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Research Article

ARE DIAGNOSTIC AND LABORATORY ERRORS CAUSING FATAL DEATHS?

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A B S T R A C T

Laboratory blood studies can reveal a little information about organ systems throughout the body. The amount of blood taken for a laboratory test is not harmful. Human body manufactures a couple of milliliters of new blood every day. Blood studies may give information about the levels of sodium, potassium, calcium and other chemicals. Presence of certain enzymes and information about the coagulation characteristics, levels of sugar, urea, cholesterol, alcohol, protein, and other drugs of patients blood sample.Incorrect laboratory tests account for significant harm. Researchers estimated that the number of patients suffering from missed diagnostic tests are annually in thousands. These are potentially preventable, subject to the condition if proper attention is paid. Errors can include misdiagnosis or delayed diagnosis, administration of the wrong drug to the wrong patient or in the wrong way, giving multiple drugs. That interact negatively, surgery on an incorrect site, failure to remove all surgical instruments, failure to take the correct blood type into account, or incorrect record-keeping.

INTRODUCTION

Mistakes and failures are integral part of any great effort worth the mention.Your best teacher is your last mistake. Developing new manifolds by revitalizing old ideas. The quality of thinking action decide your strength. Is it a sin or boon to admit patient in a hospital for treatment?. Medical error is not included on death certificates or in rankings of cause of death. Hospital is expected to be a safe place. When you take a sick patient to the hospital, you expect that the patient is in good hands and under the umbrella of experienced doctors. Errors in diagnosis, misdiagnosis of psychological disorder, competency, education and training are the main features causing fatal deaths. A medical error is a preventable adverse effect of care, whether or not it is evident or harmful to the patient.

Laboratory blood studies can reveal a little information about organ systems throughout the body. The amount of blood taken for a laboratory test is not harmful. Human body manufactures a couple of milliliters of new blood every day. Blood studies may give information about the levels of sodium, potassium, calcium and other chemicals. Presence of certain enzymes and information about the coagulation characteristics, levels of sugar, urea, cholesterol, alcohol, protein, and other drugs of patients blood sample.

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Diagnostic error can be defined as a diagnosis that is missed, wrong or delayed, as detected by some subsequent definitive test or finding. The ensuing harm results from the delay or failure to treat a condition present when the working diagnosis was wrong or unknown, or from treatment provided for a condition not actually present.

Incorrect laboratory tests account for significant harm. Researchers estimated that the number of patients suffering from missed diagnostic tests are annually in thousands. These are potentially preventable, subject to the condition if proper attention is paid.

Diagnosing diseases and disorders requires highly developed skill on the part of the physician or other medical professional .Usually the diagnosis calls for systematic use of instruments and diagnostic aids, various tests, and, often with sophisticated instruments and machines.

Quality systems are the mainstay of clinical laboratory management. The comprehensive laboratory testing process must be continually monitored and evaluated to ensure reliable test results and set the foundation for quality improvement. While such efforts have resulted in significant improvements in many of the processes, errors still occur. In order to implement corrections and improve the testing process, the laboratorian must identify the various sources of errors.

Last two decades has witnessed phenomenal advances in the field of medicine following revolutionary changes taking place

in the application of technology and as a consequence, Biochemistry and Microbiology have evolved as the most important branch of evidence based medicine.

The quality of any laboratory test result is dependent on many variables, it begins with skill, and knowledge when preparing the patient and specimen are essential to the provision of the highest quality standards for testing and services. The patient must first be properly prepared so that the best possible specimen can be collected. Next, the actual collection of the specimen must be completed. Then, the specimen should be properly processed, packaged and transported to the laboratory in a timely manner and under environmental conditions that will not compromise the integrity of the specimen. After all of these activities take place, a quality analysis can be performed.

Each test needs Specific specimen requirements .Specimen requirements include information such as specimen volume, collection and transport containers as well as transport temperature. If additional information is needed for the interpretation of the test results or there are specific instructions for patient preparation, they are listed along with specimen requirements. It is important that an adequate specimen volume is submitted for analysis. The volume is enough for initial analysis as well as for any confirmatory tests that must be performed. If an inadequate specimen is submitted, it is not possible to perform the initial test or required confirmatory procedures.

It should be remembered that test results are uniformly reliable .It is clear that no single positive test should be taken as a diagnosis. Nor a subsequent negative test result be accepted as evidence of cure.

