Error Reduction and Prevention in Surgical Pathology

Raouf E. Nakhleh
Keith E. Volmar
Editors

Second Edition

Springer

Error Reduction and Prevention in Surgical Pathology

Raouf E. Nakhleh • Keith E. Volmar
Editors

Error Reduction and Prevention in Surgical Pathology

Second Edition

Springer

Editors
Raouf E. Nakhleh
Mayo Clinic Florida
Jacksonville, FL
USA

Keith E. Volmar
Rex Healthcare
Raleigh, NC
USA

ISBN 978-3-030-18463-6 ISBN 978-3-030-18464-3 (eBook)
https://doi.org/10.1007/978-3-030-18464-3

This Springer imprint is published by the registered company Springer Nature Switzerland AG
The registered company address is: Gewerbestrasse 11, 6330 Cham, Switzerland

Preface

The first edition of *Error Reduction and Prevention in Surgical Pathology* was an opportunity to pull together into one place all the ideas related to errors in surgical pathology and to organize a discipline in error reduction.

The second edition is an opportunity to refine this information. Most notably, the second edition has a second editor that brings a fresh and younger perspective. In this edition, we wanted to continue to include what works and to improve sections that have not met the mark. We tried to reorganize the book to improve its usability and practicality and to include topics that were not previously addressed.

In the introductory section, we include general principles and ideas that are necessary to understand the context of error reduction. In addition to general principles of error reduction and legal and regulatory responsibilities, we added a chapter on regulatory affairs and payment systems which increasingly may be impacted by error reduction and improvement activities. This later chapter is particularly important in view of the implementation of various value-based payment programs, such as the Medicare Merit-Based Incentive Payment System, that became law in 2015.

The remainder of the book is organized in a similar manor to the first edition with chapters devoted to all aspects of the test cycle, including pre-analytic, analytic, and post-analytic.

The pre-analytic section is focused on specimen identification before the specimen gets to the lab as well as within the lab. Tissue processing, routine histology, and immunostains are addressed in this section from the technical and procedural aspect of the work.

The analytic section emphasizes how pathologists do their work and how diagnoses are made. There is an attempt to understand the factors that are necessary to achieve an accurate diagnosis. The practice of medicine for pathologists is dependent greatly on a pathologist's subjective ability to interpret tissue and manage cases appropriately to arrive at an accurate diagnosis. Central to this is the pathologist's knowledge and experience. Other factors that may be needed in any particular case include clinical correlation, standardized criteria and terminology, ancillary studies, and a system of review.

In the first edition, the post-analytic section was focused on the creation and delivery of reports as well as other aspects of communication. While this is maintained with emphasis on procedures, structures, and delivery systems of pathology reports, new chapters were added to focus other important factors that significantly enhance patient care by reducing error. These include the leveraging of information technology to understand fully how error occur within a laboratory, tracking and managing these problems over time and conducting root cause analysis to continuously improve the system.

The final chapter is devoted to disclosure of errors. This topic has only recently been introduced to the field of pathology but is important to understand because patient outcomes is what really matters, and the pathology community has to understand the effect of errors on patients. We also have to be prepared for the possibility of being involved with error disclosures.

Jacksonville, FL, USA — Raouf E. Nakhleh
Raleigh, NC, USA — Keith E. Volmar

Contents

Contributors

Timothy Craig Allen, MD, JD Department of Pathology, The University of Mississippi Medical Center, Jackson, MS, USA

Richard W. Brown, MD System Laboratory Services, Memorial Hermann Health System, Houston, TX, USA

Diana M. Cardona, MD Department of Pathology, Duke University Medical Center, Durham, NC, USA

Y. Chen, MPH, PSSP Department of Pathology and Laboratory Medicine, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA, USA

Dhananjay Chitale Department of Pathology, Henry Ford Health System, Detroit, MI, USA

Suzanne M. Dintzis Department of Pathology, University of Washington Medical Center, Seattle, WA, USA

Bryce S. Hatfield, MD Department of Pathology, Virginia Commonwealth University Health, Richmond, VA, USA

Yael K. Heher, MD, MPH, FRCPC Department of Pathology and Laboratory Medicine, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA, USA

Michael O. Idowu, MD, MPH Department of Pathology, Virginia Commonwealth University Health, Richmond, VA, USA

Shannon J. McCall, MD Department of Pathology, Duke University, Durham, NC, USA

Carolyn Mies, MD Department of Pathology and Laboratory medicine, University of Pennsylvania, Philadelphia, PA, USA

Jonathan L. Myles, MD Department of Pathology, Robert J. Tomsich Institute of Pathology and Laboratory Medicine, Cleveland Clinic, Cleveland, OH, USA

Raouf E. Nakhleh, MD Mayo Clinic Florida, Jacksonville, FL, USA

Anil Vasdev Parwani, MD, PhD, MBA Division of Pathology Informatics, Department of Pathology, The Ohio State University, Columbus, OH, USA

Stephen S. Raab, MD Department of Pathology, University of Mississippi Medical Center, Jackson, MS, USA

Maxwell L. Smith, MD Department of Laboratory Medicine and Pathology, Mayo Clinic Arizona, Scottsdale, AZ, USA

Keith E. Volmar, MD Rex Healthcare, Raleigh, NC, USA

Part I
Introduction and General Principles

Chapter 1
General Principles of How Errors Occur and How They May Be Reduced

Maxwell L. Smith and Stephen S. Raab

How Errors Occur

Medical errors have devastating potential for the patient and provider alike. A basic understanding of how errors occur is the first necessary step in a process to identify and reduce errors. This section covers the definition of error, different classification systems for error, and various models for error causation.

