York

David W. Kennedy, MD
Professor
University of Pennsylvania Perelman School of Medicine
Philadelphia, Pennsylvania

Robert C. Kern, MD
George A. Sisson Professor of Otolaryngology
Chair, Department of Otolaryngology–Head and Neck Surgery
Northwestern University Feinberg School of Medicine
Chicago, Illinois

Julia L. Kerolus, MD
Clinical Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of Illinois at Chicago
Chicago, Illinois

Bradley W. Kesser, MD
Professor
Department of Otolaryngology–Head and Neck Surgery and Pediatrics
University of Virginia School of Medicine
Charlottesville, Virginia

Majid Khan, MBBS, MD
Associate Professor
Radiology Division of Neuroradiology
Director of Non-Vascular Spine Interventions
Johns Hopkins Hospital
Baltimore, Maryland

Paul R. Kileny, PhD, FAAA, FASHA, BCS-IOM
Professor
Department of Otolaryngology–Head and Neck Surgery
Academic Program Director
Audiology and Electrophysiology
University of Michigan, Michigan Medicine
Ann Arbor, Michigan

Jennifer Kim, MD
Associate Clinical Professor
Department of Otolaryngology–Head and Neck Surgery
Facial Plastic and Reconstructive Surgery
University of Michigan, Michigan Medicine
Ann Arbor, Michigan

Adam J. Kimple, MD, PhD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of North Carolina
Chapel Hill, North Carolina

Ericka F. King, MD
Pediatric Otolaryngology
Mary Bridge Children's Hospital
Tacoma, Washington

Diana N. Kirke, MBBS, MPhil, FRACS
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
Icahn School of Medicine at Mount Sinai
New York, New York

Elizabeth Knecht, MD
Department of Otolaryngology–Head and Neck Surgery
Pediatric Otolaryngology
University of Michigan, Michigan Medicine
Ann Arbor, Michigan

Raymond J. Konior, MD
Chicago Hair Institute
Medical Director
Oakbrook Terrace, Illinois

Shannon M. Kraft, MD
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
University of Kansas Health System
Kansas City, Kansas

Russell W.H. Kridel, MD
Clinical Professor
Department of Otorhinolaryngology–Head and Neck Surgery
University of Texas Health Science Center and McGovern Medical School at Houston
Private Practice
Facial Plastic Surgery Associates
Houston, Texas

Edward C. Kuan, MD, MBA
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of California, Irvine
Orange, California

Parvesh Kumar, MD
Professor and Chair, Department of Radiation Oncology
Vice Dean of Research
University of Nevada Las Vegas School of Medicine
Las Vegas, Nevada

Melda Kunduk, PhD
Professor
Department of Communication Sciences and Disorders
Louisiana State University
Baton Rouge, Louisiana;
Adjunct Professor
Department of Otolaryngology–Head and Neck Surgery
Louisiana State University Health Sciences Center
New Orleans, Louisiana

Ollivier Laccourreye, MD
Professor
Department of Otorhinolaryngology–Head and Neck Surgery
Hôpital Européen Georges Pompidou
Université Paris-Descartes
Sorbonne Paris-Cité, AP-HP
Paris, France

Stephen Y. Lai, MD, PhD
Professor
Departments of Head and Neck Surgery, Radiation Oncology, and Molecular and Cellular Oncology
University of Texas MD Anderson Cancer Center
Houston, Texas

Devyani Lal, MD
Professor of Otolaryngology
Mayo Clinic College of Medicine
Consultant
Department of Otolaryngology
Mayo Clinic
Phoenix, Arizona

Anil K. Lalwani, MD
Professor and Vice Chair for Research
Department of Otolaryngology–Head and Neck Surgery
Columbia University Vagelos College of Physicians and Surgeons
Medical Director
Perioperative Services
NewYork–Presbyterian Hospital
New York, New York

Derek J. Lam, MD, MPH
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Oregon Health and Science University
Portland, Oregon

Paul R. Lambert, MD
Professor and Chairman
Department of Otolaryngology–Head and Neck Surgery
Medical University of South Carolina
Charleston, South Carolina

Christopher G. Larsen, MD, FACS
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Division Director General Otolaryngology
University of Kansas Medical Center
Kansas City, Kansas

Richard E. Latchaw, MD
Professor
Department of Radiology
Division of Neuroradiology
University of California, Davis
Sacramento, California

Claire M. Lawlor, MD
Pediatric Otolaryngologist
Department of Otolaryngology
Children's National Health System
Assistant Professor of Pediatrics and Surgery
George Washington University School of Medicine and Health Sciences
Washington, DC

Colleen G. Le Prell, PhD
Emilie and Phil Schepps Professor of Hearing Science
School of Behavioral and Brain Sciences
University of Texas at Dallas
Dallas, Texas

Kevin P. Leahy, MD, PhD
Assistant Professor
Department of Otorhinolaryngology–Head and Neck Surgery
University of Pennsylvania Perelman School of Medicine
Philadelphia, Pennsylvania

Daniel J. Lee, MD, FACS
Director, Pediatric Otology and Neurotology
Associate Professor
Department of Otology and Laryngology
Massachusetts Eye and Ear
Harvard Medical School
Boston, Massachusetts

Edward R. Lee, MD
Physician
Department of Otolaryngology–Head and Neck Surgery
University of California, San Francisco
San Francisco, California

Nancy Lee, MD
Attending and Vice Chair
Department of Radiation Oncology
Memorial Sloan Kettering Cancer Center
New York, New York

Marci M. Lesperance, MD
Professor
Department of Otolaryngology–Head and Neck Surgery
University of Michigan Health System
Ann Arbor, Michigan

Laeben Lester, MD
Assistant Professor
Departments of Anesthesiology and Critical Care Medicine and Emergency Medicine
Associate Medical Director
Johns Hopkins Medicine Multidisciplinary Airway Programs
Johns Hopkins University School of Medicine
Baltimore, Maryland

Jessica Levi, MD
Associate Professor
Otolaryngology Head and Neck Surgery
Boston University/Boston Medical Center
Boston, Massachusetts

James S. Lewis Jr, MD
Professor
Department of Pathology, Microbiology, and Immunology
Vanderbilt University Medical Center
Nashville, Tennessee

Daqing Li, MD
Professor and Attending Physician
Department of Otorhinolaryngology–Head and Neck Surgery
University of Pennsylvania Health System
Philadelphia, Pennsylvania

Timothy S. Lian, MD
Professor
Chief, Division of Facial Plastic Surgery
Department of Otolaryngology
University of Florida College of Medicine
Gainesville, Florida

Whitney Liddy, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
Northwestern University
Chicago, Illinois

Charles J. Limb, MD
Francis A. Sooy Professor
Chief, Division of Otology, Neurotology and Skull Base Surgery
Director, Douglas Grant Cochlear Implant Center
Departments of Otolaryngology–Head and Neck Surgery and Neurosurgery
University of California San Francisco School of Medicine
San Francisco, California

Frank R. Lin, MD, PhD
Professor
Department of Otolaryngology–Head and Neck Surgery
Johns Hopkins University School of Medicine
Director, Cochlear Center for Hearing and Public Health
Johns Hopkins Bloomberg School of Public Health
Baltimore, Maryland

Gary Linkov, MD
Medical Director
City Facial Plastics
New York, New York

Thomas Loh, MBBS, FRCS
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
National University Health System
Singapore

Kai Johannes Lorenz, MD, PhD
Deputy Head
Department of Otorhinolaryngology, Head and Neck Surgery
German Federal Armed Hospital, Ulm
Baden-Württemberg, Germany

David G. Lott, MD
Professor
Department of Otolaryngology–Head and Neck Surgery
Mayo Clinic College of Medicine
Consultant
Department of Otolaryngology–Head and Neck Surgery
Mayo Clinic Arizona
Phoenix, Arizona

Valerie J. Lund, CBE, MBBS, MS, FRCS, FRCS(Ed), FACS(Hon)
Professor Emeritus
Rhinology and Anterior Skull Base Surgery
University College London and Royal National Throat, Nose, and Ear Hospital London, UCLH
London, United Kingdom

Lawrence R. Lustig, MD
Professor and Chair
Department of Otolaryngology–Head and Neck Surgery
Columbia University
New York, New York

Anna Lysakowski, PhD
Professor
Departments of Anatomy and Cell Biology and Otolaryngology–Head and Neck Surgery
University of Illinois at Chicago
Chicago, Illinois

Robert H. Maisel, MD, FACS
Professor
Department of Otolaryngology–Head and Neck Surgery
University of Minnesota
Hennepin County Medical Center
Minneapolis, Minnesota

Fawaz Makki, MD, MSc, FRCS(C)
Staff Surgeon
Alberta Health Services
Calgary, Alberta, Canada;
University of Alberta
Edmonton, Alberta, Canada

Devinder S. Mangat, MD, FACS
Professor for Facial Plastic Surgery
Department of Otolaryngology–Head and Neck Surgery
University of Cincinnati Medical Center
Cincinnati, Ohio;
Private practice
Vail, Colorado

Daniele Marchioni, MD
Professor
Department of Otolaryngology–Head and Neck Surgery
University Hospital of Modena
Modena, Italy

Lynette J. Mark, MD
Associate Professor
Department of Anesthesiology and Critical Care Medicine
Joint Appointment, Department of Otolaryngology–Head and Neck Surgery
Founder, Difficult Airway Response Team (DART) Program
Johns Hopkins University School of Medicine
Baltimore, Maryland

Jeffery C. Markt, DDS
Professor
Department of Otolaryngology–Head and Neck Surgery
University of Nebraska Medical Center
Omaha, Nebraska

Michael Marsh, MD
[Ch 178]
President
Otolaryngology
Arkansas Center for Ear, Nose, Throat, and Allergy
Fort Smith, Arkansas

Davide Mattavelli, MD
Assistant Professor
Unit of Otorhinolaryngology–Head and Neck Surgery
Department of Medical and Surgical Specialties, Radiological Sciences, and Public Health
University of Brescia
Brescia, Italy

Douglas E. Mattox, MD
William Chester Warren Jr MD Professor and Chair
Department of Otolaryngology–Head and Neck Surgery
Emory University School of Medicine
Atlanta, Georgia

Hilary C. McCrary, MD, MPH
Resident Physician
Department of Otolaryngology— Head and Neck Surgery
University of Utah School of Medicine
Salt Lake City, Utah

JoAnn McGee, PhD
Senior Research Scientist
VA Loma Linda Healthcare System
Loma Linda, California;
Adjunct Faculty
Department of Speech-Language-Hearing Sciences
University of Minnesota
Minneapolis, Minnesota;
Adjunct Faculty
Department of Biomedical Sciences
Creighton University School of Medicine
Omaha, Nebraska;
Adjunct Faculty
Department of Special Education and Communication Disorders
University of Nebraska
Lincoln, Nebraska

Johnathan D. McGinn, MD
Professor and Vice Chair
Department of Otolaryngology–Head and Neck Surgery
Pennsylvania State University College of Medicine
Hershey, Pennsylvania

Kinneri Mehta, MD
Resident
Department of Otolaryngology
University of Connecticut
Farmington, Connecticut

Jeremy D. Meier, MD
Associate Professor
Division of Otolaryngology–Head and Neck Surgery
University of Utah
Salt Lake City, Utah

Albert L. Merati, MD
Professor and Chief
Department of Otolaryngology–Head and Neck Surgery
University of Washington
Seattle, Washington

Barbara P. Messing, MA, CCC-SLP, BCS-S, FASHA
Director
The Milton J Dance Jr Head and Neck Center
Johns Hopkins Head and Neck Surgery
Johns Hopkins Voice Center
Greater Baltimore Medical Center
Baltimore, Maryland;
PhD Candidate
University of Queensland
Brisbane, Queensland, Australia

Anna H. Messner, MD, FACS, FAAP
Professor and Chief of Pediatric Otolaryngology
Department of Otolaryngology–Head and Neck Surgery
Baylor College of Medicine
Texas Children's Hospital
Houston, Texas

Anna Meyer, MD
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Division of Pediatric Otolaryngology
University of California, San Francisco
San Francisco, California

Michelle Mierzwa, MD
Associate Professor
Radiation Oncology
University of Michigan
Ann Arbor, Michigan

Henry A. Milczuk, MD
Professor
Department of Otolaryngology
Oregon Health and Sciences University
Portland, Oregon

Jennifer L. Millar, MSPT
Physical Therapist
Department of Physical Medicine and Rehabilitation
Johns Hopkins University School of Medicine
Baltimore, Maryland

Michelle Miller-Thomas, MD
Associate Professor
Department of Neuroradiology
Mallinckrodt Institute of Radiology
Washington University School of Medicine in St. Louis
St. Louis, Missouri

Lloyd B. Minor, MD
Carl and Elizabeth Naumann Professor for the Dean of the School of Medicine
Professor of Otolaryngology–Head and Neck Surgery
Professor of Neurobiology and of Bioengineering, by courtesy
Stanford University
Stanford, California

Stephanie Misono, MD, MPH
Assistant Professor
Director, Lions Voice Clinic
Department of Otolaryngology–Head and Neck Surgery
University of Minnesota
Minneapolis, Minnesota

Jenna L. Mitchell, MD
Texas A&M Health Science Center
Round Rock, Texas

Steven Ross Mobley, MD
Mobley MD Facial Plastic Surgery
Clinical Adjunct Associate Professor
Department of Otolaryngology–Head and Neck Surgery
University of Utah School of Medicine
Salt Lake City, Utah

Eric J. Moore, MD
Professor
Department of Otolaryngology
Mayo Clinic
Rochester, Minnesota

Nadia K. Mostovych, MD
Facial Plastic and Reconstructive Surgery
Graduate Fellow, ABFPRS
Department of Plastic Surgery
Belcara Health
Department of Otolaryngology–Head and Neck Surgery
University of Maryland
St. Joseph Medical Center
Baltimore, Maryland

Sarah Mowry, MD, FACS
Associate Professor
Residency Program Director, CWRU ENT Residency
Medical Director, UH Cochlear Implant Program
Department of Otolaryngology–Head and Neck Surgery
Case Western Reserve University
University Hospitals Cleveland Medical Center
Cleveland, Ohio

Harlan R. Muntz, MD, FACS
Professor
Division of Otolaryngology–Head and Neck Surgery
University of Utah
Salt Lake City, Utah

Wojciech K. Mydlarz, MD
Assistant Professor
Director, Head and Neck Surgery, National Capitol Region
Department of Otolaryngology–Head and Neck Surgery
Johns Hopkins University School of Medicine
Baltimore, Maryland

Sahar Nadimi, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
Loyola University Medical Center
Maywood, Illinois

Joseph B. Nadol Jr, MD
Distinguished Professor
Department of Otolaryngology
Harvard Medical School
Boston, Massachusetts

James G. Naples, MD
Beth Israel Deaconess Medical Center
Harvard Medical School
Division of Otolaryngology–Head and Neck Surgery
Boston, Massachusetts

Paul S. Nassif, MD, FACS
Assistant Clinical Professor
Department of Otolaryngology–Head and Neck Surgery
University of Southern California
Los Angeles, California;
Director, Nassif MD, Inc and Associates
Beverly Hills, California

Matthew R. Naunheim, MD, MBA
Instructor
Department of Otolaryngology
Massachusetts Eye and Ear
Boston, Massachusetts

Gregory S. Neel
Department of Otolaryngology–Head and Neck Surgery
Mayo Clinic Arizona
Phoenix, Arizona

Marc E. Nelson, MD, MS
Associate Professor
Department of Otolaryngology
Pediatric ENT Center
Akron Children's Hospital
Akron, Ohio

Rick F. Nelson, MD, PhD
Assistant Professor
Otolaryngology–Head and Neck Surgery
Indiana University
Indianapolis, Indiana

Piero Nicolai, MD
Professor
Unit of Otorhinolaryngology–Head and Neck Surgery
Department of Medical and Surgical Specialties, Radiological Sciences, and Public Health
University of Brescia
Brescia, Italy

Carrie L. Nieman, MD, MPH
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
Johns Hopkins University School of Medicine
Core Faculty
Cochlear Center for Hearing and Public Health
Johns Hopkins Bloomberg School of Public Health
Baltimore, Maryland

Richard J. Noel, MD, PhD
Associate Professor and Chief
Division of Pediatric Gastroenterology, Hepatology, and Nutrition
Duke University Medical Center
Durham, North Carolina

S.A. Reza Nouraei, BChir, PhD, FRCS
Robert White Professor of Laryngology
Consultant Laryngologist and Tracheal Surgeon
The Robert White Centre for Airway Voice and Swallowing
Poole Hospital, NHS Foundation Trust
Poole, Dorset, United Kingdom

Ajani Nugent, MD
Department of Otolaryngology–Head and Neck Surgery
Emory University School of Medicine
Atlanta, Georgia

Daniel W. Nuss, MD, FACS
George D. Lyons MD Professor and Chairman
Department of Otolaryngology–Head and Neck Surgery
Louisiana State University School of Medicine
New Orleans, Louisiana

Brian Nussenbaum, MD, MHCM, FACS
Executive Director
American Board of Otolaryngology–Head and Neck Surgery
Houston, Texas

Rick M. Odland, MD, PhD
Professor
Department of Otolaryngology
University of Minnesota
Chief
Department of Otolaryngology
Hennepin Healthcare
Minneapolis, Minnesota

Richard G. Ohye, MD
Edward L. Bove MD Professor of Cardiac Surgery
Head, Section of Pediatric Cardiovascular Surgery
University of Michigan Medical School
Ann Arbor, Michigan

Bert W. O'Malley Jr, MD
Professor and Chair
Department of Otolaryngology–Head and Neck Surgery
University of Pennsylvania Health System
Philadelphia, Pennsylvania

Robert C. O'Reilly, MD
Division of Otolaryngology
Children's Hospital of Philadelphia
Professor, Department of Otorhinolaryngology–Head and Neck Surgery
Perelman School of Medicine at the University of Pennsylvania
Philadelphia, Pennsylvania

Richard R. Orlandi, MD
Professor
Division of Otolaryngology–Head and Neck Surgery
University of Utah School of Medicine
Salt Lake City, Utah

Hilary L.P. Orlowski, MD
Assistant Professor
Department of Neuroradiology
Mallinckrodt Institute of Radiology
Washington University School of Medicine in St Louis
St. Louis, Missouri

Giancarlo Ottaviano, MD, PhD
Department of Neurosciences—ENT Section
University-Hospital of Padova
Padova, Italy

Nitin A. Pagedar, MD, MPH
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
University of Iowa
Iowa City, Iowa

James N. Palmer, MD
Professor
Department of Otorhinolaryngology–Head and Neck Surgery
University of Pennsylvania Perelman School of Medicine
Philadelphia, Pennsylvania

Blake C. Papsin, MD, MSc, FRCS(C), FAAP, FRCS
Professor
Department of Otolaryngology–Head and Neck Surgery
Faculty of Medicine
University of Toronto
Otolaryngologist-in-Chief
Department of Otolaryngology–Head and Neck Surgery
The Hospital for Sick Children
Toronto, Ontario, Canada

Albert H. Park, MD
Chief, Pediatric Otolaryngology
Professor, Division of Otolaryngology–HNS
University of Utah
Salt Lake City, Utah

Stephen S. Park, MD
Professor
Department of Otolaryngology–Head and Neck Surgery
University of Virginia
Charlottesville, Virginia

Matthew S. Parsons, MD
Associate Professor
Department of Neuroradiology
Mallinckrodt Institute of Radiology
St. Louis, Missouri

G. Alexander Patterson, MD, FRCS(C), FACS
Joseph C Bancroft Professor
Department of Surgery
Washington University School of Medicine in St. Louis
St Louis, Missouri

Phillip K. Pellitteri, DO, FACS
Chair
Department of Otolaryngology–Head and Neck Surgery
Guthrie Health System
Sayre, Pennsylvania;
Clinical Professor
Department of Otolaryngology–Head and Neck Surgery
Temple University School of Medicine
Philadelphia, Pennsylvania;
Clinical Professor
Department of Surgery
Geisinger Commonwealth School of Medicine
Scranton, Pennsylvania

Jonathan A. Perkins, DO, FACS
Professor
Department of Otolaryngology–Head and Neck Surgery
University of Washington School of Medicine
Director, Vascular Anomalies Program
Seattle Children's Hospital
Seattle, Washington

Stephen W. Perkins, MD, FACS
Clinical Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Indiana University School of Medicine
President
Meridian Plastic Surgeons
Indianapolis, Indiana

Bailey Pierce, BS
Charles E. Schmidt College of Medicine
Florida Atlantic University
Boca Raton, Florida

Shirley S.N. Pignatari, MD, PhD
Associate Professor
Department of Otorhinolaryngology–Head and Neck Surgery
Federal University of São Paulo
São Paulo, Brazil

Steven D. Pletcher, MD
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
University of California, San Francisco
San Francisco, California

Dennis S. Poe, MD, PhD
Professor
Department of Otolaryngology
Harvard Medical School
Boston Children's Hospital
Boston, Massachusetts

Aron Popovtzer, MD
Head of Head and Neck Unit
Vice Chair, Oncology Center
Davidoff Cancer Center
Rabin Medical Centet
Tel Aviv University Medical School
Petah Tikva, Israel

Gregory N. Postma, MD
Professor and Vice Chairman
Department of Otolaryngology–Head and Neck Surgery
Medical College of Georgia at Augusta University
Augusta, Georgia

James C. Prueter, DO
Otology and Skull Base Surgery Fellow
Swedish Neuroscience Institute
Seattle, Washington

Michael P. Puglia II, MD, PhD
Lecturer
University of Michigan
Department of Anesthesiology
CS Mott Children's Hospital
Ann Arbor, Michigan

Z. Jason Qian, MD
Resident
Department of Otolaryngology–Head and Neck Surgery
Stanford University School of Medicine
Stanford, California

Alicia M. Quesnel, MD
Assistant Professor
Department of Otolaryngology
Massachusetts Eye and Ear
Harvard Medical School
Boston, Massachusetts

Reza Rahbar, DMD, MD
Professor
Department of Otolaryngology
Harvard Medical School
Associate Otolaryngologist-in-Chief
McGill Chair in Pediatric Otolaryngology
Department of Otolaryngology and Communication Enhancement
Boston Children's Hospital
Boston, Massachusetts

Virginia Ramachandran, AuD, PhD
Education and Training Specialist
Oticon, Inc.
Somerset, New Jersey

Vijay R. Ramakrishnan, MD
Associate Professor
Department of Otolaryngology
University of Colorado School of Medicine
Department of Neurosurgery
University of Colorado School of Medicine
Aurora, Colorado

Gregory W. Randolph, MD, FACS, FACE
Director, General and Thyroid/Parathyroid Endocrine Surgical Divisions
Massachusetts Eye and Ear
Professor of Otolaryngology–Head and Neck Surgery
Claire and John Bertucci Endowed Chair in Thyroid Surgical Oncology
Harvard Medical School
Boston, Massachusetts

Krishna Rao, MD, PhD
Associate Professor
Division of Hematology/Medical Oncology
Department of Internal Medicine
Simmons Cancer Institute
Southern Illinois University School of Medicine
Springfield, Illinois

Lesley Rao, MD
Assistant Professor
Department of Anesthesiology and Pain Management
Washington University School of Medicine in St. Louis
St. Louis, Missouri

Christopher H. Rassekh, MD
Professor
Department of Otorhinolaryngology–Head and Neck Surgery
University of Pennsylvania
Philadelphia, Pennsylvania

Lisa M. Reid, MD
Associate Professor
Department of Surgery
Cooper University Hospital
Camden, New Jersey

Lou Reinisch, PhD
Associate Provost
Academic Affairs
New York Institute of Technology
New York, New York

Eleni Rettig, MD
Instructor of Otolaryngology–Head and Neck Surgery
Harvard Medical School
Associate Surgeon
Brigham and Women's Hospital and Dana-Farber Cancer Institute
Boston, Massachusetts

Matthew H. Rigby, MD, MPH, FRCS(C)
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
Dalhousie University
Halifax, Nova Scotia, Canada

Alejandro Rivas, MD
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
The Otology Group of Vanderbilt
Vanderbilt University
Nashville, Tennessee

K. Thomas Robbins, MD
Professor Emeritus
Division of Otolaryngology–Head and Neck Surgery
Executive Director Emeritus
Simmons Cancer Institute at SIU
Simmons Endowed Chair of Excellence in Oncology
Southern Illinois University School of Medicine
Springfield, Illinois

Daniel S. Roberts, MD, PhD
Assistant Professor
Department of Otolaryngology
University of Connecticut
Farmington, Connecticut

Brianne Roby, MD
Assistant Professor
Department of Otolaryngology
University of Minnesota
Minneapolis, Minnesota;
Pediatric Otolaryngologist
Pediatric ENT and Facial Plastic Surgery
Children's Hospitals and Clinics of Minnesota
St. Paul, Minnesota

J. Thomas Roland Jr, MD
Mendik Foundation Chairman and Professor
Department of Otolaryngology–Head and Neck Surgery
NYU Langone Medical Center and NYU School of Medicine
New York, New York

Ohad Ronen, MD
Director
Head and Neck Surgery Unit
Department of Otolaryngology–Head and Neck Surgery
Galilee Medical Center
Nahariya, Israel;
Azrieli Faculty of Medicine
Bar-Ilan University
Safed, Israel

Kristina W. Rosbe, MD
Professor and Chief of Pediatric Otolaryngology
Department of Otolaryngology–Head and Neck Surgery
University of California, San Francisco
San Francisco, California

Richard M. Rosenfeld, MD, MPH, MBA
Distinguished Professor and Chairman
Department of Otolaryngology
SUNY Downstate Medical Center
Brooklyn, New York

Bruce E. Rotter DMD, MS
Professor and Dean
Southern Illinois University
School of Dental Medicine
Edwardsville, Illinois

Christopher R. Roxbury, MD
Assistant Professor
Rhinology and Endoscopic Skull Base Surgery
University of Chicago
Chicago, Illinois

Michael J. Ruckenstein, MD
Professor
Department of Otolaryngology–Head and Neck Surgery
Hospitals of the University of Pennsylvania
Philadelphia, Pennsylvania

Christina L. Runge, PhD
Professor
Chief, Division of Communication Sciences
Director, Koss Cochlear Implant Program
Department of Otolaryngology and Communication Sciences
Medical College of Wisconsin
Milwaukee, Wisconsin

Leonard P. Rybak, MD, PhD
Research Professor
Department of Otolaryngology
Southern Illinois University School of Medicine
Springfield, Illinois

Robert Saadi, MD
Resident
Department of Otolaryngology
Hershey Medical Center
Hershey, Pennsylvania

Thomas J. Salinas, DDS
Professor
Department of Dental Specialties
Mayo Clinic
Rochester, Minnesota

Sandeep Samant, MD
Chief, Division of Head and Neck and Skull Base Surgery
Professor and Vice-Chairman
Department of Otolaryngology–Head and Neck Surgery
University of Tennessee Health Science Center
Memphis, Tennessee

Robin A. Samlan, PhD
Associate Professor
Department of Speech, Language, and Hearing Sciences
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of Arizona
Tucson, Arizona

Guri S. Sandhu, MBBS, MD, FRCS, FRCS (ORL-HNS)
Consultant Otolaryngologist/Airway Surgeon
Department of Otolaryngology–Head and Neck Surgery
Charing Cross Hospital
Imperial College Healthcare NHS Trust
London, United Kingdom

Kathleen M. Sarber, MD
Assistant Professor
Department of Surgery
F. Edward Hébert School of Medicine
Uniformed Services University of the Health Sciences
Bethesda, Maryland

Cara L. Sauder, PhC, CCC-SLP
Speech Pathologist
Department of Speech and Hearing Sciences
University of Washington
Seattle, Washington

Richard L. Scher, MD, FACS
Professor Emeritus
Head and Neck Surgery and Communication Sciences
Duke University Health System
Durham, North Carolina;
Executive Director
ENT Procedure Innovation and Development
Olympus Corporation
Southborough, Massachusetts

Anne G.M. Schilder, MD, PhD
Professor
evidENT
Ear Institute
University College London
National Institute of Health Research
University College London Hospitals Biomedical Research Centre
London, United Kingdom

Joshua S. Schindler, MD
Associate Professor
Department of Otolaryngology
Oregon Health and Science University
Medical Director
OHSU–Northwest Clinic for Voice and Swallowing
Portland, Oregon

Cecelia E. Schmalbach, MD, MSc, FACS
David Myers MD Professor and Chair
Department of Otolaryngology– Head and Neck Surgery
Director, Temple Head and Neck Institute
Lewis Katz School of Medicine at Temple University
Philadelphia, Pennsylvania

Scott R. Schoem, MD, MBA
Director
Department of Otolaryngology
Connecticut Children's Medical Center
Hartford, Connecticut;
Clinical Professor
Department of Otolaryngology
University of Connecticut School of Health Sciences
Farmington, Connecticut

Michael C. Schubert, PT, PhD, FAPTA
Professor
Departments of Otolaryngology–Head and Neck Surgery
and Physical Medicine and Rehabilitation
Johns Hopkins University School of Medicine
Baltimore, Maryland

Joseph Schulte, MD
Fellow
Department of Neuroradiology
Johns Hopkins University
Baltimore, Maryland

Yehuda Schwarz, MD
Director of Pediatric Otolaryngology Service
Department of Otolaryngology–Head and Neck Surgery
Samson Assuta Ashdod University Hospital
Faculty of Health Sciences
Ben Gurion University of the Negev
Be'er Sheva, Israel;
Senior Physician
Department of Otolaryngology–Head and Neck Surgery
Shaare Zedek Medical Center
Jerusalem, Israel

James J. Sciubba, DMD, PhD
Professor (Retired)
Department of Otolaryngology–Head and Neck Surgery
Johns Hopkins School of Medicine
Consultant
The Milton J. Dance Head & Neck Center
The Greater Baltimore Medical Center
Baltimore, Maryland

Anthony P. Sclafani, MD, FACS
Director
Department of Facial Plastic Surgery
Weill Cornell Medical Center
Professor
Department of Otolaryngology–Head and Neck Surgery
Weill Cornell Medical College
New York, New York

Hadi R. Seikaly, MD, MAL, FRCS(C)
Professor of Surgery and Oncology
Director, Division of Otolaryngology–Head and Neck Surgery
Zone Clinical Department Section Chief of Otolaryngology–Head and Neck Surgery
Department of Surgery
University of Alberta and Alberta Health Services
Edmonton, Alberta, Canada

Samuel H. Selesnick, MD
Professor and Vice Chairman
Department of Otolaryngology–Head and Neck Surgery
Weill Cornell Medical College
New York, New York

Brent A. Senior, MD, FACS, FARS
Professor
Department of Otolaryngology–Head and Neck Surgery
University of North Carolina
Chapel Hill, North Carolina

Anu Sharma, PhD
Professor
Department of Speech, Language, and Hearing Science
Institute of Cognitive Science
Center for Neuroscience
University of Colorado
Boulder, Colorado

Jeffrey D. Sharon, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of California, San Francisco
San Francisco, California

A. Eliot Shearer, MD, PhD
Clinical Fellow in Pediatric Otolaryngology
Department of Otolaryngology and Communication Enhancement
Boston Children's Hospital
Boston, Massachusetts

Clough Shelton, MD, FACS
C. Charles Hetzel Jr MD and Alice Barker Hetzel Presidential Endowed Chair in Otolaryngology
Professor and Chief, Division of Otolaryngology–Head and Neck Surgery
University of Utah
Salt Lake City, Utah

Seiji B. Shibata, MD, PhD
Clinical Fellow in Otology/Neurotology
Department of Otolaryngology–Head and Neck Surgery
University of Iowa Hospitals and Clinics
Iowa City, Iowa

Yelizaveta Shnayder, MD, FACS
Professor
Department of Otolaryngology–Head and Neck Surgery
University of Kansas School of Medicine
Kansas City, Kansas

Elizabeth A. Shuman, MD
Resident Physician
Department of Otolaryngology–Head and Neck Surgery
University of California, San Francisco
San Francisco, California

Douglas R. Sidell, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
Division of Pediatric Otolaryngology
Stanford University
Stanford, California

Parul Sinha, MBBS, MS
Resident
Department of Otorhinolaryngology–Head and Neck Surgery
Washington University School of Medicine in St. Louis
St. Louis, Missouri

Davud B. Sirjani, MD, FACS
Associate Professor
Department of Otolaryngology
Stanford University
Stanford, California

Jonathan R. Skirko, MD, MHPA, MPH
Assistant Professor
Division of Otolaryngology–Head and Neck Surgery
University of Utah
Salt Lake City, Utah

