Collaborate to the reduction of diagnostic errors

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ABSTRACT

A diagnostic error is a failure to establish an accurate and timely explanation of the patient's health problems or simply a failure to communicate that explanation to the patient. Diagnostic errors have received less attention than the therapeutic risk issue, because data on this type of errors are generally scarce, there are few reliable measures available, often the error is identified only in retrospect and, fortunately, not all diagnostic errors result in adverse outcomes. Fifteen years after "To err is human", "Improving diagnosis in health care" is a similar book dedicated to the topic. It focuses on two critical elements: patients are fundamental for the prevention of this risk and diagnostic process is a collaborative work. No single data source, method, setting or circumstance is sufficient to understand the multiple causes and risks of every diagnostic error. The advancement of the current understanding of diagnostic error requires the involvement of all stakeholders in all contexts. A cultural change of the approach is needed as well a system for measuring the problem, in order to establish its extent and nature, to determine the causes and risks of diagnostic errors, to evaluate the effectiveness of the intervention, to pursue skills in education and training and finally to define responsibility for diagnostic performance. Clinical laboratories cannot face this challenge individually and alone, but cooperating with all the involved subjects, from clinicians to other diagnostic services and patients. Furthermore, this topic cannot be ignored, because risks affect everyone, both as professionals and as patients.

Key-words: *diagnosic error, clinical laboratories, diagnosis*

INTRODUCTION

Diagnostic error is a particular type of critical error in healthcare, less considered in comparison to clinical risk issues and other possible errors in disease treatments.

Since the publication of the famous "To Err is Human"[1], which revolutionized the perception of clinical risk in healthcare systems and triggered a new health risk management, 15 years have passed before a similar publication dealt with this topic with the same systematic approach, focusing on the diagnosis items. "Improving diagnosis in health care"[2] was published only few years ago, in 2015, but it represents a fundamental text that focuses on two critical elements: patients are essential for the solution of this risk and diagnostic process is a collaborative work.

A diagnostic error is the failure to establish an accurate and timely explanation of the patient's health problems or simply the failure to communicate this explanation to the patient. This kind of error includes a series of possible events linked both to the information content and to transmission times with connections to other information (Table 1).

Handling diagnostic errors is often difficult because related data are generally scarce, there are few reliable measurements available, and often the error is only identified afterwards.

A conservative estimate has found that each year 5% of US adults, who seek outpatient care, experience a misdiagnosis (1). An autopsies research that has lasted for decades, has shown that diagnostic errors contribute to about 10% of patient deaths. Medical record reviews suggest that diagnostic errors account for 6 to 17% of hospital adverse events (2). Diagnostic errors are the leading reason for medical malpractice claims, are nearly twice as likely to have resulted in patient death as other claims and account for the largest proportion of total payments (3). Most people will experience at least one misdiagnosis in their lifetime, sometimes with devastating consequences.

[1] *Kohn LT, Corrigan JM, Donaldson MS eds. Institute of Medicine (US) Committee on Quality of Health Care in America. To Err is Human: Building a Safer Health System. Washington (DC): National Academies Press (US), 2000*
[2] *Balogh EP, Miller BT, Ball JR eds. Committee on Diagnostic Error in Health Care; Board on Health Care Services; Institute of Medicine; The National Academies of Sciences, Engineering, and Medicine. Improving diagnosis in health care. Washington (DC): National Academy Press (US), 2015.*

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Table 1

Types of diagnostic errors.

Types of diagnostic errors	Examples for Laboratory Medicine
Delayed diagnosis	Too long to produce analysis results
Failure to diagnose an unrelated disease	Excessive use of appropriateness criteria: exclusive tests for the suspected and not wide-ranging pathology
Failure to diagnose a related disease	Excessive use of appropriateness criteria and errors in the interpretation of the results - lack of consultant activity
Missed diagnosis	Wrong results (analytical phase), tests not requested (pre-pre-analytical), results not correctly reported (post-analytical) or evaluated (post-post-analytical)
Failure to recognize complications	Lack of monitoring tests
Misdiagnosis	Inappropriate test requests (pre-pre-analytical), wrong results (analytical phase), results not correctly reported (post-analytical) or evaluated (post-post-analytical)

Diagnostic errors also translate into costs for the healthcare system as well as, obviously, for the patients. In a Johns Hopkins Medicine Centre evaluation of 350 000 claims over 25 years, worth $38 billion, 28.6% were related to diagnostic errors, worth 35.2% (4).

