

DIAGNOSTIC ERROR IN HEALTHCARE

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AN OVERVIEW OF RESEARCH ON THE INCIDENCE OF MISDIAGNOSIS AND RELATED OUTCOMES

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1. Introduction

Until recently, there has not been much research published on the complicated matter of misdiagnosis, otherwise known as diagnostic error, in healthcare systems.

Many stakeholders in healthcare systems have expressed an intuitive view that the problem of misdiagnosis is significant, but few of these have been supported by appropriate independent research or evidence based studies.

However, a few studies have in recent years undertaken the *unpopular* task of trying to determine the prevalence and impact of this phenomenon. I classify the task as *unpopular*, since, for very human reasons, misdiagnosis is an issue that no one was enthusiastically volunteering to study. These recent results have uncovered weaknesses of both processes and human ability, often with very serious side-effects for patients.

The most notable yet undertaken is the landmark study in 2015 by the National Academy of Sciences, Engineering and Medicine in the USA¹. Other similar studies and closely related research have also been done in the UK, Netherlands and Australia, and notably all produce findings that support the assertion that misdiagnosis is a serious but preventable problem.

Clearly the matter is one that needs to be dealt with carefully but, once all data has been perused, there is no doubt whatsoever that diagnostic error represents a significant weakness in healthcare systems that urgently requires attention from all stakeholders.

This overview provides the reader with a high-level indication on diagnostic error that occurs within healthcare systems, outlining some of the areas at which it occurs, reasons as to why it occurs and, most importantly, the extent to which it is occurring and the resultant outcomes. By virtue of the content of the majority of the studies perused in drafting this overview, the focused areas of misdiagnosis are mainly conditions requiring specialist in-patient treatment or otherwise serious conditions treated on an out-patient basis (eg cardiac surgery and cancer respectively).

It allows a relatively brief read to provide an indication of the problem. All findings and quoted figures are referenced, either in the Appendix or as footnotes, to allow more in-depth analysis for those readers interested in a deeper understanding of misdiagnosis.

Lastly, the terms misdiagnosis and diagnostic error are synonyms and are used interchangeably in this document. Some alternative definitions exist in various literature, such as 'diagnosis error' or 'missing diagnosis' but ultimately these all refer broadly to the same matter.

A clearer definition of the types of diagnostic errors that occur is provided in the next section.

2. Overview on Misdiagnosis

The research that has been undertaken in recent years clearly emphasise that misdiagnosis is the cause of unacceptably high levels of wastage, patient harm and even premature death.

The most likely reason that diagnostic error has not garnered more attention is that its true incidence is not widely appreciated.

So, an important factor in addressing this problem is to implement measurement of the incidence of diagnostic error and, more particularly, error-related harm. A fundamental principle of performance improvement is that *'what is not measured, cannot be improved upon'*.

This undoubtedly requires active intervention by stakeholders who hold the best interest of patients, who must be virtually all participants of the healthcare system.

Iatrogenics is the term used to describe harm that results from medical intervention. The aetiology of an intervention that is *iatrogenic* can be many and misdiagnosis is one such potential source. The focus of this overview is on misdiagnosis that results in harm (i.e. is iatrogenic in nature) and increases the cost of healthcare unnecessarily.

A further consideration is that diagnostic error can occur in several settings, not only the physician's examination room. A doctor, relying on an incorrect or failed pathology test, could be compelled, through no fault of his own, to make a diagnostic error.

It is also worth noting that there are different classifications of diagnostic error. The following classification of errorⁱⁱ, extracted from the Australian Patient Safety Foundation, defines diagnostic error as one of the following:

- "a diagnosis that was unintentionally delayed" (i.e. sufficient information was available earlier to make an accurate diagnosis), or
- "wrong diagnosis" (i.e. another diagnosis was made before the correct one), or
- "missed diagnosis" (i.e. no diagnosis was made, as judged from the eventual appreciation of more definitive information)

It should also be appreciated that not all diagnostic error necessarily results in harm – a misdiagnosed condition that is acute by nature may well pass harmlessly, without the patient or physician ever being aware of it. In such an event, the error of a "wrong diagnosis", as outlined in the second bullet point above, will never be discovered.