Heidi K. Slager, AuD
Audiologist
Department of Otolaryngology
University of Michigan
Ann Arbor, Michigan

William H. Slattery III, MD
President
House Ear Clinic
Clinical Professor
Department of Otolaryngology–Head and Neck Surgery
University of California, Los Angeles
Clinical Professor
Department of Otolaryngology
University of Southern California
Los Angeles, California

Kristine A. Smith, MD
Assistant Professor
Rhinology and Skull Base Surgery
Department of Otolaryngology–Head and Neck Surgery
University of Manitoba
Winnipeg, Manitoba, Canada;
Department of Otolaryngology–Head and Neck Surgery
University of Utah School of Medicine
Salt Lake City, Utah

Richard J.H. Smith, MD
Sterba Hearing Research Professor
Department of Otolaryngology–Head and Neck Surgery
Carver College of Medicine
University of Iowa
Iowa City, Iowa

Ryan M. Smith, MD
Assistant Professor
Department of Otorhinolaryngology–Head and Neck Surgery
Section of Facial Plastic and Reconstructive Surgery
Rush University Medical Center
Chicago, Illinois

Timothy L. Smith, MD, MPH
Professor and Director
Oregon Sinus Center at OHSU
Department of Otolaryngology–Head and Neck Surgery
Oregon Health and Science University
Portland, Oregon

Zachary M. Soler, MD, MSc
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Medical University of South Carolina
Charleston, South Carolina

Matthew E. Spector, MD, FACS
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of Michigan, Michigan Medicine
Ann Arbor, Michigan

Steven M. Sperry, MD
Head and Neck Surgeon
Department of Otolaryngology–Head and Neck Surgery
Advocate Aurora Health
Milwaukee, Wisconsin

Brad A. Stach, PhD
Director, Division of Audiology
Department of Otolaryngology–Head and Neck Surgery
Henry Ford Hospital
Detroit, Michigan

Robert P. Stachecki
Assistant Professor
Mallinckrodt Institute of Radiology
Washington University Medical Center
St. Louis, Missouri;
Department of Radiology
Barnes-Jewish St. Peters Hospital
St. Peters, Missouri

Aldo Cassol Stamm, MD, PhD
Chief, Department of Otolaryngology
Sao Paulo ENT Center
Co-Director, Skull Base
Sao Paulo Skull Base Center
Sao Paulo, Brazil

James A. Stankiewicz, MD
Former Chair and Professor
Department of Otolaryngology–Head and Neck Surgery
Loyola University/Trinity Medical Center
Maywood, Illinois

Jeffrey T. Steitz, MD
Facial Plastic and Reconstructive Surgeon
St. Louis Facial Plastic Surgery
Synergy ENT Specialists
St. Louis, Missouri

Shawn M. Stevens
Assistant Professor
Barrow Neurologic Institute
Associate
Neurotology Otology and Skull Base Surgery
Arizona Otolaryngology Consultants
Phoenix, Arizona

David L. Steward, MD
Professor
Department of Otolaryngology–Head and Neck Surgery
Division of Endocrinology
University of Cincinnati College of Medicine
Cincinnati, Ohio

David G. Stoddard Jr, MD
Rhinologist
Spokane ENT
Spokane, Washington

Janalee K. Stokken, MD
Head and Neck Institute
The Cleveland Clinic
Cleveland, Ohio

Angela Sturm, MD, FACS
Clinical Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
McGovern Medical School at UT Health
Clinical Assistant Professor
University of Texas Medical Branch at Galveston
Department of Otolaryngology–Head and Neck Surgery
Private Practice
Facial Plastic Surgery Associates
Houston, Texas

Melanie Subramanian, MD, MPHS
Resident Physician
Cardiothoracic Surgery
Washington University School of Medicine in St. Louis
St. Louis, Missouri

John B. Sunwoo, MD
Director of Head and Neck Cancer Research
Department of Otolaryngology–Head and Neck Surgery and Stanford Cancer Institute
Stanford University School of Medicine
Stanford, California

Robert A. Swarm, MD
Professor
Department of Anesthesiology
Chief, Division of Pain Management
Washington University School of Medicine in St. Louis
St. Louis, Missouri

Jonathan M. Sykes, MD
Professor Emeritus
Department of Otolaryngology–Facial Plastic Surgery
UC Davis Medical Center
Sacramento, California

Noah P. Syme, MD
Assistant Professor, Head and Neck Oncology
Department of Surgery
Division of Otolaryngology
University of New Mexico
Albuquerque, New Mexico

M. Eugene Tardy Jr., MD
Professor Emeritus of Otolaryngology–Head and Neck Surgery
Department of Otolaryngology
University of Illinois Medical Center
Chicago, Illinois

Sherard A. Tatum III, MD
Professor and Interim Chair
Department of Otolaryngology and Pediatrics
SUNY Upstate Medical University
Medical Director
Cleft and Craniofacial Center
Golisano Children's Hospital
Syracuse, New York

S. Mark Taylor, MD, FRCS(C), FACS
Professor and Head
Department of Otolaryngology–Head and Neck Surgery
Dalhousie University
Halifax, Nova Scotia, Canada

Rod A. Teasley, MD, JD
Attending Otolaryngologist
Tacoma, Washington

Steven A. Telian, MD
John L. Kemink Professor of Neurotology
Division of Otology-Neurotology
Department of Otolaryngology–Head and Neck Surgery
University of Michigan Medical School
Ann Arbor, Michigan

David J. Terris, MD
Regents' Professor
Department of Otolaryngology–Head and Neck Surgery
Medical College of Georgia at Augusta University
Augusta, Georgia

Aaron L. Thatcher, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of Michigan
Ann Arbor, Michigan

J. Regan Thomas, MD
Professor, Facial Plastic Surgery
Department of Otolaryngology–Head and Neck Surgery
Northwestern University Feinberg School of Medicine
Chicago, Illinois

Sherry R. Timmons, DDS, PhD
Associate Dean for Education
Department of Oral Pathology, Radiology, and Medicine
University of Iowa College of Dentistry
Iowa City, Iowa

Tjoson Tjoa, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of California, Irvine
Irvine, California

Dean M. Toriumi, MD
Head, Division of Facial Plastic and Reconstructive Surgery
Department of Otolaryngology–Head and Neck Surgery
University of Illinois at Chicago
Chicago, Illinois

Matteo Trimarchi, Prof, MD
Associate Professor
Department of Otorhinolaryngology
IRCCS San Raffaele Hospital
Vita-Salute San Raffaele University
Milan, Italy

Terance T. Tsue, MD
Douglas A. Girod Endowed Professor of Head and Neck Surgical Oncology
Department of Otolaryngology–Head and Neck Surgery
University of Kansas School of Medicine
Vice President and Physician in Chief
University of Kansas Cancer Center
Vice President of Physician Services
The University of Kansas Health System
Kansas City, Kansas

Nathan C. Tu, MD, MHS
Clinical Neurotology Fellow
Michigan Ear Institute
Farmington Hills, Michigan

Michael D. Turner, DDS, MD
Associate Professor
Chief, Division of Oral and Maxillofacial Surgery
Icahn Mount Sinai Medical School
New York, New York

Ravindra Uppaluri, MD, PhD
Associate Professor
Harvard Medical School
Director, Head and Neck Surgical Oncology
Brigham and Women's and Dana-Farber Cancer Institute
Boston, Massachusetts

Michael F. Vaezi, MD, PhD, MSc
Professor of Medicine and Clinical Director
Division of Gastroenterology and Hepatology
Director, Center for Swallowing and Esophageal Disorders
Director, Clinical Research
Vanderbilt University Medical Center
Nashville, Tennessee

Kathryn M. Van Abel, MD
Assistant Professor
Department of Otolaryngology
Mayo Clinic
Rochester, Minnesota

Michiel W.M. van den Brekel, MD, PhD
Chairman, Department of Head and Neck Oncology and Surgery
The Netherlands Cancer Institute–Antoni van Leeuwenhoek
Professor for Oncology-Related Voice and Speech Disorders
Amsterdam Center for Language and Communication
University of Amsterdam
Amsterdam, The Netherlands

Laura Van Gerven, MD, PhD
Assistant Professor
Research Group, Experimental Otorhinolaryngology
Department of Neurosciences
Clinical Department of Otorhinolaryngology
Head and Neck Surgery
University Hospitals
Leuven, Belgium

Roderick P. Venekamp, MD, PhD
Assistant Professor
Julius Center for Health Sciences and Primary Care
General Practice
University Medical Center Utrecht, Utrecht University
Utrecht, The Netherlands

Sunil P. Verma, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of California, Irvine School of Medicine
Irvine, California;
Director
University Voice and Swallowing Center
UC Irvine Medical Center
Orange, California

Jennifer A. Villwock, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
University of Kansas Medical Center
Kansas City, Kansas

Esther X. Vivas, MD
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Emory University School of Medicine
Atlanta, Georgia

David Vokes, BHB, MBChB, FRACS
Consultant Otolaryngologist and Head and Neck Surgeon
Department of Otorhinolaryngology–Head and Neck Surgery
Auckland City Hospital
Auckland, New Zealand

P. Ashley Wackym, MD
Professor and Chair
Department of Otolaryngology–Head and Neck Surgery
Rutgers Robert Wood Johnson Medical School
New Brunswick, New Jersey

Edward J. Walsh, PhD
Senior Research Scientist
VA Loma Linda Healthcare System
Loma Linda, California;
Adjunct Faculty, Department of Speech-Language-Hearing Sciences
University of Minnesota
Minneapolis, Minnesota;
Adjunct Faculty, Department of Biomedical Sciences
Creighton University
Adjunct Faculty, Department of Otolaryngology
University of Nebraska Medical Center
Omaha, Nebraska;
Adjunct Faculty, School of Natural Resources
University of Nebraska
Lincoln, Nebraska

Rohan R. Walvekar, MD
Clinical Professor
Mervin L Trail Endowed Chair for Head and Neck Oncology
Department of Otolaryngology–Head and Neck Surgery
Louisiana State University School of Medicine
New Orleans, Louisiana

Jennifer R. Wang, MD, ScM
Assistant Professor
Department of Head and Neck Surgery
University of Texas MD Anderson Cancer Center
Houston, Texas

Tom D. Wang, MD
Professor and Director
Division of Facial Plastic and Reconstructive Surgery
Oregon Health and Science University
Portland, Oregon

Bryan K. Ward, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
Johns Hopkins University School of Medicine
Baltimore, Maryland

Randal S. Weber, MD
Professor
Department of Head and Neck Surgery
University of Texas MD Anderson Cancer Center
Houston, Texas

Richard O. Wein, MD, FACS
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
Tufts Medical Center
Boston, Massachusetts

Gregory S. Weinstein, MD
Professor and Vice Chair
Department of Otorhinolaryngology–Head and Neck Surgery
The University of Pennsylvania
Philadelphia, Pennsylvania

Erik K. Weitzel, MD
Deputy Commander
US Army Institute of Surgical Research
Director, AirMed Research Program
Professor of Surgery, USUHS
Bethesda, Maryland;
Otolaryngology/Rhinology/Skull Base Surgery
Joint Base
San Antonio, Texas

D. Bradley Welling, MD, PhD
Walter Augustus LeCompte Professor and Chair
Department of Otology and Laryngology
Harvard University
Chief of Otolaryngology
Massachusetts Eye and Ear
Massachusetts General Hospital
Boston, Massachusetts

Katherine Lisa Whitcroft, MBChB (Hons), BSc (Neuroscience), MRCS, DOHNS
ENT Specialty Registrar
Yorkshire and Humber Deanery
United Kingdom;
Research Fellow
Smell and Taste Clinic
Department of Otorhinolaryngology
Technische Universität Dresden
Dresden, Germany;
PhD Candidate
Ear Institute
University College, London
Associate Research Fellow
Centre for the Study of the Senses
School of Advanced Study
London, United Kingdom

Richard H. Wiggins III, MD
Professor, Director of Head and Neck Imaging
Departments of Radiology, Otolaryngology–Head and Neck Surgery, and BioMedical Informatics
Division of Otolaryngology–Head and Neck Surgery
University of Utah
Salt Lake City, Utah

Brent J. Wilkerson, MD
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
San Antonio Military Medical Center
San Antonio, Texas

Eric P. Wilkinson, MD
Surgeon/Partner
House Clinic
House Ear Institute
Los Angeles, California

Melissa L. Wingo, MS, PA-C
Physician Assistant
Laryngology
Bastian Voice Institute
Downers Grove, Illinois

Sarah K. Wise, MD, MSCR
Professor
Department of Otolaryngology–Head and Neck Surgery
Director, Residency Program
Emory University School of Medicine
Atlanta, Georgia

Laurelie R. Wishart, BSpPath(Hons), PhD
Research Workforce Development Officer (Allied Health)
Centre for Functioning and Health Research
Metro South Hospital and Health Service
Lecturer
School of Health and Rehabilitation Sciences
University of Queensland
Brisbane, Queensland, Australia

Erika Woodson, MD, FACS
Section Head, Otology/Neurotology
Medical Director, Hearing Implant Program
Head and Neck Institute
Cleveland Clinic Foundation
Clinical Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
The Cleveland Clinic Lerner School of Medicine
Cleveland, Ohio

Gayle Ellen Woodson, MD
Adjunct Professor
Department of Otolaryngology
Drexel University College of Medicine
Philadelphia, Pennsylvania

Peter J. Wormald, MD
Chairman and Professor
Department of Otolaryngology–Head and Neck Surgery
Professor, Skull Base Surgery
University of Adelaide
Adelaide, South Australia

Douglas M. Worrall, MD
Resident
Department of Otolaryngology
Icahn School of Medicine at Mount Sinai
New York, New York

Bozena B. Wrobel, MD, FARS
Associate Professor of Otolaryngology and Neurosurgery
Chief, Division of Rhinology and Skull Base Surgery
USC Caruso Department of Otolaryngology–Head and Neck Surgery
University of Southern California
Los Angeles, California

Mary Jue Xu, MD
Resident Physician
Department of Otolaryngology–Head and Neck Surgery
University of California, San Francisco
San Francisco, California

Thomas R. Yackel, MD, MPH, MS, MBA
Professor
Department of Internal Medicine
VCU School of Medicine
Richmond, Virginia

Carol H. Yan, MD
Assistant Professor
Division of Otolaryngology–Head and Neck Surgery
University of California, San Diego
San Diego, California

Charles D. Yingling, PhD
Clinical Professor
Department of Otolaryngology–Head and Neck Surgery
Stanford School of Medicine
Stanford, California

Diana H. Yu, MD
Assistant Professor of Clinical Medicine
Director, Interventional Pulmonology Research
Division of Pulmonary, Critical Care, and Sleep Medicine
Keck School of Medicine, University of Southern California
Los Angeles, California

Yao Yu, MD
Assistant Attending
Department of Radiation Oncology
Memorial Sloan Kettering Cancer Center
New York, New York

Bevan Yueh, MD, MPH
George L. Adams Chair for Leadership in Otolaryngology
Associate Dean for Strategy and Innovation
Professor
Department of Otolaryngology–Head and Neck Surgery
University of Minnesota
Minneapolis, Minnesota

Mark E. Zafereo, MD
Associate Professor
Department of Head and Neck Surgery
University of Texas MD Anderson Cancer Center
Houston, Texas

Renzo Zaldivar, MD
Oculofacial Plastic Surgeon
Oculofacial Plastic Surgery Consultants, PA
Cary, North Carolina

Adam M. Zanation, MD
Associate Professor
Department of Otolaryngology–Head and Neck Surgery
University of North Carolina
Chapel Hill, North Carolina

Carlton J. Zdanski, MD, FAAP, FACS
Herbert H. Thorp and Julian T. Mann Distinguished Professor
Department of Otolaryngology–Head and Neck Surgery
Surgical Director, The North Carolina Children's Airway Center
University of North Carolina School of Medicine
Chapel Hill, North Carolina

David S. Zee, MD
Professor
Departments of Neurology, Ophthalmology, and Otolaryngology–Head and Neck Surgery, and Neuroscience
Johns Hopkins University School of Medicine
Baltimore, Maryland

Daniel M. Zeitler, MD, FACS
Staff Surgeon
Department of Otolaryngology–Head and Neck Surgery
Virginia Mason Medical Center
Clinical Instructor
Department of Otolaryngology–Head and Neck Surgery
University of Washington
Seattle, Washington

Marc S. Zimbler, MD
Assistant Clinical Professor
Department of Otolaryngology–Head and Neck Surgery
NYU Langone Medical Center
New York, New York

S. James Zinreich, MD
Professor
Russell H. Morgan Department of Radiology and Radiologic Sciences
Johns Hopkins Hospital
Baltimore, Maryland

David Zopf, MD, MS
Assistant Professor
Department of Otolaryngology–Head and Neck Surgery
Pediatric Otolaryngology
University of Michigan, Michigan Medicine
Ann Arbor, Michigan

Teresa A. Zwolan, PhD, CCC-A
Professor and Director
Department of Otolaryngology
University of Michigan Cochlear Implant Program
Ann Arbor, Michigan

Preface

As with all specialties, otolaryngology–head and neck surgery continues to evolve as the result of evidence-based medicine, our ability to understand the immune response to cancer and introduction of targeted therapies, unlocking the genetic basis of disease, and advances in technology across the spectrum of surgical procedures. In response, the seventh edition of *Cummings Otolaryngology – Head and Neck Surgery* has added 12 new chapters in addition to expanding the archive of narrated video clips. Video clips, now totaling 73 (up from 49), are cited in the text with live links to eBook and Expert Consult.

New chapters in the otology and skull base section reflect the growing acceptance of middle ear endoscopy and eustachian tube surgery in daily clinical practice and the increasing recognition of the public health importance of hearing, vestibular disorders, and geriatric otology. New insights into allergy, chronic rhinosinusitis, and facial pain are highlighted. New chapters in pediatric diseases include pediatric cochlear implantation, advances in otologic surgery, vestibular disorders, and pediatric speech disorders. Pediatric airway management includes new chapters on laryngeal cleft surgery and management of pediatric tracheostomy. Changes in the epidemiology, science, novel staging, and treatment of HPV-related head and neck cancer are detailed in updated chapters. In addition, new chapters highlight computer-simulated and modeled dentomandibular reconstruction and advances in the technology and approaches to transoral surgery for upper aerodigestive tract tumors.

New material is now available on our digital platform, Expert Consult, to complement several otology and neurotology chapters in the text. This content includes a 29-slide deck of labeled temporal bone sections arranged in series, providing a valuable educational resource for understanding ear anatomy and associated function.

We continue to keep the text concise, yet representative of the major and notable developments in the field. As with the last edition, the seventh features access to an eBook and the Expert Consult website, which includes enhanced text and images from the book, a full reference list for each chapter, as well as videos demonstrating ACGME (Accreditation Council for Graduate Medical Education) *Key Indicator Procedures*, and more. The video component provides residents and practitioners the opportunity to visualize and better understand the critical elements of these core procedures.

Our goal is to further the education of those now associated with otolaryngology and head and neck surgery and provide a foundation for the next generation to follow. Our editors and contributors, by tradition, have worldwide representation, thus reflecting the global contributions to the field. Through the combined effort of all contributors, the seventh edition will continue to be the definitive resource of our specialty.

Paul W. Flint
Howard W. Francis
Bruce H. Haughey
Marci M. Lesperance
Valerie J. Lund
K. Thomas Robbins
J. Regan Thomas

Acknowledgments

As senior editor, I dedicate this edition to Mark Richardson and John Niparko, both former editors, colleagues, and friends who met untimely deaths. Here are a few thoughts to share.

John Niparko and I started our faculty careers together under the mentorship of Charlie Cummings. We arrived at Johns Hopkins a week apart and soon shared a lab, both interested in the central connections affecting diseases in our areas of interest, the cochlear nucleus for John and the nucleus ambiguous for me (by definition I was faced with the more daunting challenge). We learned together about the challenges of collaboration and we grew together as a result of this relationship. Over time, I realized I would be the true beneficiary in this partnership. As we both moved on to our clinical calling, John soon became recognized as the leader in outcomes research in cochlear implantation, mentoring numerous future leaders now coming of age. In a generation, there are only a handful of individuals that succeed in influencing both the practice of medicine and economics of medicine across their specialty. John stands tall among them.

After 2 years of general surgery, Mark Richardson was my first otolaryngology attending at the University of Washington. His compassion for pediatric otolaryngology and empathy for his patients was infectious, and at the same time life balance was key to Mark…I worked hard, yet we had many laughs together in clinic and OR. I somehow survived the rotation, and so did Mark. We crossed paths again at Johns Hopkins, where Mark and Ellen became dear friends with the Flints and the opportunity to assume the chair at OHSU under Dean Richardson was an honor. We shared a hallway at the oral board exams. We butted heads over the budget. Our friendship grew. Over the years, I could see the influence Mark had on the specialty and beyond. As Chair, he attracted the best and brightest residents. Mark was a superb dean and leader in academic medicine and was able to guide the school of medicine through rocky times. I still admire his ability to deal with heated board issues and somehow find the simple solution to complex problems.

It is my sincere privilege to dedicate this textbook to two great leaders in otolaryngology–head and neck surgery.

Paul W. Flint

I would like to thank Paul Flint for this opportunity to participate in the continuing legacy of the Cummings text. My role as editor of the otology, neurotology, and skull base section brings my career full circle, and as such, I devote my efforts in honor of all the teachers, mentors, and sponsors that I have had along my academic and professional journey from Montego Bay, Jamaica, to Los Angeles, Boston, Baltimore, and Durham, NC. Charles Cummings and John Niparko, in particular, loom large in the development of my professional identity as an academic otolaryngologist and neurotologist. As their past resident, fellow, and junior colleague, there is no greater honor than to be entrusted with continuing their legacy in this role. I thank my work colleagues and the wider community of otolaryngologist–head and neck surgeons who continue to inspire me for their commitment to the highest standards of excellence and also the values of compassion, inclusivity, and fairness that will keep our specialty innovative, intellectually vibrant, and increasingly relevant in broader considerations of population health. Finally, I would like to acknowledge the shared sacrifice of my family in making it possible for me to serve in this profession at the full extent of my abilities, including my wife, Sarah, my children, Natalie and Ben, and my parents, Millicent and Howard.

Howard W. Francis

It continues to be a distinct honor and pleasure to be part of the editorial team assembled for this seventh Edition of *Cummings Otolaryngology–Head and Neck Surgery*. The publishers and authors have been tireless in their work to produce chapters that are comprehensive in scope and depth. My sincere thanks go to each author and their family, who inevitably have put up with liberal amounts of "burning the midnight oil." I must also acknowledge my assistant, Sarah Pete, my PA, Vanessa Hernandez, and our office staff, who hold the fort for clinical matters while one is working on academic projects. Similarly, the fellows and my colleagues at Advent Health Celebration Otolaryngology–Head & Neck Surgery have been highly supportive. Thank you Scott Magnuson, MD, Michael Seidman, MD, Jim Bekeny, MD, and all the Celebration Florida crew.

The ability to purvey knowledge starts with one's education. My thanks go to my late parents, Thomas and Marjorie Haughey, my teachers, medical professors, and otolaryngology residency and fellowship mentors in both Auckland, New Zealand and at the University of Iowa, Iowa City, IA.

My family has unswervingly endorsed the time away required for this project, so heartfelt love and thanks go to my wife, Helen, as well as to each of my children and grandchildren.

As we enjoy the content of this book and its online components, I keep in mind the ultimate source of all knowledge and truth: in the words of Proverbs 26: "… The Lord gives wisdom and from his mouth come knowledge and understanding." My sincere hope is that readers learning to and practicing otolaryngology–head and neck surgery will benefit from this textbook, better accomplishing our specialty's goal of top-quality patient care.

Bruce H. Haughey

It is again my pleasure to serve as editor of the pediatric otolaryngology chapters for the premier textbook in otolaryngology–head and neck surgery. I am grateful to Dr. Flint and Dr. Cummings for the opportunity.

I owe a debt of gratitude to the authors for sharing their wealth of experience to benefit future generations of otolaryngologists. These chapters represent many hours of reviewing the literature, gathering images, writing and revising, often during evenings and weekends after clinical and other obligations are met. Finally, I thank my husband, Edward Karls, and my children, Matthew, Michelle, Maria, and Melanie, for their love, patience and support.

Marci M. Lesperance

I thank Paul Flint and his colleagues for my continued involvement in this prestigious project, the publishers for their exemplary efficiency in its management, and my husband, David Howard, for his constant support and encouragement.

Valerie J. Lund

In previous editions of the book, I have used this important opportunity to memorialize my parents and honor my beloved family, respected colleagues, mentors, and the numerous trainees with whom I have connected. However, among those I have previously acknowledged is my dearest wife, Gayle Woodson, who deserves an acknowledgment encore. Over many years together, she has excelled as a caring partner, insightful advisor, and dedicated soulmate. While becoming highly successful within her own career, she has unselfishly supported my endeavors throughout our many years in academic medicine. Thank you, Gayle.

K. Thomas Robbins

I am genuinely honored to again have the privilege of serving as an editor of this outstanding and internationally recognized textbook. As the otolaryngology specialty knowledge and information base continues to expand and grow, this multivolume textbook serves as a recognizable source of up-to-date information and a key reference for modern patient treatment. As an individual who has been privileged to maintain a career within an academic environment, this textbook provides a solid source of expertise and information for my residents and fellows in training.

It is particularly rewarding for me as an individual whose career has been focused on a subspecialty within otolaryngology to provide outstanding insight and information into the areas of facial plastic and reconstructive surgery. I am greatly appreciative to the contributing authors of this volume for providing their expertise and sharing their experience.

My wife, Rhonda Churchill Thomas, deserves my ongoing appreciation and gratitude for her enthusiastic and always present support for my professional activities. Likewise, I offer my sincere appreciation to my children, Ryan, Aaron, and Evan, for their inspiration and example.

J. Regan Thomas

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SECTION 6 Pharynx, Larynx, Trachea, and Esophagus

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PART I Measuring Outcomes and Performance

1 Outcomes Research

Stephanie Misono, Bevan Yueh

KEY POINTS

- Outcomes research, or clinical epidemiology, is the study of treatment effectiveness or the success of treatment in the nonrandomized, real-world setting. It allows researchers to gain knowledge from observational data.
- Bias and confounding can affect researchers' interpretation of study data. Accurate assessments of baseline disease status, treatment given, and outcomes of treatment is critical to sound outcomes research.
- Many types of studies are available to evaluate treatment effectiveness and include randomized trial, observational study, case-control study, case series, and expert opinions. The concept of evidence-based medicine uses the level of evidence presented in the aforementioned studies to grade diagnostic and treatment recommendations. Meta-analyses can summarize findings across multiple studies and provide important insights into the body of literature.
- Outcomes in clinical epidemiology can be difficult to quantify, and thus instruments measuring these outcomes must meet criteria of the Classical Test Theory (reliability, validity, responsiveness, and burden) or the Item Response Theory to be considered psychometrically valid.
- Many outcomes instruments have been created to assess health-related quality of life. These scales are generic or disease specific, including assessment of head and neck cancer, otologic disease, rhinologic disease, pediatric disease, voice disorders, sleep disorders, and facial plastic surgery outcomes.

INTRODUCTION

The time when physicians chose treatment based solely on their personal opinions of what was best is past. This era, although chronologically recent, is now conceptually distant. In a health care environment altered by abundant information on the internet and continual oversight by managed care organizations, patients and insurers are now active participants in selecting treatment. Expert opinions are replaced by objective evidence representing multiple stakeholders, and the physician's sense of what is best is being supplemented by patients' perspectives on outcomes after treatment.

Outcomes research (clinical epidemiology) is the scientific study of treatment effectiveness. The word "effectiveness" is critical because it pertains to the success of treatment in populations found in actual practice in the real world, as opposed to treatment success in the controlled populations of randomized clinical trials in academic settings ("efficacy").[1,2] Success of treatment can be measured using survival, costs, and physiologic measures, as well as health-related quality of life (HRQOL).

To gain scientific insight into these types of outcomes in the observational (nonrandomized) setting, outcomes researchers and care providers relying on evidence-based medicine (EBM) need to be fluent in methodologic techniques that are borrowed from a variety of disciplines, including epidemiology, biostatistics, economics, management science, and psychometrics. A full description of the techniques in clinical epidemiology[3] is beyond the scope of this chapter. The goal of this chapter is to provide a primer on the basic concepts in effectiveness research and to provide a sense of the breadth and capacity of outcomes research and clinical epidemiology.

HISTORY

In 1900, Dr. Ernest Codman proposed to study what he termed the "end-results" of therapy at the Massachusetts General Hospital.[4] He asked his fellow surgeons to report the success and failure of *each* operation and developed a classification scheme by which failures could be further detailed. Over the next two decades, his attempts to introduce systematic study of surgical end-results were scorned by the medical establishment, and his prescient efforts to study surgical outcomes gradually faded.

Over the next 50 years, the medical community accepted the randomized clinical trial (RCT) as the dominant method for evaluating treatment.[5] By the 1960s, the authority of the RCT was rarely questioned.[6] However, a landmark 1973 publication by Wennberg and Gittelsohn spurred a reevaluation of the value of observational (nonrandomized) data. These authors documented significant geographic variation in rates of surgery.[7] Tonsillectomy rates in 13 Vermont regions varied from 13 to 151 per 10,000 persons, even though there was no variation in the prevalence of tonsillitis. Even in cities with similar demographics and similar access to health care (Boston and New Haven), rates of surgical procedures varied tenfold. These findings raised the question of whether the higher rates of surgery represented better care or unnecessary surgery.

Researchers at the Rand Corporation sought to evaluate the appropriateness of surgical procedures. Supplementing relatively sparse data in the literature about treatment effectiveness with expert opinion conferences, these investigators argued that rates of inappropriate surgery were high.[8] However, utilization rates did not correlate with rates of inappropriateness and therefore did not explain all of the variation in surgical rates.[9,10] To some, this suggested that the practice of medicine was anecdotal and inadequately scientific.[11] In 1988 a seminal editorial by physicians from the Health Care Financing Administration argued that a fundamental change towards study of treatment effectiveness was necessary.[12] These events subsequently led Congress to establish the Agency for Health Care Policy and Research in 1989 (since renamed the Agency for Healthcare Research and Quality [AHRQ]), which was charged with "systematically studying the relationships between health care and its outcomes."

Abstract

Outcomes research or clinical epidemiology is the study of treatment effectiveness or the success of treatment in the nonrandomized, real-world setting. It allows researchers to gain knowledge from observational data. Bias and confounding can affect researchers' interpretation of study data, and an accurate assessment of baseline disease status, comorbidities, treatment given, and outcomes of treatment is critical to sound outcomes research. Outcomes can be evaluated in terms of efficacy or effectiveness. Many types of studies are available to evaluate treatment effectiveness and include the randomized trial, observational study, case-control study, case series, and expert opinions. The concept of evidence-based medicine uses the level of evidence presented in the aforementioned studies to grade diagnostic and treatment recommendations. Meta-analyses can summarize findings across multiple studies and provide important insights into the body of literature. Outcomes in clinical epidemiology can be difficult to quantify, and thus instruments measuring these outcomes must meet criteria of the Classical Test Theory (reliability, validity, responsiveness, and burden) or the Item Response Theory to be considered psychometrically valid. Many outcomes instruments have been created, which assess health-related quality of life. These scales are generic or disease specific, including assessment of head and neck cancer, otologic disease, rhinologic disease, pediatric disease, voice disorders, sleep disorders, and facial plastic surgery outcomes.

Keywords

Outcomes research
clinical epidemiology
health services research
bias
outcomes instruments

In the past decade, outcomes research and the AHRQ have become integral to understanding treatment effectiveness and establishing health policy. Randomized trials cannot be used to answer all clinical questions, and outcomes research techniques can be used to gain considerable insights from observational data (including data from large administrative databases). With current attention on EBM and quality of care, a basic familiarity with outcomes research is more important than ever.

KEY TERMS AND CONCEPTS

The fundamentals of clinical epidemiology can be understood by thinking about an episode of treatment: a patient presents at baseline with an index condition, receives treatment for that condition, and then experiences a response to treatment. Assessment of baseline state, treatment, and outcomes are all subject to forces that may influence how effective that treatment appears to be. We will begin with a brief review of bias and confounding.