Wrong drug, wrong dose, bad combination bad reaction gives medical errors.(1)

Globally, it is estimated that 142,000 people died in 2013 from adverse effects of medical treatment; this is an increase from 94,000 in 1990. However, a 2016 study of the number of deaths that were a result of medical error in the U.S. placed the yearly death rate in the U.S. alone at 251,454 deaths, which suggests that the 2013 global estimation may not be accurate.(2,3). Medical errors now third leading cause of death in USA.(4)

Hospital medical errors are the third leading cause of death in the United States. That's 700 people per day, notes Steve Swensen. "And most of those have a second victim: the nurses, doctors, social workers, managers, pharmacists involved in their care."(5). Medical error-the third leading cause of death in the US.(6).

Sizable numbers of Americans are harmed as a result of medical errors. Two studies of large samples of hospital admissions, one in New York using 1984 data and another in Colorado and Utah using 1992 data, found that the proportion of hospital admissions experiencing an adverse event, defined as injuries caused by medical management, were 2.9 and 3.7 percent, respectively. (7) The proportion of adverse events attributable to errors (i.e., preventable adverse events) was 58 percent in New York, and 53 percent in Colorado and Utah.(8) When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of these two studies imply that at least 44,000 and perhaps as many as 98,000 Americans die in hospitals each year as a result of medical errors.(9) Even when using the lower estimate, deaths in hospitals due to preventable adverse events exceed the number attributable to the 8th-leading cause of death.(10) Deaths due to preventable adverse events exceed the deaths attributable to motor vehicle accidents (43,458), breast cancer (42,297) or AIDS (16,516).(11)

An error is defined as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning) (12)

Errors can include misdiagnosis or delayed diagnosis, administration of the wrong drug to the wrong patient or in the wrong way, giving multiple drugs. That interact negatively, surgery on an incorrect site, failure to remove all surgical instruments, failure to take the correct blood type into account, or incorrect record-keeping.

An adverse event is an injury caused by medical management rather than the underlying condition of the patient. An adverse event attributable to error is a "preventable adverse event(13)" Negligent adverse events represent a subset of preventable adverse events that satisfy legal criteria used in determining negligence (i.e., whether the care provided failed to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question) (14). Medical errors are associated with inexperienced physicians and nurses, new procedures, extremes of age, and complex or urgent care.(15) Poor communication (whether in one's own language or, as may be the case for Medical tourists, another language), improper documentation, illegible handwriting, inadequate nurse-to-patient ratios, and similarly named medications are also known to contribute to the problem. Patient actions may also contribute significantly to medical errors. Falls, for example, may result from patients' own misjudgments. Human error has been implicated in nearly 80 percent of adverse events that occur in complex healthcare systems. The vast majority of medical errors result from faulty systems and poorly designed processes versus poor practices or incompetent practitioners.(16)

Variations in healthcare provider training & experience(17, 18) and failure to acknowledge the prevalence and seriousness of medical errors also increase the risk.(19,20) The so-called July effect occurs when new residents arrive at teaching hospitals, causing an increase in medication errors according to a study of data from 1979-2006(21,22)

A large study reported several cases where patients were wrongly told that they were HIV-negative when the physicians erroneously ordered and interpreted HTLV (a closely related virus) testing rather than HIV testing. In the same study, >90% of HTLV tests were ordered erroneously.(23) It is estimated that between 10-15 percent of physician diagnoses are erroneous(24)

Misdiagnosis of lower extremity cellulitis is estimated to occur in 30% of patients, leading to unnecessary hospitalizations in 85% and unnecessary antibiotic use in 92%. Collectively, these errors lead to between 50,000 and 130,000 unnecessary hospitalizations and between $195 and $515 million in avoidable health care spending annually in the United States (25)

Laboratory testing is a highly complex process and, although laboratory services are relatively safe, they are not as safe as they could or should be. Clinical laboratories have long focused their attention on quality control methods and quality

assessment programs dealing with analytical aspects of testing.(26)

Major Advances and Discoveries

Can you trust all medicines in pharmacy? Are all the drugs tested on experimental animals? Is it sin or boon to conduct drug tests on animals? Drug discovery is the process by which new medications are discovered. Modern drug discovery involves the identification of screening hits, medicinal chemistry and optimization of those hits to increase the affinity, selectivity (to reduce the potential of side effects), efficacy/potency, metabolic stability (to increase the half-life), and oral bio-availability. Once a compound that fulfills all of these requirements has been identified, it will begin the process of drug development prior to clinical trials.