Patients are also heavily focused on receiving the correct diagnosis from their doctor. A survey in the USA of more than 2000 patientsⁱⁱⁱ found that 55% regarded a misdiagnosis as their main concern when consulting a doctor in an ambulatory care setting.

In the United Kingdom, the country's National Health Service ("NHS") concluded that diagnosis, including misdiagnosis, was the most common reason for complaints from patients about their healthcare service, accounting for approximately 35 percent of all complaints^{iv}.

3. Incidence of Misdiagnosis

For researchers to calculate the incidence of diagnostic error, many data sources have been analysed and methodologies employed.

Each of the sources or methods inherently possess certain strengths as well as limitations in their findings but, nonetheless, they holistically provide a much clearer view of the overall problem. Some of the main sources of data are listed below and discussed further in this section.

The following are data sources^v in various research papers – references are provided in each section as to the source of the specific data and/or research:

- Autopsies
- Standardised Patients
- Patient Surveys
- Provider Surveys
- Second Reviews
- Medical Record Reviews

Before we delve into each of the research areas outlined above, it is worth noting the findings of psychologist, Arthur Elstein, on *'how doctors reason'*^{vi}. A specialist in the field of human cognition, Elstein studied clinical decision making his entire career.

He concluded that the incidence of misdiagnosis occurs between 10 and 15% of cases.

The diverse range of research areas above that we will now investigate in more detail, largely support Elstein's estimated range.

Autopsies

The extract^{vii} below provides context for using autopsies, otherwise called post-mortem examinations, for the purposes of discovering misdiagnosis:

"Postmortem exams are considered a very strong method for identifying diagnostic errors because of the extensiveness of the examination that is possible (Graber, 2013; Shojania, 2002)."

The same paper cited above states the following:

"On average, 10 percent of post-mortem exams were associated with diagnostic errors that might have affected patient outcomes (i.e. Class I errors¹). They estimated that the prevalence of major errors (i.e., Class I and II² errors) related to the principal diagnosis or the cause of death was 25 percent."

¹ A Class I error is a major diagnostic error that likely played a role in the patient's death.

² A Class II error is a major diagnostic error, but it did not contribute to the patient's death.

Two further research papers^{viii} concluded the following:

*“Major unexpected discrepancies, that would have changed the **(clinical)** management were found in 10-20% of cases.”*

Standardised Patients

In these types of studies, patients with characteristic symptoms of common but serious ailments (eg rheumatoid arthritis, asthma, chronic obstructive pulmonary disease) are sent anonymously into practice settings by researchers.

The outcomes, reported in two separate research papers^{ix}, show that a range of between 13% and 15% of medical cases are misdiagnosed in these studies.

It must be noted that these studies would focus on smaller sub-sets of medical conditions that would be seen in usual practice, so the percentages of misdiagnosis above are not reflective of incidence across all conditions.

It does, however, emphasise that within the smaller sub-set of those more serious and chronic conditions, the incidence of misdiagnosis is still significant. Furthermore, these studies have a substantial reliability advantage over other forms of research, since they are performed in real-world settings.

Patient Surveys

Surveys can be a useful source of understanding misdiagnosis but, as is the case with all surveys, the results can be skewed by nonresponse bias and reporting bias (i.e. those patients who experienced a misdiagnosis would more likely respond to the survey, whereas patients who did not experience a problem, would less likely respond).

However, the following extracts^x are worth noting:

“More recently, 23 percent of people surveyed in Massachusetts indicated that they or someone close to them had experienced a medical error, and approximately half of these errors were diagnostic errors (Betsy Lehman Center for Patient Safety and Medical Error Reduction, 2014).”

“Weissman and colleagues (2008) surveyed patients about adverse events during a hospital stay and compared survey-detected adverse events with medical record review. Twenty-three percent of surveyed patients reported at least one adverse event, compared to 11 percent identified by medical record review.”