Bias and Confounding

Bias occurs when "compared components are not sufficiently similar."[3] The compared components may involve any aspect of the study. *Selection bias* exists if there are systematic differences between people in the comparison groups. For example, selection bias may occur if, in comparing surgical resection to chemoradiation, oncologists avoid treating patients with kidney or liver failure. This makes the comparison biased because on average the surgical cohort will accrue more ill patients and this may influence survival or complication rates. This can be addressed through random assignment of participants to different treatment groups, known as randomization. *Information bias* exists if there are systematic differences in how exposures or outcomes are measured. Information bias can include observer bias, in which data are not collected the same way across comparison groups, and recall bias, in which inaccuracies of retrospective assessment can influence findings. Observer bias can be reduced by using blinded data collection, in which measurements are made without knowledge of which comparison group they are for; single blinding means participants do not know which group they are in, and double blinding means study staff who collect and/or interpret data do not know which study participants are in which group (until blinding is removed at the end). Recall bias can be reduced by using prospective data collection, in which measurements are made as participants move forward through time as opposed to attempting to remember what happened in the past.

Similar to bias, *confounding* also has the potential to distort the results. However, confounding refers to specific variables. Confounding occurs when a variable thought to cause an outcome is actually not responsible, because of the unseen effects of another variable. Consider the hypothetical (and obviously faulty) case where an investigator postulates that nicotine-stained teeth cause laryngeal cancer. Despite a strong statistical association, this relationship is not causal, because another variable—cigarette smoking—is responsible. Cigarette smoking is confounding because it is associated with both the outcome (laryngeal cancer) and the supposed baseline state (stained teeth).

Assessment of Baseline

Most physicians are aware of the confounding influences of age, gender, ethnicity, and race. However, accurate baseline assessment also means that investigators should carefully define the disease under study, account for disease severity, and consider other important variables such as comorbidity.

Definition of Disease. It would seem obvious that the first step is to establish diagnostic criteria for the disease under study. Yet this is often incomplete. Inclusion criteria should include all relevant portions of the history, the physical examination, and laboratory and radiographic data. For example, the definition of chronic sinusitis may vary by pattern of disease (e.g., persistent vs. recurrent acute infections), duration of symptoms (3 months vs. 6 months), and diagnostic criteria for sinusitis (clinical exam vs. ultrasound vs. CT vs. sinus taps and cultures). All of these aspects must be delineated to place studies into proper context.

In addition, advances in diagnostic technology may introduce a bias called stage migration.[13] In cancer treatment, stage migration occurs when more sensitive technologies (such as CT scans in the past, and PET scans nowadays) may "migrate" patients with previously undetectable metastatic disease out of an early stage (improving the survival of that group) and place them into a stage with otherwise advanced disease (improving this group's survival as well).[14,15] The net effect is that there is improvement in stage-specific survival but no change in overall survival.

Disease Severity. The severity of disease strongly influences response to treatment. This reality is second nature for oncologists, who use TNM stage to select treatment and interpret survival outcomes. It is intuitively clear that the more severe the disease, the more difficult it will be (on average) to restore function. Interestingly, however, criteria for staging do evolve over time, and therefore it is critical to understand not just stages of severity but also how the stages are defined.

Integration of the concept of disease severity into the study and practice of common otolaryngologic diseases such as sinusitis and hearing loss is also developing. Recent progress has been made in sinusitis. Kennedy identified prognostic factors for successful outcomes in patients with sinusitis and encouraged the development of staging systems.[16] Several staging systems have been proposed, with most systems relying primarily on radiographic appearance.[17-20] Clinical measures of disease severity (symptoms, findings) are not typically included. Although the Lund-Mackay staging system is reproducible,[21] often radiographic staging systems have correlated poorly with clinical disease.[22-26] As such, the Zinreich method was created as a modification of the Lund-Mackay system, adding assessment of osteomeatal obstruction.[27] Alternatively, the Harvard staging system has been reproducible[21] and may predict response to treatment.[28] Scoring systems have also been developed for specific disorders such as acute fungal rhinosinusitis,[29] and clinical scoring systems based on endoscopic evaluation have likewise been developed.[30] The development and validation of reliable staging systems for other common disorders, and the integration of these systems into patient care, are pressing challenges in otolaryngology.

Comorbidity. Comorbidity refers to the presence of concomitant disease unrelated to the "index disease" (the disease under consideration), which may affect the diagnosis, treatment, and prognosis for the patient.[31-33] Documentation of comorbidity is important because the failure to identify comorbid conditions such as liver failure may result in inaccurately attributing poor outcomes to the index disease or treatment being studied.[34] This baseline variable is most commonly considered in oncology because most models of comorbidity have been developed to predict survival.[32,35] The Adult Comorbidity Evaluation 27 (ACE-27) is a validated instrument for evaluating comorbidity in cancer patients and when used has shown the prognostic significance of comorbidity in a cancer population.[36,37] Given its impact on costs, utilization, and QOL, comorbidity should be incorporated in studies of nononcologic diseases as well.

Assessment of Treatment

Control Groups. Reliance on case series to report results of surgical treatment is time honored. Although case series can be

informative, they are inadequate for establishing cause and effect relationships. A recent evaluation of endoscopic sinus surgery reports revealed that only 4 of 35 studies used a control group.[38] Without a control group, the investigator cannot establish that the observed effects of treatment were directly related to the treatment itself.[3]

It is also particularly crucial to recognize that the scientific rigor of the study will vary with the suitability of the control group. The more fair the comparison, the more rigorous the results. Therefore a randomized cohort study, where subjects are randomly allocated to different treatments, is more likely to be free of biased comparisons than observational cohort studies, where treatment decisions are made by an individual, a group of individuals, or a health care system. Within observational cohorts, there are also different levels of rigor. In a recent evaluation of critical pathways in head and neck cancer, a "positive" finding in comparison with a historical control group (a comparison group assembled in the past) was not significant when compared with a concurrent control group.[39]

Assessment of Outcomes

Efficacy. The distinction between efficacy and effectiveness, briefly discussed earlier, illustrates one of the fundamental differences between randomized trials and broader outcomes research. *Efficacy* refers to whether a health intervention, in a controlled environment, achieves better outcomes than does placebo. Two aspects of this definition need emphasis. First, efficacy is a comparison to placebo. As long as the intervention is better, it is efficacious. Second, controlled environments shelter patients and physicians from problems in actual clinical settings. For example, randomized efficacy trials of medications may provide continuing reminders for patients to use their medications and may even provide the medications, whereas in "real life," patients are responsible for obtaining medications and remembering to take them as directed.

Effectiveness. An efficacious treatment that retains its value under usual clinical circumstances is *effective*. Effective treatment must overcome a number of barriers not encountered in the typical trial setting. For example, disease severity and comorbidity may be worse in the community because healthier patients tend to be enrolled in (nononcologic) trials. Patient adherence to treatment may also be imperfect. Consider CPAP treatment for patients with obstructive sleep apnea. Although the CPAP is efficacious in the sleep laboratory, the positive pressure is ineffective if the patients do not wear the masks when they return home.[40] Studies of surgical treatments may have additional challenges, including differences in individual technique or skill, and more strongly held opinions (less equipoise) about what approach is superior.[41,42]

FUNDAMENTALS OF STUDY DESIGN

A variety of study designs are used to gain insight into treatment effectiveness. Each has advantages and disadvantages. The principal trade-off is complexity versus rigor because rigorous evidence demands greater effort. An understanding of the fundamental differences in study design can help to interpret the quality of evidence, which has been formalized by the EBM movement. EBM is the "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."[43] EBM is discussed in detail elsewhere in this textbook but is mentioned here because of its overlap with clinical epidemiology. We will summarize the major categories of study designs, with reference to the EBM hierarchy of levels of evidence (Table 1.1).[43,44]

Randomized Trial

RCTs represent the highest level of evidence, particularly if a group of RCTs can be examined together in a meta-analysis, because the controlled, experimental nature of the RCT allows the investigator to establish a causal relationship between treatment and subsequent outcome. The random distribution of patients also allows unbiased distribution of baseline variables and thus minimizes the influence of confounding. Although randomized trials have generally been used to address efficacy, modifications can facilitate insight into effectiveness as well. RCTs with well-defined inclusion criteria, double-blinded treatment and assessment, low losses to follow-up, and high statistical power are considered high quality RCTs and represent Level 1 evidence. Lower-quality RCTs are rated Level 2 evidence.

Cohort Study

In cohort studies, patients are identified at baseline *before* treatment (or "exposure," in standard epidemiology cohort studies investigating risk factors for disease), similar to randomized trials. However, these studies accrue patients who receive routine clinical care. Inclusion criteria are substantially less stringent, and treatment is assigned by the provider in the course of clinical care. Maintenance of the cohort is also straightforward because there is no need to keep patients and providers double blinded.

The challenge in cohort studies is to find an appropriate control group. Rigorous prospective and retrospective cohort studies *with a suitable control group* represent high-quality studies and can represent Level 2 evidence. To obtain insight into comparisons of treatment effectiveness, these studies need to use sophisticated statistical and epidemiologic methods to overcome the biases discussed in the prior section. Even with these techniques, there is the risk that unmeasured confounding variables will distort the

TABLE 1.1 Summary of Study Designs

Design	Advantages	Disadvantages	Level of Evidence
Randomized clinical trial (RCT)	• Only design to prove causation • Unbiased distribution of confounding	• Expensive and complex • Typically targets efficacy • Potentially limited generalizability	1, if high-quality RCT 2, if low-quality RCT
Observational (cohort) study	• Cheaper than RCT • Clear temporal directionality from treatment to outcome	• Difficult to find suitable controls • Confounding	2, with control group 4, if no control group
Case-control study	• Cheaper than cohort study • Efficient study of rare diseases or delayed outcomes	• Must rely on retrospective data • Directionality between exposure and outcome unclear	3
Case series	• Cheap and simple	• No control group • No causal link between treatment and outcome	4
Expert opinion	N/A	N/A	5

comparison of interest. Poor-quality cohorts without control groups, or inadequate adjustment for confounding variables, are considered Level 4 evidence because they are essentially equivalent to a case series (see later).

Case-Control Study

Case-control studies are typically used by traditional epidemiologists to identify risk factors for the development of disease. In such cases the disease becomes the "outcome." In contrast to randomized and observational studies, which identify patients before "exposure" to a treatment (or a pathogen) and then follow patients forward in time to observe the outcome, case-control studies use the opposite temporal direction. This design is particularly valuable when prospective studies are not feasible, either because the disease is too rare or because the time interval between baseline and outcome is prohibitively long.

For example, a prospective study of an association between a proposed carcinogen (e.g., asbestos) and laryngeal cancer would require a tremendous number of patients and decades of observation.[45] However, by identifying patients with and without laryngeal cancer and comparing relative rates of carcinogen exposure, a case-control study can be an alternative way to assess the same question. It should be noted that because the temporal relationship between exposure and outcome is not directly observed, no causal judgments are possible (and this particular association remains controversial).[46,47] These studies are considered Level 3 evidence.

Case Series and Expert Opinion

Case series are the least sophisticated format. As discussed earlier, no conclusions about causal relationships between treatment and outcome can be made because of uncontrolled bias and the absence of any control group. These studies are considered Level 4 evidence. If case studies are unavailable, then expert opinion is used to provide Level 5 evidence.

Other Study Designs

There are numerous other important study designs in outcomes research, but a detailed discussion of these techniques is beyond the scope of this chapter. Meta-analyses[48,49] are summaries of evidence that have rigorous criteria for study inclusion, assessment, and data analysis and can offer important insights into conclusions that can be drawn from multiple studies in the literature Other common approaches include decision analyses,[50,51] cost-identification and cost-effectiveness studies,[52-54] and secondary analyses of administrative databases.[55-57] Literature on these techniques are referenced for further reading.

Grading of Evidence-Based Medicine Recommendations

EBM uses the levels of evidence described previously to grade treatment recommendations (Table 1.2).[58] The presence of high-quality RCTs allows treatment recommendations for a particular intervention to be ranked as Grade A. If no RCTs are available but Level 2 or 3 evidence (observational study with a control group, or case-control study) exists, the treatment recommendations are ranked as Grade B. The presence of only a case series would result in a Grade C recommendation. If even case series are unavailable and only expert opinion is available, the recommendation for the treatment is considered Grade D.

TABLE 1.2 Relationships Between Grades of Recommendation and Level of Evidence[176]

Grade of Recommendation	Level of Evidence
A	1
B	2 or 3
C	4
D	5

MEASUREMENT OF CLINICAL OUTCOMES

Clinical studies have traditionally used outcomes such as mortality and morbidity or other "hard" laboratory or physiologic end points,[59] such as blood pressure, white cell counts, or radiographs. This practice has persisted despite evidence that interobserver variability of accepted "hard" outcomes such as chest x-ray findings and histologic reports are high.[60] In addition, clinicians rely on "soft" data, such as pain relief or symptomatic improvement to determine whether patients are responding to treatment, but because it has been difficult to quantify these variables, these outcomes have until recently been largely ignored.

Psychometric Validation

An important contribution of outcomes research has been the development of questionnaires to quantify these "soft" constructs, such as symptoms, satisfaction, and QOL. Recommendations for scale development procedures are constantly evolving, but a rigorous psychometric validation process is typically followed to create these questionnaires (more often termed *scales*, or *instruments*). These scales can then be administered to patients to produce a numeric score. Components of validation are briefly summarized below; a more complete description can be found elsewhere.[61-63] Three major steps in the process are the establishment of *reliability*, *validity*, and *responsiveness*; in addition, increasing consideration is also given to *burden*.

- *Reliability*. A reliable scale reproduces the same result in a precise fashion. For example, assuming there is no clinical change, a scale administered today and next week should produce the same result. This is called *test-retest reliability*. Other forms of reliability include *internal consistency* and *interobserver reliability*.[63,64]
- *Validity*. A valid scale measures what it is purported to measure. This concept is initially difficult to appreciate. Because these scales are designed to measure constructs that have not previously been measured and because the constructs are difficult to define in the first place (what is QOL?), how does one determine what the scales are supposed to measure? The abbreviated answer is that the scales should behave in the hypothesized way. A simple example of an appropriate hypothesis is that a proposed cancer-specific QOL scale should correlate strongly with pain, tumor stage, and disfigurement but less strongly with age and gender. For more complete discussion, several excellent references are listed.[61-65]
- *Responsiveness*. A responsive scale is able to detect clinically important change.[66] For instance, a scale may distinguish a moderately hearing impaired individual from a deaf individual (the scale is "valid"), but to be considered responsive, it also needs to detect whether an individual's hearing improves after surgery. Alternatively, the minimum improvement in score that represents a clinically important change might be provided.[67,68]
- *Burden*. Burden refers to the time and energy that patients must spend to complete a scale, as well as the resources necessary for observers to score the questionnaire. A scale should not be an excessive encumbrance to a patient, caregiver, or provider using it.

More recently, Item Response Theory (IRT) has been used to create and evaluate self-reported instruments. A full discussion of IRT is beyond the scope of this chapter. In brief, IRT uses

mathematic models to draw conclusions based on the relationships between patient characteristics (latent traits) and patient responses to items on a questionnaire. In addition to a general requirement for larger sample sizes than classical test theory, a critical limitation is that IRT assumes that only one domain is measured by the scale. This may not fit assumptions for multidimensional QOL scales, which may necessitate modifications of typical IRT analyses. However, if this assumption is valid, IRT-tested scales have several advantages. IRT allows for the contribution of each test item to be considered individually, thereby allowing the selection of fewer test items which more precisely measure a continuum of a characteristic.[69-72] Therefore IRT lends itself easily to adaptive computerized testing, allowing for significantly diminished testing time and reduced test burden.[69] Adaptive testing is increasing in use, and IRT will likely be the basis for more new questionnaires evaluating outcomes including QOL.

Categories of Outcomes

In informal use, the terms *health status*, *function*, and *QOL* are frequently used interchangeably. However, these terms have important distinctions in the health services literature. *Health status* describes an individual's physical, emotional, and social capabilities and limitations, and *function* refers to how well an individual is able to perform important roles, tasks, or activities.[62] QOL differs because the central focus is on the *value* that individuals place on their health status and function.[62]

Because many aspects of overall QOL are unrelated to a patient's health status (e.g., income level, marital and family happiness), outcomes researchers typically focus on scales that measure only HRQOL (health-related QOL). HRQOL scales may be categorized as either *generic* or *disease specific*. *Generic*, or general, scales are used for QOL assessment in a broad range of patients. The principal advantage of generic measures is that they facilitate comparison of results across different diseases (e.g., how does the QOL of a heart transplant patient compare with that of a cancer patient?). On the other hand, *disease-specific scales* are designed to assess specific patient populations. Because these scales can focus on a narrower range of topics, they tend to be more responsive to clinical change in the population under study. To benefit from the advantages of each type of scale, rigorous studies often use both generic and a disease-specific scales to assess outcomes.

In addition to these measures, a number of other outcomes are increasingly popular. These include patient satisfaction, costs and charges,[53,54] health care use, and patient preferences (utilities, willingness to pay).[53,73,74] Descriptions of these methods are referenced for further information.

Examples of Outcomes Measures

As mentioned previously, one of the principal contributions of outcomes research has been the development of scales to measure HRQOL and related outcomes. Scale development and validation are complex processes but are important to ensure that scales actually measure what they are intended to measure. Common pitfalls include lack of literacy level assessment and lack of clarity regarding what to do with missing data.

We will briefly highlight a variety of scales that are relevant to otolaryngology. Widely used scales in each category are listed in Table 1.3. Unless otherwise indicated, the scales in this chapter are completed independently by the patient, although numerous scales also exist that are rated by observers. The references contain details about validation data, and most also include a listing of sample questions and scoring instructions. The concept of minimal important difference[67] (i.e., the smallest numeric score change that is associated with a meaningful change for the patient) is very important for understanding scores within the relevant clinical context.

TABLE 1.3 Examples of Outcomes Measures Relevant to Otolaryngology

Disease Category		Examples
Generic	Health Status Quality of Life Utility	SF-36[75] WHO-QOL[80] QWB[76]
Head and Neck Cancer	General Radiation Specific Clinician Rated	UWQOL,[89] FACT,[90] EORTC,[86] HNQOL[92] QOL-RTI/H&N[94] PSS[91]
Otologic	General Conductive Loss Amplification Dizziness Tinnitus Cochlear Implants	HHIE[103] HSS[106] APHAB,[107] EAR[177] DHI[117] THI[118] Nimigen,[110] CAMP[111]
Rhinologic	Nasal Obstruction Chronic Sinusitis Rhinitis	NOSE[128] SNOT-20,[119] CSS,[120] RhinoQOL[127] mRQLQ,[124] ROQ[125]
Pediatric	Tonsillectomy Otitis Media Sleep Apnea	TAHSI[140] OM-6[136] OSD-6,[138] OSA-18[137]
Laryngologic	Swallowing Voice Upper Airway Dyspnea	MDADI,[160] SWAL-QOL[161] VHI,[144] VOS,[145] VRQOL[156] DI[163]
Sleep	Adult Sleep Apnea	FOSQ,[164] SAQLI[165]
Facial Plastics	Aesthetic Functional	FACE-Q,[174] RHINO[175] RHINO,[175] NOSE[129]

Refer to text for additional scales.

Generic Scales

The best-known and most widely used outcomes instrument in the world is the Medical Outcomes Study Short Form-36, commonly called the SF-36.[75] This 36-item scale is designed for adults and surveys general health status. It produces scores in eight health constructs (e.g., vitality, bodily pain, limitations in physical activities), as well as two summary scores on overall physical and mental health status. Normative population scores are available, and the scale has been translated into numerous languages. Reference to instructions, numerous reference publications, and other related information can be found at the SF-36 website (www.sf36.com).

A variety of other popular, generic scales are available as well. The Quality of Well-Being (QWB)[76,77] and the Health Utilities Index (HUI)[78,79] measure patient preferences, or utilities. The World Health Organization has developed a QOL scale (WHO-QOL)[80] as a measure of generic QOL as well as the International Classification of Functioning, Disability, and Health (ICF) to evaluate a patient's functioning and disability.[81] The ICF has been used not only as an instrument itself but also as a stand-alone reference by which to evaluate other measures of QOL and functioning.[82,83]

The Patient-Reported Outcomes Measurement Information System, developed by the National Institutes of Health (NIH), is another rich resource for measuring patient-reported outcomes. Scales offered by this system include global health measures as well as a wide variety of other measures focused on specific aspects of health and can be delivered in multiple ways, including on paper and online.[84]

Disease Specific Scales

Head and Neck Cancer. In 2002 the NIH sponsored a conference to achieve consensus on the methods used to measure and report QOL assessment in head and neck cancer.[85] There was

agreement that an adequate number of scales already exist to measure general QOL in head and neck cancer patients. The three most popular scales at this time are the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-HN35),[86] the University of Washington Quality of Life scale (UW-QOL),[87-89] and the Functional Assessment of Cancer Therapy Head and Neck module (FACT-HN).[90] Both the EORTC and FACT instruments offer additional modules that measure general cancer QOL in addition to the head and neck cancer–specific modules but are longer than the 12-item UW-QOL scale.

A clinician-rated (i.e., the clinician completes the scale, rather than the patient) scale that has achieved widespread use is the Performance Status Scale, a three-item instrument that correlates well with many of the aforementioned cancer scales.[91] A number of other excellent, validated patient-completed scales are also available, including the Head and Neck Quality of Life (HNQOL)[92] and the Head & Neck Survey (H&NS),[93] although these scales have not been used as widely. Several validated scales that focus on QOL of patients undergoing *radiation* are also in use.[94,95]

A few measures focus on symptom inventory and symptom distress directly related to head and neck cancer. These include the Head and Neck Distress Scale (HNDS)[96] and the MD Anderson Symptom Inventory, Head and Neck Module.[97]

Several new instruments have been developed as disease-specific measures within the field of head and neck cancer. For example, to assess the impact of cutaneous malignancy on QOL, the Skin Cancer Index has been validated and found to be sensitive and responsive,[98,99] and the Patient Outcomes of Surgery—Head/Neck (POS-Head/Neck) has been newly developed to assess surgical outcomes in cutaneous malignancy.[100] In addition, an instrument has been developed to assess QOL after treatment of anterior skull base lesions.[101] A questionnaire has also been developed to evaluate outcomes directly related to the use of voice prostheses after total laryngectomy.[102]

Otologic Disease. The most widely used validated measure to quantify *hearing-related QOL* is the Hearing Handicap Inventory in the Elderly (HHIE), a 25-item scale with two subscales that measure the emotional and social impact of hearing loss.[103,104] The minimum change in score that corresponds to a clinically important difference has been established.[105] However, the scale does not distinguish between conductive or sensorineural loss. The Hearing Satisfaction Scale (HHS) is specifically designed to measure outcomes after treatment for conductive hearing loss. It therefore addresses side effects or complications of treatment and is brief (15 items).[106]

Numerous validated measures exist to assess outcomes after *hearing amplification*. One popular scale is the Abbreviated Profile of Hearing Aid Benefit (APHAB).[107] This 24-item scale measures four aspects of communication ability. Values corresponding to minimal clinically important change have also been established.[108] The Effectiveness of Auditory Rehabilitation (EAR) scale addresses comfort and cosmesis issues associated with hearing aids that are overlooked in many hearing aid scales. There are two brief 10-item modules: the Inner EAR addresses intrinsic issues of hearing loss such as functional, physical, emotional, and social impairment, and the Outer EAR covers extrinsic factors such as the comfort, convenience, and cosmetic appearance.[109]

Effects of cochlear implantation on HRQOL have also recently begun to be measured. The Nijmegen Cochlear Implant Questionnaire has been used for this purpose,[110] whereas the University of Washington Clinical Assessment of Musical Perception (CAMP) has been developed to assess perception of music in cochlear implant recipients.[111]

Individuals interested in pursuing research on hearing amplification should also be aware of a number of other validated scales; only a partial listing is referenced here.[112-116] In addition to these scales, there are several excellent, validated scales that assess other aspects of otologic disease, including *dizziness*[117] and *tinnitus*.[118]

Rhinologic Disease. The ability to assess outcomes in *chronic rhinosinusitis* has dramatically improved with the development of disease-specific scales. Among the most widely used scales are the Sinonasal Outcome Test (SNOT-20)[119] and the Chronic Sinusitis Survey (CSS).[120] The SNOT-20 has 20 items, has been extensively validated, and is a shortened version of the 31-item Rhinosinusitis Outcome Measure.[121] It is responsive to clinical change and has established scores that reflect minimal important differences. The CSS is a shorter scale consisting of two components. The severity-based component has four items, and the duration-based component asks about duration of both symptoms and medication use. In addition to the SNOT and CSS, there are a number of other excellent validated sinusitis scales.[122,123] Some of these scales focus on rhinitis specifically, including the Mini Rhinoconjunctivitis QOL Questionnaire,[124] the Rhinitis Outcome Questionnaire,[125] and the Nocturnal Rhinoconjunctivitis Questionnaire,[126] whereas others focus on rhinosinusitis specifically. The Rhinosinusitis Quality of Life survey (RhinoQOL) has been validated for both acute and chronic sinusitis.[127] Additional new rhinologic scales continue to be developed.

In 2003 the American Academy of Otolaryngology-Head and Neck Surgery Foundation commissioned the National Center for the Promotion of Research in Otolaryngology (NC-PRO) to develop and validate a disease-specific instrument for patients with *nasal obstruction* for a national outcomes study. The Nasal Obstruction Symptom Evaluation (NOSE) scale is a five-item instrument that is valid, reliable, and responsive.[128,129]

Pediatric Diseases. An important difference between measuring outcomes in adults and children is that younger children may be unable to complete the scales by themselves. In these cases the instruments need to be completed by proxy, typically a parent or other caregiver. This difference in perspective should be kept in mind when interpreting the results of pediatric studies. A good generic scale, similar to the SF-36 in adults, is the Child Health Questionnaire (CHQ).[130] This is also a widely used instrument that has been extensively validated and translated into numerous languages. It is a health status measure designed for children 5 years of age and older and can be completed directly by children 10 and older. Other generic QOL assessments for children include the Pediatric Quality of Life Inventory (PedsQL) and the Child Health and Illness Profile—Child Edition (CHIP-CE).[131,132] The Glasgow Children's Benefit Inventory is a validated measure which evaluates the benefit a child receives from an intervention and is a general measure which was developed with otolaryngologic disease in mind.[133] The Caregiver Impact Questionnaire has been used to evaluate the impact of disease on the child's caregivers.[134,135]

There are a number of excellent, validated disease-specific scales for children. A number of instruments have been developed to assess the impact of *otitis media*. The most widely used OM-6 is a brief, six-item scale useful for the evaluation of otitis media–related QOL in children.[136] It has been shown to be reliable, valid, and responsive and has been widely adopted. Two scales are pertinent to children with *obstructive sleep disorders*, the Obstructive Sleep Apnea-18 (OSA-18),[137] which has been found to be valid, reliable, and responsive, and the OSD-6.[138,139] A scale has also recently been developed for studying *tonsil and adenoid* health in children.[140] Voice-related QOL has also been evaluated in children via the Pediatric Voice Outcomes Survey and the Pediatric Voice-Related Quality-of-Life survey (PVQOL).[141-143]

Voice. Numerous instruments have been developed to assess outcomes in voice, with varying psychometric properties.[144-146] The Voice Handicap Index is one of the most widely used instruments; its original form was 30 items[144] and also exists as a 10-item

shortened version (VHI-10).[147] It evaluates the psychosocial impact of dysphonia and has been validated by both Classical Test Theory[112,148] and IRT.[149] Normative values[150] and data on minimal important difference on the VHI-10[151,152] are also available. The Voice Symptom Scale (VoiSS),[153,154] the Vocal Performance Questionnaire, and the Voice-Related Quality of Life Instrument are also frequently used.[155,156] These instruments provide independent useful data that complement clinician performed perceptual evaluation.[157,158] In addition, the Singing Voice Handicap Index has been created and found to valid and reliable for assessing vocal problems specific to singers.[159]

Swallow and Other Throat Symptom Scales. Several scales specific to swallowing are available, including MD Anderson Dysphagia Inventory (MDADI),[160] a brief, 20-item scale intended to measure dysphagia in head and neck cancer patients. The SWAL-QOL is longer (44 items) but validated for use in a more general population.[161] Multiple scales exist for examining symptoms related to laryngopharyngeal reflux, with the most frequently cited being the Reflux Symptom Index.[162] The Dyspnea Index was developed specifically for adults with upper airway dyspnea (e.g., paradoxical vocal fold motion)[163] and has very good psychometric properties.

Sleep. Several validated scales are in use to assess HRQOL in adults with obstructive sleep apnea. The most widely used are the 30-item Functional Outcomes of Sleep Questionnaire (FOSQ)[164] and the 50-item Calgary Sleep Apnea Quality of Life Index (SAQLI).[165,166] In addition, the Quebec Sleep Questionnaire (QSQ) was recently validated as an additional OSA instrument.[167] Clinicians interested in a more brief instrument may wish to consider the Symptoms of Nocturnal Obstruction and Respiratory Events (SNORE-25).[168] The eight-item Epworth Sleepiness Scale (ESS) is commonly used to assess the degree of daytime sleepiness.[169] Although perhaps one of the widely used tools in sleep outcomes, a study found that its clinical reproducibility may be limited,[170] and a number of studies have shown wide variability in correlation between the ESS and objective measures of sleep apnea severity. As sleepiness and fatigue can be difficult to differentiate on QOL instruments and in clinical practice, more recently the Empirical Sleepiness and Fatigue Scales were created (using a number of items from the ESS). These scales were found to have internal consistency and good test-retest reliability and will likely aid in the evaluation of patients with OSA who are more likely to endorse sleepiness variables.[171]

Facial Plastic Surgery. Finally, numerous instruments have been developed to assess outcomes in facial plastic surgery.[172,173] These include the FACE-Q,[174] which measures patient opinion of their appearance and can be used in rhinoplasty, and the RHINO,[175] which incorporates data on both aesthetic and functional outcomes after rhinoplasty. The NOSE[129] scale can also be useful for assessing functional outcomes in rhinoplasty. Various other instruments exist for self-ratings of appearance, satisfaction, and other outcomes.

With all of these options, there is a tension between using existing, widely utilized scales, which can facilitate comparisons and combined analyses, versus specific or newly developed scales that may have better content validity or other psychometric properties. Practitioners and researchers therefore need to balance competing considerations when choosing generic and disease-specific measures.

SUMMARY AND FUTURE DIRECTIONS

Outcomes research is the scientific analysis of treatment effectiveness. In recent decades, it has contributed substantially to the national debate on health resource allocation. Outcomes research provides insight into the value of otolaryngology treatments and methods for quantifying important outcomes, particularly from the patient's perspective. Better appreciation for outcomes research will improve the level of evidence about important treatments and operations.

The impact of outcomes research is currently beginning to extend into deliberations about quality of care, as the health care system moves to establish standards for patient safety. The Leapfrog Group, a coalition of the largest public and private organizations that provide health care benefits for its employees, uses its collective purchasing power to ensure that its employees have access to, and more informed choices about, quality health care. Policymakers will increasingly look to outcomes research for insight into how to measure quality and safety, in addition to effectiveness.

It is imperative that clinicians be familiar with these basic principles. Otolaryngologists should participate in local and national outcomes research efforts to improve the evidence supporting successful otolaryngology interventions and to provide informed physician perspective in a health care environment that is increasingly driven by third party participants.

For a complete list of references, visit ExpertConsult.com.

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2 Interpreting Medical Data

Richard M. Rosenfeld

KEY POINTS

- Learning how to interpret medical data will make you a better clinician, researcher, and teacher.
- Interpreting data begins by assessing the investigation that produced it; low-quality data with a high risk of bias are of limited value, regardless of how appealing the results may seem.
- The presence or absence of a control or comparison group has a profound influence on data interpretation. An uncontrolled study is purely descriptive and cannot assess effectiveness or efficacy.
- Statistical tests often make assumptions about the underlying data. Unless these assumptions are met, the results are invalid.
- Uncertainty is present in all data because of the inherent variability in biologic systems and in our ability to assess them in a reproducible fashion. Results should be reported with effect sizes and 95% confidence intervals, which incorporate uncertainty by providing a zone of compatibility with the data.
- All statistical tests measure error. The *P* value is the likelihood of a type I error (false-positive conclusion), which occurs if a true null hypothesis is mistakenly rejected. Conversely, a type II error (false-negative conclusion) occurs when a real difference is missed and is related to statistical power and sample size.
- A study has internal validity when the data are analyzed and interpreted properly, but external validity (generalizability) requires that the study sample be representative of the larger population to which it is intended to apply.
- Confidence intervals and common sense are needed to balance statistical significance with what is clinically important to patients.
- A single study is rarely definitive. Science is a cumulative process that requires a large body of consistent and reproducible evidence before conclusions can be formed.
- Effective data interpretation facilitates moving from observations to generalizations with predictable degrees of certainty and uncertainty.

