Case Studies in Patient Safety

Foundations for Core Competencies

Julie K. Johnson, MSPH, PhD

Professor
Department of Surgery
Center for Healthcare Studies
Institute for Public Health and Medicine
Feinburg School of Medicine
Northwestern University
Chicago, Illinois

Helen W. Haskell, MA

President Mothers Against Medical Error Columbia, South Carolina

Paul R. Barach, MD, MPH

Visiting Professor
College of Medicine
University College Cork
Cork, Ireland

World Headquarters Jones & Bartlett Learning 5 Wall Street Burlington, MA 01803 978-443-5000 info@jblearning.com www.jblearning.com

Jones & Bartlett Learning books and products are available through most bookstores and online booksellers. To contact Jones & Bartlett Learning directly, call 800-832-0034, fax 978-443-8000, or visit our website, www.jblearning.com.

Substantial discounts on bulk quantities of Jones & Bartlett Learning publications are available to corporations, professional associations, and other qualified organizations. For details and specific discount information, contact the special sales department at Jones & Bartlett Learning via the above contact information or send an email to specialsales@jblearning.com.

Copyright © 2016 by Jones & Bartlett Learning, LLC, an Ascend Learning Company

All rights reserved. No part of the material protected by this copyright may be reproduced or utilized in any form, electronic or mechanical, including photocopying, recording, or by any information storage and retrieval system, without written permission from the copyright owner.

The content, statements, views, and opinions herein are the sole expression of the respective authors and not that of Jones & Bartlett Learning, LLC. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise does not constitute or imply its endorsement or recommendation by Jones & Bartlett Learning, LLC and such reference shall not be used for advertising or product endorsement purposes. All trademarks displayed are the trademarks of the parties noted herein. Case Studies in Patient Safety: Foundations for Core Competencies is an independent publication and has not been authorized, sponsored, or otherwise approved by the owners of the trademarks or service marks referenced in this product.

There may be images in this book that feature models; these models do not necessarily endorse, represent, or participate in the activities represented in the images. Any screenshots in this product are for educational and instructive purposes only. Any individuals and scenarios featured in the case studies throughout this product may be real or fictitious, but are used for instructional purposes only.

This publication is designed to provide accurate and authoritative information in regard to the Subject Matter covered. It is sold with the understanding that the publisher is not engaged in rendering legal, accounting, or other professional service. If legal advice or other expert assistance is required, the service of a competent professional person should be sought.

Production Credits

VP, Executive Publisher: David Cella Publisher: Michael Brown Associate Editor: Lindsey Mawhiney Associate Production Editor: Rebekah Linga Art Development Editor: Joanna Lundeen Art Development Assistant: Shannon Sheehan

Senior Marketing Manager:

Sophie Fleck Teague

Manufacturing and Inventory Control Supervisor: Amy Bacus

Composition: Cenveo Publisher Services Cover Design: Kristin E. Parker

Rights and Photo Research Coordinator: Mary Flatley

Cover Image: © Stockbyte/Thinkstock

Printing and Binding: Edwards Brothers Malloy

Cover Printing: Edwards Brothers Malloy

Library of Congress Cataloging-in-Publication Data

Johnson, Julie K., author.

Case studies in patient safety: foundations for core competencies / Julie Johnson, Paul Barach, and Helen Haskell. p.; cm.

Includes bibliographical references and index.

ISBN 978-1-4496-8154-8 (paper)

I. Barach, Paul, author. II. Haskell, Helen, author. III. Title.

[DNLM: 1. Patient Safety-Case Reports. 2. Clinical Competence-Case Reports. 3. Medical

Errors-prevention & control-Case Reports. 4. Quality of Health Care-Case Reports. WX 185]

R859.7.S43

610.28'9-dc23

2014038075

6048

Printed in the United States of America

19 18 17 16 15 10 9 8 7 6 5 4 3 2 1

Dedication

We dedicate this book to the memory of Lewis Wardlaw Haskell Blackman, a shining light extinguished far too soon.



CONTENTS

Contributors				
Acknowledgments				
Foreword Preface				
			Introduction	
Sec	tion I: Patient Care	00		
1	It's Hard to Kill a Healthy 15-Year-Old	00		
2	Routine Appendectomy	00		
3	The Origins of the Mid Staffordshire Inquiry into			
	the National Health Service	00		
1	Consent and Disclosure in Pediatric Heart Surgery	00		
Sec	tion II: Knowledge for Practice	00		
<u> </u>	I'm Left in Fear: An Account of Harm in Maternity Care	00		
)	A Routine Endoscopic Procedure	00		
7	The Last Run: An Undiagnosed Heart Rhythm Disturbance	00		
Sec	tion III: Practice-Based Learning and Improvement	00		
	<u> </u>	00		
3	Improving Care for People with Intellectual Disability A Cascade of Small Events: Learning from an Unexpected			
3	Improving Care for People with Intellectual Disability			
3	Improving Care for People with Intellectual Disability A Cascade of Small Events: Learning from an Unexpected	00		
3	Improving Care for People with Intellectual Disability A Cascade of Small Events: Learning from an Unexpected Postsurgical Death	00		
3 .0 Sec	Improving Care for People with Intellectual Disability A Cascade of Small Events: Learning from an Unexpected Postsurgical Death Accidental Fall in a Hospital	00 00 00		
3 .0 Sec	Improving Care for People with Intellectual Disability A Cascade of Small Events: Learning from an Unexpected Postsurgical Death Accidental Fall in a Hospital **Etion IV: Interpersonal and Communication Skills** Not Considered a Partner: A Mother's Story of a Tonsillectomy Gone Wrong	00 00 00		
Sec. 1	Improving Care for People with Intellectual Disability A Cascade of Small Events: Learning from an Unexpected Postsurgical Death Accidental Fall in a Hospital **Tion IV: Interpersonal and Communication Skills* Not Considered a Partner: A Mother's Story of a Tonsillectomy Gone Wrong Lost: A Patient's Search for Answers for Intractable Pain	00 00 00		
Sec. 1	Improving Care for People with Intellectual Disability A Cascade of Small Events: Learning from an Unexpected Postsurgical Death Accidental Fall in a Hospital *tion IV: Interpersonal and Communication Skills Not Considered a Partner: A Mother's Story of a Tonsillectomy Gone Wrong Lost: A Patient's Search for Answers for Intractable Pain The Silence of the Hospital: Lessons on Supporting Patients	00 00 00 00		
8 9 110 Sec 111	Improving Care for People with Intellectual Disability A Cascade of Small Events: Learning from an Unexpected Postsurgical Death Accidental Fall in a Hospital **Tion IV: Interpersonal and Communication Skills* Not Considered a Partner: A Mother's Story of a Tonsillectomy Gone Wrong Lost: A Patient's Search for Answers for Intractable Pain	00 00 00 00		
8 99 10 Sec 11 12 13	Improving Care for People with Intellectual Disability A Cascade of Small Events: Learning from an Unexpected Postsurgical Death Accidental Fall in a Hospital *tion IV: Interpersonal and Communication Skills Not Considered a Partner: A Mother's Story of a Tonsillectomy Gone Wrong Lost: A Patient's Search for Answers for Intractable Pain The Silence of the Hospital: Lessons on Supporting Patients	00 00 00 00 00		