As noted in Section 2 of this overview, a US study of over 2000 patients cited that 55% of patients listed a misdiagnosis as their main concern when consulting a physician. One must conclude from this that incorrect diagnosis occurs sufficiently often for patients to be aware that it is a problem worth being concerned about.

Provider Surveys

Again, survey results can be affected by several biases, including nonresponse bias (non-responders being systematically different from responders, eg being either more or less likely to have committed a diagnostic error) or reporting bias (systematic differences in the information that is revealed or suppressed, such as not reporting more serious errors in fear of potential recrimination).

The following extracts^{xi} are worth noting:

“Schiff et al. (2009) surveyed physicians and asked them to recall instances of diagnostic error. In their analysis of 583 reports of diagnostic error, they found that physicians readily recalled instances of diagnostic error; the most commonly reported diagnostic errors were pulmonary embolism, drug reactions, cancer, acute coronary syndrome, and stroke.”

“Singh and colleagues (2010b, p. 70) surveyed paediatricians about diagnostic errors and found that “more than half of respondents reported that they made a diagnostic error at least once or twice per month.”

“In another survey of physicians, 35 percent reported that they had experienced medical errors either in their own or a family member’s care (Blendon et al., 2002).”

Second Reviews

The results of several clinical reviews of pathology and radiology testing are considered in this section.

A nationwide sample and analysis^{xii} of mammogram results in the USA in 1996 found that between 10 and 30% of breast cancers were not detected.

A further 4 studies^{xiii}, of mostly abnormal or complex diagnostic cases, showed that the error rate across these studies ranged from 10% to an alarming 50%.

Again, it is important to bear in mind that these studies focus on sub-sets of difficult and complex cases. In real world scenarios, the majority of diagnostic examinations are normal.

However, even where error rates are at the overall estimated level of 10 – 15% of cases, it remains significant enough to be of major concern and substantial cost.

Medical Record Reviews

A medical record is a documented account of a patient's examination and treatment, including the patient's clinical history and symptoms, physical findings, the results of diagnostic testing, medications and other procedures. It can exist in either paper or electronic form.

This section focuses on studies that have retrospectively reviewed medical records – the results show the extent of diagnostic error that occurred.

Two studies^{xiv} from the USA focused on hospitalised patients that experienced an adverse event.

“In the Harvard Medical Practice Study of more than 30,000 patient records, diagnostic errors were identified in 17 percent of the adverse events (Leape et al., 1991)”.

“A review of 15,000 records from Colorado and Utah found that diagnostic errors constituted 6.9 percent of adverse events (Thomas et al., 2000)”.

More recently, a 2012 study^{xv} in the Netherlands performed a retrospective patient record review to assess the occurrence of diagnostic adverse events (i.e. harm associated with a diagnostic error) within Dutch hospitals. They concluded:

“ ..., rather than focusing exclusively on adverse events, the researchers had four internists review 247 patient medical records for patients with dyspnea (shortness of breath) symptoms. The reviewers used a questionnaire to identify failures in diagnostic reasoning, diagnostic errors, and harm. They found that failures in diagnostic reasoning³ occurred in 66 percent of the cases, that diagnostic errors occurred in 13.8 percent of all cases, and that the patient was harmed in 11.3 percent of cases”.

Alternative Sources

There are alternative sources of data and/or research on misdiagnosis – these include, but are not limited to, medico-legal malpractice cases, voluntary peer reviews and testing of diagnostic equipment.

These have not been considered in this review for the following reasons - malpractice cases are often skewed because the focus of the claimant is on consequence and reward rather than on an objective assessment of root cause. The testing of diagnostic equipment is reflective of instrument failure rather than human failure and voluntary peer review data is unfortunately minimal.

³ Diagnostic reasoning is explained in more detail in section 4 of this review.

4. Why Diagnostic Error Occurs

The obvious importance in further assessing misdiagnosis as a phenomenon, is to examine its root cause.

This involves several factors but, as was found by Zwaan et al. in the Dutch study noted above, the vast majority of diagnostic errors have a human cause.