The diagnostic errors can derive from various elements, some particularly critical and frequent. Inadequate communication and collaboration between doctors, patients and their families are certainly the most relevant causes. Furthermore, healthcare systems are often not well designed to support a diagnostic process. Physicians who need to make treatment decisions and support patient choices often have limited information about the diagnostic performance upon which they base their decisions. In fact, as in other areas, there is a culture that discourages transparency and diagnostic error disclosure for analysis and subsequent use for information and training purposes.

However, and fortunately, not all failures of the diagnostic process lead to an adverse outcome, as there are diagnostic errors that do not lead to wrong choices while obviously a part of the adverse effects can occur for other causes and independently of the diagnostic errors (Figure 1) (5).

The harm may not occur if a patient's symptom resolves even with a misdiagnosis. However, many diagnostic errors can be harmful because they can prevent or delay appropriate treatment, lead to unnecessary or more harmful treatment, or have psychological or financial repercussions. Improving the diagnostic process is therefore not only possible and desirable, but also represents a moral, professional and public health duty.

The process that leads to a possible adverse outcome in a patient's treatment is not only determined by the overlapping of different processes, but rather by an integrated system that sees the patient engaged in the healthcare system, entered into an information collection loop which allows to formulate a diagnostic hypothesis and subsequent treatment on the basis of this hypothesis. This is an "*engine of continuous integration and interpretation of the information*", shared between

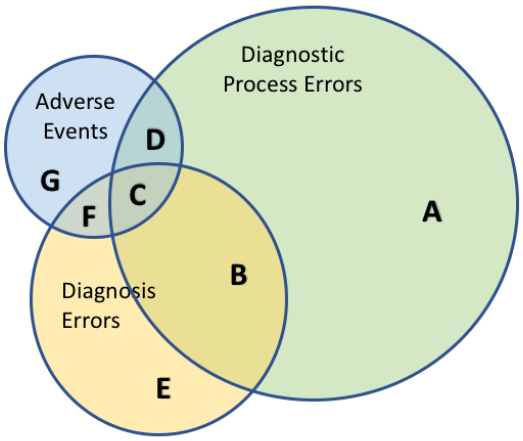

Figure 1

Relationships between diagnostic process errors, misdiagnosis, and adverse events. (reproduced modified from ref. 5)
Group A= Errors in diagnostic process (blood sample switched between two patients, the medical doctor doesn't do a physical exam for patient with abdominal pain)
Group B = Diagnostic process error with resulting misdiagnosis (patient given wrong diagnosis because blood samples switched)
Group C= Adverse outcome resulting from error-related misdiagnosis (patient is given toxic treatment and has adverse effect as result of switched samples. Fail to diagnose appendicitis because of failure to examine abdomen, and it ruptures and patient dies)
Group D= Harm from error in diagnostic process (colon perforation from colonoscopy done on wrong patient)
Group E= Misdiagnosis, delayed diagnosis or missed diagnosis, but no error in care or harm (incidental prostate cancer found on autopsy)
Group F= Adverse event due to misdiagnosis but no identifiable process error (death from acute myocardial infarction but no chest pain or other symptoms that were missed)
Group G= Adverse events but not related to misdiagnosis, delay, or error in diagnostic process, e.g., death from correctly diagnosed disease complication, or nonpreventable drug reaction (penicillin anaphylaxis in patient never previously exposed)

the professionals who take care of the patient and the patient himself and his caregivers (Figure 2) (6). Therefore, the diagnostic process should not be viewed in isolation by specialty, but as an integrated process of gathering information from the patient's history, physical examination, diagnostic tests, consultations and comparisons. Finally, data on the progression of the treatment must also continuosly be re-considered, analyzed and re-elaborated in order to verify any possible error or to adjust the first diagnostic hypothesis. The final outcomes can be evaluated both with respect to the patient and with respect to the healthcare system, trying to learn from diagnostic errors, avoided or near miss errors and accurate and timely diagnoses.