Definition of Error

In its landmark publication, the Institute of Medicine (IOM) estimated that medical error was the cause of between 44,000 and 98,000 patient deaths each year [1]. While these estimates have been challenged [2], there is no doubt that the medical system in the United States generates errors that result in patient harm and death. The IOM also estimated the financial cost of these errors between $17 billion and $29 billion annually [1]. In the present day of healthcare reform and cost reduction [3], error reduction looms large as a potential target, even in laboratory medicine [4]. Keep in mind that the estimates provided by the IOM are based on *deaths* related to medical error, and fail to include the likely larger numbers related to medical errors resulting in increased patient *morbidity* and cost.

As defined by the IOM, medical error is the failure of a planned action to be completed as intended or the use of a wrong plan to achieve a specific aim [1].

M. L. Smith
Department of Laboratory Medicine and Pathology, Mayo Clinic Arizona, Scottsdale, AZ, USA

S. S. Raab (✉)
Department of Pathology, University of Mississippi Medical Center, Jackson, MS, USA

R. E. Nakhleh, K. E. Volmar (eds.), *Error Reduction and Prevention in Surgical Pathology*, https://doi.org/10.1007/978-3-030-18464-3_1

In laboratory medicine, this equates to the failure to diagnose/result correctly the disease process/laboratory test occurring in a patient. Critical analysis of the IOM's definition reveals no requirement for patient harm. Because error identification is independent of patient outcome, many will further qualify errors as "harmful," "no harm," and "near miss" [5, 6]. Observational studies show that the majority of medical errors do not result in patient harm and fall into the "near-miss" or "no-harm" category [5]. The distinction between "near miss" and "no harm" is that "near-miss" events are errors in a work process that are caught before reaching the patient, while "no-harm" events are errors that reach the patient but do not result in harm. A good example is found in the blood transfusion service. A unit of blood is issued for patient A but is incorrectly hung on the IV rack for patient B. If, prior to hooking up the IV line, a nurse recognizes the error and returns the blood to the blood bank, this is a "near miss." However, if the nurse transfuses the blood but fortunately the patient has no adverse reaction, this would be a "no-harm" event.

Unfortunately, the term error has a negative connotation, especially in the medical field. This has led to difficulty in the transparency of reporting medical errors. This problem is furthered by a near complete lack of education with regard to error in the United States medical training system [7]. Because of these issues, some authors refer to errors as "defects" in an attempt to increase acceptance and discussion of medical error [8]. The laboratory environment is particularly suited to the term "defects" because of the similarities to manufacturing processes [9].

Classification of Error

A variety of different error classification schemas have been developed. During root causes analysis of medical errors, it is often found that errors have both active and latent components [5]. An active error is when a person or machine does something outside of the standard workflow process. An example is a pathologist picking up a slide and correctly interpreting a tubular adenoma, but reporting that on the incorrect patient. A latent error is when there are aspects of the workflow process that encourage an error. An example is having colon polyps from two different patients on the same slide tray.

Another way to classify error is by testing phase. Lundberg et al. described the total testing process (TTP), which includes six phases of laboratory testing:

1. Clinician decides to perform a test and selects a test – Pre–pre-analytic
2. Test sample is obtained and transported to the laboratory – Pre-analytic
3. Laboratory processes and interprets the test – Analytic
4. Laboratory reports the test result – Post-analytic
5. Clinician makes a treatment decision based on the results – Post–post-analytic [10]. Stroobants et al. studied the error frequency of the various phases of testing and found that the majority of errors occurred in the pre-analytical phases [4]. Of course, the laboratory often only has control of the analytical phase. Laboratorians

will often dichotomize the analytic phase into technical phases and interpretive phases as the administration and leadership over these two domains is usually different [11].

The Eindhoven Classification Model classifies errors into three main root cause domains and helps to focus the root cause on the process and latent factors rather than blaming the human perceived to be responsible [12]. The technical domain includes the information technology, tools, machines, and forms. The organizational domain includes the protocols in place, transfer of knowledge, management priorities, and the culture. The human factors are broken down into knowledge-based behaviors, rule-based behaviors, and skill-based behaviors.

In the amendment root cause analysis work by Zarbo et al., four main categories of error were determined including reporting, patient identification, specimen, and interpretive errors [8, 13].