'To err is human' goes the anecdote but not to implement methods to lower the incidence of misdiagnosis would simply be negligent.

To do so requires a deeper understanding of the root cause – we shall now examine this aspect of misdiagnosis in further detail.

There are various innately human factors that will influence a physician's ability to accurately and timeously provide a diagnosis.

These range from the physician's physical attributes, knowledge, experience through to other cognitive factors such as inherent biases, the use of heuristics and ability to engage in critical thinking.

Before we examine these various factors, the following extract^{xvi} from the National Academy of Sciences, Engineering and Medicine 2015 is worth noting:

"As an expanding body of scholarship further elucidates the causes of medical error, including the considerable extent to which medical errors, particularly in diagnostics, may be attributable to cognitive sources, insufficient progress in systematically evaluating and implementing suggested strategies for improving critical thinking skills and medical judgment is of mounting concern (Stark and Fins, 2014, p. 386)".

Types of Reasoning

It is widely accepted that humans draw conclusions in everyday life using a balanced and innate mechanism known as *dual process theory*^{xvii}. This theory directs that we use two opposing models of decision making – one analytical and one non-analytical – and that we deploy them at different times and under varying circumstances.

Non-analytical thinking^{xviii}, known as fast system 1, involves intuitive, sub-conscious, pattern recognition. It requires little memory activation and is usually triggered by stimuli of one or more of our senses. Fast system 1 thinking can also be activated by overlearned processes or implicitly learned functions.

Examples of system 1 thinking would be recognising someone's face, knowing the difference between a knife and a fork or that avoiding a snake in the garden shed takes immediate priority over other imminent tasks. You don't have to consciously think about doing these things – they are decisions based on heuristics (mental shortcuts), intuition or repeat experiences.

Analytical thinking (slow system 2) is a deliberate and conscious process driven by critical thinking. Slow system 2 processing, reflective and analytical, places a heavy load on working memory and involves hypothetical and counterfactual reasoning^{xx}.

System 2 processing requires individuals to generate mental models of what should or should not happen, in particular situations, to test possible actions or to explore alternative causes of events^{xx}.

The following graphic and explanation^{xxi} describes how the 2 processes operate concomitantly -

