Series Editor
Michael Laposata

Diagnostic Standards of Care

Clinical Chemistry

Quality in Laboratory Diagnosis

James H. Nichols
Carol A. Rauch

demos
MEDICAL

Clinical Chemistry

Quality in Laboratory Diagnosis

Diagnostic Standards of Care

Michael Laposata, MD, PhD
Series Editor

Coagulation Disorders
Quality in Laboratory Diagnosis
Michael Laposata, MD, PhD

Clinical Microbiology
Quality in Laboratory Diagnosis
Charles W. Stratton, MD

Laboratory Management
Quality in Laboratory Diagnosis
Candis A. Kinkus

Transfusion Medicine
Quality in Laboratory Diagnosis
Quentin G. Eichbaum, MD, PhD, MPH, MFA, FCAP
Garrett S. Booth, MD, MS
Pampee P. Young, MD, PhD

Clinical Chemistry
Quality in Laboratory Diagnosis
James H. Nichols, PhD, DABCC, FACB
Carol A. Rauch, MD, PhD, FCAP

Forthcoming in the Series
Hematology/Immunology

Diagnostic Standards of Care Series

Clinical Chemistry

Quality in Laboratory Diagnosis

James H. Nichols, PhD, DABCC, FACB
Professor of Pathology, Microbiology, and Immunology
Medical Director of Clinical Chemistry
Vanderbilt University School of Medicine
Nashville, Tennessee

Carol A. Rauch, MD, PhD, FCAP
Associate Professor of Pathology, Microbiology, and Immunology
Associate Medical Director of Clinical Laboratories
Associate Medical Director of Vanderbilt Pathology Laboratory Services
Vanderbilt University School of Medicine
Nashville, Tennessee

demosMEDICAL
New York

Visit our website at www.demosmedpub.com

ISBN: 978-1-62070-030-3
e-book ISBN: 978-1-61705-189-0

Acquisitions Editor: Richard Winters
Compositor: S4Carlisle Publishing Services

Medicine is an ever-changing science. Research and clinical experience are continually expanding our knowledge, in particular our understanding of proper treatment and drug therapy. The authors, editors, and publisher have made every effort to ensure that all information in this book is in accordance with the state of knowledge at the time of production of the book. Nevertheless, the authors, editors, and publisher are not responsible for errors or omissions or for any consequences from application of the information in this book and make no warranty, expressed or implied, with respect to the contents of the publication. Every reader should examine carefully the package inserts accompanying each drug and should carefully check whether the dosage schedules mentioned therein or the contraindications stated by the manufacturer differ from the statements made in this book. Such examination is particularly important with drugs that are either rarely used or have been newly released on the market.

Library of Congress Cataloging-in-Publication Data

Nichols, James H., 1961– author.
Clinical chemistry : quality in laboratory diagnosis / James H. Nichols, Carol A. Rauch.
p. ; cm. — (Diagnostic standards of care)
Includes bibliographical references and index.
ISBN 978-1-62070-030-3—ISBN 1-62070-030-1—ISBN 978-1-61705-189-0 (e-book)
I. Rauch, Carol A., author. II. Title. III. Series: Diagnostic standards of care.
[DNLM: 1. Chemistry, Clinical. 2. Clinical Chemistry Tests—methods. QY 90]
RB40
616.07'56—dc23

2013021660

Printed in the United States of America by Bradford & Bigelow.
13 14 15 16 17 / 5 4 3 2 1

Contents

Series Foreword

"Above all, do no harm." This frequently quoted admonition to health care providers is highly regarded, but despite that, there are few books, if any, that focus primarily on how to avoid harming patients by learning from the mistakes of others.

Would it not be of great benefit to patients if all health care providers were aware of the thrombotic consequences from heparin-induced thrombocytopenia before a patient's leg is amputated? The clinically significant, often lethal, thrombotic events that occur in patients who develop heparin-induced thrombocytopenia would be greatly diminished if all health care providers appropriately monitored platelet counts in patients being treated with intravenous unfractionated heparin.

