

Diagnostic difficulty in family medicine in relation to patient safety

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**UNIVERSITY OF ZAGREB
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**Diagnostic difficulty in family medicine
in relation to patient safety**

GRADUATE THESIS

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LIST OF ABBREVIATIONS

EMR: electronic medical record

GP: general practitioner

POCT: point-of-care testing

Vs: versus

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1. SUMMARY

Diagnostic difficulty in family medicine in relation to patient safety

Laure Perraut

Patient safety is a new healthcare discipline that emphasizes the reporting, analysis, and prevention of medical error that often leads to adverse healthcare events. According to research, 60 to 80% of all identified errors could be considered as preventable, making patient safety an area of growing interest both in public as well as among health care professionals.

Most experience of medical error has been gained from the secondary care environment, but little is known about the situation in primary care, where the majority of patient contacts with health care providers occurs. Four dimensions of patient safety issues have been identified in primary health care: diagnosis, prescribing, communication between patients and providers of care, and organisational issues. However, prevalence studies show that diagnostic errors predominate in general practice settings: of all adverse incidents reported in the primary care setting, 28% to 78% are related to the problems with diagnosis. Prompt diagnosis of poorly differentiated and potentially serious disease represents one of the core competencies of family physicians. Diagnosis is central to the family physician's role and diagnostic error has the potential for the most serious consequences for patients, since all management decisions, including referrals and treatment, are based on diagnosis.

Studies have begun to identify the root causes that contribute to diagnostic error. These causes include either one or more of the following: clinician cognitive factors and systems factors. Understanding the root causes that contribute to diagnostic error can bring substantial help in preventing future adverse medical events.

Key words: patient safety, family medicine, diagnostic error.

2. INTRODUCTION

Family medicine is a medical specialty devoted to comprehensive health care for people of all ages. In Europe this discipline is often referred to as general practice. The specialist is named a family physician, or a general practitioner (GP). It is the medical specialty that provides continuing and comprehensive health care for the individual and the family, regardless of gender, age or type of the problem (WONCA, 2011).

Family medicine represents a division of primary care, which is the level of health services system that provides entry into the system for all new needs and problems. Typically primary health care providers act as the first contact and principal point of continuing care for patients within a health care system, and coordinate other specialist care that the patient may need. Thus, depending on the nature of the health condition, patients may be referred for secondary or tertiary care.

Secondary care represents the level of the health care services provided by medical specialists and other health professionals who generally do not have first contact with patients, for example, cardiologists, urologists and dermatologists.

Tertiary care is specialized consultative health care, usually for inpatients and on referral from a primary or secondary health professional, in a facility that has personnel and facilities for advanced medical investigation and treatment, such as a tertiary referral hospital

Primary care differs from secondary care in several key aspects. The specialty of family medicine aims to provide longitudinal personalized care, thus is centered on lasting, caring relationships with patients and their families. Family physicians integrate the biological, clinical and behavioral sciences to provide continuing and comprehensive health care. The scope of family medicine encompasses all ages, sexes, each organ system and every disease entity (Olesen et al. 2000).

Patient safety can be at stake in both hospital and general practice settings (Gaal et al. 2011). Indeed, general practitioners deal with a very broad range of symptoms and signs many of which cannot easily be categorized into a clear diagnosis. Delineating “right or wrong” practice is more complex in primary care than in secondary care (Wilson and Sheikh 2002).

This healthcare context is a potentially high risk environment, because of the increasing complexity of care provided in outpatient settings, and the risk created by dysfunctional interfaces between inpatient and outpatient care.

Several definitions for patient safety key concepts have been published. The generally used and accepted definition of a “patient safety incident” is the following: “any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving medical care” (Runciman et al. 2009). An “error” is “a failure to carry out a planned action as intended or application of an incorrect plan.” Errors are, by definition, unintentional; they manifest by doing the wrong thing or by failing to do the right thing (Runciman et al. 2009).

According to their underlying cause, we distinguish different types of patient safety incidents. We mostly identify so-called “*Process errors*” that arise from healthcare systems dysfunction (86.1% of total errors), and “*Knowledge and skills errors*” due to gaps in erudition and expertise (13.9% of total errors). The classification of “process errors” allows us to clarify why something went wrong. They comprise administrative mistakes (30.9%), failure in investigation processes (24.8%), treatment delivery problems (23.0%), miscommunication (5.8%), and payment system mix ups (1.2%). “Knowledge and skills errors” comprise errors in the execution of a clinical task (5.8%), misdiagnosis (3.9%), and wrong treatment decisions (4.2%) (Dovey et al. 2002).