	Haspital Death	00
16	Hospital Death Small Steps: From Medication Adjustment to Permanent Disability	00
17	The Definition of Alive: The Story of an Equivocal Birth	00
	, 1	
Sec	tion VI: Systems-Based Practice	00
18	Not for IV Use: The Story of an Enteral Tubing Misconnection	00
19	Death Despite Known Drug Allergy	00
20	The Trial Meant for You: The Lifelong Medical Journey	00
	of a Child with a Complex Congenital Condition	00
Sec	tion VII: Interprofessional Collaboration	00
21	Failure to Rescue	00
22	Unmonitored: A Postsurgical Narcotic Overdose in the Hospital	00
23	The Voice That Is Missing: A Mother's Journey	0.0
24	in Patient Safety Advocacy When Healing Harms: Recovering from a Multisystem	00
⊿ ¬r	Traumatic Injury	00
Sec	tion VIII: Personal and Professional Development	00
Aft	erword Personal and Professional Development	00
Ap	pendix Recommended List of Core Competencies	
	for Health Professions	00

CONTRIBUTORS

Diana Arachi, MPH, MA, BA (Hons), Cert PMP

University of New South Wales Sydney, NSW, Australia

Julie Bailey, CBE

Founder, Cure the NHS Worcester, England

Carolyn Canfield

Citizen-patient

Honorary Lecturer

Department of Family Medicine

Faculty of Medicine

The University of British Columbia

Vancouver, BC Canada

Linda Carswell

Director, Jerry Carswell Memorial Foundation Houston, TX, USA

Dr. Bruce Chenoweth

Senior Developmental Psychiatrist Kogarah Developmental Disability Service Metro-Regional Intellectual Disability Network St George Hospital South Eastern Sydney Local Health District

Conjoint Senior Clinical Lecturer, School of Psychiatry University of New South Wales Sydney, NSW, Australia

Deborah Debono, RN, RM, BA

Centre for Clinical Governance Research Australian Institute of Health Innovation Macquarie University Sydney, NSW, Australia

Dale R. Ford, MBBS, FRACGP, FACRRM

Principal Clinical Advisor, Improvement Foundation Australia Greater Health Warrnambool Hamilton, Victoria, Australia

John James, PhD, DABT

Founder, Patient Safety America NASA Chief Toxicologist (Retired) Houston, TX, USA

Meg Harrison Humphrey

Houston, TX, USA

Linda Kenney

MITSS (Medically Induced Trauma Support Services) Chestnut Hill, MA, USA

Robert Leitner, MBBS, FRACP

Developmental Paediatrician
Director, Kogarah Developmental Assessment Service
Metro-Regional Intellectual Disability Network
St. George Hospital
South Eastern Sydney Local Health District
Sydney, NSW, Australia

viii

Janet Long, BSc (Hons), MN, PhD

John Walsh Centre for Rehabilitation Research University of Sydney Sydney, NSW, Australia

Tanya Lord, MPH, PhD

Patient Engagement Consultant Nashua, NH, USA

Nicola Mackintosh, RN, BSc, MSc, PhD

Research Fellow Division of Women's Health, School of Medicine King's College London, UK

Farah Magrabi, BE, PhD

Associate Professor Australian Institute of Health Innovation Macquarie University Sydney, NSW, Australia

Mary Ellen Mannix, MRPE

Founder, James's Project Wayne, PA, USA

Kirsten Morrise

Salt Lake City, UT, USA

Lisa Morrise, MArts

Co-Lead Partnership for Patients PFE Affinity Group LAM Professional Services, LLC Salt Lake City, UT, USA

Sandra Pintabona, RN

Perth, Western Australia, Australia

iv

Susanna Rance, PhD

Visiting Research Associate

King's College

London, UK

Senior Research Fellow

Plymouth University Peninsula

Schools of Medicine and Dentistry

Plymouth, UK

Glenda Rodgers, RNC, BSN

Troy, KS, USA

Jane Sandall, PhD, MSc, BSc (Hons), RM, RN, HV

Professor of Social Science and Women's Health

King's College

London, UK

David Skalicky, MBBS, FAFRM

Rehabilitation Physician

Northern Intellectual Disability Health

Sydney, NSW, Australia

Karen Sterner

Bastrop, TX, USA

Kathy Torpie, MS

Psychologist, International Healthcare Speaker and Patient

Experience Advisor

www.kathytorpie.com

Auckland, New Zealand

Laura Batz Townsend

Louise H. Batz Patient Safety Foundation

Austin, TX, USA

Linda Ward

Bastrop, TX, USA

Kylie Watson, BSc, BM, MSc

Research Associate King's Patient Safety and Service Quality Research Centre

London, UK

Senior Midwife and Supervisor of Midwives

Central Manchester University Hospitals

Foundation NHS Trust

Manchester, UK

Jurgen Wille

Senior Social Worker

Metro-Regional Intellectual Disability Network

South Eastern Sydney Local Health District

Sydney, NSW, Australia

Helena Williams, MBBS, FRACGP

Executive Clinical Director

Southern Adelaide-Fleurieu-Kangaroo

Island Medicare Local Limited

Blackwood, SA, Australia

xi



ACKNOWLEDGMENTS

This book has been a multiyear undertaking, and we greatly appreciate the encouragement and support from colleagues, friends, and family. We have particularly benefited from the feedback of Drs. Arnold Kaluzny, Paul Batalden, and David Leach, who provided insight and understanding of the importance of making this book a practical teaching tool that addresses the continuing challenges of improving health quality and safety in the future.