It was a desire to learn from the mistakes of others that led to the concept for this series of books on diagnostic standards of care. As the test menu in the clinical laboratory has enlarged in size and complexity, errors in selection of tests and errors in the interpretation of test results have become commonplace, and these mistakes can result in poor patient outcomes. This series of books on diagnostic standards of care in coagulation, microbiology, transfusion medicine, hematology, clinical chemistry, immunology, and laboratory management are all organized in a similar fashion. Clinical errors, and accompanying cases to illustrate each error, are presented within all of the chapters in several discrete categories: errors in test selection, errors in result interpretation, other errors, and diagnostic controversies. Each chapter concludes with a summary list of the standards of care. The most common errors made by thousands of health care providers daily are the ones that have been selected for presentation in this series of books.

Practicing physicians ordering tests with which they are less familiar would benefit significantly by learning of the potential errors

associated with ordering such tests and errors associated with interpreting an infrequently encountered test result. Medical trainees who are gaining clinical experience would benefit significantly by first understanding what not to do when it comes to ordering laboratory tests and interpreting test results from the clinical laboratory. Individuals working in the clinical laboratory would also benefit by learning of the common mistakes made by health care providers so that they are better able to provide helpful advice that would avert the damaging consequences of an error. Finally, laboratory managers and hospital administrators would benefit by having knowledge of test ordering mistakes to improve the efficiency of the clinical laboratory and avoid the cost of performing unnecessary tests.

If the errors described in this series of books could be greatly reduced, the savings to the health care system and the improvement in patient outcomes would be dramatic.

Michael Laposata, MD, PhD
Series Editor

Preface

Why do errors occur in the laboratory and how do we detect and prevent erroneous results from affecting patient care? In the complex setting of the modern laboratory, errors can occur in the preanalytical, analytical, and postanalytical phases of the testing process. Good laboratory practice now dictates much of our laboratory policies and procedures. New instrumentation incorporates the latest methodologies to prevent errors within the laboratory setting. Automated analyzers utilize specimen barcoding to order tests, aliquot samples, perform analyses, and report results, totally without human intervention. However, if the specimen is labeled with another patient's identification, all of the analytical error prevention systems will not prevent the right result from being reported to the wrong patient. If and when this occurs, there is potential for a variety of adverse events for the patient. Thus, laboratory policies must expand beyond the walls of the physical laboratory to incorporate preanalytical and postanalytical processes, involving other departments and partners in delivery of health care. Good laboratory practice must become an integral part of good "hospital" or "clinic" practice and incorporate interdisciplinary collaboration in the effort to reduce error. Many of our laboratory processes are dependent on the quality practices of staff outside of the laboratory. Proper patient identification and appropriate specimen labeling by nursing and phlebotomy staff on the unit are critical to the error-prevention mechanisms incorporated into modern, automated laboratory systems. We can therefore not work alone! We are dependent, now more than ever, on our clinical colleagues to prevent medical errors related to laboratory testing. Truly effective, good laboratory practice requires a total quality management systems approach. Without all departments working in concert, errors will continue to occur.

How do we incorporate good laboratory practice into our systems? First, we must educate our clinical colleagues about our experiences and insight. Laboratory technologists, managers, and directors uniquely understand sources of error, as knowledge and insight are gained by experience and informed by understanding of laboratory processes. On the other hand, clinicians are keenly attuned to the need for laboratory tests to support the diagnosis and continuing care of a patient. We must find a common ground to communicate our mutual knowledge and experience for the benefit of the patient. Broadly speaking, we need to define good laboratory practices across the health system. Regardless of where or how a test is conducted, fundamental principles of patient safety should apply to prevent all sources of error. Finally, we must learn from our mistakes in order to advance to a higher level of quality. Trends should not go unnoticed, and corrective actions should be mandated for errors to prevent their recurrence in the care of other patients.

This book illustrates cases where the system broke down. For whatever reason, personnel were not diligent, policies were not in place, or quality was not sufficiently monitored. In each case the system failed, and we should learn from these experiences. Patients may have been harmed, people may have been blamed, but the system surrounding them was not meeting their needs. Errors are and will continue to be inherent in all human processes; we need to create systems that detect and prevent errors from reaching the patient. This book is intended to highlight how systems can fail, so that broader organizations that include the laboratory can be proactive in developing robust mechanisms to prevent error.

James H. Nichols, PhD, DABCC, FACB
Carol A. Rauch, MD, PhD, FCAP

Acknowledgments

The authors wish to acknowledge the technologists and management staff in the clinical laboratories for identifying these cases and for their support and dedication to quality patient care. The cases reported in this book are real, although names have been changed, and identification of these issues led to performance improvement. It is our hope that by sharing these experiences, we can increase awareness of potential weaknesses and further quality improvement efforts in other laboratories. We sincerely appreciate the guidance received from our series editor, Dr. Michael Laposata.