Models of Error Causation

There are two popular models of error causation: the Swiss Cheese model and Heinrich's Safety Pyramid.

The Swiss Cheese model (Fig. 1.1) illustrates how patient harm is often the result of several errors, either latent or active, that occur in each step of the care process [14].

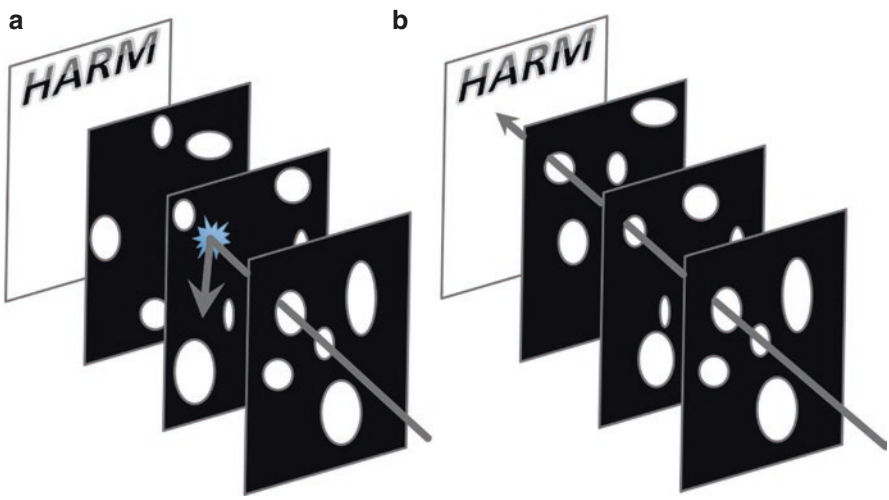

Fig. 1.1 The Swiss Cheese model of error causation. Each slice of cheese represents a set in the healthcare process. The "holes" represent errors in each individual step, either active or latent. Some of latent holes are relatively consistent. The active holes may open and close depending on worker behavior. Most errors result in a near-miss event as the subsequent step recognizes the threat and disarms it (**a**). Rarely, defects in all the steps line up and provide access to the patient for harm (**b**). (Adapted from Reason [14])

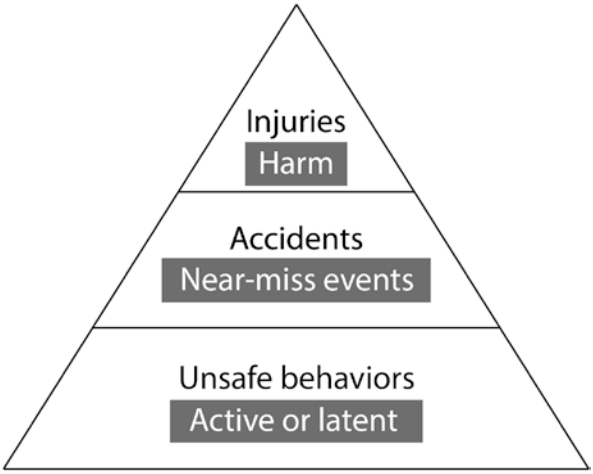

Fig. 1.2 Heinrich's Safety Pyramid. Heinrich's original concepts are in black text. Updated concepts in white text illustrating how Active and latent conditions in a system can lead to near-miss events, which ultimately have the potential for patient harm if not caught and corrected. (Adapted from Heinrich [16])

In this model, each step in a work process is represented by a single slice of Swiss cheese. The "holes" in the cheese represent latent or active defects. Most often, errors that occur in one step are caught and corrected before reaching the patient with a resulting near-miss event. However, when multiple errors across several steps line up, there is access to the patient for harm. One of the benefits of this model is that it helps to focus investigation of defects on the healthcare system as opposed to the individual. Although the model is well known in the quality literature, there is no agreement among quality and healthcare professionals as to all the details of the metaphor [15].

Heinrich investigated safety and accident causation in the industrial field and developed the Safety Pyramid, which is often referred to as Heinrich's Safety Pyramid (Fig. 1.2) [16]. His original theory was that the base of the pyramid consisted of unsafe behavior by workers. This widespread unsafe work occasionally led to accidents in the workplace, the middle tier of the pyramid. Finally, these accidents rarely led to severe workplace injuries or death, the top of the pyramid. He postulated that focusing on safe workplace behaviors (the base) would in turn decrease the frequency of accident and risk of severe injuries or death in the workplace. Heinrich's focus was on the worker and unsafe acts and this has led some to refute the usefulness of the Safety Pyramid claiming unsafe acts are not the principle cause of accidents and furthermore, that decreasing accident frequency will not reduce severe injuries [17]. However, updating the pyramid with a more current theory of active and latent errors as the base, near-miss events as the middle tier, and patient harm as the top tier results in a refined and current Safety Pyramid for healthcare.

Human Behavior

While the preceding models of error causation help to direct the investigation of the system in which workers are functioning, human behavior must also be addressed. The spectrum of human behavior and how it is managed have a direct effect on the