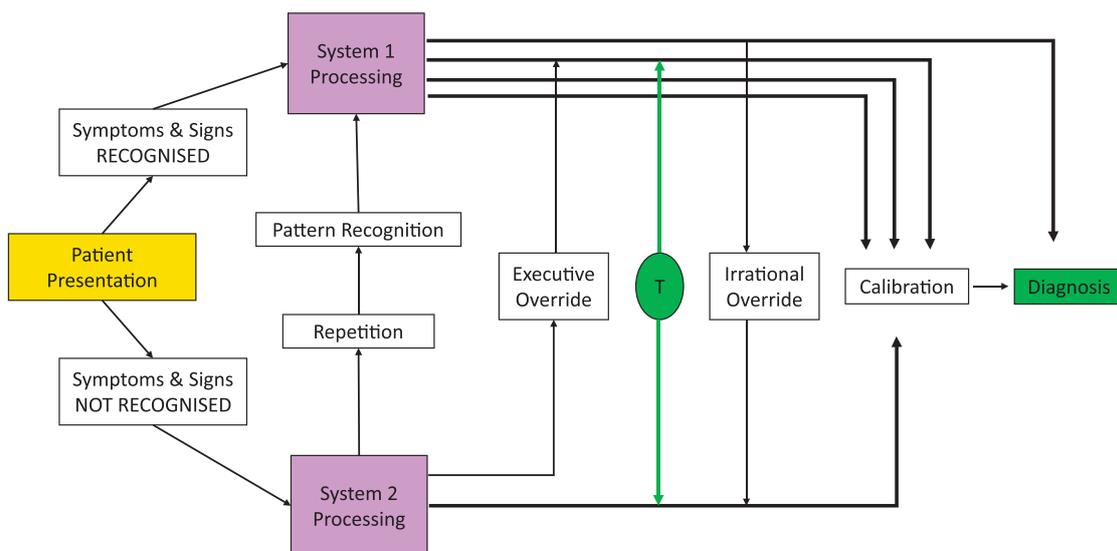


FIGURE 2-2 The dual process model of diagnostic decision making. When a patient presents to a clinician, the initial data include symptoms and signs of disease, which can range from single characteristics of disease to illness scripts. If the symptoms and signs of illness are recognized, system 1 processes are used. If they are not recognized, system 2 processes are used. Repetition of data to system 2 processes may eventually be recognized as a new pattern and subsequently processed through system 1. Multiple arrows stem from system 1 processes to depict intuitive, fast, parallel decision making. Because system 2 processes are slow and serial, only one arrow stems from system 2 processes, depicting analytical decision making. The executive override pathway shows that system 2 surveillance has the potential to overrule system 1 decision making. The irrational override pathway shows the capability for system 1 processes to overrule system 2 analytical decision making. The toggle arrow (T) illustrates how the decision maker may employ both fast system 1 and slow system 2 processes throughout the decision-making process. The manner in which data are processed through system 1 and system 2 determines the calibration of a clinician's diagnostic performance, or a clinician's understanding of his/her diagnostic abilities and limitations.

Heuristics^{xxii}

Heuristics can facilitate rapid decision making but they also lead to errors, especially when patients present with atypical symptoms or co-morbidities.

When heuristics fail to draw an accurate conclusion, it is referred to as a cognitive bias. These cognitive biases, or predispositions to think in a way that leads to failures in judgement, can also be caused by affect and motivation.

Protracted learning in regular, predictable environments increase the successfulness of heuristics, whereas uncertain and unpredictable environments are a chief cause of a heuristic failure.

There are many heuristics and biases that affect reasoning and decision making, some of which are described below^{xxiii}, these being common reasons why misdiagnosis occurs:

Affective bias refers to the various ways that our current or inherent emotional state, feelings and biases affect judgement.

Anchoring is defined as the tendency to lock onto the salient features of a patient's initial presentation and failing to adjust this original impression if later information arises.

Availability bias refers to the tendency to more readily recall diseases or conditions that have recently been observed, are common or impressed the observer.

Base Rate Neglect is the tendency to inflate or reduce the true prevalence of a disease, thereby distorting Bayesian⁴ reasoning.

Context Errors indicate cases where symptoms are misallocated based on the background or physical area against which it was perceived, eg abdominal pain must be a gastrointestinal problem.

Premature Closure, also known as search satisficing, is classified as the tendency to accept the first answer that explains the facts at hand (i.e. the symptoms) without considering alternative answers. Once the diagnosis is made, the thinking stops.

Representativeness Restraint occurs when a doctor looks for prototypical manifestations of disease patterns, failing to consider atypical variants.

Unpacking Principle is the practice of eliciting all relevant information when establishing a differential diagnosis⁵.

⁴ Bayesian reasoning (or inference) is a statistical methodology of updating probability as more information arises

⁵ Differential Diagnosis is the process of differentiating between two or more conditions which share similar symptoms

Physical & Emotional State

Beside the heuristics and cognition failures outlined above, other individual characteristics can also affect clinical reasoning.

These include intelligence, knowledge, age, affect, experience, personality, physical state and gender. Some of these are outlined in more detail below.

Affect – these factors, such as mood and emotional state, can play both positive and negative roles in clinical reasoning and the subsequent decision making (i.e. concluding a diagnosis)^{xxiv}. When an obvious solution to a problem is not present, emotions may come into play, steering the person towards a better outcome than would be produced by random choice^{xxv}. Decision making guided by emotion is decision making mediated by the ‘affect’ heuristic^{xxvi}. Where precision is important, the affect heuristic can lead to negative consequences. Affective states such as irritation and stress, due to environmental conditions, can also affect reasoning, primarily through decreasing the ability of system 2 processes (rational, analytical) to monitor and override system 1 processes (heuristics)^{xxvii}.