Specimen Receiving and Processing

OVERVIEW

The specimen receiving and processing area of the laboratory is the entry point for specimens into the laboratory. As the initial contact point, processing staff may examine a specimen and detect common preanalytical errors before the specimen is analyzed. Mislabeling, wrong tube types, transportation delays, and other mistakes can affect patient results. By detecting and correcting problems before the specimen is placed on an analyzer, staff can prevent clinical mismanagement based on erroneous results. Receiving a quality specimen is the first step toward ensuring a quality result.

PREANALYTICAL ERRORS

Labeling Errors

A large clinical laboratory receives thousands of specimens each day. Specimens can look alike, because blood in a common collection tube does not look different from another sample of blood in the same type of tube. The specimen label is the only means of distinguishing among specimens. Clinicians may envision their patient as the only one being analyzed by the laboratory, but in today's highly automated clinical laboratory, specimens are lined up and analyzed solely based on the label/barcode on the side of the tube. Often, an operator must retrieve individual specimens if they are needed for reanalysis or additional testing. Searching for a specific specimen among racks of similar specimens can be labor intensive, so automated processes that archive and manage specimen storage and retrieval can improve the laboratory's efficiency. These additional processes are also based on information contained on the specimen label. Thus, clinicians must ensure that patients are properly identified and specimens are uniquely and appropriately labeled before sending them to the laboratory. Otherwise, specimen mix-ups may occur and can lead to reporting erroneous results, and in turn to adverse events for the patient.

Case with Error

A blood gas specimen is received in the laboratory with no label. The syringe was tightly capped and sent to the laboratory through the hospital pneumatic tube system. Several specimens arrived from the same nursing unit in the pneumatic tube at the same time, each patient's specimen arriving in an individual biohazard transport bag. The specimen in question arrived in a single, patient-specific transport bag with a completed requisition, but no label on the syringe. The physician was called, and she requested that the lab just label the tube so the test could be run. Sample collection from this patient posed a challenge for

the phlebotomist, and the patient had to be stuck twice to obtain this specimen. The laboratory explained the hospital policy against relabeling specimens, but offered to analyze the specimen under the condition that a comment noting the specimen labeling error be appended to the results for the benefit of those who might utilize the result in the future. The physician was a resident and did not want his attending to see the error comment, so the specimen was canceled and re-collected.

The next sample on this patient arrived in the laboratory about an hour later. This specimen was labeled, but arrived without a test requisition. In addition, transport to the laboratory was delayed more than 45 minutes after collection. Blood gas specimens must be transported to the laboratory immediately after collection (within 30 minutes), unless the specimen is transported on ice. This specimen arrived at room temperature through the pneumatic tube. The laboratory called the physician again to cancel this specimen. The physician became irate and threatened the laboratory manager, who handed the phone over to the laboratory director. The laboratory director explained the policy and sympathized with the physician over the difficulty of obtaining specimens from this patient. The laboratory offered to analyze the specimen for electrolytes, glucose, and creatinine, but indicated that the blood gases, pH, and ionized calcium would not be valid after such a delay. Since the physician required blood gases for clinical management, the patient had to be stuck a fourth time. This time, the physician had a nurse walk the specimen to the laboratory to ensure specimen acceptability.

Explanation and Consequences

Physicians may get upset with the laboratory and may perceive laboratory policies that are intended to support patient safety as obstructive. Although the laboratory sometimes refuses a physician's request, institutions have policies and procedures to ensure reliable results. These policies contribute to patient safety by preventing the analysis of compromised specimens that could lead to incorrect and misleading test results, and subsequent inappropriate medical actions.

Unlabeled specimens can originate from any patient. There is little guarantee that an unlabeled specimen actually belongs to a "suspected"

patient, particularly with the volume of patients that are seen in busy physician offices, hospitals, and health care facilities. Physicians may request the laboratory to relabel and analyze an unlabeled or mislabeled specimen, but correcting the label does not resolve the fundamental uncertainty of patient identity. Changing the specimen label actually complicates the labeling issue by altering the actual specimen that arrived in the laboratory. A better option is to preserve the specimen label as it was received. This provides documentation of how the specimen arrived to the laboratory and supports any labeling questions raised. Discussion of a specimen identity issue with the ordering physician may help determine the best resolution of the problem, and such conversations need involvement by someone in the laboratory with sufficient authority and responsibility to make individualized decisions about specimen processing. Many times, a specimen may be ordered, collected, and labeled by staff under another person's authority. Nurses may order tests for physicians, or students may order for the attending on the unit. Discussions with the physicians of record are necessary to alert them to a labeling error and help determine the best course of action for the specimen.