In every chapter of this text, whether it relates to clinical medicine or basic science, the authors draw on their own experience and the experience of others to form valid and generalizable conclusions. Experience yields data, and interpreting data is the heart and soul of the cumulative process called *science*. Learning how to interpret medical data will make you a better clinician, researcher, and teacher.

Effective data interpretation is a habit: a combination of knowledge, skill, and desire.[1] By applying the seven habits shown in Table 2.1 and further outlined in this chapter, any otolaryngologist—regardless of his or her level of statistical knowledge or lack thereof—can interpret data. Practitioners can also improve their ability to understand and critically appraise the biomedical literature.[2] The numerous tables that accompany the text were designed as stand-alone reminders and often contain keywords with definitions endorsed by the International Epidemiological Association (IEA).[3]

This chapter also discusses the practice of data interpretation and includes specific hypothesis tests, sample size determinations, and common statistical deceptions encountered in the otolaryngology literature. You do not have to be a wizard with numbers to understand data; all you need are patience, persistence, and a few good habits that will help settle the dust that follows the clash of statistics with the human mind.

SEVEN HABITS OF HIGHLY EFFECTIVE DATA USERS

The seven habits that follow are the key to understanding data.[4] They embody fundamental principles of epidemiology and biostatistics developed in a logical and sequential fashion. Table 2.1 gives an overview of the seven habits and their corresponding principles and keywords.

Habit 1: Check Quality Before Quantity

Bias is a four-letter word that is easy to ignore but difficult to avoid.[5] Data collected specifically for research (Table 2.2) are likely to be unbiased—they reflect the true value of the attribute being measured. In contrast, data collected during routine clinical care will vary in quality depending on the specific methodology applied.

Experimental studies, such as randomized controlled trials (RCTs), often yield high-quality data because they are performed under carefully controlled conditions. In observational studies, however, the investigator is simply a bystander who records the natural course of health events during clinical care. Although more reflective of "real life" than a contrived experiment, observational studies are more prone to bias. Comparing RCTs with outcomes studies highlights the difference between experimental and observational research (Table 2.3).

The presence or absence of a control group has a profound influence on data interpretation. An uncontrolled study, no matter how elegant, is purely descriptive.[6] Case series, which appear frequently in the otolaryngology literature, cannot assess efficacy or effectiveness, but they can convey feasibility, experience, technical details of an intervention, and predictive factors associated with good outcomes or adverse events. The best case series (1) include a consecutive sample of subjects; (2) describe the sample fully and include details of interventions and adjunctive treatments; (3) account for all participants enrolled, including withdrawals and dropouts; and (4) ensure that follow-up duration is adequate to overcome random disease fluctuations.[7]

Without a control or comparison group, treatment effects cannot be distinguished from other causes of clinical change (Table 2.4).[8] Some of these causes are seen in Fig. 2.1, which depicts change in health status after a healing encounter as a complex interaction of three primary factors.[9,10]

1. *What was actually done*. Specific effects of therapy, which include medications, surgery, physical manipulations, and alternative or integrative approaches.

Abstract

Learning how to interpret medical data will make you a better clinician, researcher, and teacher. This chapter describes seven habits that can be applied to any publication or dataset to facilitate critical appraisal and understanding. Beyond the principles underlying the seven habits, we also discuss the practice of data interpretation with regard to specific hypothesis tests, sample size determination, and common statistical deceptions encountered in the otolaryngology literature. You do not have to be a wizard with numbers to understand data; all you need are patience, persistence, and a few good habits that will help temper the clash of statistics with the human mind.

Keywords

Biostatistics
epidemiology
evidence-based medicine
critical appraisal
hypothesis testing
confidence intervals

TABLE 2.1 Seven Habits of Highly Effective Data Users

Habit	Underlying Principles	Keywords
1. Check quality before quantity.	All data are not created equal; fancy statistics cannot salvage biased data from a poorly designed and executed study.	Bias, accuracy, research design, internal validity, confounding, causality
2. Describe before you analyze.	Special data require special tests; improper analysis of small samples or data with an asymmetric distribution gives deceptive results.	Measurement scale, frequency distribution, descriptive statistics
3. Accept the uncertainty of all data.	All observations have some degree of random error; interpretation requires estimating the associated level of precision or confidence.	Precision, random error, confidence intervals
4. Measure error with the right statistical test.	Uncertainty in observation implies certainty of error; positive results must be qualified by the chance of being wrong, negative results by the chance of having missed a true difference.	Statistical test, type I error, *P* value, type II error, power
5. Put clinical importance before statistical significance.	Statistical tests measure error, not importance; an appropriate measure of clinical importance must be checked.	Effect size, statistical significance, clinical importance
6. Seek the sample source.	Results from one dataset do not necessarily apply to another; findings can be generalized only for a random and representative sample.	Population, sample, selection criteria, external validity
7. View science as a cumulative process.	A single study is rarely definitive; data must be interpreted relative to past efforts and by their implications for future efforts.	Research integration, level of evidence, meta-analysis

TABLE 2.2 Effect of Study Design on Data Interpretation

Aspect of Study Design	Effect on Data Interpretation
How Were the Data Originally Collected?	
Specifically for research	Interpretation is facilitated by quality data collected according to an a priori protocol.
During routine clinical care	Interpretation is limited by consistency, accuracy, availability, and completeness of the source records.
Database or data registry	Interpretation is limited by representativeness of the sample and the quality and completeness of data fields.
Is the Study Experimental or Observational?	
Experimental study with conditions under direct control of the investigator	Low potential for systematic error (*bias*); bias can be reduced further by randomization and masking (*blinding*).
Observational study without intervention other than to record, classify, analyze	High potential for bias in sample selection, treatment assignment, measurement of exposures, and outcomes.
Is There a Comparison or Control Group?	
Comparative or controlled study with two or more groups	Permits analytic statements concerning efficacy, effectiveness, and association.
No comparison group present	Permits descriptive statements only because of improvements from natural history and placebo effect.
What Is the Direction of Study Inquiry?	
Subjects identified before an outcome or disease; future events recorded	Prospective design measures incidence (new events) and causality (if a comparison group included).
Subjects identified after an outcome or disease; past histories examined	Retrospective design measures prevalence (existing events) and causality (if a comparison group is included).
Subjects identified at a single time point, regardless of outcome or disease	Cross-sectional design measures prevalence (existing events) and association (if a comparison group is included).

TABLE 2.3 Comparison of Randomized Controlled Trials and Outcomes Studies

Characteristic	Randomized Controlled Trial	Outcomes Study
Level of investigator control	Experimental	Observational
Treatment allocation	Random assignment	Routine clinical care
Patient selection criteria	Restrictive	Broad
Typical setting	Hospital or university based	Community based
End point definition	Objective health status	Subjective quality of life
End point assessment	Masked (blinded)	Unmasked
Statistical analysis	Comparison of groups	Multivariate regression
Potential for bias	Low	Very high
Generalizability	Potentially low	Potentially high

2. *What was imagined to be done*. Placebo response, defined as a change in health status resulting from the symbolic significance attributed by the patient (or proxy) to the encounter itself. A placebo response is most likely to occur when the patient receives a meaningful and personalized explanation, feels care and concern expressed by the practitioner, and achieves control and mastery over the illness or believes that the practitioner can control the illness.[11]
3. *What would have happened anyway*. Spontaneous resolution, which includes natural history, random fluctuations in disease status, and regression to a mean symptom state.

The placebo response differs from the traditional definition of placebo as an inactive medical substance. Whereas a placebo can elicit a placebo response, the latter can occur without the former. A placebo response results from the psychologic or symbolic importance attributed by the patient to any nonspecific event in a healing environment. These events include touch, words, gestures, local ambience, and social interactions.[12] Many of these factors are encompassed in the term *caring effects*,[13] which have been central to medical practice in all cultures throughout history. Caring and

TABLE 2.4 Explanations Other Than "Efficacy" for Outcomes in Treatment Studies

Explanation	Definition	Solution
Bias	Systematic deviation of results or inferences from truth; may be intentional or unintentional	Accurate, protocol-driven data collection
Chance	Random variation without apparent relation to other measurements or variables (e.g., luck)	Control or comparison group
Natural history	Course of a disease from onset to resolution; may include relapse, remission, and spontaneous recovery	Control or comparison group
Regression to the mean	Symptom improvement independent of therapy, as sick patients return to a mean level after seeking care	Control or comparison group
Placebo effect	Beneficial effect caused by the expectation that the regimen will have an effect (e.g., power of suggestion)	Control or comparison group with placebo
Halo effect	Beneficial effect caused by treatment novelty or by the provider's manner, attention, and caring	Control or comparison group treated similarly
Hawthorne effect	Beneficial effect caused by the participant's knowledge of being evaluated and observed in a study	Control or comparison group treated similarly
Confounding	Distortion of a measure of the effect of an exposure on an outcome by other prognostic factors or variables that influence the occurrence of the outcome	Randomization or multivariate analysis
Allocation (susceptibility) bias	Beneficial effect caused by allocating subjects with less severe disease or better prognosis to the treatment group	Randomization or comorbidity analysis
Ascertainment (detection) bias	Favoring the treatment group during outcome analysis (e.g., rounding numbers up for treated subjects and rounding them down for controls)	Masked (blinded) outcome assessment

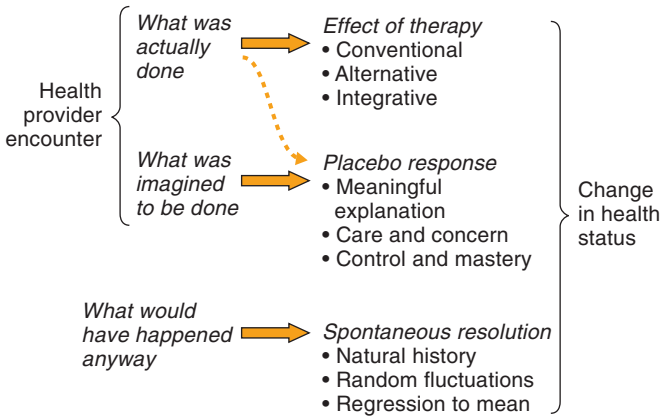

Fig. 2.1 Model depicting change in health status after a healing encounter. Dashed arrow shows that a placebo response may occur from symbolic significance of the specific therapy given or from interpersonal aspects of the encounter.

placebo effects are so important that they have been deliberately used to achieve positive outcomes in clinical practice.[14]

Questionnaires and quality-of-life surveys are particularly prone to bias (see Table 2.4) when response rates are not reported and if the measures have not been formally assessed for reliability, validity, and responsiveness.[15] Unless the authors used a "validated" measure, the results are suspect, but problems may also arise if a validated instrument is used in an inappropriate way. For example, some surveys are developed specifically to compare individuals at a point in time (discriminative surveys) and may not be valid when used to measure change in status within individuals before and after intervention (evaluative surveys). Additional bias may arise in survey research related to sampling the population, administering the questionnaire, and managing the resultant data.[16]

When data from a comparison or control group are available, inferential statistics may be used to test hypotheses and measure associations. Causality may also be assessed when the study has a time-span component, either retrospective or prospective (see Table 2.2). Prospective studies measure incidence (new events), whereas retrospective studies measure prevalence (existing events). Unlike time-span studies, cross-sectional inquiries measure association, not causality. Examples include surveys, screening programs, and evaluation of diagnostic tests. Study design, in general, can greatly impact the ability of clinicians and others to use research to assess treatment claims and to make informed health choices.[17]

Another clue to data quality is study type,[18] but this cannot replace the four questions in Table 2.2. Note the variability in data quality for the study types listed in Table 2.5, particularly the observational designs. Randomization balances baseline prognostic (confounding) factors, both known and unknown, among groups; this includes factors such as severity of illness and the presence of comorbid conditions. Because these factors also influence a clinician's decision to offer treatment, nonrandomized studies are prone to allocation (susceptibility) bias (see Table 2.4) and false-positive results.[19] For example, when the survival of surgically treated cancer patients is compared with the survival of nonsurgical controls (e.g., patients treated with radiation or chemotherapy) without randomization, the surgical group will generally have a more favorable prognosis independent of therapy because the customary criteria for operability—special anatomic conditions and no major comorbidity—also predispose to favorable results.

The relationship between data quality and interpretation is illustrated in Table 2.6 using hypothetical studies to determine whether tonsillectomy causes baldness. Note how a case series (examples 1 and 2) can have either a prospective or retrospective direction of inquiry, depending on how subjects are identified; contrary to common usage, all cases series are not "retrospective reviews." Only the controlled studies (examples 3 through 7) can measure associations, and only the controlled studies with a time-span component (examples 4 through 7) can assess causality. The nonrandomized studies (examples 3 through 6), however, require adjustment for potential confounding variables—baseline prognostic factors that may be associated with both the intervention (tonsillectomy) *and* the outcome (baldness) and may therefore distort results. As noted previously, adequate randomization helps balance prognostic factors among groups, thereby reducing confounding.

Habit 2: Describe Before You Analyze

Statistical tests often make assumptions about the underlying data. Unless these assumptions are met, the test will be invalid. Describing before you analyze avoids trying to unlock the mysteries of square data with a round key.

Describing data begins by defining the measurement scale that best suits the observations. Categorical (qualitative) observations

TABLE 2.5 Relationship of Study Type to Study Methodology

Study Type	How Were the Data Originally Collected?	Was a Control or Comparison Group Included?	What Is the Direction of the Study Inquiry?
EXPERIMENTAL STUDIES			
Basic science study	Research	Yes or no	Prospective or cross-sectional
Clinical trial	Research	Yes or no	Prospective or cross-sectional
Randomized trial	Research	Yes	Prospective
OBSERVATIONAL STUDIES			
Cohort study	Clinical care or research	Yes or no	Prospective
Historical cohort study[a]	Clinical care	Yes	Prospective
Outcomes research	Clinical care or research	Yes or no	Prospective
Case-control study	Clinical care	Yes	Retrospective
Case series	Clinical care	Yes or no	Retrospective or prospective
Survey study	Clinical care or research	Yes or no	Cross-sectional
Diagnostic test study	Clinical care or research	Yes or no	Cross-sectional

[a]Also called a retrospective cohort study or nonconcurrent cohort study.

TABLE 2.6 Determining Whether Tonsillectomy Causes Baldness: Study Design Versus Interpretation

Study Design[a]	Study Execution	Interpretation
1. Retrospective case series	A group of bald subjects are questioned as to whether or not they had a tonsillectomy.	Measures prevalence of tonsillectomy in bald subjects; cannot assess association or causality
2. Prospective case series	A group of subjects who had or who are about to have tonsillectomy are examined later for baldness.	Measures incidence of baldness after tonsillectomy; cannot assess association or causality
3. Cross-sectional study	A group of subjects are examined for baldness and for presence or absence of tonsils at the same time.	Measures prevalence of baldness and tonsillectomy and their association; cannot assess causality
4. Case-control study	A group of bald subjects and a group of nonbald subjects are questioned about prior tonsillectomy.	Measures prevalence of baldness and association with tonsillectomy; limited ability to assess causality
5. Historical (retrospective) cohort study	A group of subjects who had prior tonsillectomy and a comparison group with intact tonsils are examined later for baldness.	Measures incidence of baldness and association with tonsillectomy; can assess causality when adjusted for confounding variables
6. Cohort study (longitudinal)	A group of nonbald subjects about to have tonsillectomy and a nonbald comparison group with intact tonsils are examined later for baldness.	Measures incidence of baldness and association with tonsillectomy; can assess causality when adjusted for confounding variables
7. Randomized controlled trial	A group of nonbald subjects with intact tonsils are randomly assigned to tonsillectomy or observation and are examined later for baldness.	Measures incidence of baldness and association with tonsillectomy; can assess causality despite baseline confounding variables

[a]Studies are listed in order of increasing ability to establish causal relationship.

fall into one or more categories and include dichotomous, nominal, and ordinal scales (Table 2.7). Numeric (quantitative) observations are measured on a continuous scale and are further classified by the underlying frequency distribution, a plot of observed values versus the frequency of each value. Numeric data with a symmetric (normal) distribution are symmetrically placed around a central crest or trough (bell-shaped curve). Numeric data with an asymmetric distribution are skewed (shifted) to one side of the center, have a sloping "exponential" shape that resembles a forward or backward *J*, or contain some unusually high or low outlier values.

Depending on the measurement scale, data may be summarized using one or more of the descriptive statistics given in Table 2.8. Note that when summarizing numeric data, the descriptive method varies according to the underlying distribution. Numeric data with a symmetric distribution are best summarized with the mean and standard deviation (SD) because 68% of the observations fall within the mean ± 1 SD and 95% fall within the mean ± 2 SD. In contrast, asymmetric numeric data are best summarized with the median, because even a single outlier can strongly influence the mean. If a series of five patients are followed after sinus surgery for 10, 12, 15, 16, and 48 months, the mean duration of follow-up is 20 months, but the median is only 15 months. In this case, a single outlier, 48 months, distorts the mean.

Although the mean is appropriate only for numeric data with a symmetric distribution, it is often applied regardless of the underlying symmetry. An easy way to determine whether the mean

TABLE 2.7 Measurement Scales for Describing and Analyzing Data

Scale	Definition	Examples
Dichotomous	Classification into either of two mutually exclusive categories	Breastfeeding (yes/no), sex (male/female)
Nominal	Classification into unordered qualitative categories	Race, religion, country of origin
Ordinal	Classification into ordered qualitative categories but with no natural (numeric) distance between their possible values	Hearing loss (none, mild, moderate), patient satisfaction (low, medium, high), age group
Numeric	Measurements with a continuous scale or a large number of discrete, ordered values	Temperature, age in years, hearing level in decibels
Numeric (censored)	Measurements on subjects lost to follow-up or in whom a specified event has not yet occurred at the end of a study	Survival rate, recurrence rate, or any time-to-event outcome in a prospective study

TABLE 2.8 Descriptive Statistics

Descriptive Measure	Definition	Application
CENTRAL TENDENCY		
Mean	Arithmetic average	Numeric data that are symmetric
Median	Middle observation; half the values are smaller, and half are larger	Ordinal data; numeric data with an asymmetric distribution
Mode	Most frequent value	Nominal data; bimodal distribution
DISPERSION		
Range	Largest value minus smallest value	Emphasizes extreme values
Standard deviation	Spread of data about their mean	Numeric data that are symmetric
Percentile	Percentage of values equal to or below that number	Ordinal data; numeric data with an asymmetric distribution
Interquartile range	Difference between the twenty-fifth and seventy-fifth percentiles	Ordinal data; numeric data with an asymmetric distribution
OUTCOME		
Survival rate	Proportion of subjects surviving, or with some other outcome, after a time interval (e.g., 1 year, 5 years)	Numeric (censored) data in a prospective study; can be overall, cause specific, or progression free
Odds ratio	Odds of a disease or outcome in subjects; risk factor divided by odds in controls	Dichotomous data in a retrospective or prospective controlled study
Relative risk	Incidence of a disease or outcome in subjects; risk factor divided by incidence in controls	Dichotomous data in a prospective controlled study
Rate difference[a]	Event rate in treatment group minus event rate in control group	Compares success or failure rates in clinical trial groups
Correlation coefficient	Degree to which two variables have a linear relationship	Numeric or ordinal data

[a]Also called the absolute risk reduction.

or median is appropriate for numeric data is to calculate both; if they differ significantly, the median should be used. Another way is to examine the SD; when it is very large (e.g., larger than the mean value with which it is associated), the data often have an asymmetric distribution and should be described by the median and interquartile range. When in doubt, the median should always be used over the mean.[20]

A special form of numeric data is called *censored* (see Table 2.7). Data are censored when three conditions apply: (1) the direction of study inquiry is prospective; (2) the outcome of interest is time related; and (3) some subjects die, are lost, or have not yet had the outcome of interest when the study ends. Interpreting censored data is called *survival*, or *time-to-event*, *analysis* because of its use in cancer studies, in which survival is the outcome of interest. Survival analysis permits full use of censored observations (e.g., patients with <1 year of follow-up) by including them in the analysis up to the time the censoring occurred. Results of cancer studies are often reported with *Kaplan-Meier curves*, which may describe overall survival, disease-free survival, disease-specific survival, or progression-free survival.[21] Survival data at the far right of the curves should be interpreted cautiously because fewer patients remain, which yields less precise estimates.

A survival curve starts with 100% of the study sample alive and shows the percentage still surviving at successive times for as long as information is available. The resulting hazard function yields a continuous curve that shows how the risk of having the event or outcome (e.g., the hazard rate) changes over time.[22] Survival analysis may also be applied to any situation where time-to-event is important, not just to absence of mortality. For example, the 3-, 5-, or 10-year rates for cholesteatoma recurrence or the future "survival" of tonsils (i.e., no need for tonsillectomy) could be estimated in a cohort of children after adenoidectomy alone. Similarly, survival analysis could be used to estimate the time to occlusion or extrusion of tympanostomy tubes.

Several statistical methods are available for analyzing survival data. The Kaplan-Meier (product-limit) method records events by exact dates and is suitable for small and large samples. Conversely, the life-table (actuarial) method records events by time interval (e.g., every month, every year) and is most commonly used for large samples in epidemiologic studies. When censored data need adjustment for multiple prognostic or confounding variables, which might independently influence time-to-event, the Cox proportional hazards model can calculate hazard ratios for all variables (prognostic and confounding).[22]

The odds ratio, relative risk, and rate difference (see Table 2.8) are useful ways of comparing two groups of dichotomous (binary) data.[23] A retrospective (case-control) study of tonsillectomy and baldness might report an odds ratio of 1.6, indicating that bald subjects were 1.6 times more likely to have had tonsillectomy than were nonbald controls. In contrast, a prospective study would report results using relative risk. A relative risk of 1.6 means that baldness was 1.6 times more likely to develop in tonsillectomy subjects than in nonsurgical controls. When interpreting binary data, readers should note that the odds ratio and relative risk will be similar if the event rate is small, but for common events they can diverge widely.[24] Finally, a rate difference of 30% in a prospective trial or experiment reflects the increase in baldness caused by tonsillectomy above and beyond what occurred in controls. No association exists between groups when the rate difference equals zero or the odds ratio or relative risk equals one (unity).

Two groups of ordinal or numeric data are compared with a correlation coefficient (see Table 2.8). A coefficient (r) from 0 to 0.25 indicates little or no relationship, from 0.25 to 0.49 a fair relationship, from 0.50 to 0.74 a moderate to good relationship, and greater than 0.75 a good to excellent relationship. A perfect linear relationship would yield a coefficient of 1.00. When one variable varies directly with the other, the coefficient is positive; a negative coefficient implies an inverse association. Sometimes the correlation coefficient is squared (r^2) to form the coefficient of determination, which estimates the percentage of variability in one measure that is predicted by the other.

Habit 3: Accept the Uncertainty of All Data

Uncertainty is present in all data because of the inherent variability in biologic systems, and it is present in our ability to assess data in a reproducible fashion.[25] If we were to measure hearing in 20 healthy volunteers on five different days, it would be very unlikely for us to get the same mean result each time; this is because audiometry has a variable behavioral component that depends on the subject's response to a stimulus and the examiner's perception of that response. Similarly, if hearing were to be measured in five

groups of 20 healthy volunteers each, it would be very unlikely for us to get the same mean hearing level in each group; again, it would be unlikely because of variations among individuals. A range of similar results would be obtained, but rarely would the exact same result be obtained on repetitive trials.

Uncertainty must be dealt with when interpreting data unless the results are meant to apply only to the particular group of patients, animals, cell cultures, and DNA strands in which the observations were initially made. Recognizing this uncertainty, each of the descriptive measures in Table 2.8 is called a *point estimate* that is specific to the data that generated it. In medicine, however, the clinician seeks to pass from observations to generalizations and from point estimates to data applicable to other populations. When this process occurs with calculated degrees of uncertainty, it is called *inference*.

The following is a brief example of clinical inference. After treating five vertiginous patients with vitamin C, you remark to a colleague that four had excellent relief of their vertigo. She asks, "How confident are you of your results?"

"Quite confident," you reply. "There were five patients, four got better, and that's 80%."

"Maybe I wasn't clear," she interjects. "How confident are you that 80% of vertiginous patients you see in the next few weeks will respond favorably, or that 80% of similar patients in my practice will do well with vitamin C? In other words, can you infer anything about the real effect of vitamin C on vertigo from only five patients?"

Hesitatingly you retort, "I'm pretty confident about that number, 80%, but maybe I'll have to see a few more patients to be sure."

The real issue, of course, is that a sample of only five patients offers low precision (repeatability). How likely is it that the same results would be found if five new patients were studied? Actually, it can be stated with 95% confidence that four out of five successes in a single trial is consistent with a range of results from 28% to 99% in future trials. This *95% confidence interval* (CI) reveals *the range of values considered plausible for the population* and provides a *zone of compatibility* with the data.[26] All point estimates of effect size should ideally be accompanied by a 95% CI, yet this occurs infrequently in the otolaryngology literature, and when it does the authors rarely include an interpretation.[27]

Precision may be increased, or uncertainty may be decreased, by (1) using a more reproducible measure, (2) increasing the number of observations (sample size), or (3) decreasing the variability among the observations. The most common method is to increase the sample size, because the variability inherent in the subjects studied can rarely be reduced. Even a huge sample of perhaps 50 000 subjects still has some degree of uncertainty, but the 95% CI will be quite small. Realizing that uncertainty can never completely be avoided, statistics are used to estimate precision. Thus, when data are described using the summary measures listed in Table 2.8, a corresponding 95% CI should accompany each point estimate.

Precision differs from accuracy. Precision relates to random error and measures repeatability; accuracy relates to systematic error (bias) and measures nearness to the truth. A precise otologist may always perform a superb mastoidectomy, but an accurate otologist performs it on the correct ear. A precise surgeon cuts on the exact center of the line, but an accurate surgeon first checks the line to be sure its placement is correct. Succinctly put, precision is doing things right, and accuracy is doing the right thing. Precise data include a large enough sample of carefully measured observations to yield repeatable estimates; accurate data are measured in an unbiased manner and reflect what is truly purported to be measured. When we interpret data, we must estimate both precision and accuracy.

To summarize habits 1, 2, and 3: "Check quality before quantity" determines whether or not the data are worth interpreting (habit 1). Assuming they are, "describe before you analyze," and summarize the data using appropriate measures of central tendency, dispersion, and outcome for the particular measurement scales involved (habit 2). Next, "accept the uncertainty of all data" as noted in habit 3, and qualify the point estimates in habit 2 with 95% CIs to measure precision. When precision is low (e.g., the CI is wide), proceed with caution. Otherwise, proceed with habits 4, 5, and 6, which deal with errors and inference.

Habit 4: Measure Error With the Right Statistical Test

To err is human—and statistical. When comparing two or more groups of uncertain data, errors in inference are inevitable. If it can be concluded that the groups are different, they may actually be equivalent. If the conclusion is that they are the same, a true difference may have been missed. Data interpretation is an exercise in modesty, not pretense—any conclusion we reach may be wrong. The ignorant data analyst ignores the possibility of error; the savvy analyst estimates this possibility by using the right statistical test.[28]

Now that we have stated the problem in English, let us restate it in thoroughly confusing statistical jargon (Table 2.9). We begin with some testable hypotheses about the groups we are studying, such as "Gibberish levels in group A differ from those in group B." Rather than keep it simple, we now invert this to form a null hypothesis: "Gibberish levels in group A are equal to those in group B." Next we fire up our personal computer, enter the gibberish levels for the subjects in both groups, choose an appropriate statistical test, and wait for the omnipotent *P* value to emerge.

The P value gives the probability of making a type I error: rejection of a true null hypothesis. In other words, if $P = .10$, there is a 10% chance of being wrong when we declare that group A differs from group B based on the observed data. Alternatively, there is a 10% probability that the difference in gibberish levels is explainable by random error—we cannot be certain that uncertainty is not the cause. In medicine, $P < .05$ is generally considered low enough to safely reject the null hypothesis. Conversely, when $P > .05$, the null hypothesis of equivalent gibberish levels is accepted. Nonetheless, one might be making a type II error by accepting a false null hypothesis. Rather than state the

TABLE 2.9 Glossary of Statistical Terms Encountered When Testing Hypotheses

Term	Definition
Central tendency	A supposition arrived at from observation or reflection that leads to predictions that can be tested and refuted
Null hypothesis	Results observed in a study, experiment, or test that are no different from what might have occurred because of chance alone
Statistical test	Procedure used to reject or accept a null hypothesis; statistical tests may be parametric, nonparametric (distribution free), or exact
Type I (α) error	Wrongly rejecting a null hypothesis (false-positive error); declaring that a difference exists, when in fact it does not
P value	Probability of making a type I error; $P < .05$ indicates a statistically significant result that is unlikely to have been caused by chance
Confidence interval	A zone of compatibility with the data, which also indicates a range of values considered plausible for the population from which the study sample was selected
Type II (β) error	Failing to reject a false null hypothesis (false-negative error); declaring that a difference does not exist, when in fact it does
Power	Probability that the null hypothesis will be rejected if it is indeed false; mathematically, power is 1.00 minus type II error

TABLE 2.10 Statistical Tests for Independent Samples

Situation	Parametric Test	Nonparametric Test
COMPARING TWO GROUPS OF DATA		
Numeric scale	*t* Test	Mann-Whitney *U*,[a] median
Numeric (censored) scale	Mantel-Haenszel life table	Log rank, Mantel-Cox
Ordinal scale	—	Mann-Whitney *U*,[a] median test; chi-squared test for trend
Nominal scale	—	Chi-squared, log-likelihood ratio
Dichotomous scale	—	Chi-squared, Fisher exact, odds ratio, relative risk
COMPARING THREE OR MORE GROUPS OF DATA		
Numeric scale	One-way ANOVA	Kruskal-Wallis ANOVA
Ordinal scale	—	Kruskal-Wallis ANOVA; chi-squared test for trend
Dichotomous or nominal scale	—	Chi-squared, log-likelihood ratio
ASSOCIATING AN OUTCOME WITH PREDICTOR VARIABLES		
Numeric outcome, one predictor	Pearson correlation	Spearman rank correlation
Numeric outcome, two or more predictor variables	Multiple linear regression, two-way ANOVA	—
Numeric (censored) outcome	Proportional hazards (Cox) regression	—
Dichotomous outcome	Discriminant analysis	Multiple logistic regression
Nominal or ordinal outcome	Discriminant analysis	Log-linear model

[a]The Mann-Whitney *U* test is equivalent to the Wilcoxon rank-sum test.
ANOVA, Analysis of variance.

probability of a type II error directly, it is stated indirectly by specifying power (see Table 2.9).

Moving from principles to practice, two hypothetical studies are presented. The first is an observational prospective study to determine whether tonsillectomy causes baldness: 20 patients who underwent tonsillectomy and 20 controls are examined 40 years later, and the incidence of baldness is compared. The second study will use the same groups but will determine whether tonsillectomy causes hearing loss. This allows exploration of statistical error from the perspective of a dichotomous outcome (bald vs. nonbald) and a numeric outcome (hearing level in decibels).

Suppose that baldness develops in 80% of tonsillectomy patients (16/20) but in only 50% of controls (10/20). If we infer, based on these results in 40 specific patients, that tonsillectomy predisposes to baldness in general, what is the probability of being wrong (i.e., a type I error)? Because $P = .10$ (Fisher exact test), a 10% chance of type I error exists, so we should be reluctant to associate tonsillectomy with baldness based on this single study; the strength of the evidence against the null hypothesis is simply too much to ignore.

Intuitively, however, a rate difference of 30% (e.g., 80% minus 50%) seems significant; so what is the chance of being wrong when we conclude that it is not (i.e., a type II error)? The probability of a type II error (false-negative result) is actually 48%, the same as saying 52% power, which means we may indeed be wrong in accepting the null hypothesis; therefore, a larger study is needed before any definitive conclusions can be drawn.

Intrigued by the initial findings, we repeat the tonsillectomy study with twice as many patients in each group. Suppose that baldness again develops in 80% of tonsillectomy patients (32/40) but in only 50% of controls (20/40). The rate difference is still 30%, but now $P = .01$ (Fisher exact test). The conclusion is that tonsillectomy is associated with baldness, with only a 1% chance of making a type I error (false-positive result). By increasing the number of subjects studied, the precision is increased to a level that could move from observation to generalization with a tolerable level of uncertainty. Similarly, the strength of the evidence against the null hypothesis is now much higher.