Many factors can influence this diagnostic process, first of all the professionals involved in the processes, with their skills and knowledge. But professionals operate in an environment made up of physical structures, availability of technologies and tools, organizations and tasks, main or essential items for the healthcare system. If the patient's outcome is closely linked to his health or to the improvement of his clinical conditions, for the healthcare system the analysis of the outcomes must also concern quality as a whole, including safety, costs, efficiency, ethics aspects and public trust in the health care system itself.

"Improving diagnosis in health care" identifies eight goals that can be researched or implemented to improve diagnoses and reduce diagnostic error. It is somewhat surprising that the first of the identified objectives does not concern knowledge, skills or technology, but rather the teamwork to make the diagnostic process effective among healthcare professionals, with the direct and parallel involvement of patients and their close family members. However, the education and continuous training of health professionals in their specific domain and skills within the diagnostic process remain important and relevant elements, as well as the guarantee of supports for the correct use of information technologies.

Some elements of error management are then focused, in order to implement approaches to identify, learn from and reduce errors, in a work and culture environment that support the diagnostic process and its improvements. At the same time, the "environment" must facilitate reporting and assuming responsibility for any errors, in a non-prosecutorial or sanctioning context but aimed at improving processes. The economic element also plays an important role in improving the diagnostic process and reducing errors, tending towards a payment system that better considers the value of the service and not just the costs of the service. Finally, funding devoted to research into diagnostic processes and its errors is as necessary as for therapeutic processes (Table 2).

THE 8 GOALS

Goal 1. Facilitating more effective teamwork in the diagnostic process among health care professionals, patients, and their families

The goal introduces as new and relevant focus, the integration between healthcare professionals and the effort that the healthcare organization should make to facilitate teamwork. Really, the topics of collaboration and consideration of the patient's requests and preferences are not new. These items, together with the practice of the best available tests, have actually constituted the heart of Evidence-Based Medicine (EBM), also for diagnostics. Medicine is a discipline made up of decisions, which are in the hands of clinicians but derive from available information, scientific evidence and from the choices and preferences of correctly informed patients. Decisions need integrated information and therefore require strict collaboration between pathologists, radiologists, other diagnostic operators and the treating clinicians.

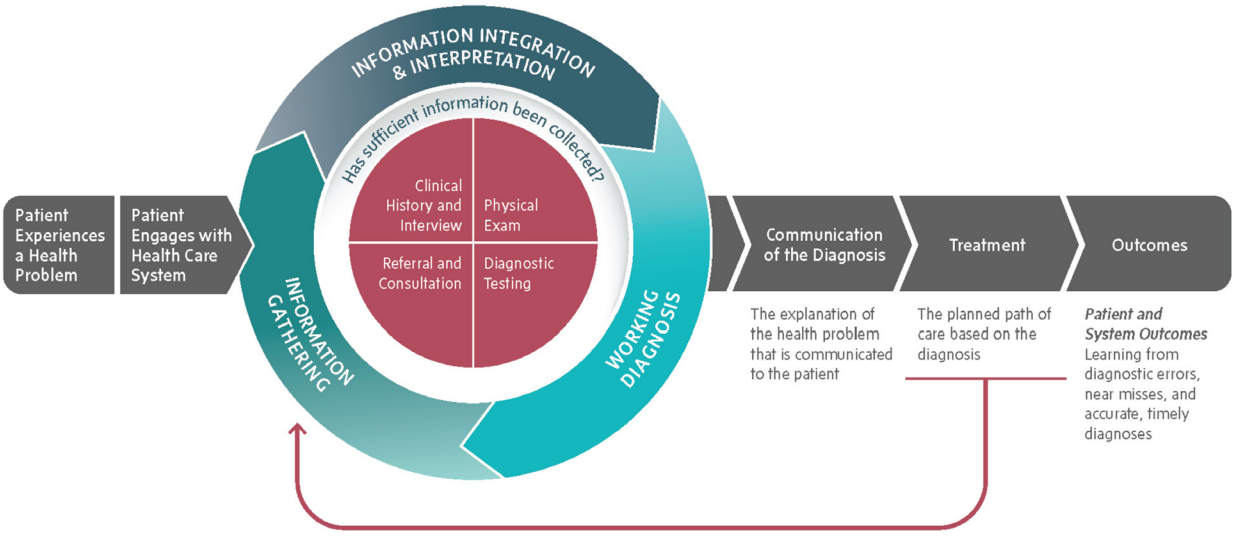

Figure 2
Conceptual model of the diagnostic process. (reprinted, with permission, from ref. 6)