We are indebted to those who have helped us understand how and why to tell a story—Tracy Granzyk, Martha Hayward, and Alide Chase, among others. The coordination and integration of the 30 contributing authors was a tremendous undertaking, and we were privileged to work with talented and knowledgeable colleagues from around the globe. Above all, we are profoundly grateful to our contributors, who were willing not only to take the time to author, and in some cases repeatedly revise chapters, but also to dig deeply into painful memories in the hope that their hard-learned lessons could benefit others.

The production of this book required a team effort at all levels and in multiple locations. Antonios Lilios of the Antonios Lilios Media Group was an indispensable partner in interviewing patients, family members, and healthcare professionals. Carolyn Oliver from the Cautious Patient Foundation, Gunnar Ohlen from the Karolinska Institute, and Maureen Bisognano from the Institute of Healthcare Improvement provided invaluable support that made it possible to conduct interviews. Doug Dotan, Sir Brian Jarman, Blair Sadler, Debora Simmons, Tanya Lord, Linda Kenney, Ilene Corina, Mary Ellen Mannix, Laura Townsend, and John James volunteered much appreciated time, resources, and wisdom. Many other people shared stories and insights that helped shape the book, including interviewees

Acknowledgments

whose stories space did not permit us to include in this volume. We are grateful to you all.

We would also like to acknowledge the assistance and guidance of the Editorial team at Jones & Bartlett Learning. Mike Brown, Chloe Falivene, and Lindsey Mawhiney patiently walked us through the publishing process. Our immediate and extended family members—LaBarre Blackman, Eliza Blackman, Helen Haskell Sr., David and Arlene Johnson, Harrison Mohr, Tore Barach, and Elijah Barach—generously and patiently adjusted their schedules and their lives to accommodate and support this project.

And finally, we acknowledge those who have suffered due to medical harm. This book is part of our commitment and covenant to patients and their families that it is possible to learn from their experiences to improve health care.

Julie K. Johnson Helen W. Haskell Paul R. Barach July 2014

xiv

FOREWORD

Robert Englander, MD, MPH

Quality and patient safety in health care have been on the forefront of the public's mind since the publication of the Institute of Medicine's seminal report *To Err Is Human* in 2000. The literature has emphasized the importance of revamping *systems and processes* to try to address the gaps in safety and quality that remain so pervasive and have eroded the public's trust. Of equal importance to the future of healthcare improvement and patient and population outcomes are the *healthcare professionals* who make up our systems of care.

Case Studies in Patient Safety: Foundations for Core Competency invites us into the world of patients, through their stories, their losses, and their suffering. It helps remind us that as healthcare professionals we devote our careers to serve patients and we need to rethink how we move from a clinician-centered to a patient- and family-centered system of care.

To be able to make this shift, we have focused over the past decade on the key desired competencies for health professionals generally and physicians specifically through their formation in education, training, and practice. Understanding why we are facing the current dilemma with health professionals not always equipped to deal with the patients, populations, and systems with which they work requires some understanding of the recent history of the notion of competencies for health professions.

Paul Batalden, a formidable figure in healthcare improvement, has among his famous quotes the statement that "Every system is perfectly designed to get the results it gets." The current design of the medical education system and the implication for its "results" is worth considering. The contemporary system of medical education

Foreword

remains predominantly based on the work of Abraham Flexner in 1910. His report was an indictment of the existing system of his time that was proprietary, without basis in the sciences, and without quality controls of any kind. He focused on the structure and process of medical education to ensure that physicians were grounded in the basic sciences and then exposed to clinical experiences only after that foundation was laid. He called for standards both for requisite preparation for medical school and for the basic two-by-two structure of medical school (2 years of basic science and 2 years of clinical science). The structure that emerged from that report has remained the predominant framework in most medical schools in North America today. Post medical school, internship and residency training provided an opportunity to bolster one's clinical care skills through application of basic science knowledge in the context of a specialty.

It is not surprising that with this emphasis on the scientific foundations of medicine, premedical education developed requisite sciences, and the Medical College Aptitude Test (MCAT) emerged as a way of testing that scientific knowledge prior to entering medical school. The other major contributor to one's application to medical school was the college transcript, with a particular emphasis on grades in the science courses. Thus, the premium competencies for entry into medical school and the first 2 years were clearly in the domain of Medical Knowledge. Patient Care competencies then took a prominent role during the clinical science years of the undergraduate medical education curriculum and residency training. And so it remained for the better part of a century. The medical education system was perfectly designed to attract individuals who were academically superior or who at least learned to do well on standardized tests, particularly in the sciences. They would then be expected to develop excellence in patient care skills through the clinical portions of education and training. The "results" of this system of education and training are extremely knowledgeable diagnosticians who are focused on the individual physician-patient dyad.

xvi

Why, then, are 100,000 patients dying unnecessarily every year in U.S. hospitals and millions more around the world? The answer seems to lie in the mismatch between the needs of the healthcare system and the output of the medical education system. Possessing competence in medical knowledge and patient care alone is no longer adequate to ensure quality care of patients and populations. In fact, the primacy of medical knowledge has probably declined to some extent with the advent of the information age. Information one did not carry in one's mind before the Internet explosion might take days, or even weeks, to find. Now that information is nearly all available at our fingertips 24 hours a day, 7 days a week.

As it began to be clear that Medical Knowledge and Patient Care competencies were necessary but not sufficient towards the end of the twentieth century, we began to take a new look at what it means to be a "good doctor." This work was spawned in large part in the United States by the Outcome Project of the Accreditation Council for Graduate Medical Education (Swing, 2007), in Canada by the CanMEDs project (Royal College of Physicians and Surgeons of Canada, 2005), and in Scotland by the Scottish Doctor initiative (Scottish Deans' Medical Curriculum Group, 2007). The overwhelming sentiment in all of these cases (and even some evidence) has emerged that possessing great medical knowledge and patient care skills is simply no longer adequate to be a good physician. For example, much data exists currently that physician empathy is correlated directly with patient outcomes (Hojat et al., 2011).