Most of the drugs are tested on less gestation period animals like mice, rats, rabbits, guinea pigs. It is very difficult to do research work on long gestation period animals like monkeys, goats, buffalos etc. To do research on human is illegal, ultra wire. The drug that is safe to animals may not be suitable to human. Most of the drugs in the pipeline have failed in clinical trials.

Developing new super manifolds by revitalizing old ideas. The quality of thinking and actions decide strength. patient safety is finally the object of medical and public attention The awareness and understanding of medical errors have expanded rapidly, with an energetic patient safety movement promoting safer health care through 'systems' solutions, thanks to a major message from the IOM report: the cause of medical errors and preventable deaths was not careless or incompetent people but bad systems(36)

History and Mechanism

Patient safety agenda is gaining momentum in the health care systems of all developed countries. However, adverse event detection systems and initiatives to reduce error rates in medicine are in their infancy. Laboratory services play a crucial role in both individual and population-based healthcare, and clinical laboratories use many different methods to reduce errors, ensure patient safety, and improve quality including quality control procedures, quality assurance programs, accreditation of laboratories and certification of education programs. Considerable advances in analytical techniques, laboratory instrumentation, information technologies, automation and organization have granted an exceptional degree of analytical quality over the past 50 years. This, in turn, has resulted in a significant decrease in error rates, analytical error rates in particular. There is consolidated evidence that nowadays, most laboratory errors fall outside the analytical phase, and that pre- and post-analytical processes are more vulnerable to error than analytical processes (34,34,35)

Significant gap in research

These are the common misconceptions about adverse events, and the arguments and explanations against those misconceptions are noted in parentheses:

- "Bad apples" or incompetent health care providers are a common cause. (Although human error is commonly an initiating event, the faulty process of delivering care invariably permits or compounds the harm, and is the focus of improvement.(27)
- High risk procedures or medical specialties are responsible for most *avoidable* adverse events. (Although some mistakes, such as in surgery, are harder to conceal, errors occur in all levels of care. Even though complex procedures entail more risk, adverse outcomes are not usually due to error, but to the severity of the condition being treated (27,102) However, USP has reported that medication errors during the course of a surgical procedure are three times more likely to cause harm to a patient than those occurring in other types of hospital care(30)
- If a patient experiences an adverse event during the process of care, an error has occurred. (Most medical care entails some level of risk, and there can be complications or side effects, even unforeseen ones, from the underlying condition or from the treatment itself) (31,32)

Current Debate

Some common reasons of not getting quality and reliable results are

1. Lack of commitment on part of staff performing the tests
2. Poor management and supervision
3. Poor understanding of quality assurance concepts
4. Analysts do not understand the concepts of assay principles
5. Reagents used are not high quality
6. Poor quality of instruments
7. Procedures are not followed as recommended
8. Under staff leads to high error rate.
9. Lack of equipment.
10. Mislabeling blood sample.
11. Un labeling blood sample.

Blood tests

Changes in blood on keeping

1. Loss of carbon dioxide occurs between cell and plasma, by biochemical changes. In order to prevent the loss of carbon dioxide, the blood is collected under liquid paraffin and plasma separated immediately.
2. Glucose in blood is fairly reduced from whole blood on standing. Nearly half the glucose is lost in two to three hours. If the technician do the test immediately, gets right value and after doing the test with late hour ,gets wrong value. This is due to glucose is converted in to lactic acid, by a process known as glycolysis.
3. This can be prevented by adding sodium floride to the anti coagulant.A mixture of sodium fluoride and potassium oxalate will prevent any loss of glucose for two or three days.
4. Formation of ammonia from nitrogenous substances, mainly, urea, may occur in blood which has been contaminated with bacteria. To over come this error, blood should be kept in sterile or refrigerator.
5. Potassium is present in greater concentration in the cells than in plasma. Serum heparinized plasma should be separated shortly after taking the blood. Diffusion of potassium occurs more rapidly in blood kept at 4c than at room temperature.

6. The pyruvate present in blood is converted in to lactic acid ,is catalysed by lactic acid dehydrogenase after collection, So, blood should be mixed immediately with protein precipitant to get correct value.