So far, most experience of medical error has been gained from the secondary care environment, but little is known about the situation in primary care, where the majority of patient contacts with health care providers will occur. Several organizations have called attention to the deficiency of patient safety research in primary and ambulatory care (Sandars and Esmail 2003). There is a perception that, even if more errors occur in primary outpatient care than in hospitals, they are unlikely to result in significant harm to patients. This notion underestimates the combined effects of patient volume, complexity, and repetitive systematic errors (Phillips et al 2004). In addition, studies suggest that errors occur frequently, and that seemingly trivial mistakes can result in severe harm, particularly for vulnerable patient populations (Phillips et al. 2004). Frequent errors in primary care, often thought to be trivial, can contribute to bad health outcomes for patients and should not be ignored, as data reveals that many errors occurring in primary and outpatient care setting are of significant source of

morbidity and mortality (Kostopoulou 2008b). Identification and reduction of medical error has to become a major priority.

Medical error in primary care occurs between 5 and 80 times per 100 000 consultations (Gaal et al. 2010). A Dutch study reported on a total of 1 to 4 patient safety incidents detected per patient per year, with a prevalence of 2,2% for all patient contacts (Gaal S et al. 2011). The causes of error are often multiple, and that in up to 50% of incident cases no cause can be identified (Sandars and Esmail 2003). Some factors can contribute to the effect of the underlying cause of an incident. These are typically factors that would not have led to the event independently and are called contributing factors. The outcome measure of an error is the severity of the incident or injury, categorized as low, moderate, high, or death. (Phillips et al. 2004). Identification of possible reasons is an essential step for understanding causation and prevention of error in primary care. (Dovey et al. 2002)

Making primary care safer for patients is complicated by a lack of understanding of the nature and distribution of errors (Dovey et al. 2002). Safety issues in the ambulatory setting differ from those in the inpatient setting. There are differences in the types of errors, the provider–patient relationship, and organizational structure. For example treatment errors predominate in inpatient settings whereas diagnostic errors do in outpatient settings. Outpatient setting also presents greater challenges for information transfer, particularly in the case of patients with complex medical needs, the responsibility for care being often shared by multiple providers at many institutions (Gandhi and Lee 2010).

Safety in primary care is a major concern in four main areas - diagnosis, prescribing, communication and organisational characteristics of primary care (Wilson and Sheikh 2002). Of all adverse incidents reported in the primary care setting, 28% to 78% are related to the problems with diagnosis, of which half were considered to be very harmful (Wilson and Sheikh 2002; Sandars and Esmail 2003). Diagnostic errors are encountered in every specialty; studies consistently demonstrate a rate of diagnostic error that ranges from <5% in the perceptual specialties (pathology, radiology, dermatology) up to 10% to 15% in most other fields. (Berner and Graber 2008). However, diagnosis is the most important function of a GP, since all management decisions, including referrals and treatment, are based on diagnosis. The gatekeeping role of a GP in countries like the UK, the Netherlands and Croatia makes diagnosis crucial for identification and treatment of a serious disease, emphasizing the

responsibility of a GP in the initial management based on proper diagnosis. Although most of the diagnostic errors are rated as moderate or as minor or insignificant, errors related to diagnosis account for the largest proportion of claims against GPs in the UK (Silk 2000) and for a third of negligence adverse events in the primary care in the United States (Phillips 2004). Diagnostic errors can have serious adverse consequences for the doctor in terms of trust, self-confidence and litigation and represent the most memorable errors in a GP's career (Kostopoulou 2008a).

Given the significance of the presented problem of diagnostic errors in family medicine, the aim of this review was to identify the extent and nature of diagnostic errors in family medicine.

3. METHODS

The online search in the PubMed database was performed in the period October - December 2014, using advanced search options and Boolean logical operators.

The following combination of MeSH search terms were used:

(Primary health care OR family practice OR general practice) AND diagnostic errors.

No limit was placed on year of publication, but the search was limited to English language publications.

The search resulted in 165 abstracts.

All the abstracts were checked for relevance. A selection of the abstracts was made according to the following criteria: we used abstracts in English, abstracts that reported original research and / or reviews, and excluded studies if their main focus was not on the identification and description of diagnostic error.