Returning to the earlier study of 20 tonsillectomy patients and 20 controls, the hearing levels for the groups are 25 ± 9 decibels (dB) and 20 ± 9 dB, respectively (mean value ± SD). What is the chance of being wrong if we infer that posttonsillectomy patients have hearing levels 5 dB lower than controls? Because $P = .09$ (*t* test), the probability of a type I error is 9%. If, however, we conclude that no true difference exists between the groups, the chance of making a type II error is 58%. Thus, little can be said about the impact of tonsillectomy on hearing based on this study, because power is only 42%. In general, studies with "negative" findings should be interpreted by power, not *P* values.

TABLE 2.11 Statistical Tests for Related (Matched, Paired, or Repeated) Samples

Situation	Parametric Test	Nonparametric Test
COMPARING TWO GROUPS OF DATA		
Dichotomous scale	—	McNemar
Ordinal scale	—	Sign, Wilcoxon signed rank
Numeric scale	Paired *t* test	Sign, Wilcoxon signed rank
COMPARING THREE OR MORE GROUPS OF DATA		
Dichotomous scale	—	Cochran *Q*, Mantel-Haenszel chi-squared
Ordinal scale	—	Friedman ANOVA
Numeric scale	Repeated measures ANOVA	Friedman ANOVA

ANOVA, Analysis of variance.

When making inferences about numeric data, precision may be increased by studying more subjects or by studying subjects with less variability in their responses. For example, suppose again that there are 20 tonsillectomy patients and 20 controls, but this time the hearing levels are 25 ± 3 dB and 20 ± 3 dB. Although the difference remains 5 dB, the SD is only 3 for this study, compared with 9 in the preceding example. What effect does this reduced variability have on the ability to make inferences? The *P* value is now less than .001 (*t* test), indicating less than a 1 : 1000 probability of a type I error if we conclude that the hearing levels truly differ.

All statistical tests measure error. Choosing the right test for a particular situation (Tables 2.10 and 2.11) is determined by (1) whether the observations come from independent or related samples, (2) whether the purpose is to compare groups or to associate an outcome with one or more predictor variables, and

(3) the measurement scale of the variables.[29] When associating an outcome with predictor variables in an observational study, a *propensity score* can be incorporated into the analysis to reduce bias from baseline factors that might influence choice of treatment (e.g., age, illness severity, prior exposures).[30]

Two events are independent if the occurrence of one is in no way predictable from the occurrence of the other. A common example of independent samples is two or more parallel (concurrent) groups in a clinical trial or observational study. Conversely, related samples include paired organ studies, subjects matched by age and sex, and repeated measures on the same subjects (e.g., before and after treatment). Longitudinal studies may include repeated measurements over time, which makes them challenging to analyze unless *mixed models* are used to explicitly account for the correlations between repeated measures within each patient.[31] Measurement scales were discussed previously, but the issue of frequency distribution deserves reemphasis. The tests in Tables 2.10 and 2.11 labeled as "parametric" assume an underlying symmetric distribution for data. If the data are sparse, asymmetric, or plagued with outliers, a "nonparametric" test must be used.

Using the wrong statistical test to estimate error invalidates results. For example, suppose intelligence quotient (IQ) is measured in 20 subjects before and after tonsillectomy, and the mean IQ increases from 125 to 128. For this three-point increase, $P = .29$ (t test, independent samples) suggests a high probability (29%) of reaching a false-positive conclusion. However, the observations in this example are related before and after IQ tests in the same subjects. What is really of interest is the mean change in IQ for each subject (related samples), not how the mean IQ of all subjects before surgery compares with the mean IQ of all subjects postoperatively (independent samples). When the proper statistical test is used (t test, paired samples), $P = .05$ suggests a true association. Related (matched) samples are common in biomedical studies and should never be analyzed as though they were independent.

Habit 5: Put Clinical Importance Before Statistical Significance

Results are statistically significant when the probability of a type I error is low enough ($P < .05$) to safely reject the null hypothesis. If the statistical test compared two groups, we conclude that the groups differ. If the statistical test compared three or more groups, we conclude that global differences exist among them. If the statistical test related predictor and outcome variables (regression analysis), we conclude that the predictor variables explain more variation in the outcome than would be expected by chance alone. These generalizations apply to all the statistical tests in Tables 2.10 and 2.11.

The next logical questions after "Is there a difference?" (statistical significance) is "How big a difference is there?" (effect size) and "Is this difference important to patients?" (minimal clinically important difference, or MCID).[32] Unfortunately, most data interpretation stops with the P value, and the other questions are never asked. For example, a clinical trial of nonsevere acute otitis media found amoxicillin superior to placebo as an initial treatment ($P = .009$).[33] Before we agree with the author's recommendation for routine amoxicillin therapy, let us look more closely at the effect size. Initial treatment success occurred in 96% of amoxicillin-treated children versus 92% of controls, yielding a 4% rate difference that favored drug therapy. Alternatively, 25 subjects (100/4) must be treated (number needed to treat) with amoxicillin to increase the success rate by one subject over what would occur from placebo alone. Is this clinically important to patients? Possibly not, especially when we balance the small benefits against the possible adverse events related to antibiotic therapy.

Statistically significant results must be accompanied by a measure of effect size that reflects the magnitude of difference between groups.[34] Otherwise, findings with minimal clinical importance may become statistically significant when a large number of subjects are studied. In the above example, the 4% difference in success rates was highly statistically significant, because more than 1000 episodes of otitis media contributed to this finding. Large numbers provide high precision (repeatability), which in turn reduces the likelihood of error. The final result, however, is a hypnotically tiny P value, which may reflect a clinical difference of trivial importance.

When comparing groups, common measures of effect size include the odds ratio, relative risk, and rate difference (see Table 2.8). For example, in the hypothetical study of tonsillectomy and baldness noted earlier, the rate difference was 30% ($P = .01$) with a 95% CI of 10% to 50%. Therefore, we can be 95% confident that tonsillectomy increases the rate of baldness between 10% and 50%, with only a 1% chance of a type I error (false-positive). Alternatively, results could be expressed in terms of relative risk. For the tonsillectomy study, *relative risk* is 1.6 (the incidence of baldness was 1.6 times higher after surgery) with a 95% CI of 1.1 to 2.3.

Effect size is measured by the correlation coefficient (r) when an outcome variable is associated with one or more predictor variables in a regression analysis (see Table 2.10). Suppose that a study of thyroid surgery reports that shoe size had a statistically significant association with intraoperative blood loss (multiple linear regression, $P = .04$, $r = .10$). A correlation of only .10 implies little or no relationship (see habit 2), and an r^2 of .01 means that only 1% of the variance in survival is explainable by shoe size. Who cares if the results are "significant" when the effect size is clinically irrelevant, not to mention nonsensical? Besides, when $P = .04$, there is a 4% chance of being wrong when the null hypothesis is rejected, which may in fact be the case here. A nonsensical result should prompt a search for confounding factors that may not have been included in the regression, such as tumor-node-metastasis (TNM) stage, comorbid conditions, or duration of surgery.

Confidence intervals are more appropriate measures of clinical importance than are P values, because CIs reflect both magnitude and precision.[35] When a study reports "significant" results, the lower limit of the 95% CI should be scrutinized; a value of minimal clinical importance suggests low precision (inadequate sample size). When a study reports "nonsignificant" results, the upper limit of the 95% CI should be scrutinized; a value indicating a potentially important clinical effect suggests low statistical power (false-negative finding). Ideally, the P value, effect size, and 95% CI for the effect size should all be reported to allow proper interpretation of study results.

Habit 6: Seek the Sample Source

When we interpret medical data, we ultimately seek to make inferences about some target population based on results in a smaller sample (Table 2.12). Rarely is it possible to study every patient, medical record, DNA strand, or fruit fly with the condition of interest; nor is it necessary—inferential statistics let us generalize from the few to the many, provided that the few studied are a random and representative sample of the many. However, random and representative samples rarely arise through divine providence; therefore, we must seek the sample source before generalizing the interpretation of the data beyond the confines of the study that produced it.

As an example of sampling, consider a new antibiotic touted as superior to an established standard for treating acute otitis media. When you review the data on which this statement is based, you learn that the study end point was bacteriologic efficacy—the ability to sterilize the middle ear after treatment. Furthermore, the only patients included in the study were those whose initial tympanocentesis revealed an organism with in vitro sensitivity to the new antibiotic; patients with no growth or resistant bacteria

were excluded. Can you apply these results to your clinical practice? Most likely not, because you probably do not limit your practice to patients with antibiotic-susceptible bacteria. In other words, the sample of patients included in the study is not representative of the target population in your practice.

A statistical test is valid only when the study sample is random and representative. Unfortunately, these assumptions are frequently violated or overlooked. A random sample is necessary, because most statistical tests are based on probability theory—playing the odds. The odds apply only if the deck is not stacked and the dice are not rigged; that is, all members of the target population have an equal chance of being sampled for study. Investigators, however, typically have access to only a small subset of the target population because of geographic or temporal constraints. When they choose an even smaller subset of this accessible population to study, the method of choosing (sampling method) affects the ability to make inferences about the original target population.

Of the sampling methods listed in Table 2.13, only a random sample is theoretically suitable for statistical analysis. Nonetheless, a consecutive or systematic sample offers a relatively good approximation and provides data of sufficient quality for most statistical tests.[36] The worst sampling method occurs when subjects are chosen based on convenience or according to subjective judgments about eligibility. Applying statistical tests to the resulting convenience (grab) sample is the equivalent of asking a professional card counter to help you win a blackjack game when the deck is stacked and cards are missing—all bets are off, because probability theory will not apply. A brute force sample of the entire population is also unsatisfactory, because lost, missing, or incomplete units tend to differ systematically from those that are readily accessible.

"Seek the sample source" means that we must identify the sampling method and selection criteria (inclusion and exclusion criteria) that were applied to the target population to obtain the study sample. When the process appears sound, we can conclude that the results are generalizable and externally valid (see Table 2.12 and Fig. 2.2). If the process appears flawed, we cannot interpret or extrapolate the results beyond the confines of the study sample.

Sometimes a study is internally valid, but the results may not be generalizable. Paradise and colleagues[37] concluded that prompt versus delayed insertion of tympanostomy tubes for persistent otitis media does not affect child development. Although the study was meticulously designed and analyzed (internally valid), the participants had mostly unilateral (63%) or discontinuous (67%) otitis media with effusion; bilateral continuous effusions were uncommon (18%). Moreover, children with syndromes, developmental delays, or other comorbidities were excluded. Whereas no benefits were seen in the healthy children studied, the results are not generalizable to the more typical population of children who receive tubes, many of whom have chronic bilateral effusions with hearing loss and developmental comorbidities.

The impact of sampling on generalizability is particularly important when interpreting a diagnostic test.[38] For instance, suppose an audiologist develops a new test for diagnosing middle ear effusion (MEE). After testing 1000 children, she reports that

TABLE 2.12 Glossary of Statistical Terms Related to Sampling and Validity

Term	Definition
Target population	Entire collection of items, subjects, patients, and observations about which inferences are made; defined by the selection criteria (inclusion and exclusion criteria) for the study
Accessible population	Subset of the target population accessible for study, generally because of geographic or temporal considerations
Study sample	Subset of the accessible population chosen for study
Sampling method	Process of choosing a sample from a larger population; the method may be random or nonrandom, representative or nonrepresentative
Selection bias	Error caused by systematic differences between a study sample and target population; examples include studies on volunteers and those conducted in clinics or tertiary care settings
Sample-size determination	Process of deciding, before a study begins, how many subjects should be studied based on the incidence or prevalence of the condition under study, anticipated differences between groups, the power desired, and the allowable level of type I error
Internal study validity	Degree to which conclusions drawn from a study are valid for the study sample; results from proper study design, unbiased measurements, and sound statistical analysis
External study validity (generalizability)	Degree to which conclusions drawn from a study are valid for a target population (beyond the subjects in the study); results from representative sampling and appropriate selection criteria

TABLE 2.13 Methods for Sampling a Population

Method	How It Is Performed	Comments
Brute force sample	All units of study accessible to the researchers are included: charts, patients, laboratory animals, and journal articles.	Time consuming and unsophisticated; bias prone, because missing units are seldom randomly distributed.
Convenience (grab) sample	Units are selected on the basis of accessibility, convenience, or by subjective judgments about eligibility.	Assume this method when none is specified; study results cannot be generalized because of selection bias.
Consecutive sample	Every unit is included over a specified time interval, or until a specified number is reached; the interval should be long enough to include seasonal or other temporal variations relevant to the research question.	Volunteerism and other selection biases can be minimized but requires judgment when generalizing to a target population.
Systematic sample	Units are selected using some simple, systematic rule, such as first letter of last name, date of birth, or day of the week.	Less biased than a grab sample, but problems may still occur because of unequal selection probabilities.
Random sample	Units are assigned numbers then selected at random until a desired sample size is attained; most common use is in clinical research to select a representative subset from a larger population.	Best method; bias is minimized, because all units have a known (and equal) probability of selection; data can be stratified based on subgroups in the population.
Cluster sample	Sample of natural groupings, or clusters, of units in a population is random (e.g., hospitals in a region, city blocks or zip codes, different office sites).	Helps create a manageable sample size, but the clusters are often homogeneous for the variables of interest.

90% of children with a positive result did in fact have MEE (positive predictive value of 90%). Yet when unselected kindergarten children were screened for MEE, the positive predictive value of the test is only 50%. Why does this occur? Because the baseline prevalence of MEE is lower in the kindergarten class (10% have MEE) than in the referral-based audiology population in which the test was developed (50% have MEE). Whereas the sensitivity and specificity of the test are unchanged in both situations, the predictive value is related to baseline prevalence (Bayes theorem); therefore, the ultimate utility of the test depends on the sample to which it will be applied.

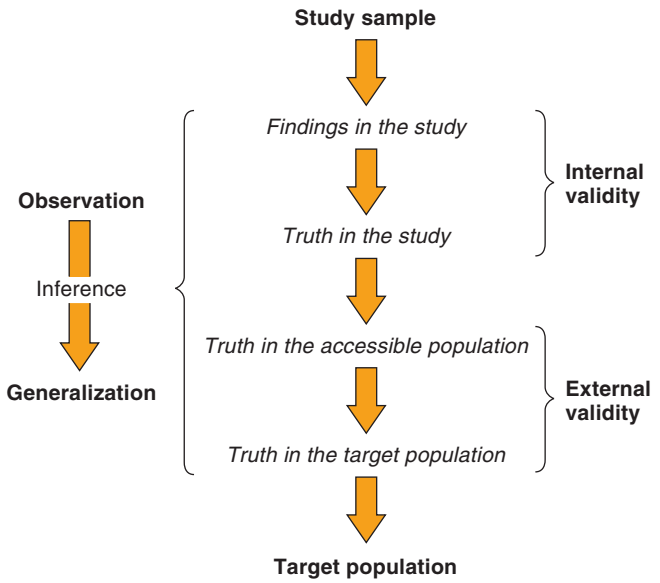

Fig. 2.2 Relationship of validity to inference. A properly designed, executed, and analyzed study has *internal validity,* meaning the findings are valid for the study sample. This alone, however, is inadequate for inference to occur. Another requirement is *external validity,* which exists when the study sample is representative of an appropriate target population. When a study has internal and external validity, the observations can be generalized.

Habit 7: View Science as a Cumulative Process

No matter how elegant or seductive, a single study is rarely definitive. Science is a cumulative process that requires a large body of consistent and reproducible evidence before conclusions can be formed.[39] When interpreting an exciting set of data, the cumulative basis of science is often overshadowed by the seemingly irrefutable evidence at hand—at least until a new study, by different investigators in a different environment, adds a new twist.[40]

Habit 7 is the process of integration: reconciling findings with the existing corpus of known similar research. It is the natural consequence of habits 1 through 3 that deal with description and habits 4 through 6 that deal with analysis. Thus, data interpretation can be summarized in three words: describe, analyze, and integrate. This is a sequential process in which each step lays the foundation for subsequent ones, just as occurs for the six habits that underlie them.

Research integration begins by asking "Do the results make sense?" Statistically significant findings that are biologically implausible or that are inconsistent with other known studies can often be explained by hidden biases or design flaws that were initially unsuspected (habit 1). Improbable results can become statistically significant through biased data collection, natural history, placebo effects, unidentified confounding variables, or improper statistical analysis. A study with design flaws or improper statistical analysis is said to have low internal validity (see Table 2.12) and should be reanalyzed or discarded.

At the next level of integration, the study design that produced the current data is compared with the design of other published studies. The level of evidence for treatment benefits generally increases as we progress from uncontrolled observational studies (case reports, case series) to controlled observational studies (cross-sectional, retrospective, prospective) to controlled experiments (RCTs). Not all RCTs, however, are of high quality, and standards for analysis and reporting must be followed to ensure validity.[41] Levels of research evidence are most often applied to studies of therapy or prevention (Table 2.14), but they can also be defined for diagnosis and prognosis.[42]

Analysis of real world data (RWD) has become an increasingly important source of information that overcomes the limitations of RCTs regarding generalizability, implementability, and pragmatism in real-life clinical settings.[43,44] RWD are data relating to

TABLE 2.14 Levels of Research Evidence for Clinical Recommendations

Level[a]	Treatment Benefits	Prevalence or Incidence	Prognosis	Diagnostic Test Assessment
1	Systematic review of randomized trials or *n*-of-1 trials	Local and current random sample surveys (or census)	Systematic review of inception cohort studies[b]	Systematic review of cross-sectional studies with consistently applied reference standard and blinding
2	Randomized trial or observational study with dramatic effect	Systematic review of surveys that allows matching to local circumstances	Inception cohort studies[b]	Individual cross-sectional studies with consistently applied reference standard and blinding
3	Nonrandomized controlled cohort or follow-up study	Local nonrandom sample	Cohort study or control arm of randomized trial	Nonconsecutive studies or studies without consistently applied reference standards
4	Case series, case-control studies, or historically controlled studies	Case series	Case series or case-control studies or poor-quality prognostic study	Case-control studies, or studies with a poor or nonindependent reference standard
5	Expert opinion or mechanism-based reasoning from physiology, bench research, or first principles	Expert opinion or mechanism-based reasoning from physiology, bench research, or first principles	Expert opinion or mechanism-based reasoning from physiology, bench research, or first principles	Expert opinion or mechanism-based reasoning from physiology, bench research, or first principles

[a]Level may be graded down based on study quality, imprecision, indirectness, inconsistency between studies, or because the absolute effect size is very small; level may be graded up if the effect size is large or very large.
[b]Inception cohort: group of individuals identified for subsequent study at an early, uniform point in the course of the specified health condition or before the condition develops.
Modified from Howick J, Chalmers I, Glasziou P, et al: Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence. Available at www.cebm.net/index.aspx?o=5653.

TABLE 2.15 Comparison of Narrative (Traditional) Reviews and Meta-Analyses

Characteristic	Narrative Review	Meta-Analysis
Research design	Free form	A priori protocol
Literature search	Convenience sample of articles deemed important by author	Systematic sample using explicit and reproducible article selection criteria
Data extraction	Selective data retrieval by one author	Systematic data retrieval by two or more authors to reduce error
Focus	Broad; summarizes a large body of information	Narrow; tests specific hypotheses and focused clinical questions
Emphasis	Narrative; qualitative summary	Numbers; quantitative summary
Validity	Variable; high potential for bias in article selection and interpretation	Good, provided articles are of adequate quality and combinability
Quality assessment	Usually not performed; all studies considered of equal quality	Assessed explicitly with criteria to measure risk of bias in study design, conduct, and reporting
Bottom line	Broad recommendations, often based on personal opinion; no discussion of heterogeneity	Estimates of effect size, based on statistical pooling of data; explicit assessment of heterogeneity among studies
Utility	Provides a quick overview of a subject area	Provides summary estimates for evidence-based medicine
Appeal to readers	Usually very high	Varies depending on focus

patient health status, or the delivery of health care, that are routinely collected from electronic health records, administrative data (claims databases), population health surveys, or patient/disease registries. RWD are particularly useful for evaluating drug safety and effectiveness, but can also be used to create case-control studies that assess association.[45]

A single study is rarely definitive; because science is cumulative, it mandates a large body of consistent and reproducible evidence before conclusions can be formed. For this reason, achieving the highest level of evidence (see Table 2.14) often requires a systematic review of available evidence, using explicit and reproducible criteria to locate, appraise, and synthesize articles with a minimum of bias.[46] Meta-analysis is a form of systematic review that uses statistical techniques to derive quantitative estimates of the magnitude of treatment effects and their associated precision. Valid systematic reviews (and meta-analyses) address focused questions, assess the quality and combinability of articles, provide graphic and numeric summaries, and can be generalized to a meaningful target population. They also contain a flow diagram that shows the fate of articles as they pass through different phases of the review process, including identification, screening, eligibility, and inclusion.[47] Graphic comparison of studies using forest and funnel plots helps assess publication trends, small-study bias, and overall combinability and consistency of included studies.[48] Systematic reviews differ greatly from traditional "narrative" review articles (Table 2.15) and are the preferred method for synthesizing research evidence.

Clinical practice guidelines are often the next step in evidence synthesis and may be defined as "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options."[49] Guidelines, therefore, build upon systematic reviews by incorporating values, preferences, and recommendation strengths, ideally based upon explicit and transparent processes that represent all stakeholders, including consumers.[50] The best guidelines contain a limited number of actionable recommendations supported by distinct evidence profiles, and are accompanied by a plain language summary for patients and consumers.

POPULAR STATISTICAL TESTS USED BY OTOLARYNGOLOGISTS

Salient features of the most popular tests in otolaryngology journals[51,52] are listed here. Note that each test is simply an alternative way to measure error (habit 4), not a self-contained method of data interpretation. Tests are chosen using the principles outlined in Tables 2.10 and 2.11, then analyzed with readily available software, which can also help select the best test for a specific dataset. Explicit guidelines are available to help authors, editors, and reviewers identify the optimal format for reporting statistical results in medical publications.[53]

t Test

Description

The *t* test is a classic parametric test for comparing the means of two independent or matched (related) samples of numeric data; it is also called the Student *t* test.

Interpretation

A significant *P* value for independent samples implies a low probability that the mean values for the two groups are equal. When the samples are matched, a significant *P* value implies that the mean differences of the paired values are unlikely to be zero. Clinical importance is assessed by examining the magnitude of difference achieved and the associated 95% CI. Because valid results depend on relatively equal variances (the SD) within each group, a statistical test is required to verify this assumption (F test).

Precautions

The *t* test produces an artificially low *P* value if the groups are small (fewer than 10 observations) or if they have an asymmetric distribution (one or more extreme outlying values); instead, a nonparametric test (Mann-Whitney *U* or Wilcoxon rank-sum test) should be used. If, however, each group contains more than 30 observations, the underlying distribution can deviate substantially from normality without invalidating the results. These *t* tests should never be used to compare more than two groups; for those, analysis of variance (ANOVA) is required.[54] When the outcome of interest is time-to-event (e.g., cancer survival, duration of hospital stay, disease recurrence), survival analysis is more appropriate than a *t* test.

Analysis of Variance

Description

ANOVA tests whether the means of three or more independent groups of continuous data differ significantly with regard to a single factor (one-way ANOVA) or two factors (two-way ANOVA). ANOVA also tests whether the effect of one factor on the response variable depends on the level of a second factor (interaction).

Interpretation

A significant *P* value implies a low probability that the mean values for all groups are equal. From a statistical standpoint, we say that the variance among groups is larger than the variance within each group. Note that ANOVA provides no information on whether individual pairs of groups differ significantly; it only tests for an overall global difference. For example, when comparing four groups of data—A, B, C, and D—the finding "$P < .05$, ANOVA" means there is less than a 5% chance that the statement "A = B = C = D" is true; however, it says nothing about AB or CD or DA, and so on. Once the investigators demonstrate a significant global difference ($P < .05$) using ANOVA, they can then use multiple comparison procedures (Bonferroni, Tukey, Newman-Keuls, Scheffe, Dunnett) for individual group comparisons.

Precautions

ANOVA will produce an artificially low *P* value if the groups contain small samples (<5 observations per group or 20 in all groups combined) with asymmetric distributions; instead, a nonparametric test (Kruskal-Wallis ANOVA) should be used. A nonparametric test is also preferred if the groups have unequal variance as determined by an *F* test. Multiple pairwise *t* tests cannot substitute for ANOVA; the effect is to greatly increase the odds of a false-positive result (type I error).

Contingency Tables

Description

Contingency tables test for an association between two categorical variables by using the chi-square statistic. A modification, called the *McNemar test*, can be used for two groups of paired data.

Interpretation

A significant *P* value implies a significant association between the two variables, whose categorical values form the rows and columns of the contingency table.[23] However, even a very small *P* value provides no information about the strength of the association (effect size); therefore, effect size can be measured with the odds ratio (2×2 table) or by Pearson's contingency coefficient (tables with more than two rows or columns). The chi-square statistic compares the observed values for each cell (row-column intersection) with the expected values that would occur by chance alone.

Precautions

As with *t* tests and ANOVA, small samples can produce an artificially small *P* value. If the expected frequency for any cell is less than 5, an alternative test must be used (e.g., Fisher exact test or the log/likelihood ratio). Beware of authors who overinterpret a "significant" chi-squared result. As with ANOVA, when $P < .05$, a global association is claimed between variables, but we cannot specify which subgroups of rows and columns are or are not associated.

Survival Analysis

Description

Survival analysis estimates the probability of an event—typically, but not necessarily, survival—based on the total period of observation, and it tests for associations with other variables of interest. Survival analysis permits maximal use of data from censored observations, which occur when a subject is lost to follow-up or when the study ends before the outcome of interest has occurred.[21,22]

Interpretation

Survival data are analyzed in two ways: the life-table method divides the time into intervals and calculates survival at each interval; the Kaplan-Meier method calculates survival each time an event occurs. Both methods produce a graph (survival curve) that shows the cumulative probability (hazard ratio) of the event versus the total period of observation. Authors sometimes eliminate the curve and instead give the event rates only for specific time periods (e.g., 1, 3, and 10 years). When two or more survival curves are compared, and the *P* value is low, a probable association exists between time to event and the factor used to stratify the curves.

Precautions

When you see a "survival curve," be sure that it has been calculated using survival analysis (life table or Kaplan-Meier), not by simply dividing cumulative events at a given time by the total subjects still around at that time. The latter method mistreats censored observations, yielding artificially low estimates; nor is it desirable to simply exclude from analysis all subjects that do not meet some arbitrary cutoff for observation time, because the rates that result may be artificially high. Whereas the life-table method requires a minimum sample size of 20 uncensored observations, Kaplan-Meier analysis requires only five uncensored observations for valid results.

Multivariate (Regression) Procedures

Description

Multivariate (regression) procedures examine the simultaneous effect of multiple predictor variables, generally three or more, on an outcome of interest. In contrast, the *t* test, one-way ANOVA, chi-square test, and survival analysis examine the univariate effect of variables on an outcome one at a time. Different multivariate procedures are used, depending on the measurement scale of the outcome variable (see Table 2.10). The most popular regression methods in general medical journals are multiple linear regression, Cox proportional hazards (for survival data), and multiple logistic regression (for a binary or dichotomous outcome).[55]

Interpretation

Multivariate analysis produces a statistical model that predicts outcomes based on combinations of individual variables. The adequacy of the model as a whole is determined by the coefficient of determination (r^2), which indicates how much variability in the response variable is accounted for by the predictors, and its associated *P* value. Each predictor variable also has an associated coefficient, whose magnitude represents the relative effect of the variable on outcome when adjusted for all the other variables in the model. A positive coefficient implies a positive association; a negative coefficient implies a negative association. When the coefficient's *P* value is small, the association is significant. Predictor variables should also be tested for interaction.

Precautions

Biased results may occur if the dataset has outliers, or if variables in the model are highly correlated with each other ($r > .90$). Although a model may precisely fit the investigator's data, there is no guarantee that it will predict outcomes for subjects outside the study with equal precision. As with any statistical test, the rule is simple: garbage in, garbage out. No degree of multivariate analysis can adjust for confounding variables that were not recorded at the start of the study.

Nonparametric Tests

Description

Nonparametric tests test hypotheses without requiring that the data have a normal (symmetric) distribution. The nonparametric equivalents of the *t* test, paired *t* test, and one-way ANOVA are the Mann-Whitney *U*, Wilcoxon signed rank, and Kruskal-Wallis tests, respectively (see Tables 2.10 and 2.11).

Interpretation

When an author uses a parametric test (e.g., *t* test or ANOVA), the data must be normally distributed or they must come from a large enough sample (about 30 or more subjects) to relax this requirement of normality. Nonparametric tests avoid this requirement by ranking the data in each group and then comparing rank sums, instead of comparing the actual values of individual observations. Whereas the parametric tests discussed above make inferences about means, nonparametric tests make inferences about medians. When doubt arises regarding whether a nonparametric test is necessary, the *P* value should be calculated both ways—parametrically and nonparametrically. If the results differ significantly, the nonparametric test is preferred.

Precautions

Very sparse datasets are not suitable for either parametric or nonparametric analysis; more sophisticated exact significance tests must be used. The Fisher exact test is a well-known exact procedure for 2×2 contingency tables. Exact tests for other situations often require statistical consultation or specialized computer software.

COMMON STATISTICAL DECEPTIONS

More than a century ago, Benjamin Disraeli noted, "There are three kinds of lies: lies, damn lies and statistics." Although such consummate skepticism is rarely justified, statistics can undoubtedly be misused—either by intent or through ignorance or carelessness—to produce incorrect conclusions (Table 2.16). Confidence and common sense have been advocated as a means to balance statistical significance with clinical importance.[56]

How does statistical misuse slip by editors, peer reviewers, and journal readers? Because of the "dazzle" phenomenon observed by Darrell Huff, author of *How to Lie with Statistics*: "If you can't prove what you want to prove, demonstrate something else and pretend that they are the same thing. In the daze that follows the collision of statistics with the human mind, hardly anybody will notice the difference."[57] Below we will describe various "dazzling phenomena" of which the researcher should be particularly wary.

Surgical Satisfaction Swindle

A surgeon claims a procedure is "highly effective," because 85% of patients were satisfied with results, 85% would have the surgery again, and 85% would recommend the procedure to family or friends. Unfortunately, virtually any survey achieves 80% or higher respondent satisfaction for a given question, and only a few patients actually express negative views.[58] Satisfaction surveys are particularly prone to positive-response bias because they often relate more to the interpersonal skills of the surgeon and the setting in which treatment was administered than to the actual outcomes achieved. Moreover, without a comparison or control group, therapeutic effects cannot be distinguished from natural history or a placebo response.[9]

Survey results are credible only if the investigators use a previously validated instrument or perform their own validation process.[59] This process includes assessing (1) test-retest reliability to ensure response stability and consistent item (question) interpretation, (2) internal consistency to determine whether allegedly similar items tap similar content domains, (3) construct validity to verify that items actually measure what they purport to measure, (4) discriminant validity to show that respondents with different levels of satisfaction or disease have measurably different survey scores, and (5) responsiveness to demonstrate that the change in survey scores before and after intervention is sufficient to detect clinically meaningful levels of change within an individual.

Standard Error Switcheroo

When you see results reported as "mean value ± X," do not assume that *X* is the SD unless specifically stated. Sometimes *X* is actually the standard error (SE), a number that is always smaller than SD. Actually, SD and SE are very different, so understanding why many authors report the latter is difficult, unless they are enamored by the smaller value. When describing a set of data, SD is always preferred because it measures how variable individual observations are within a sample.[60] If the data have a symmetric distribution, the mean ± 2 SD describes about 95% of observations. In contrast,

TABLE 2.16 Statistical Deceptions Used in Journal Articles

Deception	Problem	Solution
Standard error is used instead of standard deviation.	Range is artificially low, making data look better than they are.	Always use standard deviation when summarizing data.
Small sample study results are taken at face value.	Results are imprecise and would likely vary if the study were repeated; uncertainty is ignored.	Determine the range of results consistent with data by using a 95% confidence interval.
Post hoc *P* values are used for statistical inference.	Statistical tests are valid only when hypotheses are formulated before examining the data.	Post hoc *P* values must be viewed as hypothesis-generating, not hypothesis-testing.
Some results are "significant," but there are a large number of *P* values.	"Significant" results may be false positives, because each *P* value has a 5% error rate.[a]	Reduce the number of *P* values through multivariate analysis or analysis of variance.
Subgroups are compared until statistically significant results are found.	If you torture the data sufficiently, they will eventually confess to something.	Subgroup comparisons are valid only when all groups as a whole are significantly different.
No significant difference is found between groups in a small sample study.	A significant difference may have been missed because of inadequate sample size.	Be wary of study results until the authors discuss power and sample-size results.
Significant *P* values are crafted through improper use of hypothesis tests.	Small studies with asymmetrically distributed data require special methods of analysis.	Be wary of results unless a nonparametric or exact statistical test was used.
Inflated sample sizes and biased results are reported when paired samples (or organs) are analyzed independently.	Paired data require special techniques for analysis and cannot be unbundled into a larger sample.	Use proper statistical techniques for paired data (see Table 2.11), and use data from only one side when dealing with paired organs.

