

DIAGNOSTIC ERROR REDUCTION IN THE UNITED STATES AND IN ITALY THROUGH THE INTERVENTION OF DIAGNOSTIC MANAGEMENT TEAMS

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ABSTRACT

A major challenge to most countries is the growing cost of healthcare. The cost of laboratory testing is approximately 3% of the total clinical costs. On the other hand, waste from inappropriate admissions to clinical departments is reported to be as high as 15%. A frequently used approach to save dollars in healthcare is the random reduction in the budget for laboratories, with a focus on reduction of the number of unnecessary laboratory tests. The World Health Assembly has approached the problem by publishing a list of essential in vitro diagnostic tests, in order to achieve a global rationalization of the problem.

A much more thoughtful strategy to saving healthcare finance is to improve the efficiency of the diagnostic process. This report presents an opportunity to reduce diagnostic error and increase

the efficiency of diagnostic testing. Reduction in time to a correct diagnosis provides a major financial as well as a clinical benefit. In addition, reducing both overutilization and underutilization of laboratory tests while achieving the correct diagnosis is a major benefit to challenged healthcare budgets.

One approach taken to achieve major savings in healthcare has been the creation of “Diagnostic Management Teams,” composed of experts in specialty areas of medicine who are primarily based in the clinical laboratory to advise physicians on the selection of only necessary tests and the interpretation of complex test results.

Key Words: Diagnosis, Diagnostic Error, Laboratory Medicine, Diagnostic Management Team

INTRODUCTION

The Global Problem of Diagnostic Error

At the World Health Assembly, there is continuous discussion about the use of financial resources to promote health and well-being. Despite the large number of deaths from diagnostic errors, there is still limited awareness of the mortality and morbidity reduction that could occur with an investment to improve the accuracy and speed of diagnoses [1]. It has long been stated that information from clinical laboratory tests accounts for as much as 70% of the diagnoses that are made. When considering the accompanying diagnostic areas of anatomic pathology and radiology, the percent of diagnoses established by using information from one or more of these areas in industrialized countries where they are readily available is likely to approach 90%.

The growth of genetic testing is now allowing identification of disorders that were either undiagnosed or misdiagnosed, and therefore not effectively treated. The area of genetic testing that permits identification of effective drugs, called pharmacogenomics, is expanding dramatically. Treatment with the right drug at the right time often depends upon performance of a genetic laboratory test initially, and the recognition of this opportunity for more effective drug therapy with laboratory testing is still quite limited across the globe.

Alongside the improvement in clinical outcome that could be realized by modest investments in the diagnostic process are the tremendous financial benefits from achieving an accurate diagnosis rapidly. The reduction in expenditures resulting from shortened time to effective treatment and shortened length of stay for hospitalized patients far exceeds the dollars spent on testing, no matter how healthcare is paid for in different countries. Complications of diseases and the requirement to treat advanced disease rather than early disease are both extremely expensive [2, 3]. The response of many hospital leaders, particularly those without clinical experience, is to invoke universal reductions and expenditures, without any understanding that a missed or delayed diagnosis is associated with losses in other budgets outside the diagnostic specialties [4].

Importantly, the citizens of most countries across the globe are largely unaware that poor clinical outcomes could be prevented if the diagnostic process were improved. Healthcare providers in many countries can lose patients, and therefore income, if they reveal to their patients that they were responsible for a diagnostic error. Procedural errors, such as removing the wrong kidney in a case of renal carcinoma, or treatment with the wrong dose of a drug are easily recognized causes of mortality and morbidity, but this is not so for the much larger number of errors related to establishing a diagnosis [2]. While there has been much attention to improving processes to reduce procedural errors, in most countries there is little if anything that would help make institutions and

individual healthcare providers aware that they have made a diagnostic mistake and that a poor outcome is attributable to their incorrect selection of diagnostic tests or their failure to interpret the results of diagnostic tests correctly [3] (Fig. 1).