Table 2

Goals to improve diagnosis and reduce diagnostic error (6)

Goals to improve diagnosis and reduce diagnostic error	Examples regarding Laboratory Medicine
1. Facilitate more effective teamwork in the diagnostic process among health care professionals, patients, and their families	Structuring prescriptive and interpretative consultancy activities, for applicants and patients (times, accesses, consultant on duty...)
2. Enhance health care professional education and training in the diagnostic process	Academic and training institutions should revise their programs by adding lectures and internships on diagnostics (appropriately request tests, interpret, act accordingly...)
3. Ensure that health information technologies support patients and health care professionals in the diagnostic process	Giving access to integrated results and reports, as well as information and consultancy sites (e.g. LTO), soon also via chatbot
4. Develop and deploy approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice	External Verification Test (EQA) failures may be investigated in audits with clinicians, with reference to patient outcome.
5. Establish a work system and culture that supports the diagnostic process and improvements in diagnostic performance	Every update and innovation introduced in laboratory diagnostics could be an opportunity for meetings to compare and share diagnostic processes along the patient's journey
6. Develop a reporting environment and medical liability system that facilitates improved diagnosis by learning from diagnostic errors and near misses	Implement accident and near-miss reporting registries and databases, similar to clinical areas
7. Design a payment and care delivery environment that supports the diagnostic process	Tariffs are needed that define diagnoses and not measurements. A striking example are autoimmune diseases.
8. Provide dedicated funding for research on the diagnostic process and diagnostic errors	Epidemiological studies could be conducted examining the relationship between excess deaths and laboratory tests (e.,g. lipid references value and AMI, or the results of tests and the outcomes of screening (e.g. PSA, Hepatitis C, ...)

However, to reduce diagnostic errors it is also necessary that patients and their families have the opportunity to know and learn, creating environments where they feel comfortable participating in the diagnostic process, sharing feedback and concerns about possible errors diagnostics and on “next lose events”. A useful but sometimes still not fully available element is the easier access to electronic medical records and their own clinical data.

Goal 2. Enhancing health care professional education and training in the diagnostic process

Knowledge of diagnostic processes is not as completely widespread as might be supposed, even among specialized technical operators. In fact, the diagnostic process considers several areas, such as clinical reasoning, teamwork, communication with the patient, their families and other health professionals, the appropriate use of the tests and the application of the results to the subsequent decision-making process, also through the use of health information technologies. Healthcare professional education providers should ensure that curricula and lifelong learning programs address all of these areas. These competencies should be maintained over time, and healthcare facility certification and accreditation organizations should ensure that healthcare professionals working there have and maintain the competencies necessary for effective performance in the diagnostic process. In the world of laboratory medicine, scientific societies seem to be strongly oriented in this direction, both by contributing to the training contents through structured courses, and by defining the levels of knowledge and competence of the professionals, both in their training and post-graduate - specialties (7,8).

Goal 3. Ensuring that health information technologies support patients and health care professionals in the diagnostic process

In recent decades, information technology (IT) applied to diagnostic processes has proven to be a vital aid for error prevention, as it demonstrates usability, incorporates human factors knowledge, integrates measurement capability, adapts well to clinical workflow, provides decision support and facilitates the timely flow of information between patients and healthcare professionals involved in the diagnostic process.

A continuous evaluation, with respect to all possible dimensions and implications (clinical efficacy, safety, economic, organizational, social/ethical) is necessary along with the evaluation of other technologies used in healthcare. Also, with this aim, the free exchange of information on user experiences in real time with the design and implementation of health informatics can be an important aid to the improvement of diagnostic processes and the reduction of errors.