[a]Assuming that .05 is selected as the level of statistical significance.

the SE is an inferential, not a descriptive, statistic; it measures how variable the mean is from one sample to another.

Consider a study of 25 patients undergoing rhinoplasty that reports a mean blood loss of 150 ± 30 mL, and 30 is the SD. We now know that 95% of subjects had a blood loss of 150 ± 60 mL (assuming the data are normally distributed). To obtain the SE, divide the SD by the square root of the sample size. In this example, the square root is 5, giving an SE five times smaller than the SD: 6 vs. 30. The mean blood loss now is written as 150 ± 6 mL, where 6 is the SE. Obviously this looks better than the SD, but what exactly does it mean? It means "based on our results, if we extrapolate to the general population of rhinoplasty patients, we estimate with 95% confidence that the mean blood loss will be 150 ± 12 mL." This statement no longer describes the study data, but makes an inference about some hypothetical population. Unless the authors clearly state that this is their intent, the SD should have been used.

Small Sample Whitewash

Because medical research is costly and time consuming, it is a luxury to study large samples. Fortunately, meaningful conclusions can be derived from small samples by estimating uncertainty (precision) with a 95% CI. Remember—statistics is the art and science of dealing with uncertain data; the smaller the sample, the greater the uncertainty. Beware of authors who claim their sample is too small for statistical analysis; that is precisely when they need it most.

For example, while perusing the *Journal of Low Budget Research*, an article on an innovative new surgical procedure captures your attention. The authors operate successfully on four of four elephants (100% success rate) and conclude that "testing in humans is indicated based on these superb results." Do you agree? Actually, the range of results (exact 95% binomial CI) consistent with this single experiment on four elephants is 47% to 100%! Knowing that the population success rate—for elephants, at least—may be as low as 47%, you may now disagree with the need for human testing. Conversely, if the investigators succeeded in 40 of 40 elephants, the 95% CI would be 93% to 100%—a much greater level of confidence secondary to the tenfold increase in sample size.

Here is another way to appreciate the value of confidence limits on small samples. Imagine you are about to cross a very flimsy and tenuous-appearing bridge. Your reassuring guide states you have nothing to worry about because the first four travelers crossed it successfully. The statistical basis for your persistent trepidation stems from the fact that four of four successes is consistent with up to a 53% failure rate, as noted in the preceding paragraph—not a very reassuring statistic to stake your life on!

Post Hoc *P* Values

A fundamental assumption underlying all statistical tests is that the hypothesis under study was fully developed before the data were examined in any way. When hypotheses are formulated post hoc, after even the briefest glance at the data, the basis for probability statements is invalidated. Unfortunately, there is no way of knowing at which stage of the research process a hypothesis was developed. Therefore, unless the investigators state specifically that the test was planned a priori, it is best to infer with caution.

As physician-friendly computer programs and online resources for statistical analysis continue to proliferate, more physicians are likely to analyze their own data. Unless the probability framework that underlies hypothesis tests is understood and appreciated (habits 3 and 4), the risk of post hoc *P* values will increase dramatically as they become easier to produce. When the primary research purpose is to test an a priori hypothesis, the *P* value will aid in statistical inference. When hypotheses are generated after the study, however, *P* values cannot be used to make inferences. Instead, they become a means of identifying promising associations that might form the new a priori hypotheses in a follow-up investigation.

Multiple *P* Value Phenomenon

When a journal article or data table is chock-full of *P* values, realize that some "significant" *P* values ($P < .05$) are likely to occur by chance alone.[61] Consider, for example, that a researcher performs 20 individual hypothesis tests on a group of observations (calculates 20 *P* values). If the subjects studied do not differ beyond random variation, the chance is only 36% that none of the *P* values will be significant. Furthermore, the chance of there being one, two, or three significant *P* values is 38%, 19%, and 6%, respectively.

What accounts for the multiple *P* value phenomenon? The problem arises because each test is based on a cutoff of $P < .05$ as a measure of significance; the effect of performing multiple tests is to inflate this 5% error level for the study as a whole. Where α is the level of significance for each individual test (generally .05), and n is the number of tests performed, the probability of obtaining at least one spurious result is $1 - (1 - \alpha)^n$.

Multiple *P* values can arise when pairwise comparisons are made among several groups of data or when numerous hypothesis tests are applied to a single dataset. When several groups are compared, ANOVA overcomes the multiple *P* value problem created by repeated *t* tests. Furthermore, special multiple comparison tests are available with ANOVA that can search for subgroup differences, as long as a global difference exists among the groups.[62] When a single dataset is being studied, multivariate analysis will eliminate the multiple *P* value problem induced by repeated univariate tests (e.g., *t* test, chi-square calculation).

Selective Analysis of Results

It is important to check for selective analysis of the results in every study that compares three or more groups of subjects, including animal research. Authors may pluck out a few groups for pairwise comparisons and then pontificate on the "statistically significant" findings they discover. Unfortunately, this violates a basic tenet of statistics: you cannot compare subgroups of data unless you first check for statistically significant differences between all groups considered simultaneously. For categorical data, a chi-square is first calculated for the entire contingency table; if $P < .05$, the authors can then extract subsets of the table for selective analysis, as long as they adjust for multiple comparisons. For continuous data, ANOVA should be used (not multiple pairwise *t* tests) as described previously.

Powerless Equalities

Some authors would like to convince you that a new treatment or diagnostic test is equivalent to an established standard (e.g., a non-inferiority trial). In particular, support for the use of a new antibiotic or antihistamine often arises from a randomized trial that claims no significant difference ($P > .05$) from another drug. When interpreting these results, look not at the *P* value but at the statistical power; the size of the *P* value is pertinent only when a statistically significant result is given. Power tells the probability that the investigators would have detected a true difference, given that one really existed.

Two caveats should be kept in mind when considering the results of a non-inferiority trial. First, the sample size needed to show equivalence of two interventions is usually much larger than that required for a placebo-controlled study. Second, results should be presented using both a traditional intention-to-treat (ITT) analysis, which includes all randomized subjects, and a per-protocol analysis, which only includes subjects who completed the

intervention and remained in the study. Analyzing a non-inferiority trial with only an ITT approach could make an inferior treatment appear non-inferior if poor patient adherence impacted efficacy in all groups.[63]

Paired Data Proliferation

Paired data exist when subjects are assessed twice or when paired organs (e.g., ears, eyes) are analyzed. Authors can artificially inflate paired data in one of two ways. One common method is to treat measurements in subjects before and after an intervention as two independent groups, and then compare them with a *t* test. This may severely distort the group differences, because the paired observations from each subject have been decoupled and made independent. Instead, the researcher should use statistical tests for paired data (see Table 2.11), which analyze the difference in paired measurements by subject.

Another way to artificially inflate data is to treat data from paired organs as independent measurements. For example, a diagnostic test study could treat measurements on the left and right ears as independent, yielding a sample size that is twice as large as the number of subjects studied. The increased precision from this inflated sample size comes at the expense of validity, because the data points are not truly independent, which violates a fundamental assumption of many statistical tests. The proper way to analyze paired-organ data is to randomly pick one organ (one side) from each patient to contribute to the analysis.

UNDERSTANDING SAMPLE SIZE

A sample size calculation before beginning a study ensures that the planned number of observations will offer a reasonable chance of obtaining a clear answer at the end.[64] This is of paramount importance in animal studies, in which sample size is limited by financial constraints, concerns over animal welfare, and limited laboratory space.[65] For example, a groundbreaking experiment in 10 giraffes is of little value, when a sample size of 20 is needed for adequate power or precision. Similarly, why experiment on 200 chinchillas, when only 100 are adequate to test a hypothesis? Such considerations are by no means limited to basic science research. Why devote endless hours to abstracting data from 500 patient charts, when only 150 observations would suffice?

Calculating sample size is an essential first step in evaluating or planning a research study.[66] Basic requirements for all sample-size calculations include (1) estimates of the smallest difference desired to be detected between the groups (minimal clinically important difference), (2) level of confidence that any difference detected is not simply due to chance (typically 95% or 99%), and (3) level of confidence that the difference detected will be as small as what was specified earlier (typically 80% or 90%), assuming that such a difference truly exists. In addition, sample-size calculations for numeric data require some estimate of the variability (variance) among observations.

Determining the minimal clinically important difference to be detected is based solely on clinical judgment. When comparing categorical data, the difference of interest is that between proportions (rate difference, see Table 2.8); for example, an investigator may wish to know if success rates for two drugs differ by at least 20% for otitis media, but a difference of perhaps 5% may be important when treating cancer. In contrast, differences in numeric data are expressed as a difference in means; for example, a researcher may wish to know if a potentially ototoxic drug decreases mean hearing by at least 5 dB, or if a new surgical technique decreases blood loss by at least 200 mL.

Outcomes measured on a numeric scale require an estimate of variance to calculate sample size. Because variance is defined as the square of the SD, a method is needed to estimate SD to derive variance. If pilot data are available, some estimate of SD may already exist. Alternatively, one can "guess" the SD by realizing that the mean value ± 2 SD typically encompasses 95% of the observations. In other words, the SD of a set of measurements can be approximated as one fourth of the range of that set of measurements. Suppose you are interested in detecting a 200-mL difference in blood loss between two procedures, and based on your clinical experience, you expect that about 95% of the time you will see a difference that ranges from 100 mL to 500 mL. Subtracting 100 from 500 and dividing by 4 gives 100 as an estimate of SD. Squaring the SD yields 10 000, which estimates variance.

The remaining elements of a sample-size calculation reflect basic principles of statistical error (habit 4). Recognizing that errors are unavoidable (see Table 2.9), an investigator can specify in advance the levels of tolerance and then calculate a sample size that will accomplish this goal. Tolerating a 5% probability of type I error (false positive) is the same as being 95% certain that any difference detected is not simply due to chance. Tolerating a 20% probability of a type II error (false negative) is the same as being 80% certain that a true difference of the magnitude already specified (80% statistical power) is not missed.

The size of the sample needed in a given study increases when the difference of interest is small, the variance of the observations is high (applies to numeric data only, not proportions), and the tolerance for error is low. More subjects are also required to determine whether any difference at all exists between groups (two-tailed statistical test) than to determine whether one group fares better or worse than another (one-tailed statistical test). A two-tailed test is considered more conservative and should always be used, unless it was determined a priori—before examining the data—that a one-tailed test was appropriate. A one-tailed test requires about half the sample size as a two-tailed test to show significance, and it produces *P* values about half as small when applied to the data.

IMPORTANCE OF PRINCIPLES

My goal throughout this chapter has been to convince you that effective interpretation of medical data involves much more than statistics or numeric formulae. Rather, it is a systematic process of moving from observations to generalizations with predictable degrees of certainty and uncertainty. Every physician is involved in this process to some extent, whether a solo practitioner in a rural community or a full-time academician in a large university. Moving from observations to generalizations is the foundation for all scientific progress, a foundation that could not exist without a systematic process for interpreting data.

The seven habits listed in Table 2.1 provide a systematic framework for interpreting data, of which statistical tests are only a small part. Although habit 4—measure error with the right statistical test—generates *P* values, it is sandwiched between habits 1 through 3 and habits 5 through 7. *P* values are part of the process but represent neither the beginning nor the end. We begin by verifying that the data are of sufficient quality and precision to merit statistical analysis (habits 1 through 3). We end by seeking clinically significant findings that can be generalized beyond the study and that are consistent with prior knowledge and experience (habits 5 through 7). Obsession with *P* values—what has been called the "religion of statistics"—may produce medical publications, but it rarely achieves effective data interpretation.[67,68]

Every clinician need not be a statistician, but all should understand the fundamental principles of data analysis and interpretation. When understood and applied, the habits in Table 2.1 will permit intelligent, synergistic dialog among clinicians and statisticians. Such dialog ideally precedes any serious research endeavor, because even the most elegant statistics cannot adjust for biased data or confounders that were never measured.[69] The statistician excels at analyzing data the right way, but the clinician's leadership ensures that the right data are analyzed. Furthermore,

clinical importance (habit 5) is best determined by clinicians, not statisticians. Clinicians are also best equipped to decide how the cost, harms, and adverse events of interventions might offset benefits suggested by the best available data.[70]

The principles established in this chapter are a large part of the core competencies recommended for evidence-based practice, which fall under the broad categories of ask, acquire, appraise and interpret, apply, and evaluate.[71] By consistently recalling the uncertainty of all medical data and the inevitability of error in drawing conclusions, clinicians can apply the seven habits and principles described herein to facilitate honest, appropriate, and evidence-based care for their patients.

For a complete list of references, visit ExpertConsult.com.

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3 Evidence-Based Performance Measurement

Thomas R. Yackel

KEY POINTS

- All physicians have a moral and ethical obligation to act professionally as agents for the health of their patients by engaging in quality improvement.
- Physician performance measurement can be used for research, medical error reduction, patient safety, certification, credentialing, or licensing and disciplining. The purpose for which a measure is intended will determine how it is created.
- Health services research that demonstrates quality gaps and rising health care costs fuel the demand for clinical performance measures.
- Quality can be measured by assessment of clinical outcomes, processes of care, capacity and structure, administrative parameters, cost and efficiency, and patient experience.
- Physician measurement should be founded on evidence-based guidelines, relevant and reliable data, and best clinical expertise.
- Physicians should educate themselves about the various perspectives of other stakeholders and their roles in supporting quality care.

MOTIVATION FOR PHYSICIAN PERFORMANCE MEASUREMENT

Professional, political, and societal interest in measuring quality in health care continues to be a dominant theme in medicine; it affects clinical care, physician education, research, and health policy. The demand for quality initiatives and measurement of outcomes of health care delivery has been motivated by multiple events and conditions. Most prominent among these is the sustained rapid increase in health care costs, at five times the average rate of inflation, and the observation from health services research that, despite spending more per capita than any other nation in the world on health care, the United States lags in many areas of public health and wellness.[1-5]

Despite persistence of economic and market forces that incentivize volume and intensity of service, research shows that higher volume and intensity of health care services do not lead to better aggregated quality of life or public health. Overall, only about half of all Americans receive the recommended health interventions identified by consensus standards of care. Even more striking than the low overall proportion of those who receive recommended care is the wide variation that exists across health conditions, races, genders, and socioeconomic divisions.[6-8] Dissatisfaction with the health care system is higher in the United States than in parallel western nations. Likewise, the percentage of U.S. citizens who did not get health care because of cost constraints is higher than in many other western nations. A huge gap exists between the consensus recommended appropriate care and the care that is actually delivered for easily identifiable and definable conditions.[3] Large geographic variations in care, unexplainable by patient demographics and characteristics, are easily observable over a broad range of conditions. These geographic variations are far more significant than even the health care disparities seen as a result of ethnic or health literacy differences in the population.[6-11] Unacceptably high rates of mortality and morbidity related to medical error have been the subject of many reports from both federal agencies and independent health services researchers.[2,6,12] Finally, there seems to be no correlation between the per capita cost of health care and the quality of health care delivered on a range of observations and bases.[10] The combination of all these factors has led to the current need for physician performance measures.

WHAT IS QUALITY AND WHO DEFINES IT?

Quality improvement and physician performance have taken center stage, yet there is no way to consistently define *quality* and its measurement. Each stakeholder, including the patient and the physician, has a reasonable perspective for viewing quality differently.[1,3] A patient might define *quality care* as the relief of symptoms, perception of cure, or an improvement in lifestyle. However, the physician might define it as the achievement of a particular desired or expected medical or surgical outcome. An employer may see quality care as a return on investment for premiums paid, reduced liability for injury, and a workforce that is healthy, productive, and present in the workplace. A health plan purchaser may look at global health outcomes and the need to spread vast resources over large populations with competing needs. Therefore defining what constitutes quality and, hence, deciding exactly what to measure to determine whether quality is being delivered, continues to be debated.

In oversimplified terms, most measures of clinical quality or performance today fall into the following categories:

- Outcomes measure
- Process measures
- Capacity and structure measures
- Administrative measures
- Cost and efficiency measures
- Patient experience or satisfaction measures

The measurement of each of these segments has value but also pitfalls. Purchasers of health care have access to voluminous claims and economic data, making administrative, cost-effectiveness, and capacity measures attractive.[13,14] Although many physicians opposed to administrative or efficiency measures clamor for outcomes measures as the only valid assessment of physician performance, in truth physicians rarely have complete control over all the factors that determine medical outcomes. As a result, many issues arise when it comes to measuring individual physician performance within a system of care or when the physician is operating within a team environment. Additionally, for valid outcome measures, effective risk adjustment must occur to reflect differences in the case mix of the patients served; this is often neglected, which results in misleading outcomes data. Process measures are easier to define and are more attributable to the practitioner; however, focusing primarily on processes of care can be deceptive when no one takes responsibility for the final outcome. Levels of evidence for different types of interventions can vary greatly, especially when medical care for chronic conditions primarily involving medication management are being compared with acute surgical care, for which randomized, double-blind, controlled studies may

Abstract

Evidence-based performance measurement and quality improvement are essential to understand the future of health care delivery.

Keywords

Performance measurement
evidence-based
quality improvement

not exist or even be feasible. Because many elements—such as availability of support services and tertiary care, patient compliance, comorbidities, ethnic and religious practices, and preferences—can all influence the assessment of medical outcomes, measuring performance attributable to and under the control of the physicians being measured must be a common basic theme if fairness and true patient-centered quality improvement are to be achieved.[13,15]

The concept of patient-reported outcomes and the related issue of "shared accountability" for health outcomes have gained traction in recent years. Gathering data directly from patients is one method of validating physician performance without relying on self-reported physician data or expensive external chart reviews. Potentially this could include aggregated global or population data for health care systems or large group practices or data at the level of the individual physician. The setting of standards for data integrity and validity is an extremely challenging process. It introduces concern for the role of the patient and his or her accountability for personal health choices and behaviors that influence desired health outcomes. Some social experience with patient accountability has been gained through employer programs. Although employer-sponsored wellness and healthy-lifestyle incentives are not new, very little has been done to measure the global effect and report on the patient's accountability for his or her health and for the public health in general. Current health services researchers are calling for specific standards of measuring and holding patients accountable for decisions and health choices they make that influence the quality of care. Diet and exercise; risky behaviors; tobacco, alcohol, and drug use; compliance with physician-directed care; and medication adherence are only a few examples of ways in which patient behavior affects health care outcomes. It makes little sense to hold physicians accountable for patient choices they cannot control; however, through patient education, an effective doctor-patient relationship, and appropriate communications and follow-up, physicians *do* have some influence on patient behavior. Therefore it is difficult to draw the public policy line on accountability.

The purpose for which measures are developed has a powerful influence on measures structure and what kinds of measures are used. Among other reasons, performance is measured today for the following overlapping purposes:

- Research, development, and improvement of the effectiveness of an intervention
- Reduction of medical error
- Improved patient safety
- Certification of achievement to meet standards for maintaining board certification
- Credentialing or accreditation to document training, competence, or proficiency for privileging, payment, or inclusion in a plan, group, or tier
- Licensing and discipline to identify, limit, and punish poor performance

Both overlap and synergy are found among these categories, and distinct subcategories further separate these types of measures. The American Medical Association (AMA) House of Delegates addressed criteria and standards for acceptable elements of any pay-for-performance system. As the quality movement matures and value-based purchasing takes different forms, embracing such criteria will become increasingly important to ensure patient centeredness.

THE PROCESS OF BUILDING A COHERENT SYSTEM OF PERFORMANCE MEASUREMENT

Three basic principles must underscore the roles of physicians and their organizations in addressing performance and quality improvement. First, it is essential that *practicing physicians*—not just methodologists and health policy scientists—actively and formally engage in prioritizing, developing, field testing, and implementing quality initiatives and performance measures. Second, demand for quality and its definition and measurement must be aggregated. Third, physicians and their organizations must be unified in their response to this demand.

Engaging in the Development of Performance Measures

Many stakeholder groups are placing powerful impetus behind defining quality improvement and implementing measurement. This is primarily motivated by the desire to improve efficiency in the utilization of resources to advance patient safety, reduce medical error, address inequity and maldistribution of health care, and control a national and global crisis of escalating health care costs.[1,14,16] If physicians fail to engage in ensuring that any definition of *quality*, and any program for improvement, is truly based on scientific evidence and is relevant and valid to improving patient health outcomes, then proprietary measurement will focus solely on administration, capacity, and cost. Although these are legitimate concerns, physicians must insist on keeping the focus on improving patient health, not on driving profitability for purchasers of health care.[17]

Aggregating Demand for Performance Measurement

With so many organizations involved in quality initiatives and the development of measures, one of the greatest concerns physicians have is trying to "aggregate the demand" for measures—in other words, to make sure that payers, purchasers, licensing and certification processes, and quality improvement organizations that demand measurement have common elements that can be addressed by a coherent response; that the measures are based on solid evidence; and that they are focused on similar quality improvement goals. The ideal situation is to standardize data points, create a single or simplified set of measures for a given clinical condition or intervention, and establish agreement among stakeholders to accept a unified process of measuring quality. Responding to these pressures, the Centers for Medicare and Medicaid Services (CMS) has launched a comprehensive "Meaningful Measures" program. The initiative identifies high-priority areas for quality measurement and improvement while also reducing the burden on practicing clinicians. Part of the emphasis, especially important for surgeons, is the focus on patient-reported functional outcome measures. Older measures will be retired, with the goal of a smaller number of more impactful and comprehensive quality improvement metrics.[18]

Unifying the Response to the Demand for Performance Measurement

The medical profession is not homogeneous. Specialists of varying backgrounds, training, and experience may treat similar conditions and bring diverse perspectives to their delivery of health care services. Undesired variation in health care and its outcomes is one of the hallmarks of poor quality.[3,7,12] It is not in the patient's or society's best interest to have varying processes and quality measures for a given clinical condition coming from competing specialties or groups. For example, pediatricians, family physicians, otolaryngologists, emergency physicians, and infectious disease specialists could all develop and implement competing guidelines and performance measures for treating otitis media based on limited perspective and with varying data points and recommendations. This fosters unhealthy competition and turf battles and is unlikely to improve the quality of care. By engaging in multidisciplinary work groups, definitions can be standardized, best evidence can be reviewed and analyzed, scope and purpose of measurement can be agreed upon, learning can take place, and acceptable guidelines and measures can be developed that all physicians who treat otitis

media, regardless of specialty perspective, can use to improve their clinical care. Creating evidence-based guidelines and performance measures is labor intensive and costly. By collaborating in a multidisciplinary fashion, waste of resources from competing and parallel development processes can be avoided.

In designing a validated, relevant, and attributable system of measurement, the following process is useful, involving the best combination of rigor and scientific foundation with practical implementation at the physician-patient level:

- Identify gaps in care and quality and prioritize those that can be measured and improved.
- Develop or identify the best evidence or guidelines for clinical care.
- Develop specific performance measures that are physician attributable, implementable, effective, practical, and affordable (see the Institute of Medicine domains for quality care: effective, efficient, equitable, timely, safe, and patient-centered).[12]
- Use validated, relevant, patient-oriented performance measures in systems and populations for credentialing, licensing, certifying, and documenting competence.[19,20]

Quality-Based or Value-Based Purchasing

A sea change is currently underway in regard to the manner in which physician services are recognized, reported, and remunerated. The traditional system of paying for volume and intensity of care is being replaced by quality-based or value-based purchasing of health care services.[14]

The concept of rewarding excellence is based not only on the desire for improved quality but also on the premise that poor-quality care is more expensive than high-quality care.[7,10,21,22] Although certainly debatable, evidence supports this contention in specific areas. Intuitively, healthy populations will consume fewer health care interventions than sick ones, and this will cost less. So improving public health, encouraging healthier lifestyles, and using effective preventive medical interventions all make sense. Schematically, many discussions have linked the issue of quality to cost by relegating poor-quality medical care into three categories:

- Too little care (lack of preventive services, early detection, and wellness and lifestyle programs)
- Too much care (wasteful, duplicated, or overly costly care)
- The wrong kind of care (unneeded or unestablished care, medical errors, unnecessarily risky or unsafe care)

It is clear that if poor quality in medical outcomes is the result of unneeded care, reducing the overuse of services and improving quality would reduce health care costs. From this has sprung a new genre of "overuse" measures. Based on health services research that challenges the need for certain interventions, procedures, or tests, overuse measures intend to address the duplicated, wasted, and unnecessary medical care being prescribed. Patients and physicians need to work in concert to ensure that health care decisions and choices consider the optimal outcomes and the optimal use of resources. It is also not hard to believe that if the wrong kind of care is replaced by the most effective care, costs would also be reduced. It is less obvious that correcting the problem of too little care or providing more timely care would also reduce costs. But global statistics from developed nations with better public health, preventive health, and healthy behavior or lifestyle systems are suggestive; they have demonstrably superior public health outcomes—such as lower infant mortality, improved longevity, and better chronic disease management—compared with the United States, and they achieve this at a much lower per capita cost.[23,24]

As a result of this premise, purchasers of health care are implementing strategies that reward better medical outcomes and improved effectiveness and efficiency of care. The forces behind these strategies include the dramatic increases in health care costs in the United States—at a rate more than five times the annual inflation rate, constituting evidence that higher intensity and volume of services do not lead to better outcomes—and the development and acceptance of standards for organizing and implementing quality initiatives.[4]

MEDICAL PROFESSIONALISM: THE PHYSICIAN-PATIENT RELATIONSHIP

At the core of physician performance measurement is the ethical and moral obligation of all physicians to practice according to the highest standards. This is true globally, and the issues and discussions of evidence-based practice, quality improvement, and physician performance measurement are universal. *Medical professionalism* is defined as a set of values, behaviors, and relationships responsible for public trust in physicians.[25] The difference between a "profession" and a "trade" has often been defined by the fiduciary responsibility of the professional to act in the best interest of the public or the receiver of the service rather than in the personal self-interest of the provider.[25-27] In medicine, in addition to legal requirements, virtually every association or physician group has an ethical code or stated commitment to act in the best interest of the patient.[28]

In the absence of sustained physician leadership in addressing quality, physician trust is in danger of erosion. Many fear the commercialization of health care over the last century has undermined the tradition of "doing good" in exchange for making a profit. The covenant between the physician and patient has become a contract between physician and intermediary, creating a loyalty that is now divided between the patient and the organization that contracts on behalf of the patient, whose motive is cost containment and profit for shareholders.[17] A statement of medical professionalism has been developed jointly by the American College of Physicians–American Society of Internal Medicine Foundation, the American Board of Internal Medicine, and the European Federation of Internal Medicine and is endorsed by many major physician associations in the United States, including the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS).[29]

The ethical basis of medical care is called into question as a result of the recent well-documented health services research focused on data that undesirable variations in physician practice and clinical outcomes are not explained by patient factors but are due to failure of medical practitioners and systems of care that do not incorporate the latest and best evidence or practices into health care delivery. Because health care delivery in most parts of the western world is still highly individual, reliance on individual physician judgment remains dominant. Data show unwarranted and unexplained variations from recommended care on a regular basis across all disciplines.[3,4,7] Physician autonomy is being challenged because population and systems studies suggest that patients are being harmed and best practices are not being followed. Personal physician accountability is an increasing focus.[3,30] By engaging in collaborative team care and combining the best available evidence for treating a condition with the physician's judgment and patient preferences, better care can be achieved.[4,25,31,32]

Professionalism and the ethical and moral imperative for physicians to put their patients first should be *the* major driving force for physician performance measurement and quality improvement. This needs to be done in conjunction with the creation and application of systems and processes to eliminate the opportunity for error, identify error before it affects patients, mitigate the effects of error, and thus improve patient safety and outcomes.[21,22] Physicians will need to become voluntary champions for working in concert with all elements of health care delivery systems to accomplish this. Even in low-performing systems, high-performing physicians contribute a greater individual effort and can achieve improved outcomes compared with low-performing physicians in high-performing systems. Improvement seems to be optimal only

when individual physician attitudes and capabilities are expanded at the same time that system improvements and accelerators of quality are used.[33] Employers, governments, and other purchasers, contractors, administrators, and managers of health care have a reciprocal duty to help create the organizational capacity and infrastructure to support physicians in providing optimal care and fulfilling their ethical obligation to the patient. Optimal health care implies both organizational and clinical excellence. For a physician to maintain professionalism in our current environment, there must be a shared commitment and collaboration with the patient, fellow professionals, and the institution or system within which health care is provided, but only to the extent that all elements of the system support patients' interests first.[13,15,25,34-36]

Stakeholder Roles in Defining and Implementing Quality Improvement and Measurement Activity

To understand the landscape of physician performance measurement, it is important to first identify and understand the roles of key stakeholders in the public health care arena as well as their individual and sometimes competing perspectives. Current demand for measuring physician performance is driven by patients and public interest groups as well as by physicians and their associations. In addition to physicians and their patients, many other groups have a legitimate and often powerful stake in measuring outcomes and performance. These stakeholders include physician educators and academic institutions, certifying boards and bodies, agencies whose missions revolve around quality, public and private purchasers of health care services (e.g., federal and state governments, employers, and private insurers), hospitals and health care systems, outpatient clinics and freestanding procedural centers, public interest groups, and many group collaboratives and agencies of all of these. Table 3.1 outlines some of the major stakeholder groups and participants in defining and advancing quality in health care delivery.[34,37]

TABLE 3.1 Stakeholder Groups[a]

Stakeholder Group	Examples
Government purchasers and agencies	Centers for Medicare and Medicaid Services Quality improvement organizations Agency for Healthcare Research and Quality Veterans Administration Department of Defense
Private purchasers of health care and their collaborations	Health plans and insurance companies Employers Private group and independently rated insurance plans America's Health Insurance Plans The Leapfrog Group National Business Group on Health Pacific Business Group on Health
Licensing, certifying, and educational oversight bodies	Federation of State Medical Boards and state licensing boards American Board of Medical Specialties and professional certifying boards Accreditation Council on Graduate Medical Education Accreditation Council for Continuing Medical Education Association of American Medical Colleges
Private health quality agencies	National Committee for Quality Assurance The Joint Commission
Physician societies	National, state, and county medical associations National specialty societies
Academic institutions	Medical schools Residency training programs Allied health training programs
Collaborative organizations of many stakeholder groups	National Quality Forum AQA AMA-PCPI (the Consortium) Hospital Quality Alliance

[a]This is not a comprehensive list but shows examples of some of the largest or most influential stakeholders. For more detail, see Table 3.2.

AMA-PCPI, American Medical Association–Physician Consortium for Performance Improvement.

Anatomy of Performance Measures

If physicians are to retain their traditional leadership role in caring for patients, they and their organizations must take a leadership role in defining and measuring quality and performance in their professional behavior. Specialty societies and practice experts must insist that performance measures be relevant, patient centered, focused on medical and health outcomes, validated, practical, affordable, and attributable to those whose performance is being measured. Performance measures should be based on the best available evidence, such as quality clinical guidelines that systematically inform and assist physicians and their patients in decision-making about appropriate care.[32] Developers of performance measures—including medical specialty societies, academicians, methodologists, and systems experts—must have a process in place with agreed-upon standards for reviewing and evaluating clinical evidence and for creating guidelines for treating relevant conditions.

A clinical performance measure can be most simply viewed as an equation or fraction that represents the frequency of an appropriate and recommended intervention. It contains a denominator, the number of patients for whom a given intervention or recommendation applies; a numerator, the number of patients who actually received the recommended intervention; and exclusions, those patients for whom the recommended care was not given for specific reasons identified and excluded by the measure (Fig. 3.1). Although simple in concept, in reality the development and implementation of a performance measure can be extremely complicated and controversial. The process of translating guidelines into performance measures involves reviewing the action statements inherent or explicitly recommended in the guideline, defining the patient populations to whom the actions do and do not apply, developing a logical scheme for collecting information to measure how often the actions recommended in the guideline are carried out, and creating the tools for physicians to efficiently and accurately collect that information affordably and with little disruption of their clinical activity.