After applying the selection criteria, 78 abstracts remained.

A detailed reading of these papers resulted in final 34 articles for the purpose of this review.

4. RESULTS

4.1. The extent of diagnostic error in family medicine

Errors related to diagnosis are reported in the studies as the most common error category in primary care, varying from 26% to 78% of all identified errors (Bhasale et al. 1998a; Bhasale 1998b; Ely et al. 1995; Silk 2000; Fisseni G et al. 2008; Khoo et al 2012).

Most medico-legal claims against family physicians are related to delayed or missed diagnosis, accounting for twice as many cases as medication errors. In a Dutch study regarding complaints against family physicians submitted to disciplinary tribunals in the Netherlands, 24% of the total number of complaints and 44.6% of complaints with serious health outcome were related to wrong diagnosis (Gaal 2011a). In a similar study from the United States, 59% of malpractice claims involved diagnostic errors that harmed patients; 59% of these errors were associated with serious harm and 30% resulted in death of a patient (Gandhi et al. 2006).

The most common missed or delayed diagnoses in the primary care setting are pulmonary embolism, acute coronary syndrome, stroke and malignancies (Gaal 2011b; Schiff et al, 2009). In addition to these, conditions that seem to be particularly problematic or for which it is easier to find a misdiagnosis, include asthma, drug reactions or overdose and depression (Wilson and Sheikh 2002), but also other common conditions in primary care like pneumonia, decompensated congestive heart failure, acute renal failure and urinary tract infections (Singh 2013).

4.2. The nature of diagnostic error in family medicine

Primary care physicians work under significantly different conditions from their hospital colleagues. In primary care setting, patient usually presents with poorly defined, often psychological or social symptoms, whose problems have not yet been defined to a certain category, so there is a broad range of possible diagnosis.

In order to provide the adequate clinical care, a right diagnosis is essential, although not sufficient on its own. To reach the right diagnosis, physicians must take a complete medical history and perform the right physical examinations and further tests (Minue et al. 2014).

Prompt diagnosis of poorly differentiated and potentially serious disease represents one of the core competencies of family physicians. Management decisions, including referrals, are based on diagnosis. Missing serious conditions (such as cancers) can have devastating consequences for patients. It can also have serious adverse consequences for the doctor in terms of trust, self-confidence and litigation (Kostopoulou 2008a).

Errors related to diagnosis can be classified as

- misdiagnosis / wrong diagnosis (another diagnosis was made before the correct one),
- missed diagnosis (no diagnosis was ever made),
- delayed diagnosis (sufficient information was available earlier).

(Graber et al. 2005; Schiff et al. 2009).

Several studies focused on identification of the root causes that contribute to diagnostic error.

Although these two realms overlap, diagnostic errors have traditionally been dichotomized into so-called **cognitive** (e.g. faulty clinical reasoning) and/or **system-related factors** (e.g. inefficient processes and poor communication)(Singh et al. 2007; Schiff et al. 2009; Kostopoulou and Delaney 2007).

4.2.1. Cognitive factors

Cognitive errors reflect errors in diagnosis from faulty data collection or interpretation, flawed clinical reasoning or incomplete knowledge. Medical knowledge is of obvious importance, and insufficient knowledge can result in inadequate decision-making for both diagnostic and treatment purposes. However, errors in clinical reasoning occur in most cases in which the diagnosis is missed, delayed or wrong.

Diagnostic error is typically viewed as cognitive failing, often caused by biases linked to non-analytical, intuitive thinking. Cognitive factors include perceptual and thought processes, which are in turn influenced by differences in clinician training and experience, predisposition to cognitive and affective biases, fatigue, stress and a variety of other elements (Singh et al. 2012).

According to Schiff et al, the **diagnostic process** can be divided into seven stages: (1) access and presentation, (2) history taking/collection, (3) the physical exam, (4) testing, (5) assessment, (6) referral, and (7) follow-up (Schiff 2005). Errors occur most frequently in the testing phase, i.e. failure to order, report, and follow-up laboratory results (44%), followed by clinician assessment errors, i.e. failure to consider and overweighing competing diagnosis (32%), history taking (10%), physical examination (10%), and referral or consultation errors and delays (3%)(Schiff et al. 2009).