Types of blood to be used

Whole blood

Ammonia, barbiturates, carboxy hemoglobin, glucose, hemoglobin, lead, urea, pyruvate, sulphonamides, and non protein nitrogen etc,

Serum: Albumin, globulin, aldolase, aminoacids, amylase, bilurubin, bromide, calcium, cholesterol, copper, creatinine, creatin, creatine kinase , iron, isocitrate dehydrogenase, lactate dehydrogenase, lipase, lipids, magnecium, phosphorus, acid phosphatase, alkaline phosphatase, Protein -bound iodine, salicylates, sodium , transaminases, uric acid,
vitamin A.

Plasma*:* Ascarbic acid, bicarbonate fibrinogen.

Red cells: Glucose 6 phosphate dehydrogenase, pyruvate kinase, abnormal hemoglobin.

Glucose, Urea, Uric acid, Creatinine can be estimated both in serum and plasma, as there will be no interference.

Ideas where research go next

1. Acid phosphatase is present in red blood cells. Haemolysed sample gives high results.
2. Red blood cells are rich in LDH, hence avoid haemolysis. Haemolysed samples should not be assayed.
3. Creatine phosphokinase (CPK or CK). It is not found in Red blood cells and its level is not affected by haemolysis.
4. For the most accurate blood sugar testing, wash hands with soap and dry thoroughly before testing.
5. Using expired or poorly stored stripes can result in accurate reading.
6. Driver may be efficient, it depends on the machine. Check the blood sugar meter accurately, periodically.

Testing Blood sugar immediately after meals or snacks will give you result that are probably too high. Wait for two hours after eating to get the best readings.

References

1. Anna Medaris, Miller.-March 30, 2015.Health care.
2. Frellick, Marcia (3 May 2016). "Medical Error Is Third Leading Cause of Death in US Marcia Frellick". Medscape. Retrieved 7 May 2016.
3. Jump up to:[ab] Daniel Makary; Daniel, Michael (3 May 2016). "Medical error-the third leading cause of death in the US". BMJ. Retrieved 7 May2016.
4. John Hopkins-News and Publications -For the Media - Current News Releases
Release Date: May 3, 2016.
5. January 23, 2017-Tait Shanafelt, MD, Christine A. Sinsky, MD, FACP & Stephen Swensen, MD, MMM, FACR
6. Mayo Clinic American Medical Association. Martin A Makary, professor1, Michael Daniel, research fellow1
Correspondence to: M A Makary
BMJ 2016; 353 doi: https://doi.org/10.1136/bmj.i2139 (Published 03 May 2016) Cite this as: BMJ 2016;353:i2139.
7. Brennan, Troyen A.; Leape, Lucian L.; Laird, Nan M., *et al*. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study I. *N Engl J Med*. 324:370-376,1991. See also: Leape, Lucian L.; Brennan, Troyen A.; Laird, Nan M., *et al*. The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II. *N Engl J Med*. 324(6): 377-384, 1991. Thomas, Eric J.; Studdert, David M.; Burstin, Helen R., *et al*. Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado. Med Care forthcoming Spring 2000.
8. Thomas, Eric J.; Studdert, David M.; Newhouse, Joseph P., *et al*. Costs of Medical Injuries in Utah and Colorado. Inquiry. 36:255-264, 1999. See also: Leape, *et al*., 1991. Brennan, *et al*., 1991. [PubMed]
9. American Hospital Association. Hospital Statistics. Chicago. 1999.
10. Centers for Disease Control and Prevention (National Center for Health Statistics). Deaths: Final Data for 1997. National Vital Statistics Reports. 47(19):27, 1999.
11. Centers for Disease Control and Prevention (National Center for Health Statistics). Births and Deaths: Preliminary Data for 1998. National Vital Statistics Reports. 47(25):6,1999. [PubMed]
12. Reason, James T. Human Error. Cambridge, MA: Cambridge University Press; 1990.
13. Brennan, *et al*., 1991. Leape, *et al*., 1991. See also Brennan, *et al*., 1991.
14. Weingart, N. Saul; Wilson, Ross; Gibberd, Robert W.; Harrison, Bernadette (2000). "Epidemiology of medical error". *BMJ Publishing Group*. Retrieved 2006-03-17.
15. Palmieri, P. A.; DeLucia, P. R.; Ott, T. E.; Peterson, L. T.; Green, A. (2008). The anatomy and physiology of error in averse healthcare events. Advances in Health Care Management. 7. pp. 33-68. doi:10.1016/S1474-8231(08)07003-1. ISBN 978-1-84663-954-8. ISSN 1474-8231.
16. Neale, Graham; Woloshynowych, Maria; Vincent, Charles (July 2001). "Exploring the causes of adverse events in NHS hospital practice". *Journal of the Royal Society of Medicine*. 94(7): 322-30. PMC 1281594 . PMID 11418700.
17. Wu AW, Folkman S, McPhee SJ, Lo B (April 1991). "Do house officers learn from their mistakes?". *JAMA*. 265 (16): 2089-94. doi:10.1001/jama.265.16.2089. PMID 2013929.
18. Michael L. Millenson (2003). "The Silence". Health Affairs. 22(2): 103-112. doi:10.1377/hlthaff.22.2.103. PMID 12674412. Retrieved 2008-03-23.
19. Henneman, Elizabeth A. (1 October 2007). "Unreported Errors in the Intensive Care Unit, A Case Study of the Way We Work". *Critical Care Nurse*. 27 (5): 27-34. PMID 17901458. Retrieved 2008-03-23.
20. Phillips DP; Barker GE (May 2010). "A July Spike in Fatal Medication Errors: A Possible Effect of New Medical Residents". *J Gen Intern Med*. 25 (8): 774-779. doi:10.1007/s11606-010-1356-3. PMC 2896592 . PMID 20512532.