OTHER STAKEHOLDER PERSPECTIVES

Virtually every stakeholder group is heavily involved in quality initiatives and performance measures development. In this section, a representative sample of additional major agencies and organizations is briefly introduced. Because of the varying perspectives and backgrounds of these stakeholders, an extensive collection of collaborations and consortia has emerged to combine resources, align incentives and goals, and promote quality across stakeholder groups. This has created a wide array of potential activity with which physicians might be required to engage. Table 3.2 summarizes some of the related acronyms and terms; a few of them are briefly discussed here.

The Agency for Healthcare Research and Quality (AHRQ) is charged by the federal government to serve as the health services research arm, just as the National Institutes of Health serves as the basic and clinical research arm. In addition to fostering research into quality, performance measurement, technology assessment, preventive medical care, delivery systems, and health care costs, the AHRQ is a major source of funding for academic and community-based organizations engaged in health services research and implementation

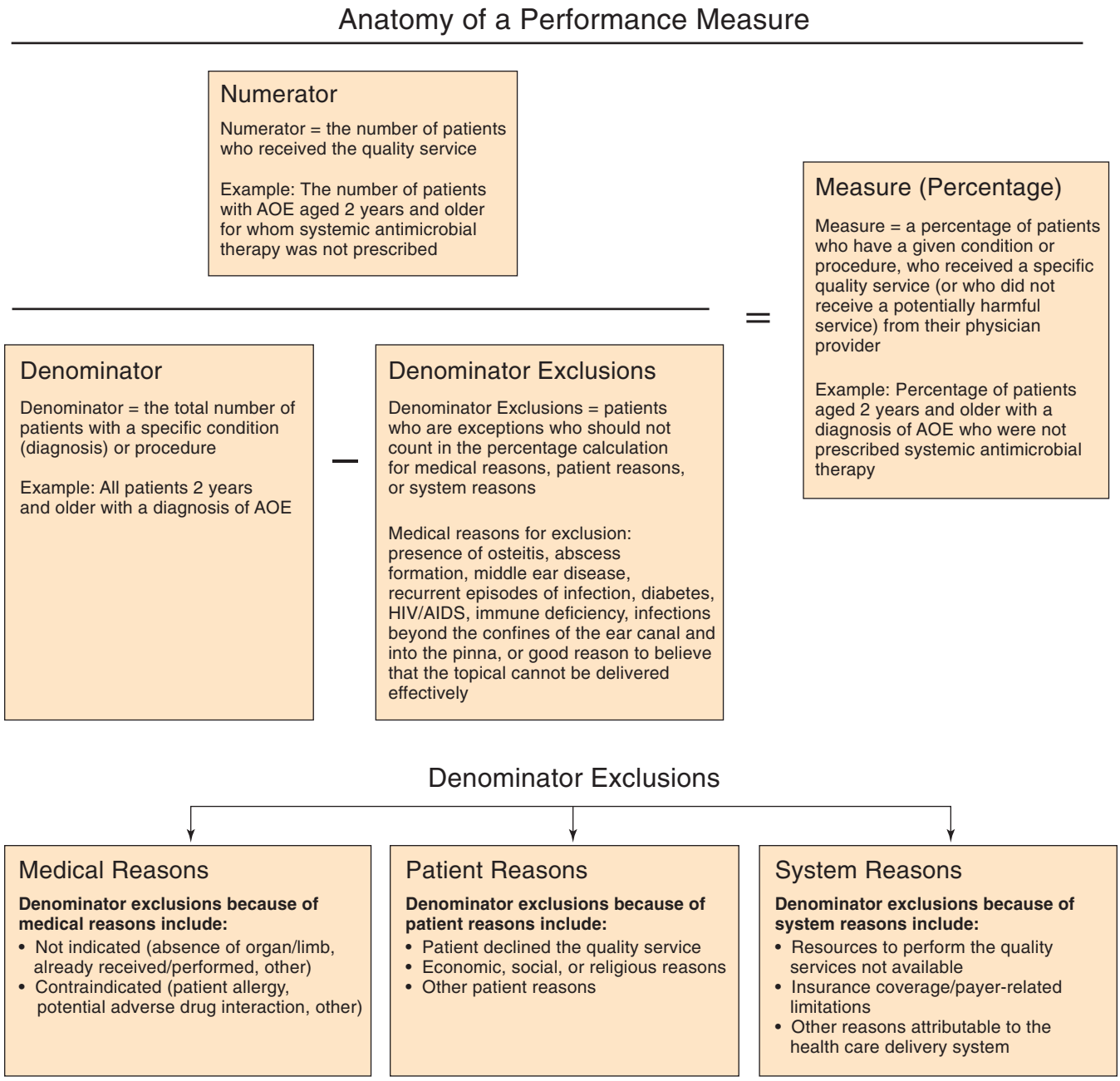

Fig. 3.1 Anatomy of a performance measure. Both the schematic and a current example of an existing measure of quality in treating acute otitis externa *(AOE)* are applied for illustration. One of the measures of improved quality in treating AOE is the avoidance of unnecessary administration of systemic antibiotics. Compliance with this measure of quality is demonstrated. *HIV/AIDS*, Human immunodeficiency virus/acquired immunodeficiency syndrome (From the American Academy of Otolaryngology–Head and Neck Surgery Foundation.)

activity. The AHRQ supports evidence-based clinical practice, develops and tests measures, and promotes the use of measures through dissemination of guidelines and measures. The AHRQ also provides support for many of the quality improvement initiatives undertaken by the CMS.

The National Committee for Quality Assurance (NCQA) is a private nonprofit quality organization that has been accrediting health plans and developing performance measures since 1990. Their method is simple—measure, analyze, improve, repeat. Organizations that qualify for the NCQA seal must first pass rigorous review and thereafter report annually on a set of measures and deliver high-quality care and service. The performance measurement set used in the NCQA's accreditation process, and most frequently reported to purchasers and the public, are the Health Plan Employer Data and Information Set (HEDIS) measures and Consumer Assessment of Health Providers and Services (CAHPS) surveys of patient experiences of care. CAHPS was developed by the AHRQ and has survey instruments that apply not only to patient experiences with health plans but also with individual physicians and clinician group practices.

The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations, or JCAHO) creates standards and

TABLE 3.2 Glossary of Terms and Acronyms of Groups Engaged in Defining, Measuring, or Reporting on Quality in Health Care

Acronym or Abbreviation	Title of Group and Description
AAMC	The Association of American Medical Colleges is a nonprofit organization established in 1876. The AAMC is the principal administrator of the Medical College Admission Test (MCAT) and is involved in the accreditation of medical schools that grant medical degrees and of teaching hospitals in the United States and Canada
ABMS	The American Board of Medical Specialties was established in 1933 and is a nonprofit physician-led organization that oversees the certification and ongoing professional development of physician specialists by its 24 medical specialty member boards. The ABMS works closely with its member boards to set educational and professional standards for the evaluation and certification of physician specialists
ABOto	The American Board of Otolaryngology, founded in 1924, is the second oldest of the 24 ABMS member boards. The mission of the American Board of Otolaryngology (ABOto) is to assure that, at the time of certification and recertification, diplomates certified by the ABOto have met the ABOto's professional standards of training and knowledge in otolaryngology–head and neck surgery For a more complete review of board certification in otolaryngology–head and neck surgery, refer to the *Booklet of Information* published by the ABOto, available at www.aboto.org/BOI.htm
ACCME	The Accreditation Council for Continuing Medical Education is the overseeing body for continuing medical education (CME) in the United States. The ACCME sets the standards for the accreditation of all providers of CME activities The ACCME's seven member organizations are the American Board of Medical Specialties (ABMS), the American Hospital Association (AHA), the American Medical Association (AMA), the Association of American Medical Colleges (AAMC), the Association for Hospital Medical Education (AHME), the Council of Medical Specialty Societies (CMSS), and the Federation of State Medical Boards (FSMB)
ACGME	The Accreditation Council for Graduate Medical Education is the body responsible for the accreditation of postgraduate medical training programs (i.e., internships, residencies, and fellowships—now all called "residencies") for medical doctors in the United States. It is a nonprofit private council that evaluates and accredits medical residency programs. The ACGME oversees the postgraduate education and training for all allopathic and the majority of osteopathic physicians in the United States
ACO	An *accountable care organization* is an entity defined in regulation in the implementation of the Patient Protection and Affordable Care Act (PPACA) of 2010. It is a group of health care providers who provide coordinated care or chronic disease management and thereby improve the quality of care patients get. The organization's payment is tied to achieving health quality goals and outcomes that result in cost savings
ACS	The American College of Surgeons is an educational association of surgeons created in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Members of the ACS are referred to as "Fellows." The *FACS* (Fellow, American College of Surgeons) after a surgeon's name means that the surgeon's education and training, professional qualifications, surgical competence, and ethical conduct have passed a rigorous evaluation and have been found to be consistent with the high standards established and demanded by the College
AHIP	America's Health Insurance Plans is a national political advocacy and trade association with about 1300 member companies that provide health insurance coverage to more than 200 million Americans. AHIP was formed through the merger of the Health Insurance Association of America (HIAA) and the American Association of Health Plans (AAHP)
AHRQ	The Agency for Healthcare Research and Quality, formerly known as the Agency for Health Care Policy and Research, is a part of the U.S. Department of Health and Human Services (HHS), which supports research designed to improve the outcomes and quality of health care, reduce its costs, address patient safety and medical errors, and broaden access to effective services
AMA	The American Medical Association, founded in 1847 and incorporated in 1897, is the largest association of medical doctors and medical students in the United States. The AMA's mission is to promote the art and science of medicine for the betterment of the public health, to advance the interests of physicians and their patients, and to promote public health
AMA-PCPI	The AMA-convened Physician SCC for Performance Improvement is a physician-led initiative that includes methodologic experts, clinical experts representing more than 100 national medical specialty societies, state medical societies, medical specialty boards, the AHRQ, the National Committee for Quality Assurance (NCQA), the Joint Commission, the Centers for Medicare and Medicaid Services (CMS), and other stakeholders. In conjunction with the stakeholders represented, the SCC develops performance measurement sets and clinical quality-improvement tools useful for the practicing physician. The SCC's vision is to fulfill the responsibility of physicians to patient care, public health, and safety by becoming the leading source organization for evidence-based clinical performance measures and outcomes reporting tools for physicians
AQA	Formerly called the *Ambulatory Care Quality Alliance,* the AQA was formed in 2004 by the Agency for Healthcare Research and Quality (AHRQ), America's Health Insurance Plans (AHIP), American College of Physicians (ACP), and the American Academy of Family Physicians (AAFP). The AQA is one of two consensus organizations, along with the National Quality Forum (NQF), that can approve measures for implementation on a national level for Medicare and Medicaid programs and for other health plans. The AQA is composed primarily of health plans (payers that include CMS), employers (purchasers), clinicians (physicians and nonphysicians), consumer groups, and supporting industries
B2E or BTE	Bridges to Excellence, a not-for-profit coalition-based organization (predominantly purchaser-driven) was created to encourage voluntary participation in quality health care initiatives by recognizing and rewarding health care providers who demonstrate that they deliver safe, timely, effective, efficient, equitable, and patient-centered care
CAHPS	The Consumer Assessment of Healthcare Providers and Systems is a public-private initiative to develop standardized surveys of patients' experiences with ambulatory and facility-level care, first launched and funded by the AHRQ in 1995. Health care organizations, public and private purchasers, consumers, and researchers use CAHPS results from standardized surveys to assess the patient-centeredness of care, compare and report on performance, and improve quality of care. A surgical CAHPS instrument has been developed with support from the ACS with participation from other surgical societies, including otolaryngology
CER	*Comparative effectiveness research* is defined by the AHRQ as the best available evidence of the effectiveness, benefits, and harms of different options for health care interventions. Evidence is generated from research studies that compare medical treatment options, surgeries, drugs, devices, tests, images, or methods of delivering care. Evidence can arise from review of existing research findings or from newly designed studies specifically focused on comparative effectiveness (see http://effectivehealthcare.ahrq.gov/index.cfm/what-is-comparative-effectiveness-research1/)

Continued

TABLE 3.2 Glossary of Terms and Acronyms of Groups Engaged in Defining, Measuring, or Reporting on Quality in Health Care—cont'd

Acronym or Abbreviation	Title of Group and Description
CMS	The Centers for Medicare and Medicaid Services, previously known as the *Health Care Financing Administration* (HCFA), is a federal agency within the U.S. Department of HHS that administers the Medicare program and works in partnership with state governments to administer Medicaid, the State Children's Health Insurance Program (SCHIP), and health insurance portability standards
EHR (EMR; HIT)	Electronic health record (electronic medical record or health information technology)
FSMB	The Federation of State Medical Boards is a not-for-profit organization composed of 70 medical licensing and disciplinary boards of the United States and its territories and serves as an authoritative source of research, policy development, education, and information. The FSMB's primary mission is to improve the quality, safety, and integrity of health care by promoting high standards for physician licensure and practice and assisting state medical boards in protecting the public. The FSMB monitors state and federal legislative initiatives, works collaboratively with state and federal regulatory agencies, and offers legislative assistance to and on behalf of its member medical boards
HQA	The Hospital Quality Alliance works to improve care through information; it is a public and private collaboration to improve the quality of care provided by the nation's hospitals by measuring and publicly reporting on that care. Quality performance information collected from the more than 4000 participating hospitals is reported on *Hospital Compare*, a website tool developed by the CMS
IHI	The Institute for Healthcare Improvement is a not-for-profit organization that aims to lead the improvement of health care throughout the world. Its goals are to improve the lives of patients, the health of communities, and the joy of the health care workforce by focusing on initiatives in safety, effectiveness, patient-centeredness, timeliness, efficiency, and equity
IOM	The Institute of Medicine is one of the four U.S. National Academies and is a not-for-profit, nongovernmental American organization chartered in 1970 as a part of the National Academy of Sciences. The IOM reports, such as "To Err Is Human," are often referred to in the development of quality-improvement initiatives. The IOM domains are effectiveness, efficiency, equity, patient-centeredness, safety, and timeliness
The Joint Commission	Known as the *Joint Commission on Accreditation of Healthcare Organizations* (JCAHO) until 2007, the Joint Commission is a U.S.-based nonprofit organization formed in 1951 with a mission to maintain and elevate the standards of health care delivery through evaluation and accreditation of health care organizations
Leapfrog Group	The Leapfrog Group is an employer group formed by a number of major U.S. corporations. It strongly encourages the adoption of a number of safer practices in hospitals, including electronic health records, proper staffing of intensive care units, concentration of highly technical surgical procedures in high-volume centers, and implementation of NQF Safe Practices
MAP	The Measure Applications Partnership is convened by the NQF and reviews performance measures for potential use in federal quality improvement and public reporting initiatives. It works to harmonize the federal performance measurement process with private quality initiatives, and it operates under statutory authority through provisions of the PPACA (see https://www.qualityforum.org/map/)
NBGH	The National Business Group on Health members are primarily Fortune 500 companies and large public sector employers, including the nation's most innovative health care purchasers, who provide health coverage for more than 50 million U.S. workers, retirees, and their families. The NBGH fosters the development of a safe, high-quality health care delivery system and treatments based on scientific evidence of effectiveness
NCQA	The National Committee for Quality Assurance is a private nonprofit committee that creates standards and measures for quality. It was established in 1990 with support from the Robert Wood Johnson Foundation. The NCQA accredits and certifies a wide range of health care organizations, including health plans and physician organizations. Health plans that seek accreditation by the NCQA measure performance, often utilizing data from tools such as the Healthcare Effectiveness Data and Information Set (HEDIS) and the CAHPS survey. The NCQA also has a voluntary program to recognize individual physicians who follow evidence-based guidelines and use evidence-based measures and up-to-date information and systems to enhance patient care
NGC	The National Guidelines Clearinghouse at guideline.gov is a public, online, comprehensive database of evidence-based clinical practice guidelines. The NGC is an initiative of the AHRQ and the Department of HHS, and its mission is to provide physicians, nurses, and other health professionals, health care providers, health plans, integrated delivery systems, purchasers, and others an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation, and use. The NGC was originally created by the AHRQ in partnership with the AMA and the American Association of Health Plans (now AHIP)
NPP	The National Priorities Partnership, convened by the NQF, is a multidisciplinary group of 52 entities that collaborate to achieve better health, safety, equity, and value in the U.S. health care system. Members include business, consumer, academic, medical, nursing, pharmaceutical, insurance, quality improvement, and other organizations. The NPP works to identify specific ways to implement the National Quality Strategy and provides input to HHS on progress (see qualityforum.org/npp/)
NQF	The National Quality Forum is a voluntary, consensus standards-setting organization as defined by the National Technology Transfer and Advancement Act of 1995. The NQF is the other of two consensus organizations, along with the AQA, that can endorse measures on a national level for CMS quality programs and for other health plans. The NQF is a membership organization created to develop a national strategy for health care quality measurement and reporting. It has participation from consumers, purchasers, health plans, hospitals (providers), health professionals (including physicians and nonphysicians), accrediting bodies, labor unions, and supporting industries
NQMC	The National Quality Measures Clearinghouse (www.qualitymeasures.ahrq.gov), sponsored by the AHRQ and HHS, is a public repository for evidence-based quality measures and measure sets. The NQMC also provides excellent educational resources for those who want to learn more about quality measures
NSQIP	The ACS National Surgical Quality Improvement Program is the first nationally validated, risk-adjusted, outcomes-based program to measure and improve the quality of hospital surgical care. The program uses a prospective, peer-controlled, validated database to quantify 30-day risk-adjusted surgical outcomes, which allows valid comparison of outcomes among all hospitals in the program. The ACS NSQIP is available to all private-sector hospitals that meet the minimum participation requirements, complete a hospital agreement, and pay an annual fee. The goal is the reduction of surgical mortality and morbidity. The Veterans Administration (VA) has a parallel system (VA NSQIP) to compare its results against the ACS NSQIP private sector data

TABLE 3.2 Glossary of Terms and Acronyms of Groups Engaged in Defining, Measuring, or Reporting on Quality in Health Care—cont'd

Acronym or Abbreviation	Title of Group and Description
ONC	The Office of the National Coordinator for Health Information Technology (HIT) provides counsel to the Secretary of HHS and departmental leadership for the development and nationwide implementation of an interoperable HIT infrastructure. Use of this infrastructure will improve the quality, safety, and efficiency of health care and the ability of consumers to manage their health information and health care
PBGH	The Pacific Business Group on Health, a business coalition of 50 purchasers, seeks to improve the quality and availability of health care while moderating cost. Since 1989, the PBGH has played a leading role both nationally and in California in health care quality measurement and system accountability through public reporting
PCPI	Physician SCC for Performance Improvement (see AMA PCPI)
PPACA	The Patient Protection and Affordable Care Act became law in 2010 and is designed to improve access to higher quality health care and to reduce cost of care. It is described in more detail in the text of this chapter
PQRS	The Physician Quality Reporting System is provided for in PPACA legislation and requires physicians who treat Medicare and Medicaid beneficiaries to report on specific quality metrics endorsed and identified by CMS. Initially it will reward reporting physicians with a bonus for Medicare payment. Beginning in 2015, physicians will be penalized with reduced payment if they are not reporting on required measures based on 2013 reporting
QASC	Government agencies, physicians, nurses, pharmacists, hospitals, insurers, employers, consumers, accrediting agencies, and others have formed the Quality Alliance Steering Committee to better coordinate the promotion of quality measurement, transparency, and improvement in care. Through the efforts of the QASC, Americans will have helpful information on health care available through the internet
QIOs	Quality Improvement Organizations monitor the appropriateness, effectiveness, and quality of care provided to Medicare beneficiaries. They are private-contractor extensions of the federal government that work under the auspices of the CMS
SQA	The Surgical Quality Alliance, which is convened by the ACS, aims to bring more than 20 surgical specialties and anesthesiology together to coordinate the definition and measurement of surgical quality and to respond to federal and private quality-related initiatives. The SQA provides a forum to coordinate efforts among specialties to monitor and participate effectively in patient data registries, data aggregation, and the development, validation, and implementation of physician performance measures

measures performance for hospitals, freestanding ambulatory care centers, office-based surgery, long-term care facilities, and others. Its mission is to continuously improve the safety and quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations. Its standards cover structural characteristics and processes of care and include standards that measure the degree to which facilities conform to guidelines for promoting a set of national patient safety goals.

The AMA-convened Physician Consortium for Performance Improvement (PCPI), also called *the Consortium*, is composed of representatives of more than 170 national and state medical societies, other professional groups, federal agencies, individual members, and methodologic experts in measures development. They select topics for performance measures development that are actionable, for which established clinical recommendations are available, and for which feasible data sources exist. They then recruit cross-specialty work groups from all of the specialties relevant to a measures set. The process of translating guidelines into performance measures involves reviewing the action statements inherent in the guideline, defining the patient populations to whom the actions do and do not apply, developing a logical scheme for collecting information to measure how often the actions recommended in the guideline are carried out, and creating the tools for physicians to collect that information as part of their ongoing clinical activities. Some medical specialty societies undertake the translation of guidelines into performance measures themselves, but many choose to work through the Consortium (Fig. 3.2).

The National Quality Forum (NQF) is a voluntary consensus standards organization with a broad membership of providers, payers, and health plans working to create a standardized national set of measures that can be used to evaluate the entire spectrum of care. The NQF endorses national standards for measurement created by other groups and promotes public reporting of health care performance data that provide meaningful information about quality of care. Because of its broad stakeholder makeup, NQF endorsement facilitates the rapid acceptance and implementation of quality activity; it has endorsed quality measures developed by the AMA-PCPI, which have then been adopted for use by both CMS and private-sector purchasers of health care.

The Centers for Medicare and Medicaid Services (CMS, not to be confused with CMSS, the Council of Medical Specialty Societies) is an agency of the federal government responsible for managing the health care services for all qualifying civilian beneficiaries of federal health care. *The Department of Veterans Affairs (VA)* has a similar responsibility for qualifying retired or ex-military personnel, as does the *Department of Defense* for active military personnel. These agencies are critical to include in this discussion, because they cover the health care of large numbers of people, they have been charged by presidential order to measure and improve the delivery of quality health care, and each is engaged in specific independent and collaborative quality initiatives.[38]

In addition to the alliances and consortia already mentioned, independent private groups of purchasers and administrators of health care have been organizing for years in an attempt to control what they observe to be unsustainable increases in health care costs in the private sector, just as CMS, the VA, and the Department of Defense are working to do the same for government health care beneficiaries. Private collaborations on quality are numerous at local, state, and federal levels. A sampling of examples of the activities of several of these can be seen in a report from the AAMC. However, a representative group of prominent and influential corporations and employers would include the Leapfrog Group, the National Business Group on Health (NBGH), and the Pacific Business Group on Health (PBGH). Because these groups' constituent employer members collectively pay billions of dollars in health care premiums, their concerns carry great weight in the debate about quality and cost.

Standardization and Implementation of Measures

For years, the management of expensive chronic conditions by specialty medical care providers fueled the impetus for measuring performance. However, a number of activities are underway in many surgical societies and within the specialty of otolaryngology/head and neck surgery that are intended to bring all of the various

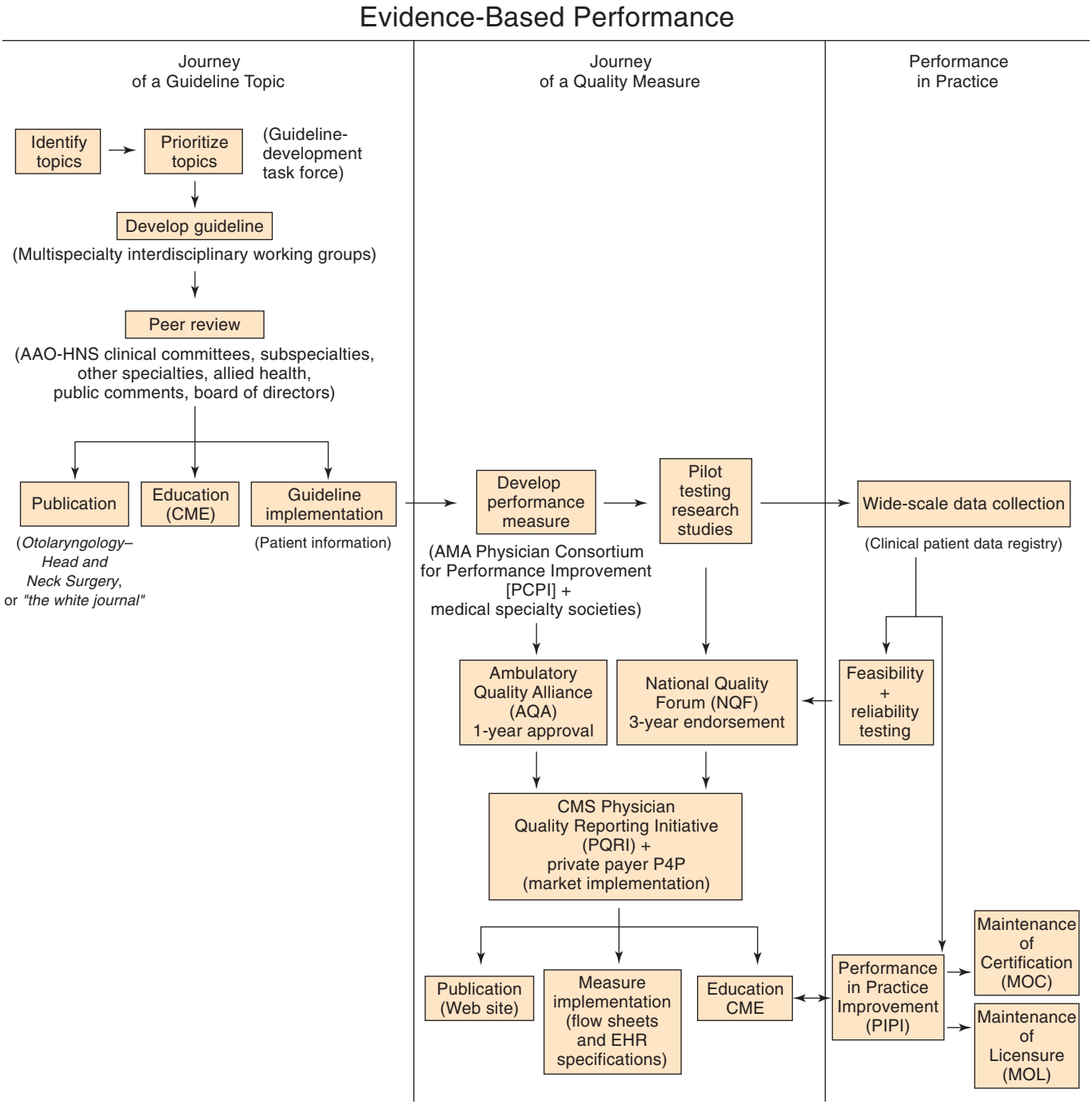

Fig. 3.2 Evidence-based performance. The current pathway from topic identification to implementation of quality measures is outlined. *AAO-HNS*, American Academy of Otolaryngology–Head and Neck Surgery; *AMA*, American Medical Association; *CME*, continuing medical education; *CMS*, Centers for Medicare and Medicaid Services; *EHR*, electronic health record (From the American Academy of Otolaryngology–Head and Neck Surgery Foundation.)

stakeholders together to agree on standard data elements common to all surgeons and the quality measures to be used to assess perioperative care and the performance of the health care system and individual physicians within that system. Otolaryngologists should be aware of the leadership role that their societies are playing in surgical quality.

Distinctive characteristics of acute surgical care and the unique issues related to measurement, data collection, and reporting for surgical care are sometimes not adequately addressed through processes designed for chronic care. In response, the American College of Surgeons (ACS) convenes the surgical specialty societies in an effort to educate surgeons about the issues, to strategize about how to best communicate the message of the unique aspects of surgical care, and to speak with one unified voice on those issues of surgical quality measurement where there is consensus. This activity has led to the formation of the *Surgical*

Quality Alliance (SQA), of which the AAO-HNS is a member. The SQA is staffed by the ACS and is supported through the staff and volunteer physician time of its member surgical specialty societies.

Hundreds of "guidelines" related to otolaryngology exist, and they come from many sources and are of variable quality, rigor, and usefulness. Most are consensus statements with low levels of evidence, weak recommendations, or merely suggested clinical pathways or indicators. Although more rigorous processes for increasing the level of evidence for head and neck medical and surgical care are currently being used, it is useful to examine the strength of past recommendations, to identify best evidence, and to strengthen existing evidence where possible. Since 2006, the AAO-HNS has developed and engaged in a dynamic process for identifying, prioritizing, developing, validating, and implementing multidisciplinary evidence-based guidelines and submitting them for development of performance measures. To ensure rigor in this process, a guidelines development manual, now in its third edition, has been published with input from multiple disciplines, which is used by each topic-specific task force.[39] Representation from all relevant specialties on each guideline is sought to ensure that guidelines are broadly acceptable and to prevent specialty bias. Nine otolaryngology societies, allied health, and the ABO form the Guidelines Task Force, which meets quarterly throughout the year to formulate a pipeline of evidence for quality-improvement activity. The Guidelines Task Force and prioritized content-specific work groups are producing rigorous guidelines for high-quality performance measures developed through the PCPI. Increasingly, otolaryngologists will find themselves collaborating in new ways to improve and report on quality health care through ACOs and value-based payment systems intended to incentivize improved outcomes and better use of resources.[40]

BARRIERS TO IMPLEMENTATION OF PERFORMANCE MEASUREMENT

The development of performance measures should be founded on the best science. Combining health services research with *type 2 knowledge transfer*—that is, the extension of clinical advances from the bedside into populations and systems—should always be about making patients better. Not every proposed quality initiative turns out to be implementable or effective when broadly applied. An open, curious, and critical mind is no less necessary in investigating the effectiveness of quality initiatives than in basic science and clinical research. Significant challenges must be overcome to implement and benefit from measuring performance in practice. First, as described, the process of identifying and strengthening the level of evidence for the care being delivered is daunting. *Eminence-based medicine*—that is, patient care based on tradition or (un)critical opinion—must be replaced by the best available evidence in practice. Residency training programs must engage and educate their residents and fellows in these processes and must keep the focus on evidence and data, combined with the best clinical expertise and patient preferences.[31,41,42] Educational (CME) processes must be implemented to ensure that physicians are aware of existing guidelines and best practices rather than relying on the idiosyncrasies and unwarranted variation from undocumented past experience. One of the most significant and difficult barriers is the resistance to change at all levels from organizations, departments, and entrenched practitioners. Even in processes as innocuous as safe medication review and coordination of care, it is difficult to alter a professional lifetime of behavior. And in an environment of cost consciousness and budget neutrality, individual physicians are feeling the pressure of having to personally fund a change in behavior being imposed by outside influences.[43]

The Surgeon's Role in Performance Measurement

Perhaps no other issue will affect physicians' clinical practice, quality of care, professional satisfaction, and economics more in the next decade than performance measurement. Otolaryngologists, their colleagues in related specialties, and their respective medical societies have embarked on a bold course to ensure that practicing clinicians develop an inventory of evidence-based guidelines that can apply to every practitioner as quickly and efficiently as possible. The vision for the future will include the increasing integration of physician educational programming with real-time point-of-care access to content, decision support systems, links to existing evidence-based guidelines and performance measures of care for specific diagnoses, documentation in the EHR and data registry of care given, and seamless reporting to certifying boards, state licensing boards, purchasers of health care, and any other entities that require such documentation. Every otolaryngologist will eventually be required to participate in programs that provide incentives for quality of care and must have evidence-based performance measures that are relevant to his or her practice, that are easy to collect and report, and that are shown to have a positive measurable impact on patient outcomes.

For a complete list of references, visit ExpertConsult.com.

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PART II General Otolaryngology

4 History, Physical Examination, and the Preoperative Evaluation

Ericka F. King

KEY POINTS

- A careful history and detailed physical examination are the cornerstone of excellent patient care.
- The operating microscope and rigid and flexible endoscopes are useful adjuncts to the basic head and neck examination. Establishing rapport with the patient prior to their utilization, especially in vulnerable patients, is critical to patient comfort, safety, and maximizing the information that can be obtained from the study.
- Preoperative laboratory testing should be ordered based on findings from the directed history and physical examination, as well as the degree of anticipated surgical risk, and not on a routine basis.
- Patients with active comorbid disease need a thorough preoperative evaluation. The otolaryngologist must work closely with the patient's primary care physician and appropriate subspecialists to ensure that a plan of action to mitigate associated increases in morbidity and mortality perioperatively is in place.
- Routine perioperative antibiotics can be eliminated in most clean head and neck procedures that do not enter the aerodigestive tract, as well as straightforward clean-contaminated procedures, including adenotonsillectomy and septoplasty.
- Bridging of patients on chronic oral anticoagulation therapy should be reserved for those at high risk for perioperative thromboembolism, including those with mechanical heart valves, active cancer, recent stroke, and severe coagulopathy.