THE PROBLEM OF DIAGNOSTIC ERROR IN THE UNITED STATESIn the United States, many incentives in the diagnosis and treatment of patients that enable diagnostic error [5]. The abundance of lawsuits for medical mistakes creates a defensive position among healthcare providers. This prompts unnecessary “defensive” testing. The lack of attention to laboratory medicine in medical school [6], and for those in practice, produces more than 10,000 new physicians in the United States who “do not know what they do not know.” The United States also suffers from substantial payment for diagnoses in anatomic pathology and in radiology, but little payment for establishing a diagnosis in laboratory medicine. This has resulted in having few experts able to help clinicians order the correct laboratory tests and interpret the results correctly. A recent report [7] identified the barriers to widespread use of experts consultation services through a diagnostic management team in the United States.

THE PROBLEM OF DIAGNOSTIC ERROR IN ITALY

Currently, the Italian government is conducting a review of its healthcare spending. Many of these reductions in expenditures include activities in the clinical laboratory, and the steps being taken are compromising the speed and accuracy of diagnoses. In Italy, as in other countries, improvement in diagnostic services that cost little can save thousands to millions of euros. For example, in Italy where thalassemia is common, the clinical center in Rome for patients with

thalassemia and other anemias was recently closed. The proposed savings from this closure of approximately €10 million annually is likely to lead to much larger healthcare costs for this patient population who are now less likely to be identified and, even if identified, less likely receive the correct treatment. It will be impossible to calculate the costs of these losses in diagnostic and treatment support for these patients. Although Italy may have different obstacles to rapidly establishing and accurate diagnosis that are present in the United States, the number of obstacles is still substantial enough to require a major infrastructure development in the countries healthcare delivery system. The barriers to diagnostic management team implementation in Italy are more similar than different from those in the United States.

AN OPTION TO IMPROVE THE SPEED AND ACCURACY OF DIAGNOSES IN BOTH COUNTRIES

In the United States, over the past 20 years but most prominently in the past few years, teams of diagnostic experts have been forming to support clinical colleagues who are in direct contact with patients. These teams, known as diagnostic management teams provide advice on laboratory test selection and test result interpretation [8-10]. The experts have updated information about diagnoses in specialized areas, for example, in bleeding and clotting disorders. When experts can provide information while clinical decisions are being made, in a local or distant environment from the healthcare provider seeing the patient, the likelihood for an efficient diagnostic process is substantially increased. Communication between the diagnostic management team and the treating health care provider is becoming simpler and it now allows for back and forth questioning until a diagnosis is achieved. When the diagnosis is established, the patient is ready for treatment, and the most up-to-date information from those who read the latest journals in their specialty, is

now available. Diagnostic management teams have been created and successfully implemented in many areas, including coagulation, leukemia and lymphoma, transfusion medicine, microbiology/infectious disease, and even to review cases of presumed child abuse for the presence of an underlying bleeding disorder.

At Vanderbilt University in Nashville, TN, USA, the diagnostic management team in coagulation was able to dramatically decrease the length of stay and the cost of care for patients with pulmonary embolism and for patients with intracranial hemorrhage [11]. The diagnostic management team for patients with leukemia and lymphoma in that same institution has improved the speed and accuracy of the diagnosis of hematologic malignancies [8].

There is now global interest in the creation of diagnostic management teams. Recent conferences focused on the creation of diagnostic management teams in Galveston, TX, USA, in 2017 and 2018 have been held, and the information from these meetings has spread globally. Healthcare delivery and payment for healthcare varies significantly from country to country. However, a constant finding in all countries, both industrialized and non-industrialized, is the abundance of barriers to establishing a rapid and accurate diagnosis. The specific barriers may be different from one country to another, but in each country there are many. The implementation of diagnostic management teams across the globe has the opportunity to remove many of the obstacles to achieving a rapid and correct diagnosis by providing expert recommendations on test selection and results interpretation in real time.

The first essential in vitro diagnostics list was released by the World Health Organization in May 2017, as a recognition of the importance of diagnosis before treatment. It includes more than 100 tests and will increase every year to guide countries on appropriate test selection [12,13].

CONCLUSIONS

The need for communication between healthcare providers in direct contact with patients and expert diagnosticians is extremely high, and the need is growing as more complex genetic results are appearing in the clinical records of patients. The challenges to generate an accurate and rapid diagnosis are exemplified by the situations in the United States and Italy, and most likely reflect a global need as diagnostic information becomes more abundant and more expensive.

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