Diagnostic hypotheses are made early in the consultation and guide subsequent history and examination in a hypothetico – deductive reasoning. The commonly taught sequential approach to history taking and examination, resulting in differential diagnosis and ultimately a final diagnosis, is not what practitioners do in reality.

According to Heneghan et al, **diagnostic reasoning** can be split into a three stage model:

- (1) initiation of diagnostic hypotheses;
- (2) refinement of the diagnostic hypotheses;
- (3) defining the final diagnosis (Heneghan et al. 2009).

The first trigger for a diagnosis usually occurs early in the consultation. Heneghan identified four possible strategies within the *initiation stage* (Heneghan et al. 2009)

- “*Spot*” diagnosis arises from an unconscious recognition of a particular non-verbal pattern, usually visual (dermatological condition such as acne) or auditory (a barking cough). The spot diagnosis is almost instantaneous and does not require further history from the patient to trigger the possible diagnosis. The main determinant is clinical experience with a given condition and is used in about 20% of cases.
- *Self labeling* — The patient may tell you what they perceive to be the diagnosis, often based on their own previous experience of a problem (e.g. “I have tonsillitis”). This strategy directs subsequent refinement of the diagnosis.
- *Presenting complaint* (for instance, “I have abdominal pain” or “I have a headache”) is used most often by GPs. Traditional textbooks are recognizing this step at the outset of the consultation.
- *Pattern recognition trigger* — Elements in the history or examination may trigger the hypothesis (e.g. thirst, feeling unwell and looking unwell in an adolescent triggers the possibility of diabetes type 1).

Once the initial possible diagnoses are formed, other strategies are used to narrow the possibilities. Five strategies have been identified in the **refinement stage**, which are not mutually exclusive (Heneghan et al. 2009):

- *Restricted rule outs*: This diagnostic strategy depends on learning the most common cause of the presenting problem and a shortlist of serious diagnoses which must be ruled out; it is aimed at preventing errors in clinical practice. (e.g. the most common type of headache are tension-type headache and migraine, but malignant hypertension, subarachnoid hemorrhage and temporal arteritis must be ruled out).
- *Stepwise refinement* is based on either the anatomical location of the problem or the putative underlying pathological process. An example is deciding whether conjunctivitis is allergic or infectious.
- *Probabilistic reasoning* is the use of symptoms, signs or diagnostic tests to rule in or rule out a diagnosis. It requires knowing the degree to which a positive or negative result of a test adjusts the probability of a given disease. Example: use of electrocardiograms in the assessment of chest pain.

- *Pattern recognition fit*: symptoms and signs are compared to previous patterns or cases, and a disease is recognized when the actual pattern fits. This is the refinement strategy most commonly used by GPs. Its use relies on memory of known patterns, but no specific rule is used.
- *Clinical prediction rule*: is a formal version of pattern recognition, based on a well defined and widely validated series of similar cases (ex: streptococcal sore throat rules, ABCD score for stroke risk...). Which rules are useful and how they can best be used in practice remains an important unanswered question.

Less than 50% of cases after refinement stage result in the certainty of a “known diagnosis” without further testing. Thus GPs use other strategies in the *final stage of diagnosis*, including ordering further tests, test of treatment, and test of time (*Heneghan et al. 2009*):

- *Known diagnosis*: a sufficient level of certainty of the diagnosis to start the appropriate treatment, or to rule out serious disease without further testing
- *Ordering further tests*: a standard test is used to rule in or rule out the disease
- *Test of treatment*: when the diagnosis is uncertain, the response to treatment is often used to refute or confirm it (e.g. use of inhalers in nocturnal cough)
- *Test of time*: the course of the disease is used to predict when a person should be better or worse; a “wait and see” strategy allows the diagnosis to become more obvious (e.g a patient with abdominal pain and no “red flags”)
- *No label applied*: no diagnostic label could be assigned to the patient (presentations were often vague and didn’t fit a recognizable pattern). Various strategies can be used: recalling the patient for further review, using an exploratory investigation, sharing uncertainty with the patient, or referral to secondary care for a second opinion.