When specimens are found to be acceptable for analysis, any specimen identification uncertainties should be noted as a comment with the test result. Labeling comments are important alerts because they warn of the potential for errors in specimen labeling to those interpreting the results. In a physician's office, because a limited number of staff may have access to view results, labeling issues with individual samples may be more easily communicated and resolved in this setting. However, for hospitalized patients, since multiple physicians, residents, and staff may be involved in a patient's care and have access to test results, they all must know that a patient identification may be suspect.

Labeling errors can encompass a variety of mistakes beyond unlabeled specimens. Samples can be mislabeled with another patient's name or contain incorrect information, such as name misspelling or wrong demographics such as age or sex. Partially labeled specimens contain two appropriate

identifiers, but may be missing important information, such as specimen source or date/time of collection. Illegible labels that have been smudged or partially destroyed are also commonly encountered. Institutions should have a specimen labeling policy to determine how labeling errors will be handled. Some cases may present unique situations that require individual consideration, despite the existence of a labeling policy.

Case with Error

The laboratory receives a call from an outpatient orthopedics clinic that the test results reported for a patient may not belong to that patient. Fluid analysis and microbiology results on a joint aspirate of the left knee for John Smith actually belong to Rebecca Johnson. Both patients were seen in the clinic yesterday with knee complaints, but only Rebecca Johnson had joint fluid collected. John Smith was discharged without a procedure. The clinic requests that the test results be moved from John Smith's medical record to Rebecca Johnson's record. This is the second specimen mislabeling to occur in the last 2 weeks from this clinic.

Explanation and Consequences

Laboratories should carefully consider how they handle mislabeled test results. A joint fluid is an unusual sample that cannot easily be re-collected. If the mislabeling is noted before analysis, the test could be analyzed and the test result commented in order to alert staff to the labeling issue. However, when the identity of a test result comes into question after analysis, the laboratory should never move the test from one patient's medical record to another patient's chart. That result has been released and visible to clinicians for some period of time on a specific patient's record. Removing the result entirely from a patient's record could create a conflict if treatment or other care decisions have already been made based on the result. A good practice would indicate that a specific result was reported incorrectly at a particular

date/time and actually belonged to another patient. Such a comment would immediately alert clinicians of the labeling error. This would prevent clinicians from taking further action without completely removing the test from the patient's record. By replacing the test result with a comment, staff would be warned of the error and also preserve the original report should a question about the result arise in the future.

The test result should also not be moved to another patient's medical record, because the identity of the test result is now in question. While the result may not belong to John Smith, there is no evidence that it actually belongs to Rebecca Johnson. The laboratory has only the specimen label in writing under John Smith's name, and a verbal conversation with clinic staff to support the true specimen identity. While some hospitals may request completion of an error report prior to moving a result, best practice would result in the test only as a comment in Rebecca's record (without the actual test result), indicating the mislabeling communication that took place with the name of the clinic staff and date/time of the call, and include reference to the specimen identification number that could trace the result to the other patient's record. In this manner, the result trail is preserved from the label on the specimen received in the laboratory through analysis and reporting of the result, as well as correction of the result after reporting in the medical record of both patients within the electronic record.

Since this clinic had multiple occurrences of specimen mislabeling, the laboratory should offer continuing education to avoid additional problems in the future. Physicians routinely collect the specimens, set the unlabeled containers on a shelf outside the examination room, and support staff later label the specimens and complete the test requisitions on behalf of the physician when there is time down the hall at a work station. This process could easily lead to mislabeling opportunities when exam rooms turn over with new patients before the specimens are labeled. The key to quality specimen results is maintaining the integrity of specimen identification from patient through collection, analysis, and reporting of results. The person collecting the specimen should identify the patient using a minimum of two different identifiers such as full name and date of birth or medical record number. The specimen should then be labeled with the same

unique identifiers in the presence of the patient at the bedside, immediately after collection. Passing the specimen to others for labeling presents an opportunity for error. Unlabeled specimens should never be stored in a common area like a hallway or a counter where there is a potential for mix-up with other specimens or labels.