In recent years, a growing concern has emerged about the new frontiers of IT, starting from the scientific treatment of data, evolving from artificial intelligence (AI) (already present for years in diagnostic processes) through the use of more or less complex algorithms, towards the trainable (machine learning) and self-training systems (automated machine learning, deep learning).

The concern that these systems could replace complex human jobs, in terms of role and responsibility affects many human activities and healthcare in particular. However, to avoid the risk of falling prey to easy and unjustified alarmism or obtuse and exaggerated optimism, it is essential to deepen one's knowledge of the world of AI, partly transversal to laboratory medicine. But creating or collaborating with multidisciplinary teams may not be enough. To safely govern these new technologies, clinical laboratories themselves must develop a core of skills and knowledge on machine learning and deep learning algorithms, on the results achieved by current AI systems in medicine, on the already evident limits and risks of this technology, including ethical and privacy issues and its improper or harmful use.

Today, AI is already being used successfully in many areas of medicine, including imaging, surgical care, genomic data analysis, monitoring patients via wearable devices, and developing new drugs. However, the results obtained must be critically balanced against possible risks and evaluated in a broader context. In particular, the following critical issues could be highlighted:

- the reliability of the AI is based on the training data provided: in case of incomplete, incorrect or unrepresentative data, the results provided by the AI may not be correct; inaccurate results could also be provided when AI is applied to solve problems for which it has not been trained, as in the recent cases of misuse of ChatGPT (9);
- who should be held legally liable for errors made by AI, including diagnostic or treatment errors? The attribution of this responsibility could be particularly complex;
- how to evaluate and validate machine learning or deep learning algorithms? While some algorithms are simple to understand, others are very difficult to interpret. The "opacity" of some AI algorithms and possible solutions is the research field of a recent AI approach called "explanatory AI", which aims to make the decision-making processes of machines more transparent and understandable for humans in order to explain how and why an algorithm produced a certain result or made a certain decision;
- AI poses numerous ethical issues: it could be used to discriminate patients on the basis of some characteristics; the use of large amounts of sensitive data increases the risk of unauthorized access to personal and medical information; finally, the use of these technologies could be reserved for a minority with unequal treatment of patients.

All these concerns deserve an important reflection by professionals and a constant commitment by scientific societies, in order to be actors and not passive spectators of this change. Furthermore, it must be considered what these systems can do, to prevent other risks of error, determined by two dominant variables in healthcare: the quantity of treatments to be provided and time. If we consider the classic formula that represents the risk as:

$$Risk = Likelihood \times Impact$$

considering the single diagnostic activity, and particularly the clinical laboratory diagnostics, the risk appears to be not very critical, both because the probability is low (in the analytical phases we generally work with performance at least >4σ), and because only a limited percentage of diagnostic errors results in an adverse outcome (Figure 1).

However, a low probability multiplied by thousands of events soon becomes significant. Moreover, time is critical both because it represents a stress element of the system and because the response delay of a correct diagnosis can cause as much damage as a wrong diagnosis. We could therefore represent the laboratory diagnostic risk as:

$$Risk = \frac{(Likelihood \times Impact \times Number\ of\ Reports)}{Time}$$

A few years ago, the World Health Organization's Institute of Medicine reported that the global health workforce shortage will reach 12.9 million in the coming decades (10). Even in the richest countries, primary care is becoming increasingly expensive and inconvenient, often with waiting times that make it not attainable. About half of the adult population in developed countries has at least one chronic condition (25% have at least two) (11). In this context, clinicians and clinical pathologists think and act in chaotic clinical environments, under pressure, and continually confronted with uncertainty, which is an integral part of the diagnostic process (12). Thus, it is estimated that at least one misdiagnosis will occur in the care of nearly every patient in their lifetime.

We have seen how in Laboratory Medicine the number of "reports" to be produced and, above all, the expected turnaround times are particularly critical elements of "risk" and these "drives" were also the major factors determining the organizations and re-organizations of the past decades. IT, and subsequently also Automation Technology (AT), have strongly contributed to these re-organizations and have been a fundamental way for the prevention of diagnostic errors, affecting both the analytical phases, but also the pre- and post-analytic processes.