This novel book, through its portrayal of patient stories and suffering, powerfully illustrates the importance of competencies beyond the domains of Medical Knowledge for Practice and Patient Care. The authors use a list of 58 competencies in eight domains that the Association of American Medical Colleges published in a recent review of 158 competency lists that looked across disciplines, health-care professions, countries, and the continuum of physician education and training. These competencies represented as best we could all of the physician competencies in those 158 lists (Englander et al.,

xvii

Foreword

2013). The domains of competence began with those established by the ACGME Outcome Project: Medical Knowledge, Patient Care, Professionalism, Interpersonal and Communication Skills, Practice-Based Learning and Improvement, and Systems-Based Practice, and added the domains of Interprofessional Collaboration and Personal and Professional Development. The authors have identified the core competencies that are at work in the patient stories as a way to think about how to integrate competencies into classroom discussions.

Through a series of patient stories about medical errors they or loved ones experienced, this book provides compelling evidence that we are on the right track to defining the range of competencies required of the twenty-first-century physician. And yet, these stories also make it clear that we have a long way to go. One cannot help but be moved by these tragic stories of patients who have been made victims by the systems and individuals that let them down. What is striking as one reads these stories is the rarity with which Medical Knowledge or Patient Care competencies serve as the primary culprit in the error. To the contrary, perhaps the most common provider deficits gleaned across these stories are in the realms of Professionalism and Interpersonal and Communication Skills. How poignant, then, to underscore what is really important to being a good healthcare provider. These stories compel us to think about what competencies we really *need* our healthcare providers to possess to perform optimally in our healthcare system such as it is. And perhaps more importantly, if you are a medical educator, I implore you to think about the implications for your educational system. What is the optimal design for a system in which the final results are care providers competent in all the domains?

Finally, I hope you will be as grateful as I am to the patients and their family members for the courage and candor to share their stories to help steer us in the right direction as we begin to imagine and develop a new system far different from the one imagined by Flexner over a century ago.

xviii

References

- Englander, R., Cameron, T., Ballard, A. J., Dodge, J., Bull, J., & Aschenbrener, C. A. (2013). Toward a common taxonomy of competency domains for the health professions and competencies for physicians. *Academic Medicine*, 88(8), 1088–1094.
- Flexner, A. (1910). *Medical education in the United States and Canada: A report to the Carnegie Foundation for the Advancement of Teaching*. New York: The Carnegie Foundation for the Advancement of Teaching.
- Hojat, M., Louis, D. Z., Markham, F. W., Wender, R., Rabinowitz, C., & Gonnella, J. S. (2011). Physicians' empathy and clinical outcomes for diabetic patients. *Academic Medicine*, 86(3), 359–364.
- Institute of Medicine (IOM). (2000). To err is human: Building a safer health system. Washington, D.C.: National Academy Press.
- Royal College of Physicians and Surgeons of Canada. (2005). *The CanMEDS 2005 physician competency framework: Better standards. Better physicians. Better care.* In: Frank JR, ed. Ottawa, Ontario, Canada: The Royal College of Physicians and Surgeons of Canada. Available at: http://www.royalcollege.ca/portal/page/portal/rc/common/documents/canmeds/resources/publications/framework_full_e.pdf.
- Scottish Deans' Medical Curriculum Group (SDMCG). (2007). Learning outcomes for the medical undergraduate in Scotland: A foundation for competent and reflective practitioners. Available at: http://www.scottishdoctor.org/resources/scottishdoctor3.doc.
- Swing, S. R. (2007). The ACGME outcome project: Retrospective and prospective. *Medical Teacher*, 29(7), 648–654.

xix



Learning from Patient Stories

Julie K. Johnson, Helen W. Haskell, and Paul R. Barach

"They always say time changes things, but actually you have to change them yourself."

—Andy Warhol

Patient safety and patient-centered quality care have emerged as key drivers across the world for healthcare reform. Although there has never been more awareness and resources devoted to overall system improvement, care experience, quality, and safety, there remain opportunities to achieve savings, reduce risks, and improve performance. Current approaches are not producing the pace, breadth, or magnitude of improvement that patients demand and providers expect. Patients still experience needless harm. Patients and their family members struggle to have their voices heard. Proscriptive rules, guidelines, and checklists are helping to raise awareness and prevent some harm, but these efforts fall short of providing an ultrasafe system. A new system is needed—one that is centered around patients and their clinical microsystem, rendering clinical care processes that are more predictable, effective, efficient, and humane.

One does not have to look very far to find evidence of the devastating effects of medical errors on patients and their families. All too

Preface

often what is seen in the aftermath of an adverse event is a sensationalized story. The story illustrates that sometimes things can go horribly wrong and that the people who are there to help are part of a system that fails to protect the patient from more harm. This message produces fear and anger instead of creating an informed path forward. The stories pull at the heartstrings but fail to spur reflection, clinician engagement, and action for change.

We have been troubled by the repetitive nature of the errors and the tragic outcomes that emerge from the stories and the lack of systematic learning about preventing future events. In response, we set out to collect a set of stories that will help patients, their families, and their providers learn how medical errors and system failures lead to patient harm. The idea for the book is based on the story of Lewis Blackman, a 15-year-old boy who died from complications following elective surgery. We published a case study on Lewis's experience (Johnson et al., 2012), and we were delighted to discover that the case study approach was a powerful way to share Lewis's story as well as an effective method to teach about system failures, medical error, and harm prevention. When using the case as a teaching tool, we would first share the story from the family's perspective, provide a brief analysis of the events, and then invite learners to discuss what could be learned from the event. We were asked if we had other stories to share about patient harm from medical error, and that is how this book came to be.

Our aim is to present the stories as told from the firsthand perspective of the patient and family. This presented us with a challenge in developing the case studies because, like a Rashomon, there are multiple perspectives to each story. We chose to tell the story from the unique perspective of the patient. We acknowledge that this may present a limited retelling of the "full facts" as they unfolded. The stories we have collected are the patients' perceptions, and their reality, regardless of whether all the details can be supported by the evidence at hand. In the end, we agreed that we wanted to ensure that the patient's voice would be heard, highlighting their mental

wwii

model and mind-set as they experienced, witnessed, and understood the events.

The cases presented are devastating accounts of the patient and family experiences. While developing the book, colleagues would ask us, "Why are you focusing on the bad stories when there are so many stories with good outcomes? Shouldn't we learn from those, too?" And they are right. Our healthcare systems, across the world, have shining examples of how caregivers can heal and provide lifesustaining interventions, most of the time. However, we believe that for healthcare systems to become reliably better, that is, to deliver quality care, all the time, we need to enlist patients, families, and their stories. For us, this is, as Kierkegaard said, about "meeting people where they are." To do that, we need to allow patients and families to share their experiences and stories in their voice, and we need to accept that their experiences can have lessons for us all.