Age^{xxviii} - It is probable that a doctor’s age will impact his/her clinical reasoning abilities. Older and more experienced clinicians may be better able to employ system 1 processes in diagnosis, due to well-developed mental models of disease and symptoms. However, as they age, they tend not to consider alternatives and switching tasks during the diagnostic process. Not all individuals experience cognitive or memory decline at the same rate or time, though many people start to experience moderate declines in analytical reasoning capacity at some point in their 70s.

Experience^{xxix} - A novice and an expert will employ different decision-making practices. These obviously relate to the experience gained over many years but also of importance is that differences exist in the way that expert and novice clinicians reason about their patients’ health problems. Experienced nurses, for instance, collect a wider range of cues than their novice counterparts during clinical decision making. Expert clinicians are more likely to rely on system 1 processing during the diagnostic process and be more accurate than novices. While some have argued that experts are more susceptible to premature closure (i.e. accepting a diagnosis before it has been sufficiently verified), there is evidence that experience is more likely to lead to diagnostic flexibility than an explicit metacognitive rule requiring one to “consider alternatives”.

Intelligence and Knowledge^{xxx} - Intelligence obviously refers to ability to engage in high-level cognitive tasks such as reasoning, problem solving, and decision making. High scores on IQ tests indicate skill at cognitive tasks and tendencies to engage system 2 processes to evaluate and override system 1 processing. Although intelligence that allows overriding system 1 processing is important, it rarely suffices, by itself, for good clinical reasoning. A concomitant, sufficiently large knowledge base of both biological science and disease conditions is required. The extent of this knowledge base is clearly reliant on memory and training, two factors that will vary substantially between doctors.

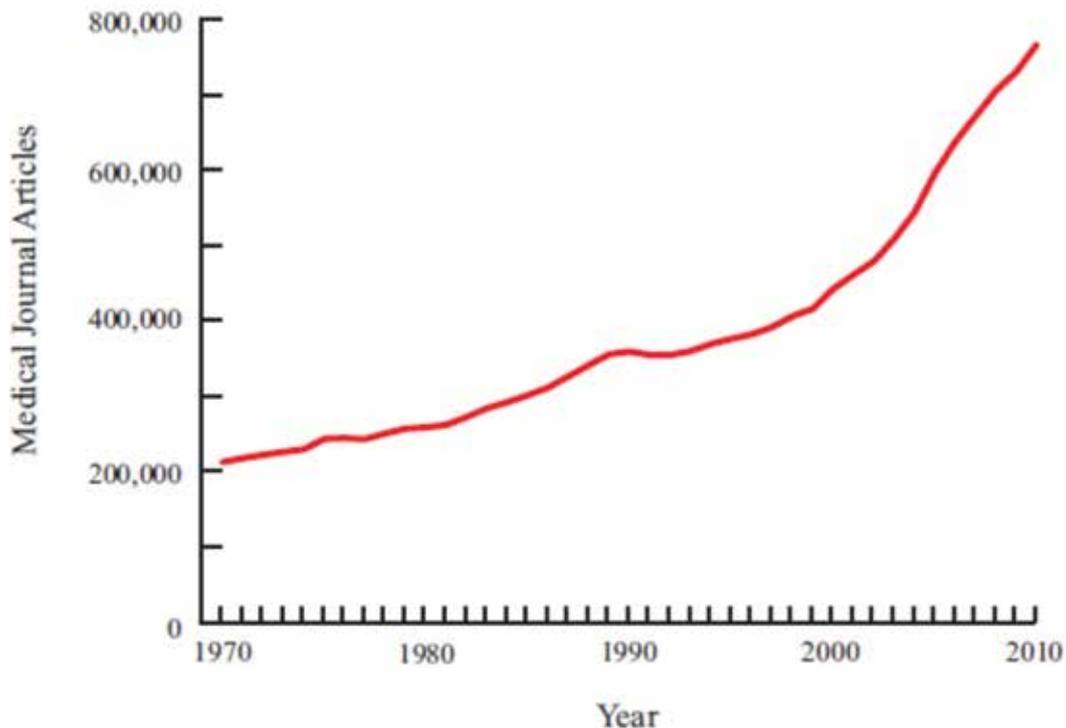
Personality & Physical State^{xxxi} - Individual personality does have an influence on clinical reasoning and decision making. Arrogance, as an example, may lead to overconfidence, a personality trait identified as causing diagnostic error. Alternative traits, such as openness and agreeableness, could improve decision making in some individuals, if it raises their willingness to investigate divergent views and feedback. Fatigue and sleep deprivation have been found to impede system 2 processing interventions on system 1 processes.