Right from the farsighted vision of Lundberg's brain to brain loop (13) it was clear how the outcome for the patient also relied on two other fundamental phases, which represent the evaluation of the patient and the consequent choice of tests (pre-preanalytical phase) and the integrated evaluation of information and the choice of treatments (post-postanalytical phase). Laboratory medicine cannot exempt itself from its mission even in these "extra-laboratory" phases, cooperating for the best use of the tests and the correct interpretation and evaluation of the results. In these areas, data science seems to have an emerging role, and can become a formidable tool to reduce the fallibility of the system, rather than being a competitive risk for professionals (Figure 3).

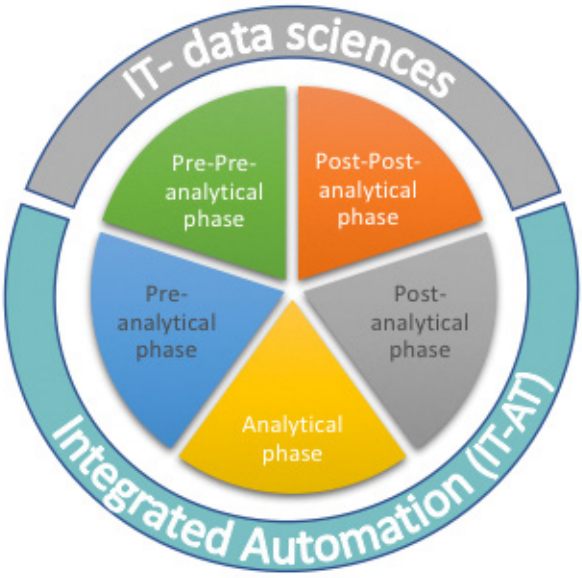

Figure 3
Intervention areas of information technologies (IT) with respect to the phases of the laboratory diagnostic process, according to the brain-to-brain loop. If IT and AI are structural to the internal processes of the clinical laboratory and contribute decisively to the reduction of errors in the pre-analytical, analytical and post-analytical phases, the possibilities deriving from data sciences seem to be able to offer the same help and shield for the pre-pre and post-post analytical areas.

Data science and AI applications can be relevant not only professionally, but also for patients. For professionals, these tools can reduce variability, compensate for workloads and stress conditions, standardize processes, reduce training gaps, and manage complex information. However, these systems interact with people at ever deeper levels, and even in the field of human health they can help to facilitate access to care, guarantee territorial equity and available services, act as mediators for the interpretation of information in a progressive evolution of the relationship between patients and healthcare, all mediated by increasingly interactive and semantic WEB interfaces. In the future we will probably have to move from the evidence-based evaluation of the effectiveness of treatments, supported by AI (electronic and digital health records, big data) to the mandatory evaluation of the same AI and data science applications with Evidence Based Medicine approaches.

Goal 4: Developing and implementing approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice

Healthcare errors are unavoidable, and measuring and monitoring them has always been a challenge. In the diagnostic field, while some areas are heavily guarded and can be classified among the best controlled and monitored, others, especially non-analytical phases, are not or are controlled in much lesser extent. For these reasons, accrediting institutions and health insurers may require health care organizations to have programs in place to monitor the entire diagnostic process. Healthcare organizations should implement procedures and practices to provide systematic feedback on diagnostic performance to individual healthcare professionals, care teams and clinical and organizational leaders. Tailored activities to search for undetected errors should also be funded, such as performing routine autopsies on a representative sample of deceased patients, with no complaints pending.

In the specific areas of laboratory medicine, tools are needed to quantify the quality of each step and action in the diagnostic process, comparing it to references. Continuous monitoring through quality indicators is an extremely consolidated practice in the analytical phase and is increasingly being used in the pre- and post-analytical phases, while for the pre-pre and post-post phases there is still a long way to go, also from a theoretical point of view, about “what to do” and not just “how to do”.

However, if the focus of quality is patient outcome, clearly, we need to take control that the right test is required for the specific person, timely measured with reliable and safe analytical methods, and that the result is understood, interpreted and determines the correct therapeutic action: in other words, we have to reach the control of the entire diagnostic process, up to its outcome.