The book presents a challenge on how to think differently about how best to emotionally and intellectually engage patients and healthcare providers in healthcare transformation, which is the core work of this generation of caring professionals. We welcome your feedback about how you use these cases, as well as your suggestions and ideas for improvement.

Reference

Johnson, J., Haskell, H., & Barach, P. (2012). The Lewis Blackman Hospital Patient Safety Act: It's hard to kill a healthy 15-year-old. In: McLaughlin, C., Johnson, J., & Sollecito, W. (eds.), *Implementing continuous quality improvement in health care: A global casebook*. Sudbury, MA: Jones & Bartlett Learning.

xxiii



Setting the Stage for Patient Safety: Foundations for Core Competencies

Julie K. Johnson, Paul R. Barach, and Helen W. Haskell

"People must always come before numbers. It is the individual experiences that lie behind statistics and benchmarks and action plans that really matter, and that is what must never be forgotten when policies are being made and implemented."

—Robert Francis (2010)

Donald Schön speaks of the challenges in implementing meaningful change as moving from "The ivory tower to the swampy lowland" (Schön, 1983). We take this to mean that if health care as an industry aims to provide patient care that is safe and of high quality and value, we must move from academic theory and rhetoric to implementation strategies that are grounded in the day-to-day challenges of making health care safer. Stories of patient experiences, especially those that highlight the gaps, inconsistencies, and errors in the caregiving process can offer the bridge from theory to improvement.

Fundamental flaws in the healthcare system make it more difficult and less rewarding than ever to work in health care. The convergence of a complex amalgam of forces prevents clinicians from doing what they most want to do: Put their patients first at every step in the care process every time. Two separate, but closely related, forces drive this book—the need to improve the quality, safety, and value of health care for patients and the need to improve education, training, and joy of healthcare professionals. When designing strategies to

improve patient safety and health professionals' education, patients and their families cannot be overlooked. The stories of patient harm as told from the perspectives of patients and their families are the bridge between theory and action for improving education and practice.

We believe in the role and power of stories to effect change. Australian Aborigines say that the big stories—the stories worth telling and retelling, the ones in which you may find the meaning of your life—are forever stalking the right teller, sniffing and tracking like predators hunting their prey (Moss, 1999). Our hope is that the stories included in this book will: (1) support the use of patient stories to address multiple intercalated competencies across the health professions; (2) guide the formation of junior health professionals, as well as the continued development of established health professionals; (3) provide the foundation for joy and lifelong learning focused around the patient journey; and (4) prompt dialogue among the healthcare training and delivery communities about how to more effectively use patient stories to improve and assess interprofessional core competencies.

This introduction sets the stage for *Case Studies in Patient Safety:* Foundations for Core Competencies. We start with an overview of the magnitude of the problem of medical errors and patient harm, present lack of clinician engagement as a barrier to improving quality and safety of care, and discuss how patients are at the heart of improvement work. We outline the role of systems improvement efforts and how safety science has helped reconceptualize clinical risk. Regulators, accreditors, and policy makers have been front and center in incentivizing better care by more effective incentive alignment, which leads us directly into a discussion about the formation of health professionals, including education, training, and accreditation. We present a set of core competencies for health professions and discuss the challenges educators face in teaching these competencies to individuals as well as to healthcare teams. Finally, we make the case for the unique power of patient stories and outline how the

xxvi

case studies included in the book fit into the core competency framework.

The Impact of Medical Errors and Patient Harm

More than a decade has passed since the Institute of Medicine (IOM) published reports that focused national, as well as international, attention on the problem of medical errors and preventable harm to patients (IOM, 1999, 2001). The magnitude of the problem, as estimated by the IOM of as many as 98,000 deaths in U.S. hospitals per year, was initially hotly debated, but has since been widely accepted and replicated in other studies around the world. Although some questioned the validity of these numbers, a careful review suggests that these numbers are conservative estimates. Any estimate of an error rate is inexact, due to limitations of:

- Methods of data collection, analysis, and interpretation
- Unknown levels of underreporting (Pietro, Shyavitz, Smith, & Auerbach, 2000)
- Difficulty of retrospective analysis (Hayward & Hofer, 2001; McNutt, Abrams, & Arons, 2002)

The problem of medical errors leading to patient harm is not unique to the U.S. healthcare system. Across the world, people seeking care in hospitals are harmed 9.2% of the time, with death occurring in 7.4% of these events (de Vries et al., 2008). Furthermore, it is estimated that 43.5% of these harm events are preventable. A recent study that extrapolated the results of four studies that used a global trigger tool to identify medical error estimated that the number of patients harmed in the United States may be much higher—between 210,000 and 440,000 patient deaths each year (James, 2013). Based on statistics from the Centers for Disease Control (CDC) about the leading causes of death in the United States, these updated estimates would make medical errors the third leading cause of death, following

xxvii

heart disease and cancer (CDC, 2013). These estimates are reflected in studies from several countries (Davis, Stremikis, Schoen, & Squires, 2014).

The potential for patient harm does not stop at the hospital doors. It has been reported that nearly 1 in 5 patients suffer adverse events fairly soon after coming home from the hospital (Traynor, 2003). In one study, 76 of 400 consecutively discharged patients suffered a total of 78 adverse events within 5 weeks after being discharged home from the hospital. Twenty-three of the adverse events were deemed to be preventable, and 24 were classified as ameliorable (i.e., of a severity that could have been greatly reduced by altering procedures for patient care).

The evidence base supporting strategies to improve patient safety is now stronger than ever before (Shekelle et al., 2013; Wachter, Pronovost, & Shekelle, 2013). A body of evidence has emerged that highlights the types of errors that frequently occur and has identified medical error as a major public health problem that cannot be ignored. Progress has been made on multiple fronts during the past several decades. Patient safety and patient-centered care have become key drivers in healthcare reform. Clinicians, researchers, and policy makers have worked to improve the safety of patient care. Regulators, accreditors, and payers incentivize healthcare organizations to improve patient safety and reduce preventable adverse events by adopting evidence-based patient safety practices that reduce preventable adverse events.