Specimen labeling errors may not be immediately apparent. Errors with one specimen may implicate that specimen in a labeling error and bring errors for multiple specimens into question. Thus, processing staff need to be diligent of the potential for mistakes and verify the integrity of specimen identification with each and every specimen arriving in the laboratory.

Case with Error

Two presurgical urine pregnancy tests arrive from an affiliate hospital on pediatric patients, Frances Smith, age 13, and Jennifer Richards, age 15. One of the urine specimens was light straw color and had two labels on opposite sides of the container, one for Frances Smith and the other for Jennifer Richards. The second specimen arriving in the courier delivery was a dark brown color and had the name Jennifer Richards on the sample. Since the identity of both specimens is now in question, the preoperative unit at the affiliate hospital was contacted with a request to re-collect both specimens. Staff indicated that they were holding surgery and anesthesia until the results of the pregnancy tests were available and requested that the laboratory rush the test performance.

The next two samples arrived by stat courier. One of the specimens was a light, straw color while the other specimen was dark brown. This time, both specimens contained a label for the same patient, Frances Smith. Given the previous specimens and the different color of the two current specimens, the preoperative unit was contacted again. The laboratory spoke with the nurse manager, explained

the problem with the previous specimens, and the appearance of the current specimens. Staff would collect another set of specimens, and the nurse manager of the unit would observe the labeling.

The next set of samples arrived shortly. The straw-colored sample was labeled with Jennifer Richards' name and the dark-colored urine was labeled Frances Smith. One of the patients was positive for pregnancy creating a greater concern for everyone involved, given the previous specimen mix-ups and the age of the patients. Both results were verified under the name of the final set of samples. All previous test requests were canceled with a comment noting possible mislabeling and need for specimen re-collection. The case was sent to the affiliate hospital's quality management office for follow-up.

Explanation and Consequences

On review of the case, staffing on the day of surgery was expected to be short due to planned vacations. Workers from the previous night attempted to streamline patient admissions the following morning by prelabeling the collection containers and completing the requisitions in advance, trying to be helpful to the morning operations. Yet, despite the good intentions, in the rush to prepare patients for surgery in the morning, they did not notice that extra labels had already been printed and the specimen containers were already labeled. The morning staff simply followed their routine practice, identified patients, printed labels, and labeled the specimens as they always would. Staff did not expect the specimen containers to already be labeled and did not check to verify the labels already on the containers. In the morning, operations were very delayed and in the rush to expedite the surgeries, the operating room staff failed again to double-check their labeling.

This case exemplifies the need for a labeling process that is explicitly followed each time a specimen is collected so that each specimen is already linked to the correct patient and results can be safely entered into the patient's records. Shortcuts, like prelabeling tubes, present the opportunity for error and must be avoided. Specimens should be labeled in the presence of a patient to ensure the specimen label matches the positive patient identification. Once a urine

specimen is collected, staff should double-check that the identification on the specimen matches the patient prior to sending the specimen to the laboratory. Urine specimens should also be labeled on the side of the container and not on the lid, which could be separated from the sample, or exchanged or mixed with another lid in the laboratory during processing and analysis.

Collection in the Incorrect Tube Additive

Specimen collection tubes are color coded to indicate different additives. Some additives prevent clotting and allow the analysis of plasma, while other additives inhibit glycolysis and metabolism. Color-coded tubes may also contain a gel barrier that facilitates sample processing. These different collection tubes have different intended purposes and are generally not interchangeable. Certain tests may require specific types of collection tubes, processing, or transport prior to analysis. Failure to follow the recommended collection and processing instructions can compromise the quality of test results.

Case with Error

A purple-top microtainer tube (0.5 mL volume) containing EDTA preservative arrives in the laboratory, but the requirements for the test requested specify collection in a red-top gel tube with no additives. The neonatal unit is contacted. Staff involved in specimen collection request the specimen be sent back to the unit. To comply, the laboratory processor sends the tube back to the unit after canceling the tests. The next specimen from the patient arrives about an hour later in the same purple-top EDTA microtainer, but this smaller tube was now pushed into a larger 10 mL red-top gel tube. The specimen is accompanied by a Patient Safety Report claiming possible patient harm; the allegation is that the laboratory delayed patient care by not running the tests requested and required more blood to be drawn from a neonatal patient.