21. "New residents linked to July medication errors", amednews, June 21, 2010, American Medical Association
22. Siemieniuk, Reed; Fonseca, Kevin; Gill, M. John (November 2012). "Using Root Cause Analysis and Form Redesign to Reduce Incorrect Ordering of HIV Tests". Joint Commission *Journal on Quality and Patient Safety*. 38 (11): 506-512. PMID 23173397.
23. Berner, E. S.; Graber, M. L. (2008). "Overconfidence as a cause of diagnostic error in medicine". *American Journal of Medicine*. 121: S2-S23. doi:10.1016/j. amjmed.2008.01.001.
24. Weng, Qing Yu; Raff, Adam B.; Cohen, Jeffrey M.; Gunasekera, Nicole; Okhovat, Jean-Phillip; Vedak, Priyanka; Joyce, Cara; Kroshinsky, Daniela; Mostaghimi, Arash. "Costs and Consequences Associated With Misdiagnosed Lower Extremity Cellulitis". *JAMA Dermatology*. doi:10.1001/ jamadermatol. 2016.3816.
25. Plebani M[1],*Clin Chem Lab Med*. 2006;44(6):750-9.
26. Errors in clinical laboratories or errors in laboratory medicine?
27. Weingart SN, Wilson RM, Gibberd RW, Harrison B; Wilson; Gibberd; Harrison (March 2000). "Epidemiology of medical error". *BMJ*. 320 (7237): 774-7. doi:10.1136/bmj.320. 7237.774. PMC 1117772 . PMID 10720365
28. Gardner, Amanda (6 March 2007). "Medication Errors During Surgeries Particularly Dangerous". The Washington Post. Retrieved 2007-03-13.
29. René Amalberti, MD; Yves Auroy, MD; Don Berwick, MD, MPP; Paul Barach, MD, MPH (3 May 2005). "Five System Barriers to Achieving Ultrasafe Health Care". *Annals of Internal Medicine*. 142 (9): 756-764. doi:10.7326/0003-4819-142-9-200505030-00012. PMID 15867408. Retrieved 2006-07-12
30. US Agency for Healthcare Research & Quality (2008-01-09). "Physicians Want To Learn from Medical Mistakes but Say Current Error-reporting Systems Are Inadequate". Retrieved 2008-03-23.
31. Institute of Medicine (2000). To Err Is Human: Building a Safer Health System. Washington, DC: The National Academies Press. doi:10.17226/9728. ISBN 978-0-309-26174-6
32. Zhang J; Pate, VL; Johnson TR (2008). "Medical error: Is the solution medical or cognitive?". *Journal of the American Medical Informatics Association*. 6 (Supp1): 75–77. doi:10.1197/jamia.M1232
33. Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. *Clin Chem* 1997; 43:1348-51.
34. Bonini P, Plebani M, Ceriotti F, Rubboli F. Errors in laboratory medicine. *Clin Chem* 2002;48:691-8.
35. Astion ML, Shojana KG, Hamil TR, Kim S, Ng VL. Classifying laboratory incident reports to identify problems that jeopardize patient safety. *Am J Clin Pathol* 2003; 120:18-26.
36. Leape, LL. Errors in medicine. *Clin Chim Acta* 2009; 404:2-5 Google Scholar, Crossref, Medline

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