Yet, despite large investments in effort and financial resources, we continue to see the effects of solutions that do not address the underlying systems of care and fail to recognize the context-dependent nature of clinical improvement (Phelps & Barach, 2014). Patients often struggle to have their voices heard. Processes of care are not as efficient as they could be, and costs continue to rise at alarming rates, while quality and safety issues remain.

xxviii

Early efforts at improving safety were somewhat naïve. According to Wachter and colleagues (2013), there were beliefs that "adopting some techniques drawn from aviation and other 'safe industries,' building strong information technology systems, and improving patient safety culture" would result in safer systems of care and improved patient safety. These efforts often paid scant attention to the underlying culture and misaligned financial and political incentives. In reality, safer patient care requires ongoing, systematic efforts guided by strong, value-based, and courageous leadership that is willing to be truthful to clinicians and patients about the challenges ahead. Building reliability into healthcare operations can only occur with a culture of transparency and reflection designed with the patient and the clinical microsystems at the frontlines of care.

Lack of Clinician Engagement as a Barrier to Improving Quality and Safety of Care

Misalignment of financial incentives, lack of clear transparent accountability, and limited clinician engagement remain the biggest obstacles in addressing the growing implementation gap in providing cost-effective, high-quality care. Physician discontent and cynicism and the growing numbers of burnt-out clinicians all point to a serious gap in trust and lack of engagement in clinical improvement (Jorm, 2012). Engaging clinicians and creating authentic partnerships are key to facilitation of clinician adoption of new care models.

Effective improvement of care will require meaningful efforts to address the engagement gap with clinicians in large part because new care models require doctors to significantly change their behavior. Trust-building steps in which clinicians can see and understand the value and effort in implementing improvement strategies are key. Lencioni (2002) posits that teams fail because they fall prey to five dysfunctions that undermine their cohesiveness and reliability:

xxix

- 1. Absence of trust
- 2. Fear of conflict
- 3. Lack of commitment
- 4. Avoidance of accountability
- **5.** Inattention to results

Members of effective cohesive teams learn to trust one another, but only if they are able to engage and challenge each other in a respectful manner around ideas, commit to decisions and plans of action, hold one another accountable for delivering against those plans, and focus on the achievement of collective results.

Patients at the Heart of Improvement

Patient-centered care has been defined as care that is respectful of, and responsive to, individual patient preferences, needs, and values and ensures that patient values guide all clinical decisions (IOM, 2001).

The current fragmentation of healthcare services makes effective application of a patient-centered model of quality improvement difficult, if not impossible. Care that is truly patient centered can only be achieved with active patient engagement at every level of care design and implementation. Patients who feel respected, attended to, and in full partnership of their care are more compliant with their medications and medical appointments, feel better about their care, and have better overall health (Blue Shield of California, 2012).

At the most basic, patient-centered care involves a reconceptualization of the patient from the passive object of medical intervention to an active "consumer" or "user" of health services who coproduces and "owns" his or her own health. Reframing of patient care is needed from a task-oriented, practitioner-centered model to a systems-based, patient-centered model that looks to the actual relationships within the sociotechnical microsystems in which care is actually

www

delivered (Barach & Johnson, 2006). This must also include a commitment to full disclosure when things go awry, setting up peer support programs for clinicians who have harmed patients, and long-term support for patients, families, and providers who are involved in adverse care (Australian Commission on Safety and Quality in Healthcare, 2011).

Safety Science and Systems Improvement

There has been an important reconceptualization of clinical risk through the emphasis on how upstream "latent factors" enable, condition, or exacerbate the potential for "active errors" and patient harm. Decades of work within and outside health care point to system flaws that conspire and set good people up to fail. Understanding the characteristics of a safe, resilient, and high-performing system requires research to optimize the dynamic relationships between people, tasks, and their organizational and physical environments (Mohr & Batalden, 2006). The sociotechnical approach suggests that adverse incidents can be examined from both an organizational perspective that incorporates both the concept of latent conditions and the cascading nature of human error, commencing with management decisions and actions (or inactions). Organizational resilience is found in the responsiveness of care delivery teams to an emerging hazard. Some teams are more resilient than others and are able to recover from failed decisions and processes. That is, they are able to recover from errors reliably and reduce future patient harm, whereas others contribute to patient harm, do not learn from their errors, and repeat them (Hollangel, Woods, & Leveson, 2006).

People often find ways of getting around processes that seem to be unnecessary or that impede the workflow. This is known as *normalization of deviance*. By a deviant organizational behavior, we are referring to "an event, activity or circumstance, occurring in and/or produced by a formal organization that deviates from both formal design goals and normative standards or expectations, either in the

xxxi

fact of its occurrence or in its consequences" (Vaughn, 1999). Once a community normalizes a deviant organizational practice, it is no longer viewed as an aberrant act that elicits an exceptional response; instead, it becomes a routine activity that is commonly anticipated and frequently used (Vaughan, 1996).

A permissive ethical climate, an emphasis on financial goals at all costs, and an opportunity to act amorally or immorally all contribute to managerial decisions to initiate deviance. This accumulated acceptance of cutting corners or making workarounds over time poses a great danger to health care. Similar findings have been described in investigations into major episodes of clinical failure, suggesting that health systems are failing to heed the lessons of history (Dyer, 2001; Queensland Health Systems Review, 2005).

Incentivizing Better Care: Regulators, Accreditors, and Policy Makers

Major changes are needed in the design and delivery of effective healthcare systems. Given the pressures to deliver better value, the systems that will thrive will focus on quality of care (including costefficiency) through innovative healthcare delivery that results from the alignment of incentives with payers, patients, and other participants in the healthcare equation. Jim Collins (2001), in his seminal book *From Good to Great*, underscores the fundamental need for leaders to address misaligned incentives and encouraging employees to speak up to produce reliable outcomes.

The Joint Commission (TJC) revamped its regulatory framework focusing on clinician engagement given the ongoing data suggesting that, despite much regulatory effort, harm in healthcare systems continued to happen. In 2002, TJC established the National Patient Safety Goals (NPSGs) program to help accredited organizations address specific areas of concern with regard to patient safety and to create national benchmarks that were evidence based and that could be upheld in public.

xxxii

Payers have been focusing on this misalignment and providing financial incentives to improve the quality and safety of patient care. For example, in 2008 Medicare stopped reimbursing hospitals for treating eight avoidable hospital-acquired conditions—foreign object retained after surgery, air embolism, blood incompatibility, stages III and IV pressure ulcers, in-hospital falls and trauma, catheter-associated urinary tract infection (UTI), vascular catheter-associated infection, and certain surgical site infections—as a way to discourage and penalize hospitals for poor-quality care and encourage them to eliminate avoidable complications.