Different strategies are used in each of these 3 main stages. For example, the initial complaint, “spot” diagnosis or pattern may trigger the possible diagnoses (hypotheses); then, specific elements of history or examination are elicited to rule in or rule out competing possibilities; finally, one or several strategies may be used to confirm the final diagnosis. For some diagnoses a high level of certainty at the initiation stage may lead straight to a final known diagnosis, missing out the refinement step (e.g. diagnosing simple acne)

Clinicians make diagnoses using 2 different systems of thinking. The *System 1* is intuitive, automatic and requires little cognitive capacity, the *System 2* is reflective, analytical and requires cognitive capacity. **System 1** uses heuristic, pattern recognition approach, developed through clinical experience. This method requires less cognitive load, making it a faster way to make the right diagnosis, in about 10 seconds. Thus this is an efficient way of thinking. **System 2** uses the hypothetical-deductive, analytical method, relying on working memory to generate a differential diagnoses list by gathering information. It requires more cognitive load, it is a slower way to make diagnosis, taking about 1 to 7 minutes (Stanovich and West 2000). Thus, expertise in diagnosis is not a matter of acquiring an all-inclusive reasoning strategy, as several strategies may lead to the same diagnosis. The great majority of medical diagnoses are made using automatic, efficient cognitive processes, and these diagnoses are correct most of the time.

Professional behavior primarily includes making a thorough physical examination, weighing the signs and symptoms against the possibility of a serious disease. The essential purpose of this step is to filter out life-threatening illnesses. Actually, when conducting an adequate physical examination, missing a diagnosis is often not cause for disciplinary action while facing malpractice claims. That's why for example the tribunals in the Netherlands do not expect physicians to establish correct diagnoses for all their patients, but they do expect the use of a recommended physical examination and diagnostic tests whenever necessary (Gaal et al. 2011b).

Diagnostic errors are not immediately noticed and feedback about the outcome of the diagnostic process is often delayed if not missing. More importantly, people have limited access to their cognitive processes and hence are unlikely to report them (Kostopoulou 2008a)

Another major factor contributing to diagnostic error according to Berner and Graber is **physician overconfidence** (Berner and Graber 2008). Berner and Graber hold a thesis that physicians in general under appreciate the likelihood that their diagnoses are wrong and that this tendency to overconfidence is related to both intrinsic and systemically reinforced factors. They make this conclusion based on their study in which the level of physician confidence showed no correlation with their ability to predict the accuracy of their clinical diagnosis, and the confidence level of the worst performers was actually higher than that of the top performers (Berner and Graber 2008).

What are the Causes of Cognitive Error?

Most of the cognitive errors in diagnosis occur during the “synthesis” step, as the physician integrates his medical knowledge with the patient’s history and findings (Bhasale 1998b). Rarely, the reason for not knowing may be lack of knowledge per se. More commonly, cognitive errors reflect problems of gathering data (such as failing to elicit complete and accurate information from the patient), failure to recognize the significance of data (such as misinterpreting test results), or most commonly, failure to synthesize or “put it all together”.

Diagnostic error is typically viewed as cognitive failing, often caused by biases linked to non-analytical, intuitive thinking. This process is largely subconscious and automatic (Berner and Graber 2008).

- **Heuristics** are the strategies that people use deliberately in order to simplify judgmental tasks that would otherwise be too hard for the typical human mind to solve (Gilovich T, Griffin D, Kahneman D. *Heuristics and Biases*. The psychology of intuitive judgement. Cambridge: Cambridge University Press; 2002). Research has revealed a wide variety of heuristics, which are powerful clinical tools that allow problems to be solved quickly and, typically, correctly. *Availability heuristics* is defined as a mental shortcut that relies on immediate examples that come to mind (e.g. a weekend gardener with linear strikes of itchy vesicles on the legs is easily diagnosed as having contact sensitivity to poison ivy). It is used when the clinicians assess common problems. The *representativeness heuristic* would be used with conditions presenting characteristic clinical presentation (e.g. chest pain irradiating to the back, varying with posture and associated with a cardiac friction rub in a patient with pericarditis). Unfortunately, the unconscious use of heuristics can predispose to diagnostic errors: if a problem is solved using the availability heuristic, it is unlikely that the clinician considers a comprehensive differential diagnosis, because the diagnosis appears so immediately obvious. Similarly, using the representativeness heuristic by just matching the patient’s clinical presentation to the prototypical case, the clinician may not take into account that other diseases may be much more common and present similarly. (Berner and Graber 2008; Wellber 2011).
- **Premature closure** represents narrowing the choice of diagnostic hypotheses too early in the process, such that the correct diagnosis is never seriously considered. Once

our minds find an adequate solution to the problem we are facing, we tend to stop thinking of additional solutions.