Continual Learning

Virtually all professions now have either officially regulated or, at least, voluntary continual learning and professional development programmes.

The medical profession is no different in this regard, but it is worth noting to what extent medical professionals can keep up with available information. The graph below^{xxxii} shows the number of medical journal articles published annually in the USA since 1970. Clearly there has been a very substantial and steady increase over the past 4 decades.

The massive growth and improvement in treatment and diagnostic technologies, as well as knowledge on diseases, do present a challenge to doctors in keeping fully up-to-date with the latest developments. According to one study^{xxxiii}, general practitioners would need to read 627.5 hours per month (>20 hours per day) to keep up to date.



5. Conclusion

The facts and research outlined in this overview have specifically been well referenced, to emphasise that the problem of misdiagnosis in healthcare is significant but also greatly underestimated.

There is a growing body of objective evidence to demonstrate that diagnostic error exists, the aetiology thereof in the healthcare system and, most importantly, what can be done to minimise it and the resultant effects.

The follow on from this review will be to seek these solutions and, fortunately, in that regard, there are some promising training skills, diagnostic services and tools that are being developed, that can be used by healthcare funders to have a positive impact on the incidence of misdiagnosis.

In closing, one 2010 study^{xxxiv} investigated the impact of using a *diagnostic decision support system* on the costs of diagnostically challenging cases. The results of the study were that the treatment costs fell by an average of 12%.



Appendix

- ⁱ *“Improving Diagnosis in Healthcare”* - National Academy of Sciences, Engineering and Medicine 2015 (USA)
- ⁱⁱ Graber et al, 2005 (Australia)
- ⁱⁱⁱ *“You Gov survey of medical misdiagnosis”*, Isabel Healthcare, 2005 (USA)
- ^{iv} Parliamentary and Health Service Ombudsman, 2014 (UK)
- ^v *“Improving Diagnosis in Healthcare”* - National Academy of Sciences, Engineering and Medicine 2015 (USA) (pg 96); *“The incidence of diagnostic error in medicine”* – Dr Mark Graber, *BMJ Qual Saf*, 2013 (USA)
- ^{vi} *“Clinical reasoning in medicine”* - Elstein, A. 1995 (UK)
- ^{vii} *“Improving Diagnosis in Healthcare”* - National Academy of Sciences, Engineering and Medicine 2015 (USA), pg 100
- ^{viii} Shojania K, Burton E, McDonald K, et al. *The autopsy as an outcome and performance measure; Evidence report/Technology assessment #58* (Prepared by the University of California at San Francisco-Stanford Evidence-based Practice Center under Contract No.290–97–0013). AHRQ Publication No 03-E002. Rockville, MD: Agency for Healthcare Research and Quality, 2002. Sonderegger-Iseli K, Burger S, Muntwyler J, et al. *Diagnostic errors in three medical eras: a necropsy study*. *Lancet* 2000;355:2027–31.
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- ^x *“Improving Diagnosis in Healthcare”* - National Academy of Sciences, Engineering and Medicine 2015 (USA), pg 116
- ^{xi} *“Improving Diagnosis in Healthcare”* - National Academy of Sciences, Engineering and Medicine 2015 (USA), pg 115
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“As an expanding body of scholarship further elucidates the causes of medical error, including the considerable extent to which medical errors, particularly in diagnostics, may be attributable to cognitive sources, insufficient progress in systematically evaluating and implementing suggested strategies for improving critical thinking skills and medical judgment is of mounting concern.”

The ethical imperative to think about thinking - diagnostics, metacognition, and medical professionalism – Meredith Stark & Joseph Fins

Diagnostic Error in Healthcare

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