Equally, around the world, the findings of the Francis Report into the failings of care at the UK Mid Staffordshire Hospital (Francis, 2010), the Special Commission into Acute Care Services in New South Wales Public Hospitals (Garling Inquiry) (Garling, 2008), and the cover-up by the Clinical Quality Commission (CQC) of the University Hospitals of Morecambe Bay NHS Trust (Care Quality Commission, 2013) highlight the problems with lax regulatory oversight (Vaughan, 1999). These inquiries found that during the periods under investigation many staff, patients, and managers had raised concerns about the standard of care provided to patients. The tragedy was that they were ignored and the concerns were covered up. Senior managers seemed more concerned about protecting their reputation and their next job than about the lives of patients in the systems under their oversight (Care Quality Commission, 2013). Finally, and perhaps of most concern, these public reports documented a widespread culture of denial, a lack of attentiveness to patient concerns, and pervasive normalized deviance (Vaughan, 1999).

Implications for Training and Education

The IOM (1999) recommended a focus on the initial and continuing education and training of healthcare professionals in order to have the greatest impact. The IOM recommended that healthcare organizations make patient safety a priority by establishing patient

xxxiii[|]

safety programs that would "establish interdisciplinary team training programs, that incorporate proven methods for team management" (p. 135). The IOM also recommended that standards and expectations for healthcare organizations and professionals place a greater emphasis on team-based patient safety. The IOM proposed that such standards should mandate periodic recertification and relicensing of doctors, nurses, and other key providers. Recertification would focus both on provider competence and on knowledge of patient safety practices, such as functioning effectively in an interdisciplinary healthcare team.

At the heart of efforts to improve patient safety, we need an approach to healthcare training that produces professionals who not only demonstrate competence in clinical skills, but who are also accountable to a core set of competencies, with competency defined as "an observable and measureable ability, integrating multiple components such as knowledge, skills, values, and attitudes" (Englander et al., 2013). The gap between training of healthcare professionals and meeting patient needs remains wide. Without reliable and valid measures, learning deficiencies cannot be diagnosed, accurate feedback cannot be provided, and appropriate instructional strategies for remediation cannot be selected.

Core Competencies for Health Professions Education

Education has shifted toward competency-based education across the health professions with varied competency frameworks emerging from different countries. For example, frameworks for physician competencies have been developed in different countries—these include the Outcome Project of the Accreditation Council for Graduate Medical Education (ACGME) (Swing, 2007) and American Board of Medical Specialties (ABMS) in

xxxiv

the United States, the CanMEDS Framework of the Royal College of Physicians and Surgeons of Canada (Curriculum & Group, 2007), the Scottish Doctor Project in Scotland (Curriculum & Group, 2007), and the Framework for Undergraduate Medical Education in the Netherlands (Laan, Leunissen, & Van Herwaarden, 2010). Some health professions, such as nursing, have used competency frameworks for decades, although integration of core competencies into health professions education can be slow. Although different disciplines recognize the value of competency-based education, there has not been a common set of competencies for health professionals. Englander and colleagues reviewed 153 health professions' competency lists, to identify a robust list of competency domains, published as of June 2012 that could accommodate all healthcare professions. **Table FM-1** summarizes the eight competency domains. The full set (58 competencies) is included in the appendix. The Association of American Medical Colleges (AAMC) has put forth the list as a recommended common taxonomy of competencies for research and educators within medicine and other health professions (Englander et al., 2013).

These competency domains have implications for health professional education, training, and accreditation. Some of the domains represent areas that have been taught and assessed as part of the rich tradition of health professions education, for example, Patient Care and Knowledge for Practice. Other domains, such as Systems-Based Practice and Practice-Based Learning and Improvement, are more challenging for educators to assess, and they continue to struggle with teaching these competencies to individuals as well as to healthcare teams functioning within a clinical microsystem. The competencies have improved our understanding in describing a framework of professionalism, but they challenge educators especially in regards to education and assessment.

XXX71

Table FM-1 Competency Domains

Competency Domain	Definition of Competence
Patient Care	Provide patient-centered care that is compassionate, appropriate, and effective for the treatment of health problems and the promotion of health.
Knowledge for Practice	Demonstrate knowledge of established and evolving biomedical, clinical, epidemiological, and socialbehavioral sciences, as well as the application of this knowledge to patient care.
Practice-Based Learning and Improvement	Demonstrate the ability to investigate and evaluate one's care of patients, to appraise and assimilate scientific evidence, and to continuously improve patient care based on constant self-evaluation and lifelong learning.
Interpersonal and Communication Skills	Demonstrate interpersonal and communication skills that result in the effective exchange of information and collaboration with patients, their families, and health professionals.
Professionalism	Demonstrate a commitment to carrying out professional responsibilities and an adherence to ethical principles.
Systems-Based Practice	Demonstrate an awareness of and responsiveness to the larger context and system of health care, as well as the ability to call effectively on other resources in the system to provide optimal health care.
Interprofessional Collaboration	Demonstrate the ability to engage in an interprofessional team in a manner that optimizes safe, effective patient- and population-centered care.
Personal and Professional Development	Demonstrate the qualities required to sustain lifelong personal and professional growth.

The Power of the Patient Story in Teaching Core Competencies

Patient stories capture the rich complexity and dynamic progression of the patient journey and offer a rare opportunity for providers and

NNN911

teachers to explore the competency domains beyond direct patient care and discipline-specific knowledge. This text, Case Studies in Patient Safety: Foundations for Core Competencies, makes an effort to systematize the telling and recording of stories of patient harm, the learning from these stories, and strategies for how we apply them in progressing a competency-based framework. The patient stories offer a way to integrate and teach health professional core competencies in a manner that is both relevant and engaging for clinicians. Using the core competencies as a lens for thinking about the cases, we see where the competencies can support and encourage highvalue, patient-centered care for patients and their families. Our focus on complex real-world patient cases ensures that patients and their experiences are always at the center of all educational efforts. In real life, patient care does not come neatly compartmentalized into discrete categories. The biggest challenge educators face in actuating the competencies for healthcare professionals is that the individual competencies are isolated and difficult to assess in the reductionist approach that is usually taken.