- **Confirmation Bias** and **Related Biases** reflect the tendency to seek out data that confirm one's original idea rather than to seek out disconfirming info.
- **Context Errors** result from characterizing a problem in terms of the organ system involved (e.g. a patient with abdominal pain is likely to be diagnosed as having a GI problem, although chest organs can sometimes present with similar symptoms).

As physicians gain experience and expertise, most problems are solved by some sort of pattern recognition process. Most of the time this pattern recognition serves the clinician well. However, according to research by Kostopoulou, number of critical cues was a significant predictor of diagnostic accuracy in management of difficult diagnostic problems, while no effect of experience was detected (Kostopoulou et al, 2008a).

There are possibilities for improving cognitive aspects of diagnosis by training designed to improve cognition and by implementing some system – level changes (e.g. second opinions, decision support systems, timely access to specialist consultants) (Graber et al. 2002).

Graber et al identified potential **cognitive interventions** to reduce diagnostic error into three categories:

- (1) Increasing knowledge and expertise,
- (2) Improving clinical reasoning and decision – making skills,
- (3) Providing cognitive “help” from colleagues, consultants and tools (Graber 2012).

Diagnostic error could potentially be reduced by increasing physician's structured knowledge and experience, the essential basis of expertise. Feedback provides a way to improve expertise, calibration and error awareness. A second way to reduce cognitive factors is to improve clinical reasoning, specifically encouraging both analytical and non-analytical reasoning, as diagnoses are made by some interacting combination of intuitive, automatic processing (system 1) and deliberate, rational consideration (system 2) (Norman and Eva 2010). It has been argued that intuition can be improved by learning the potential shortcomings (biases) of intuitive decision-making so as to understand and avoid them. A central element of reflective practice is to consider alternative diagnoses. The clinicians should invoke what has been called the universal antidote, ‘Could this be something else?’

(Ely et al. 2012). A third kind of intervention to reduce diagnostic error is to get help, either through other people or through the use of decision support tools.

4.2.2. System-related factors

System – related factors refer to organizational vulnerability to diagnostic error and may include faulty communication practices, inadequate coordination of care, inadequate supervision, poorly designed technology and work environment, reduced availability of resources or personnel, inadequate feedback, and a culture that does not necessarily promote effective learning from error. Research suggests that almost 65% of diagnostic errors have an important contribution of system errors, of which many are abnormal test results that were lost to follow up (missed results) (Wahls 2007). In a Dutch study, of the 211 patient safety incidents, 116 were classified as organization related (Gaal 2011b).

The safety culture of a healthcare organization is defined as the product of individual and group values, attitudes, competencies and patterns of behavior. Organizations with a positive safety culture are characterized by communication founded on mutual trust and openness, by shared perceptions of the importance of safety and by organizational learning and confidence in the efficacy of preventative measures (Zwart et al. 2011).

System-based interventions are favored by many as the preferred approach for addressing diagnostic error, as it is easier to focus on changing the healthcare environment rather than to act on cognitive factors (Singh et al. 2012). System approaches assume that the individual physician's cognition is adequate for the diagnostic and metacognitive tasks, but that he/she needs more, and better, data to improve diagnostic accuracy.

The diagnostic process includes multiple sites of care in a complex and fragmented ambulatory care environment and presents challenges in coordinating care. Diagnoses are made in time-pressured primary care visits, where providers are often unaware of the final patient outcome. Consequently, outpatient diagnostic errors may be more common than realized and result from many types of process-of-care breakdowns.

For example, in countries with a strong primary health care system, such as the Netherlands, patients receive most of their medical care by family physician, who provides care for a full range of medical conditions across an extended period of time (Gaal et al. 2011a). Hence, the threshold for hospital admission in the Netherlands is probably higher compared with countries that have less well-developed primary care systems. This higher threshold could constitute a potential safety risk, as the family physician must make clinical decisions with the aid of only a few diagnostic possibilities. Conversely, this same threshold could actually reduce the risk of iatrogenic damage to patients; fewer false positive test results could occur as a result of less testing in the primary setting and less 'over-testing' of the patient could occur in the primary care setting, compared to the hospital setting.

Five dimensions of ambulatory care from which diagnostic errors may arise were identified in the work by Singh et al: (1) the provider – patient encounter, (2) performance and interpretation of diagnostic tests, (3) follow-up of patients and diagnostic test results, (4) subspecialty consultation, and (5) patients seeking care and adhering to their instruction/appointments, i.e. patient behaviors (Singh and Weingart 2009).