Goals 5 and 6: Establishing a work system and culture that supports the diagnostic process and improvements in diagnostic performance - Developing a reporting environment and medical liability system that facilitates improved diagnosis by learning from diagnostic errors and near misses

In our social context, the fear of being criticized and prosecuted for mistakes overcomes the awareness that only the review of experiences, even the negative ones, can improve the system and reduce fallibility. The growing “compensatory” climate in our health systems seems playing against a transparent and proactive approach. But precisely the reimbursing risks should represent one of the major driving forces towards new pathways to really reduce the probability of diagnostic errors. Promoting policies and practices that foster a non-punitive culture and value arousing discussions and feedback on diagnostic performance is a goal that requires educational and regulatory efforts. A reorganization needs to be of help to redesign the work systems where the diagnostic process takes place, regarding the activities of the health workers, the patients and their families in order to facilitate accurate and timely diagnoses.

In the same area is goal 6, aimed at encouraging the voluntary reporting of diagnostic errors and “near misses”, as well as promoting a legal environment that facilitates the timely identification, disclosure and learning from diagnostic errors. The insurance and judicial system could play a fundamental role, provided that systems rewarding preventive activities, (also for future protection), instead of defensive or punitive activities have be identified.

Professional liability insurance companies should collaborate with healthcare professionals on opportunities to improve diagnostic performance through education, training, and practice improvement approaches, and increase participation in such programs.

Goal 7: Designing a payment and care delivery environment that supports the diagnostic process

The current systems of participation to health care costs, both public and private, are based on payment for services. If it is true that the diagnostic element strongly influences the path of the patient with respect to the related pathology, it consequently also influences it in terms of costs. For example, inappropriate or missing tests can delay treatment, determine other more expensive investigations, lengthen hospitalization times, induce unnecessary therapies. On the other hand, there may be tests that are "expensive" in themselves but contribute to reduce other activities, relieving the system of visits, simplifying monitoring also by telematic tools, interrupting expensive therapies earlier or predicting individual responsiveness, etc.

Payment per performance pushes the system to seek service efficiency, to do more at the lowest cost. Systems can therefore be made more efficient, even if efficiency does not guarantee effectiveness. Linking diagnostic performance to diagnostic questions would already shift attention more to EBM logics. Even if a payment system completely "by diagnosis" is perhaps complex and difficult to achieve, however linking the request to the service to a lesser extent, and more to the diagnostic request could change the pricing of the services themselves, e.g. integrating reflex paths also to different diagnostic areas, including laboratory medicine, pathology, radiology, etc. Eventually, a payment system "by outcome" would lead to the economic recognition of the diagnostic "Value" (14). Posteriori costs are difficult to evaluate, but an integration of the diagnostic costs in the overall cost of the treatment could be studied (using Diagnosis Related Groups, DRGs, for example).

Goal 8: Providing dedicated funding for research on the diagnostic process and diagnostic errors.

Research that can generate earnings is more easily financed, and perhaps, for this reason, this goal is rather difficult to achieve. It would be necessary to have an objective measure of the costs of diagnostic errors, really estimated to be much higher than the therapeutic costs, and to see the problem not in terms of gain, but in terms of cost reduction (15). This could lead to commit dedicated funding for the implementation of this task, as well as pursuing and encouraging public-private partnership opportunities between a broad range of stakeholders, to support research into the diagnostic process and diagnostic errors in particular. Unfortunately, the health care financing crisis raises questions about whether there is room for such actions in the near future.

CONCLUSION

The diagnostic process is complex, can start anywhere and can take multiple paths. No single data source, method, setting or circumstance will be sufficient for patients, diagnostic teams and organizations to understand the multiple causes and risks of every diagnostic error. The progression of the current understanding of diagnostic error requires the involvement of all stakeholders in all contexts. We need a cultural change of approach and a system for measuring the problem, in order to establish its extent and nature, determine causes and risks of diagnostic error, evaluate the effectiveness of the intervention, establish the needed skills in education and training, verify the responsibility for diagnostic performance.

Clinical laboratories cannot face this challenge individually and alone, but in collaboration with all the involved subjects, from clinicians to other diagnostic services and patients. On the other hand, clinical laboratories cannot ignore this problem, because risk affects everyone, both as professionals and as patients.

CONFLICT OF INTEREST

None

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