The importance of obtaining a thorough history and physical examination cannot be underestimated. In many cases, a carefully conducted clinical evaluation can elucidate the diagnosis. In others, it is critical for directing further evaluation and for avoiding unnecessary testing. Careful consideration of the patient's presentation determines the urgency of further management and prevents potentially harmful delays in care. Otolaryngology–head and neck surgeons are privileged in the extraordinary amount of information that can be ascertained by a meticulous physical examination, because pertinent structures are easily accessed and extended evaluation tools, including fiberoptic endoscopes, are readily available.

Likewise, the preoperative evaluation is a vital part of surgical decision making. The patient's comorbidities and other relevant factors must be taken into account to accurately assess the risk involved in a surgical procedure, and these must be weighed in the analysis of whether benefits outweigh potential harms. By appropriately managing comorbidities perioperatively, risk can be decreased to the utmost extent possible, and operative complications can be reduced. Integral to this is an appreciation of the ideal set forth in the Hippocratic Oath: "Above all else, do no harm." It is the surgeon's responsibility to ensure that appropriate patient assessment has been completed before entering the surgical suite.

OBTAINING THE HISTORY

The first step in gathering the patient history begins before the patient sets foot in the clinic, with a thorough review of patient records to include:

- The referring physician's concern that prompted the patient's visit
- Relevant laboratory values and diagnostic studies, including previously obtained radiographic images and reports
- Previous operative and pathology reports
- For malignant and unusual lesions, the original pathologic slides for review by the pathology department for a second opinion

Electronic health records (EHRs) are increasingly used and have the advantage of being more legible and less fragmented than paper records, and they are rapidly transferred electronically. However, a large amount of material is contained within the EHR, much of which is not directly relevant to the visit, which necessitates time to sift through. Variable formats among different software packages present the consulting physician with additional challenges in efficiently identifying important information within EHRs.

The physician should first determine and document the patient's chief complaint, which may differ from the referring physician's objective for the consultation. Addressing the patient's primary concerns is important in establishing rapport, increasing the efficiency and flow of the visit, and allowing the patient to participate in his or her own care. The latter is one of the central tenets of patient-centered care, an approach that may improve both patient satisfaction and health outcomes.[1,2]

The history of the present illness expands upon the chief complaint. The physician must thoroughly understand the nature of the illness, including relevant temporal, aggravating, and relieving factors, past therapy, and the presence or absence of pain. In the head and neck, many organ systems are intertwined, and it is critical to ask about the impact of the disease process on related systems; for example, the presence of dysphagia in a patient with an airway complaint. As the practitioner listens to the patient, a picture emerges that includes a list of differential diagnoses to consider. Further questioning should be undertaken to begin to discriminate between items on this list.

A discussion of the patient's medical history leads the otolaryngologist to a better understanding of the patient and often reveals information that is important in the consideration of further workup and treatment. The practitioner should inquire about any

Abstract

A careful history and physical examination is the cornerstone of excellent patient care. From review of records prior to the clinic visit to extended examination with endoscopes, every step of the complete history and head and neck examination is vital. Preoperative evaluation and management of comorbid disease are also critical. Preoperative investigations have utility in selected populations, but routine usage should be avoided. Likewise, the use of perioperative antibiotics and bridging of chronic anticoagulants must be considered on an individual basis to avoid undue morbidity. The otolaryngologist must be aware of diseases affecting other organ systems that may impact the safety and success of their surgery.

Keywords

history
physical examination
perioperative evaluation
comorbid disease
thromboembolism prophylaxis
anticoagulant bridging

previous emergency department visits, hospitalizations, and health problems that have required the care of a physician. A problem list of active health issues should be compiled and maintained, reflecting any changes that occur while the patient is under the otolaryngologist's care. A complete surgical history is important to obtain to understand the impact of comorbidities on the current complaint, to anticipate anatomic alternations, and to assess anesthetic risks that may be encountered, should further surgical treatment be undertaken. A history of difficult intubation is particularly important to elicit to anticipate any challenges that may arise in the operating theater.

Medication allergies are crucial to note prominently in the medical chart. True allergy should be distinguished from adverse effects of a medication. In addition, all medications and current dosages should be accurately recorded, and compliance with prescribed medications should be assessed. A history of noncompliance may need to be taken into account when deciding between courses of care, particularly when considering conservative management that would require close observation and follow-up.

A careful social history must be obtained, including:

- Tobacco exposure. Note first- and second-hand exposure, and specifically ask about cigarette, cigar, and chewing tobacco consumption, either current or past use.
- Alcohol consumption. Ask direct questions regarding the amount consumed, frequency, choice of beverage, and duration of use.
- Past and current recreational and intravenous (IV) drug use
- Sexual history. This is of particular importance in light of the role that human papillomavirus plays in some head and neck cancers. Assessing risk for human immunodeficiency virus, hepatitis C, and other sexually transmitted diseases is also important.
- Other exposures. Occupational and vocational exposures to irritants, potential carcinogens, and noise should be elucidated if relevant to the chief complaint. A history of prior therapeutic irradiation, including modality (implants, external beam, or by mouth) and dosage should be ascertained. A history of accidental radiation exposure is also important to document.
- Environment. An understanding of the patient's physical living environment and available social support is significant in assessing postoperative needs and appropriate disposition planning. Assessment of the patient's ability to perform critical activities of daily living is equally important. One frequently utilized tool, especially in head and neck cancer patients, is the Karnofsky Performance Status Scale (Table 4.1).[3]

The family history is often quite revealing, and asking patients questions about their familial history of hearing loss, congenital defects, atopy, or cancer may uncover pertinent information that may alter the direction of evaluation.

Finally, a review of systems is part of every comprehensive history. This review includes changes in the patient's respiratory, cardiac, neurologic, endocrine, gastrointestinal, urogenital, musculoskeletal, cutaneous, and psychiatric systems. A review of all the elements of the complete history is given in Box 4.1.

TABLE 4.1 Karnofsky Performance Status Scale

Definition	%	Criteria
Able to carry on normal activity and to work; no special care is needed	100	Normal; no complaints; no evidence of disease
	90	Able to carry on normal activity; minor signs or symptoms of disease
	80	Normal activity with effort; some signs or symptoms of disease
Unable to work; able to live at home, care for most personal needs; a varying amount of assistance is needed	70	Cares for self; unable to carry on normal activity or to do active work
	60	Requires occasional assistance; able to care for most personal needs
	50	Requires considerable assistance and frequent medical care
Unable to perform self-care; requires equivalent of institutional or hospital care; disease may be progressing rapidly	40	Disabled; requires special care and assistance
	30	Severely disabled; hospitalization is indicated, death not imminent
	20	Very sick; hospitalization necessary; active supportive treatment necessary
	10	Moribund; fatal processes progressing rapidly
	0	Dead

From Hanks G, Cherny NI, Christakis NA, et al. *Oxford textbook of palliative medicine,* ed 4. New York, 2010, Oxford University Press.

PHYSICAL EXAMINATION

The otolaryngologist must develop an approach to the head and neck examination that allows the patient to feel comfortable while the physician performs a complete and comprehensive evaluation. Many of the techniques used by the otolaryngologist may leave a patient feeling alienated if not done correctly. Thus it is essential to establish a rapport with a patient before proceeding with the examination.

The hands should be washed before and after each examination. Portions of the head and neck examination should only be done with the examiner wearing gloves and, in some instances, protective eye covering. Universal precautions are mandatory in today's practice of medicine and have the added benefit of showing the patient that the examiner is concerned about disease transmission, which builds trust.

General Appearance

Much information can be gleaned by assessing the general behavior and appearance of the patient. An assessment of the vital signs should be conducted. The level of alertness and orientation should be noted, as well as the presence of signs of distress or toxicity, such as increased work of breathing, diaphoresis, and rigors. The patient's affect may suggest psychiatric issues such as depression, anxiety, or frank psychosis. Acute intoxication may be evident and may obviate the patient's ability to consent to the examination or treatment. Poor personal hygiene may be a clue to a difficult home environment or even homelessness, which the patient may have been reluctant to directly disclose when discussing social history. Tar-stained fingernails, teeth, or moustache are harbingers for heavy tobacco consumption. Disturbed gait and ability to navigate the examination room may point toward potential vestibular or neurologic impairment.

Head and Facies

The head should be examined for overall shape, symmetry, and signs of trauma. Areas of hair loss should be noted if relevant, and scalp lesions should be identified. Facial skin is inspected for signs of sun damage, lesions, and the presence of rhytids. The face is analyzed for the presence of dysmorphic features. Facial symmetry is evaluated, both at rest and with motion. The American Academy of Otolaryngology–Head and Neck Surgery Facial Nerve Grading System is a respected standard for reporting gradations of nerve function (Table 4.2).

The facial skeleton—including the bony nasal dorsum, orbital rims, malar eminences, maxilla, and mandible—should be carefully palpated for bony deformities, irregularities, and step-offs; this is especially important in patients with recent facial trauma. The

BOX 4.1 History

Introduce yourself

REVIEW

Medical records
Radiographic images
Laboratory values
Pathology specimens

INQUIRE ABOUT CHIEF COMPLAINTS

Location
Duration
Temporal characteristics
Aggravating and relieving factors
Related complaints

REVIEW PATIENT HISTORY

Medical history
Surgical history
Allergies
Medications
Social history
Living situation
Family history

RISK FACTORS

Tobacco and alcohol use
Drug use
Sexual practices

REVIEW SYSTEMS

Respiratory
Cardiac
Neurologic
Endocrine
Gastrointestinal
Urogenital
Musculoskeletal
Skin
Psychiatric

TABLE 4.2 American Academy of Otolaryngology–Head and Neck Surgery Facial Nerve Grading System

Grade	Facial Movement	
I	Normal	Normal facial function at all times
II	Mild dysfunction	Forehead: moderate to good function Eye: complete closure Mouth: slight asymmetry
III	Moderate dysfunction	Forehead: slight to moderate movement Eye: complete closure with effort Mouth: slightly weak with maximum effort
IV	Moderately severe dysfunction	Forehead: no movement Eye: incomplete closure Mouth: asymmetric with maximum effort
V	Severe dysfunction	Forehead: no movement Eye: incomplete closure Mouth: slight movement
VI	Total paralysis	No movement

regions overlying the paranasal sinuses may be firmly palpated or tapped for tenderness, which may be present during an episode of sinusitis. The temporomandibular joint is evaluated by placing the examiner's fingers over the temporomandibular joint region anterior to the external auditory canal and asking the patient to open and close the jaw. Dislocation, locking, or clicking of the joint is consistent with an intraarticular disk disorder, which can be responsible for otalgia and headache.

The parotid gland should be inspected for overlying skin changes or gland enlargement and to identify visible masses. The glands are then palpated to detect tenderness and characterize any masses, including location, size, mobility, and compressibility. Bimanual palpation with a gloved hand inside the oral cavity allows further evaluation of masses, as well as expressing saliva from Stenson's duct, important in suspected sialadenitis or sialolithiasis. The preauricular and retroauricular lymph nodes should be systematically assessed.

Eyes

The shape and angulation of the palpebral fissures are noted, along with any rounding of the canthi or increase in intercanthal distance. The conjunctiva and sclera are inspected for any infection, swelling, or discoloration. The eyelids are assessed for retraction and lid lag, which can be consistent with hyperthyroidism. The presence of strabismus or spontaneous nystagmus is noted, and extraocular movements are evaluated to provide an assessment of the oculomotor, trochlear, and abducens nerves, and gaze-evoked nystagmus. The pupils are assessed for response to light and accommodation. In some cases, fundal examination may be important and can indicate the need for more detailed ophthalmologic examination.

Ears

Auricles. The postauricular region should be inspected for healed surgical incisions. Clinical signs of mastoiditis that include tenderness, erythema, and fluctuance should be sought in the patient with otalgia and fever. In trauma patients, ecchymosis overlying the mastoid (Battle sign) is indicative of temporal bone fracture.

The position and shape of the pinna should be noted, including any asymmetry present. The overlying skin should be examined for evidence of erythema, drainage, and crusting consistent with infection. Psoriasis of the auricle or external auditory canal with its attendant flaking, dry skin, and edema is another common finding. Ulcerations and rashes can be consistent with viral infections as a result of herpes simplex and herpes zoster. Signs of solar damage and lesions consistent with skin cancer should be noted and warrant biopsy. Loss of the normal cartilaginous landmarks is seen in inflammatory and infectious lesions, as well as in the setting of auricular hematoma. Pain upon manipulation of the pinna indicates inflammation or infection of the pinna or external auditory canal.

The areas anterior to the root of the helix and tragus may have preauricular pits, sinuses, or skin tags. Any drainage should be noted.

External Auditory Canal. The outer third of the auditory canal is cartilaginous, with fairly thick skin that contains hair follicles, sebaceous glands, and apocrine glands that produce cerumen. The inner two-thirds of the canal is osseous and has only a thin layer of skin overlying the bone. To visualize the ear canal, gently grasp the pinna and elevate it superiorly and posteriorly to straighten the canal and allow atraumatic insertion of the otoscopic speculum. The overall patency of the canal should be evaluated; difficulty in inserting a properly sized speculum could indicate the presence of stenosis that may be congenital or acquired in nature.

Cerumen commonly accumulates in the canal, often obstructing it; this may require careful removal to ensure complete examination. The color and consistency of drainage or debris should be noted, and cultures should be considered. Foreign bodies may be found, with the majority lateral to the isthmus, and should be removed with an operating microscope. Disk-style batteries need to be

removed emergently. Once the canal is clear of debris, the quality of the ear canal skin should be evaluated. Erythema and edema in the setting of white, moist debris is consistent with otitis externa. In older patients, atrophy of the external auditory canal skin is frequently seen and may be associated with psoriasis or eczema of the canal. In addition, any masses or skin lesions should be noted. Cutaneous cancers, such as squamous cell carcinoma, can involve the ear canal skin, and careful documentation and biopsy of any lesions should be undertaken. The presence of granulation tissue at the junction of the cartilaginous and bony canal should raise concern for malignant otitis externa, particularly in patients who have diabetes or in those who are immunocompromised. Lacerations may be present in the setting of trauma, which may include temporal bone fractures.

Tympanic Membrane. The tympanic membrane should be visible after the canal has been cleared of any debris. As depicted in Fig. 4.1, the membrane is oval and cone shaped, and it is surrounded by the fibrous white annulus. The central portion of the membrane attaches to the handle of the malleus, which terminates in the umbo. The lateral process of the malleus is readily seen in the superior tympanic membrane and will be quite prominent in retracted membranes. Superior to this process is the pars flaccida, wherein the tympanic membrane lacks the radial and circular fibers present in the pars tensa, which comprises the remainder of the eardrum. The pars flaccida must be critically examined, because it is the most common location for retraction pockets, debris, and cholesteatoma. The normal tympanic membrane should be pearly gray and translucent, which allows examination of the structures of the middle ear, including the promontory and round window. The stapes and eustachian tube opening are visible in some ears. The clinician must also assess for areas of myringosclerosis, which appear as chalky white patches, frequently seen in regions of previous trauma. A thickened, erythematous membrane, occasionally with bullae, is consistent with myringitis; but a thin, atelectatic membrane draped closely over the underlying middle ear structures may indicate adhesive otitis media, and prominent radial blood vessels can indicate a chronic middle ear effusion. Perforations should be noted with their location, proximity to the annulus, and approximate size expressed as a percentage of the drum perforated.

Pneumatic otoscopy should be performed, particularly when middle ear disorders are of concern. First, an appropriately sized speculum is used to seal the ear canal. With gentle pressure from the pneumatic bulb, the tympanic membrane will move back and forth, if the middle ear space is well aerated. With a retracted drum, it is helpful to depress the bulb prior to sealing the canal to generate negative pressure. Perforations and middle ear effusions are common causes of immobile tympanic membranes.

The middle ear should be assessed for the presence of any fluid. Serous effusions often appear as amber fluid, sometimes with air-fluid levels or air bubbles. Mucoid effusions will appear dull gray to white in color, with loss of the typically visualized middle ear landmarks, and the tympanic membrane will often be retracted. White masses, often with associated perforation and granulation tissue, are consistent with acquired cholesteatoma. A white pearl behind an intact tympanic membrane, often in the anterior-superior quadrant, is likely to represent congenital cholesteatoma. Vascular masses should prompt consideration of middle ear glomus tumor; the clinician may also note a Brown sign, in which the mass blanches with pneumatic otoscopy.

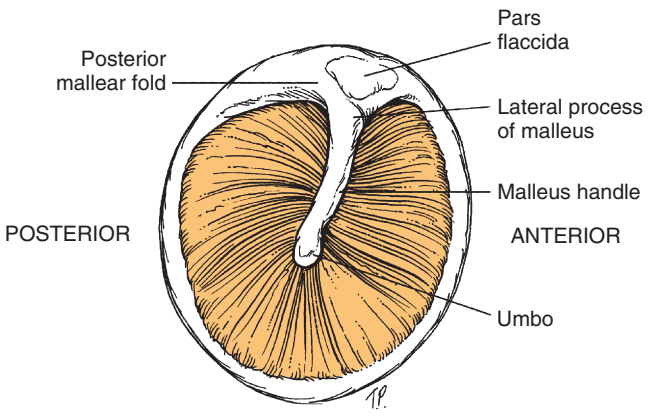

Fig. 4.1 The tympanic membrane.

Hearing Assessment. Tuning fork tests, usually done with a 512-Hz fork, allow the otolaryngologist to distinguish between sensorineural and conductive hearing loss (Table 4.3). Tuning fork tests have a role in assessing hearing when an audiogram is not available, as well as in confirming audiometric findings. All tests should be conducted in a quiet room without background noise and in ears cleared of cerumen and debris.

The Weber test is performed by placing the vibrating 512-Hz tuning fork in the center of the patient's forehead, at the bridge of the nose, or on the central incisors with the patient's teeth tightly clenched. The patient then is asked if the sound is louder in one ear or is heard in the midline. The sound waves should be transmitted equally well to both cochleae through the skull. A unilateral sensorineural hearing loss causes the sound to lateralize to the ear with the better cochlear function. However, a unilateral conductive hearing loss causes the Weber test to lateralize to the side with the conductive loss, because less competing background noise is detected through air conduction. A midline Weber result is referred to as "negative." "Weber right" and "Weber left" refer to the direction to which the sound lateralized.

TABLE 4.3 Tuning Fork Testing

Weber	**Weber "Negative"**	**Weber Right**
Weber	Sound is midline ("negative"): normal	Sound localizes right or left: ipsilateral conductive or contralateral sensorineural hearing loss
Rinne	Air > bone conduction: normal or ipsilateral mild sensorineural hearing loss	Bone > air conduction: ipsilateral conductive hearing loss
Example:		
1. Right conductive hearing loss: Weber lateralizes to right; Rinne on right bone > air		
2. Right sensorineural loss: Weber lateralizes to left; Rinne air > bone bilaterally		
Rinne	**Rinne "Positive"**	**Rinne "Negative"**
Patient response	"Sound is louder when the fork is by the canal."	"Sound is louder when the fork is on the mastoid process."
Interpretation	Air conduction louder than bone conduction; normal	Bone conduction louder than air conduction; conductive hearing loss
Begin with a 512-Hz fork; then include 256- and 1024-Hz forks.		

TABLE 4.4 Tuning Fork Assessment of Degree of Hearing Loss

Hearing Loss (dB)	256 Hz	512 Hz	1024 Hz
<15	+	+	+
15–30	–	+	+
30–45	–	–	+
45–60	–	–	–

+: positive Rinne, air conduction > bone conduction.
–: negative Rinne, bone conduction > air conduction.

To further elucidate the nature of unilateral hearing loss, the Rinne test is performed. The 512-Hz tuning fork is placed firmly on the mastoid process, and patients are instructed to tell the examiner when they are no longer able to hear the sound. The fork is then quickly transferred in front of the ear canal, and patients are asked if they can again hear sound. If the sound is still audible, it is deemed a positive test, indicating that air conduction is greater than bone conduction; this is seen in ears with a mild sensorineural loss, as well as normal hearing ears. If the sound is no longer heard when the tuning fork is placed in front of the canal, bone conduction is deemed greater than air conduction, and this is termed a *negative Rinne test* consistent with conductive hearing loss. These tests can be repeated with the 256- and 1024-Hz tuning forks; negative responses provide an indication of the degree of conductive hearing loss (Table 4.4).

Nose

The external nose should be inspected from the frontal, profile, and base views for any deformity or asymmetry. The projection of the tip and dorsum and the width of the alar base are considered. The soft tissue envelope is inspected for skin quality and thickness, and for the presence of any lesions or discoloration.

Anterior rhinoscopy using a headlamp and nasal speculum allows assessment of the nasal septum and inferior turbinates. The speculum should be directed laterally to avoid touching the sensitive septum with the metal edges. Drainage, clot, and foreign bodies should be noted. The anterior septum, where numerous small branches of the external and internal carotid arteries meet (Kiesselbach plexus), should be evaluated for prominent, superficial ectatic vessels that may be responsible for epistaxis. Anterior septal deviations and bony spurs are often evident, and palpation of the anterior septum with gloved fingers can be helpful in determining the presence of caudal deviation. The characteristics of the mucosa of the inferior turbinate may range from the boggy, edematous, pale mucosa seen in those with allergic rhinitis to the erythematous, edematous mucosa seen in those with sinusitis. Polyps and masses may be visualized and warrant endoscopic examination. The patency of the nasal airway bilaterally should be noted.

Nasal endoscopy using rigid endoscopes allows thorough examination of even the most posterior portions of the nasal cavity but carries a risk of laceration in an uncooperative patient. After applying a local anesthetic and topical decongestant spray, the rigid zero-degree endoscope may be passed into the nose along the nasal floor, noting the appearance of the septum, inferior turbinate, and eustachian tube orifice. The appearance of the mucosa following decongestion is noted, and it is compared with the appearance on anterior rhinoscopy. The endoscope is then removed and reintroduced above the inferior turbinate to view the middle turbinate, and is again passed posteriorly to the nasopharynx. The tip is withdrawn to the head of the middle turbinate and is then directed laterally to view the lateral nasal side wall, when the patient is able to tolerate this. Accessory ostia from the maxillary sinus may be visible and often are mistaken for the true maxillary ostium, which is located behind the uncinate and is not usually visible. In patients who have undergone endoscopic sinus surgery, many of the sinus ostia can be evaluated endoscopically. The procedure is then repeated on the other side. Flexible fiberoptic scopes can also be used and are safer in young children and other unpredictable patients, but these often provide inferior optics and are less able to be directed into the lateral and superior aspects of the nasal cavity.

Nasopharynx

The nasopharynx extends from the skull base to the soft palate, and this can be a challenging area to examine. In the patient with a high posterior soft palate and small tongue base, the otolaryngologist may use a small dental mirror and a headlamp to visualize the nasopharynx. By having the patient sit upright in the chair, the physician may firmly pull the tongue forward while opening the patient's mouth to place the mirror just posterior to the soft palate. The structures of the nasopharynx are seen when the mirror is oriented upward.

Utilization of a fiberoptic nasopharyngoscope allows excellent visualization of this area. The midline also should be inspected for any masses, ulcerations, or bleeding areas. Another technique uses a 90-degree rigid scope, which is advanced through the mouth, with the beveled edge placed posterior to the soft palate; the nasopharynx may be seen in its entirety, and both compared for symmetry using this technique.

Regardless of the technique used, the adenoids, eustachian tube orifice, torus tubarius, and fossae of Rosenmüller should be inspected on each side. Whereas children have adenoid tissue present, adults should not have much adenoid tissue remaining in this area; the presence of tissue should prompt consideration of lymphoma or human immunodeficiency virus (HIV) infection. All patients with unilateral otitis media should have their nasopharynx inspected for possible nasopharyngeal masses. Nasopharyngeal carcinoma most commonly presents in the fossa of Rosenmüller. In young male patients, nasopharyngeal angiofibromas are locally aggressive but histologically benign masses that most commonly occur in the posterior choana or nasopharynx. Cysts in the superior portion of the nasopharynx may represent a benign Tornwaldt cyst or a malignant craniopharyngioma.

Oral Cavity

The boundaries of the oral cavity extend from the skin-vermillion junction of the lips, hard palate, anterior two-thirds of the tongue, buccal membranes, upper and lower alveolar ridge, and retromolar trigone to the floor of the mouth. The oral cavity may be best visualized with a well-directed headlamp and a tongue depressor in each gloved hand. A systematic approach to examination ensures that no mucosal surface will go unexamined.

The lips and oral commissures should be carefully inspected for any lesions concerning for carcinoma. Smooth submucosal nodules may denote a mucocele. Note any fissures or cracking consistent with angular stomatitis or cheilosis.

Next, the patient is asked to open the mouth, and the presence or absence of trismus is noted. The general condition of the teeth and gingiva should be noted along with the occlusion. The retromolar trigone should be inspected bilaterally; cancers in this area are commonly asymptomatic until locally advanced, and the opportunity to identify small, asymptomatic lesions should not be missed.

The dorsal, ventral, and lateral surfaces of the tongue should be carefully inspected for induration or ulcerative lesions. Gently grasping the anterior tongue with a gauze sponge allows the examiner to move the anterior tongue from side to side, and asking the patient to lift the tongue toward the hard palate allows examination of the floor of mouth and Wharton ducts. The examiner should palpate the floor of the mouth using a bimanual approach.

The buccal mucosa should be inspected for white plaques that may represent oral thrush, which easily scrapes off with a tongue blade, or leukoplakia, which cannot be removed. More worrisome for a precancerous condition is erythroplakia. Therefore, all red lesions and most white lesions should be biopsied. While examining the buccal membranes, the physician should note the location of the parotid duct, or Stenson duct, as it opens near the second upper molar. Small yellow spots in the buccal mucosa are sebaceous glands, commonly referred to as *Fordyce spots*, and are not abnormal. Aphthous ulcers, or the common canker sore, are painful white ulcers that can be on any part of the mucosa but are commonly present on the buccal membrane.

The hard palate may have a bony outgrowth known as a *torus palatinus*. These midline bony deformities are benign and should not be biopsied, although growths that are not in the midline should be more carefully evaluated as possible cancerous lesions. Similar bony lesions along the lingual surface of the mandible, called *mandibular tori*, may also be present.

Oropharynx

The oropharynx includes the posterior third of the tongue, the anterior and posterior tonsillar pillars, the soft palate, the lateral and posterior pharyngeal wall, and the vallecula (Fig. 4.2).

The tonsil size is typically denoted on a scale, and many scales are in use. The Brodsky scale appears to have reasonable intra-observer and interobserver reliability.[4] With this scale, 0 indicates the tonsils are entirely within the tonsillar fossa; 1+ indicates the tonsils are located just outside the fossa and occupy less than 25% of the total width of the oropharynx; 2+ tonsils occupy 26% to 50%; 3+ tonsils are 51% to 75% of the oropharyngeal width; and 4+ tonsils occupy more than 75% of the oropharyngeal width. The term "kissing tonsils" implies that the tonsils meet in the midline, entirely within the tonsillar fossa. The surfaces of the tonsils are examined for concerning lesions, exudates, erythema, and tonsilliths. A common cause for a foreign body sensation in the back of the throat, tonsilliths are yellow or white concretions in the tonsillar crypts which often cause the patient to have halitosis; these may be removed with a cotton-tipped swab. Tonsillar asymmetry is most often benign, but when the enlarged tonsil has an atypical appearance, lymphoma must be considered.

The tonsillar pillars, soft palate, uvula, and lateral and posterior pharyngeal walls are then inspected. Bulges in the soft palate or pharyngeal walls can indicate an abscess, mass, or aneurysm; palpation of these areas can be very helpful but may trigger the patient's gag reflex. Deviation of the uvula is seen with masses of the lateral soft palate, most commonly peritonsillar abscesses. Elongation of the uvula may be seen in sleep apnea. A bifid uvula may occur in isolation, or it can be accompanied by midline lucency of the soft palate and a notch on the posterior hard palate, which is consistent with a submucosal cleft palate. Cobblestoning of the mucosa in the posterior oropharynx indicates the presence of submucosal lymphoid hypertrophy and is often seen in the setting of infection, allergic rhinitis, and reflux.

The base of the tongue can be visually inspected with the aid of a dental mirror and can be palpated with a gloved finger. The patient should be aware of the possibility that gagging may ensue when this is done. In patients with strong gag reflexes, with anatomy unfavorable for mirror examination, or when a concerning lesion needs to be thoroughly examined, flexible fiberoptic examination may be necessary. By carefully passing the flexible fiberoptic endoscope through the anesthetized nose, the interaction of the soft palate and tongue base during swallowing also may be viewed.

Larynx and Hypopharynx

The larynx is often subdivided into the supraglottis, glottis, and subglottis. The area of the *supraglottis* includes the epiglottis, the aryepiglottic folds, the false vocal cords, and the ventricles. The *glottis* comprises the inferior floor of the ventricle, the true vocal folds, and the arytenoids. The *subglottis* generally is considered to begin 5 to 10 mm below the free edge of the true vocal fold and to extend to the inferior margin of the cricoid cartilage (Fig. 4.3).

The hypopharynx extends from the superior edge of the hyoid bone to the inferior aspect of the cricoid cartilage and is composed of three subsites: (1) the piriform sinuses, (2) the posterior hypopharyngeal wall, and (3) the postcricoid area. This area, rich in lymphatics, may harbor tumors that often are detected only in advanced stages; early detection of these relatively "silent" carcinomas is important and should not be missed.

The examiner should not only detect anatomic abnormalities but also should observe how the larynx and hypopharynx are

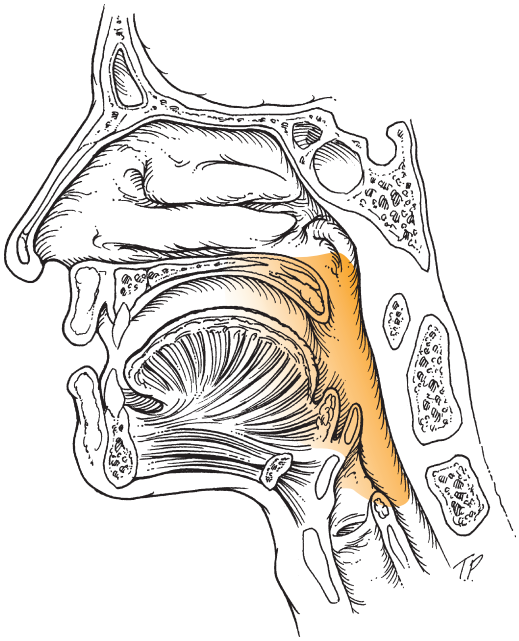

Fig. 4.2 The oropharynx, which includes the posterior third of the tongue, soft palate, tonsillar pillars (anterior and posterior), lateral and posterior pharyngeal wall, and vallecula.

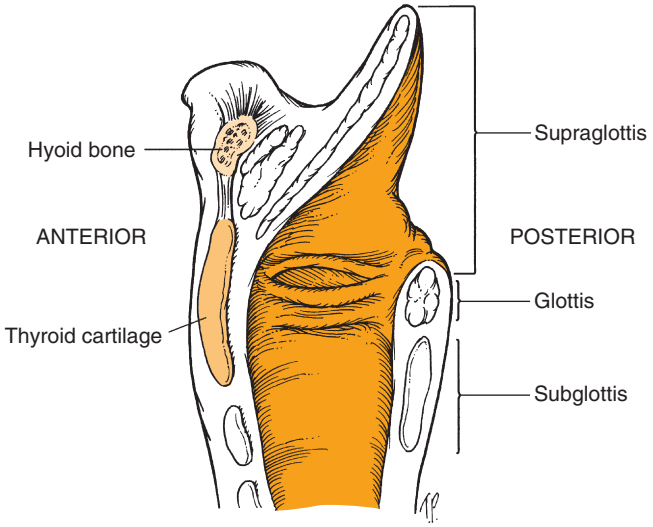

Fig. 4.3 The larynx.