- **The provider – patient encounter:** During an encounter, diagnostic errors may occur if the provider does not receive accurate / sufficient data to make a correct diagnosis, in a situation when inaccurate or second hand information is obtained by colleagues, trainees or patients themselves. The error may propagate when the problem list contains outdated information about the patient's active medical issues if the provider is rushed or distracted or relies on diagnostic tests instead of thorough clinical examination;
- **Performance and interpretation of diagnostic tests.** This problem commonly occurs when tests are ordered unnecessarily, when the wrong test is ordered, or when the test is inappropriate. Problems related to diagnostic testing may also result from patient non-adherence to pre-test instructions (e.g., fasting status or bowel preparation) or failure to show up for the scheduled test (Singh and Weingart 2009). Another problem represents the mishandling of abnormal test results ("missed results"), which contribute to the majority of diagnostic delay. In a study by Wahls and Cram, the most

common missed results included imaging studies (29%), clinical laboratory (22%) and anatomic pathology (9%)(Wahls and Cram 2007).

- **Inadequate follow-up** of diagnostic test results may occur if management systems do not communicate abnormal results to ordering clinicians in a timely manner. Clinicians may also fail to communicate abnormal test results to their patients. Patients may misunderstand the clinician's follow-up instructions. Additional system barriers to effective follow up include prolonged waiting times for follow-up appointments, insurance coverage, and ambiguity regarding the clinician who is responsible for follow-up (e.g. primary care provider vs. specialist) (Singh and Weingart 2009).
- **The subspecialty consultation process** is another area vulnerable to diagnostic errors. Primary care physicians may fail to order an appropriate consultation; consultants, in turn, may fail to communicate their recommendations to the primary care physician. Clinicians often gain useful information from consultants about difficult-to-diagnose cases, but may be disappointed when the consultant does not meet their expectations. Consultants may fail to address the issue faced by the referring clinician, or may be confused about their role in the case (Singh and Weingart 2009).
- **Patient behaviors.** Patients differ in the aspects of care-seeking and adherence to treatment. Health literacy is another significant and underestimated problem, in which some patients are not able to communicate effectively with their clinicians. They may not be able to relay symptoms accurately, or to understand physicians' recommendations (Singh and Weingart 2009).

In a study by Singh regarding the process breakdowns related to diagnostic error, the most frequently involved processes were patient – physician clinical encounter (78.9%), referrals (19.5%), patient-related factors (16.3%), follow up and tracking of diagnostic information (14.7%) and performance and interpretation of diagnostic tests (13.6%) (Singh 2013).

Breakdown in communication represents another common and important cause of error and potential harm to patients. These include difficulties in doctor–patient relationship and poor communication and co-ordination of care between health care professionals, both within primary care and between primary and secondary care (Wilson and Sheikh 2002). According

to Singh, communication breakdown represents major contributor to diagnostic errors and is increasingly recognized as preventable factor in adverse events (Singh et al. 2007; Bhasale 1998b). Two forms of communication are relevant for the diagnostic process:

- *interpersonal communication* (i.e. verbal exchange of information between two individuals) and
- *informational communication* (the processing and management of data such as notes in the medical record, written instructions, laboratory values, imaging reports) (Singh et al. 2007).

To improve communication errors and patient safety, electronic information systems for the delivery of health care data have been proposed. Adopting electronic medical records (EMR) and information technology could significantly improve the quality of information transfer in terms of reducing the problem of missing clinical information, providing effective decision support tools, clinical reminders and diagnostic aids. Additionally, EMR can include a notification system that immediately alerts the clinician about abnormal test result or automated program that reviews all test results and alerts the clinician about abnormal test result that has not received appropriate follow up. Test results may be reported directly to the patients via secure electronic pathways and standardized physician – patient communication software may improve shared decision making in the diagnostic process (Singh 2007).

Use of guidelines and protocols have some but limited success in improving diagnostic accuracy (Berner and Graber 2008). Decision support tools and electronic information systems may be of greater benefit but this has yet to be proved empirically. Indeed, many computer systems currently use alerts so often that many doctors simply choose to ignore them; systems should be “user centered design” to not add a new level of complication and hence increase the likelihood of harm.