The stories we have collected are contextualized and grounded within the clinical microsystem, or multiple microsystems, which allow a holistic integration of the core competencies, while respecting the patient journey. The stories address and bring together the medical knowledge in the cases with the social, sociological, and relational aspects of the patient–provider interaction. The book is organized into eight sections, each representing a core competency. Each section starts with a brief overview of the competency and a description of the case studies that are included in the section. Each case is presented in a consistent format, an editors' note that provides the context, specific learning objectives for the case, the story as told from the patient/family perspective, and a case discussion written by the editors to prompt thinking about some of the relevant patient safety issues. The case ends with questions for classroom discussion.

The allocation of cases to a particular competency is based on how well the case describes elements of that competency. Most of the

xxxvii

cases relate to and touch upon multiple competencies. For example, in Case 1, Lewis Blackman's death in the hospital following surgery, was allocated to the section on Patient Care, but it is also relevant to Knowledge for Practice, Professionalism, and Interpersonal and Communication Skills. The final section in this book is Personal and Professional Development. This book of case studies provides a vehicle for Personal and Professional Development, where health professionals "demonstrate the qualities required to sustain lifelong personal and professional growth."

References

- Australian Commission on Safety and Quality in Healthcare. (2011). Patient-centred care: Improving safety and quality through partnerships with patients and consumers. Sydney: Author.
- Barach, P., & Johnson, J. (2006). Understanding the complexity of redesigning care around the clinical microsystem. *Quality & Safety in Health Care*, 15(Suppl 1), i10–i16.
- Blue Shield of California. (2012). Empowerment and engagement among low-income Californians: Enhancing patient-centered care. San Francisco: Author.
- Care Quality Commission. (2013). Project Ambrose.
- Centers for Disease Control and Prevention (CDC). (2013). Leading causes of death. Available at: http://www.cdc.gov/nchs/fastats/lcod.htm.
- Collins, J. (2001). Good to great: Why some companies make the leap and others don't. New York: Harper Collins.
- Curriculum & Group. (2007). Learning outcomes for the medical undergraduate in Scotland: A foundation for competent and reflective practitioners (3rd ed.). Dundee, Scotland: AMEE Office.
- Davis, K., Stremikis, K., Schoen, C., & Squires D. Mirror, Mirror on the Wall, 2014 Update: How the U.S. Health Care System Compares Internationally, The Commonwealth Fund, June 2014.
- De Vries, E., Ramrattan, M., Smorenburg, S., Gouma, D., & Boermeester, M. (2008). The incidence and nature of in-hospital adverse events: A systematic review. *Quality and Safety in Health Care*, 17, 216–223.
- Dyer, C. (2001). Bristol inquiry condemns hospital's "club culture." BMJ, 323, 181.
- Englander, R., Cameron, T., Ballard, A. J., Dodge, J., Bull, J., & Aschenbrener, C. A. (2013). Toward a common taxonomy of competency

XXXVIII

- domains for the health professions and competencies for physicians. *Academic Medicine*, 88, 1088–1094.
- Francis, R. (2010). *Independent inquiry into care provided by Mid Stafford-shire NHS Foundation Trust*. London: The Stationery Office.
- Garling, P. (2008). Final Report of the Special Commission of Inquiry: Acute care in NSW public hospitals. New South Wales, Australia, State of NSW.
- Hayward, R. A., & Hofer, T. P. (2001). Estimating hospital deaths due to medical errors: Preventability is in the eye of the reviewer. *JAMA*, 286, 415–420.
- Hollangel, E., Woods, D., & Leveson, N. (eds.). (2006). Resilience engineering: Concepts and precepts. Aldershot, England: Ashgate.
- Institute of Medicine. (1999). *To err is human: Building a safer health system*. Washington, D.C.: National Academy Press.
- Institute of Medicine. (2001). Crossing the quality chasm: A new health system for the 21st century. Washington, D.C.: National Academy Press.
- James, J. (2013). A new, evidence-based estimate of patient harms associated with hospital care. *Journal of Patient Safety*, *9*, 122–128.
- Jorm, C. (2012). Reconstructing medical practice: Engagement, professionalism and critical relationships in health care. Surrey, UK: Gower.
- Laan, R. F., Leunissen, R. R., & Van Herwaarden, C. L. (2010). The 2009 framework for undergraduate medical education in the Netherlands. *German Journal for Medical Education (GMS Z Med Ausbild)*, 27, Doc35.
- Lencioni, P. (2002). The five dysfunctions of a team. San Francisco: Jossey-Bass.
- Moss, R. (1999). Dream Gates. Louisville, Colorado: Sounds True.
- McNutt, R. A., Abrams, R., & Arons, D. C. (2002). Patient safety efforts should focus on medical errors. JAMA, 287, 1997–2001.
- Mohr, J., & Batalden, P. (2006). Integrating approaches to health professional development with approaches to improving patient care. In: McLaughlin, C., & Kaluzny, A. (eds.), *Continuous quality improvement in health care: Theory, implementations, and applications* (3rd ed.). Boston: Jones & Bartlett.
- Phelps, G., & Barach, P. (2014). Why the safety and quality movement has been slow to improve care? *International Journal of Clinical Practice*, 68(8), 932–935.
- Pietro, D. A., Shyavitz, L. J., Smith, R. A., & Auerbach, B. S. (2000). Detecting and reporting medical errors: Why the dilemma? *BMJ*, 320, 794–796.
- Queensland Health Systems Review. (2005).

xxxix

- Schön, D. (1983). The reflective practitioner: How professionals think in action. New York: Basic Books.
- Shekelle, P. G., Pronovost, P. J., Wachter, R. M., McDonald, K. M., Schoelles, K., . . . Walshe, K. (2013). The top patient safety strategies that can be encouraged for adoption now. *Annals of Internal Medicine*, 158, 365–368.
- Swing, S. R. (2007). The ACGME outcome project: Retrospective and prospective. *Medical Teacher*, 29, 648–654.
- Traynor, K. (2003). Adverse events occur after hospital discharge, study finds. *American Journal of Health-System Pharmacy*, 60, 534.
- Vaughan, D. (1996). The Challenger launch decision: Risky technology, culture, and deviance at NASA. Chicago: University of Chicago Press.
- Vaughan, D. (1999). The dark side of organizations: Mistake, misconduct, and disaster. *Annual Review of Sociology*, 25, 271–305.
- Wachter, R. M., Pronovost, P., & Shekelle, P. (2013). Strategies to improve patient safety: The evidence base matures. *Annals of Internal Medicine*, 158, 350–352.