The use of electronic medical record (EMR) can additionally help in reducing patient–provider encounter errors (Wahls 2007). Access to medical history information (including medication and problem lists) can function to improve accuracy in data gathering. In addition, advanced EMR integrates laboratory, radiology and clinical notes and provides the capability of making test result information available as soon as it has been finalized by the diagnostic service. Some decision-support tools, as well as computer- or web-based information sources, also may serve as systems-level interventions that have the potential to increase the total

expertise available, and thus have the potential to reduce diagnostic errors, especially when coupled with EMR (Singh and Weingart 2009).

To reduce errors during diagnostic testing, point-of-care testing (POCT) should be encouraged. This allows for testing at or near the site of patient care, ensures convenience and effective communication of results, and increases the likelihood that the patient will obtain the test in a timely manner (Singh and Weingart 2009).

Better methods to track patient and test result follow up should be used, potentially using information technology resources. Additionally, methods for ensuring timely follow-up of critical results should be standardized in all clinical practices, as planned follow-up after the initial diagnosis allows time for other thoughts to emerge, and time for the clinician to apply more conscious problem-solving strategies to the point at issue.

Moreover, follow-up means acknowledging that patients are co-producers in diagnosis to ensure that our diagnoses are as accurate as possible, as many pieces of data emerge only through subsequent follow-up. What coproduction of diagnosis really should mean is that the patient is a partner in thinking through and testing the diagnostic hypothesis and has various important roles to play (Schiff 2008). Patients could help confirming or refuting a diagnostic hypothesis based on temporal relationships, they can note relieving or exacerbating factors that otherwise might not have been considered; patients can also carefully assess the response to treatment to help determine whether the diagnosis or treatment is correct or not.

Finally, the patients could help feeding back the nuances of the comments of a specialist referral.

Another general category of a systems approach is to design systems to provide feedback to the clinician. Feedback is an essential element in developing expertise: it confirms strengths and identifies weaknesses, guiding the way to improved performance (Berner and Graber 2008). It has been argued that overconfidence represents a mismatch between perceived and actual performance. It is a state of miscalibration that, according to existing paradigms of cognitive psychology, should be correctable by providing feedback. Hence, accurate feedback can improve the basis on which the clinicians are judging the frequency of events, which may improve calibration (Berner and Graber 2008).

Some factors can contribute to the effect of the underlying cause of an incident. These are typically factors that would not have led to the event independently and are called contributing factors. The effect of contributing factors was studied in the research by Kostoupoulou: in 71 out of 78 reported patient safety events, work organization was the most frequent contributing factor, including excessive task demands, fragmentation of care and unavailability of information (Kostopoulou 2007). The probability of incidents was also higher if more care providers had been involved in a study by van Dulmen, confirming the negative effect of fragmentation of care on patient safety (van Dulmen et al. 2011).

As a matter of concern in organizational characteristics, leadership has a central role to making systems safer. Clear lines of responsibility need to be created to determine who will follow up on which results, as a flow of information travels during transition of a patient's care from the hospital to other settings. Communication between inpatient and outpatient settings is critical to patients medical care handling (Wilson and Sheikh 2002). Discharging hospitals need to implement high-quality discharge summaries, and outpatient physicians' offices need to ensure patient visits during which clinicians can review the discharge materials (Gandhi and Lee 2010). Finally, patients can help monitor their care, mainly by properly communicating with their primary care physician.

5. CONCLUSIONS

Diagnostic errors are the most common adverse events reported by family physicians. Diagnosis is central to the family physician's role and diagnostic error has the potential for the most serious consequences for patients.

Studies have begun to identify the root causes that contribute to diagnostic error. These causes include either one or more of the following: clinician cognitive factors and systems factors.

Strategies to reduce misdiagnoses should focus on improving the match between the physician's self-assessment of errors and actual errors, in order to increase physician awareness and correction. The individual approaches assume that the physician's cognition needs improvement. System approaches assume that the individual physician's cognition is adequate for the diagnostic and metacognitive tasks, but that he/she needs more, and better, data to improve diagnostic accuracy. These two approaches are not mutually exclusive, and the major aim of both is to improve the physician's calibration between his/her perception of the case and the actual case.

Highlighting diagnostic error cases can help remind leaders of health care institutions of their responsibility to foster conditions that will better address and minimize the occurrence and consequences of errors that might otherwise have remained hidden.

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